

**Large Hospitals and Health Systems**  
 HCCA 21<sup>st</sup> Annual  
 Compliance Institute  
  
 PREAM1  
**MARCH 26, 2017**

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**Session Goals**

- Opportunity for large hospital and health system compliance officers to engage in a collaborative discussion of both emerging and chronic challenges unique to such organizations.
- Share model practices and practical solutions.
- A panel of experienced large system compliance professionals will introduce and speak to such topics, engage the audience in an interactive exchange of perspectives and approaches and solicit additional issues of concern.
- Take away from this session an enhanced understanding of challenges common to compliance programs in large organizations, new approaches to these challenges and the wisdom of your colleagues.

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**Discussion Facilitators**

Suzie Draper – VP, Business Ethics and Compliance  
Intermountain Healthcare

Margaret Hambleton – VP, Corporate Compliance Officer  
Dignity Health

Cheryl L. Wagonhurst – Law Office of Cheryl L. Wagonhurst  
Former Chief Compliance Officer Tenet Healthcare  
and former Partner, Foley & Lardner, LLP

John Steiner – Protenus, Inc.

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## Evolution of a Compliance Program

### *Birth of Healthcare Compliance*

- 1996 HIPAA – (Health Insurance Portability and Accountability Act)
- Caremark decisions
- Use of FCA in healthcare

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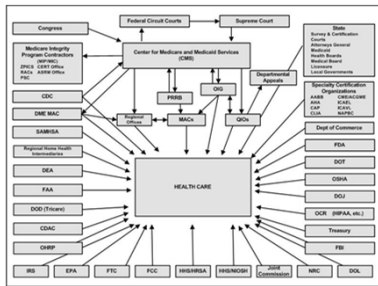
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## Evolution of a Compliance Program

### *Government Enforcement and Oversight*



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## Evolution of a Compliance Program

### *Regulatory Agency – Enforcement and Oversight*

- Healthcare compliance in the Trump administration
  - Who knows????
  - Healthcare enforcement continues to be a profitable endeavor for the government
  - Best guess – unlikely to have significant changes to compliance requirements
    - Funding
    - Cut in regulations – President's Executive Order

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### Evolution of a Compliance Program

#### *Regulatory Agency – Enforcement and Oversight*

- Federal Compliance Program Guidance
  - stipulates the need for an *Effective Compliance Program*
  - Silent on how to measure effectiveness
  - Emphasizes that to be *effective*, the program "**must**"
    - Be fully implemented
    - Be adequately resourced
    - Have an annual independent audit of "effectiveness" (select programs)
    - Have effective board oversight
  - Increased push for "outcomes" and "performance" measures

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### Evolution of a Compliance Program

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    - Be adequately resourced
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    - **Have effective board oversight**
  - Increased push for "outcomes" and "performance" measures

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### Evolution of a Compliance Program

#### *Board Oversight*

- Compliance function should be separate from, and not report directly to, legal counsel
- Boards should get regular updates on compliance efforts – can't bury head in sand
- Boards must be proactive in identifying areas of risk within particular organization/industry

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### Corporate Governance Responsibilities

#### *Duty of Care*

Director shall perform his/her duties, including duties as a member of any committee of the board upon which the director may serve:

- o In **good faith**;
- o In a manner that director believes to be in the **best interests of the corporation**; and
- o With **such care**, including reasonable inquiry, **as an ordinarily prudent person** in a like position would use under similar circumstances.

The conscientious pursuit by directors of principles of best practices is the foremost approach to the duty of care and best prophylactic against director liability.

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### Corporate Governance Responsibilities

#### *Duty of Inquiry*

**Cannot be passive** and must actively participate in decisions.

Must **make reasonable inquiries** regarding potential decisions:

- o Healthy skepticism and questioning
- o Asking for clarification regarding issues and impact of decisions
- o What would an ordinarily prudent person ask or want to know under similar circumstances?

**Reliance on others** for information and answers:

- o Reliable and competent officers and employees;
- o Legal counsel, accountants and others with professional or expert competence; and
- o Board committees as to matters within their designated authority.

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### Corporate Governance Responsibilities

#### *Duty of Oversight*

In re Caremark International Inc. Derivative Litigation

**"But it is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so that it may satisfy its responsibility."**

"And obviously too, no rationally designed information and reporting system will remove the possibility that the corporation will violate laws or regulations, or that senior officers or directors may nevertheless **sometimes be misled or otherwise fail reasonably to detect acts** material to the corporation's compliance with the law."

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### Review and Oversight of Compliance Program

Based on the legal principles and resources as described, the Board:

- Has an affirmative **duty to reasonably oversee implementation and operation** of an effective program for **organizational compliance** with key federal and state laws.
- Must assure that the Compliance Program has **effective systems in place to regularly report on** the results of the **Compliance Program's work** (including internal audit) to the Board of Directors (or a committee thereof).
- Is entitled to **rely**, in good faith, **on officers and employees as well as corporate professional experts/advisors** (when board believes confidence in experts is warranted) regarding compliance, Compliance Program and effectiveness of Compliance Program.

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### DOJ Prosecutorial Manual

- Eligibility for "cooperation credit" - must provide the DOJ with "all relevant facts" regarding corporate misconduct
- Civil and Criminal corporate investigations should focus on individuals
- Routine communications required
- Criminal investigations - "Department lawyers should not agree to a corporate resolution that includes an agreement to dismiss charges against, or provide immunity for, individual officers or employees."
- Focus of civil counsel should be on individuals as well as the company and should evaluate whether to bring suit against an individual based on considerations that go beyond that individual's ability to pay
- Plans to resolve cases should take into consideration resolution of related individual cases

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### Evolution of a Compliance Program Regulatory Agency – Enforcement and Oversight

- Federal Compliance Program Guidance
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    - Be fully implemented
    - Be adequately resourced
    - Have an annual independent audit of "effectiveness" (select programs)
    - Have effective board oversight
  - o **Increased push for "outcomes" and "performance" measures**

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### What are you telling your board with these measurements?

#### *Unintended Stories*

- Hotline statistics – timeliness and adequacy of responses
- Investigation statistics
- Likelihood and severity of top risk areas
- Training completion rates
- Predictive analytics (behavior, ROI, non-official reporting channels)
- Policy dissemination
- Corrective action plans completion – from audits
- Audit findings

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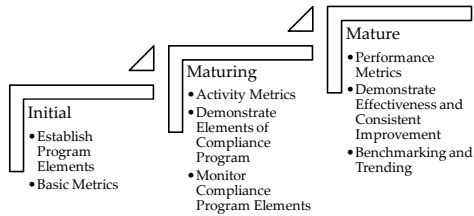
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### Compliance Program Evolution



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### Risk Assessment

#### *8<sup>th</sup> Element of an Effective Compliance Program*

- Government guidance
  - Federal Sentencing Guidelines
    - "Organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps..."
  - OIG Program Guidance
    - "Institutions should consider conducting risk assessments to determine where to devote audit resources..."

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### Risk Assessment

#### *Risk Impact*

- Severity measure
- Define scoring terms in very specific terms
  - Numeric scoring
  - High – Low
  - Example: High=Loss or additional expense greater than 1% of gross revenue (financial impact)

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### Risk Assessment

#### *Vulnerability Scoring*

- Consider without controls to understand the inherent risk
- Specific definition of terms (scores)
- Vulnerability may include:
  - Likelihood of failure
  - History of failure
  - Rate of change
  - Complexity of process
  - Detectability of failure

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### Risk Assessment

#### *Evaluating the Control Environments*

- Extent of variation
- Routine review or audit of process
- Human factors
  - Standard work
  - Communication, hand-offs, redundancy, work around, reliance on memory, etc.

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### Risk Assessment

#### *Risk Tolerance*

- Continuum ranging from total avoidance of risk to total acceptance
- Tied to mission and organizational governance and leadership
- Understand that you probably cannot address all risks identified

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### Risk Assessment

#### *Work Plan Development*

- Identifying and prioritizing risks creates risk if nothing will be done with the information
- Audits are not corrective action!
- Understand the root cause
- Resources available

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### Work Plan Activities

#### *CMS: Overpayments*

##### CMS: "60 Day Repayment Rule"

- **Rule:** Providers that receive an overpayment must report and return the overpayment.
- **Timing:** Overpayments must be reported by the later of:
  - (i) the date which is 60 days after the date on which the overpayment was identified; or
  - (ii) the date any corresponding cost report is due.
- **Identification:** Occurs when a provider, through reasonable due diligence, has or should have identified receipt of and quantified the amount of the overpayment.
- **Lookback Period:** Overpayments must be reported and returned only if identified within 6 years of the date payment was received.
- **Method:** Use of claims adjustments, credit balances, self-reported refunds or another appropriate process to satisfy the obligation to report

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### Work Plan Activities

*CMS: Overpayments*

- CMS: "60 Day Repayment Rule"

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graph LR; A[Receipt of Credible Information] -- "Reasonable Diligence Investigation  
6 Months" --> B[Identification and Quantification of an actual Overpayment]; B -- "60 Days" --> C[Report and Return Overpayment];
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### Stark / Anti-Kickback

*Stark Phase 5 Regulations – November 2015*

**Eased requirements around documenting physician relationships**

- Flexibility around how arrangements are documented "in writing"
- Documenting the term of an arrangement
- More flexibility for "holdover" arrangements – arrangements that continue past initial term, under the same terms

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### Stark / Anti-Kickback

*Stark Phase 5 Regulations – November 2015*

**Added two new exceptions**

- "Timesharing arrangements" for use of equipment, expertise, etc.
- Payments to physicians to assist in compensating non-physician practitioners for primary care

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**Stark / Anti-Kickback**  
*Stark Phase 5 Regulations – November 2015*

**Other**

- Clarifications on whether certain situations constitute "remuneration"
- Made regulatory language more consistent throughout

**Current discussions of Stark**

- Much current discussion relates to how Stark might interfere with **value-based payment** and **population health**.
  - e.g., a February 2017 Healthcare Leadership Council White Paper argues that Stark regulations create challenges for implementing value-based payment initiatives, and recommending solutions

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**Stark / Anti-Kickback**  
*Stark Regulations – Recent Cases*

**Columbus Regional Healthcare System (Georgia – Sept. 2015)**

- Overpaid employed physicians in salary and directorships

**North Broward Hospital District (Sept. 2015)**

- Overpaid nine employed physicians

**Adventist Health System (Sept. 2015)**

- Overpaid and provided improper benefits to employed physicians

**Halifax Hospital Medical Center System**

- Employed neurosurgeon salaries were above FMV

**Tuomey Health Care System (Sept. 2016)**

- Government pursued case against Tuomey CEO

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**Stark / Anti-Kickback**  
*Significant Cases*

- Tuomey case – bolstered government enforcement actions
- North Broward and other settlements seemed to have similar fact patterns:
  - High compensation levels
  - Relatively low to average production levels
  - Coding and billing issues to boot
- Lack of "commercial reasonableness" unless compensation to physician is covered by personally performed services

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**Stark / Anti-Kickback**  
*Stark Regulations – Recent Cases*

**OIG Fraud Alert (June 2015)**

- "Physician compensation arrangements may result in significant liability."
- "Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide."
- OIG will go after physicians who enter into questionable medical directorship arrangements.

**Physician Compensation**

- Oversight Structure

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**Stark / Anti-Kickback**  
*Compliance Tips*

- Contract review approval structure – should be reviewed and revised accordingly
- Review arrangements with employed physicians
- North Broward – addressed "downstream" revenue
- Focus on FMV and "commercial reasonableness"
- Don't allow your FMVs to become stale

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**Key Decisions Regarding Applicability of CoPs to FCA**

- Historically some providers prevailed in FCA cases based upon noncompliance with condition of participation
  - *U.S. ex rel. Ortolano v. Amin Radiology* – State regulation addressing certification of nuclear medicine tech not a condition of payment
  - *U.S. ex rel. Gampie v. Gilead Scis.* - Switch to unapproved manufacturing sources for APIs (that did not have NDA) not a condition of payment
- – But, *U.S. ex rel. Escobar v. Universal Health Svcs.* - Supreme Court held that violation of Medicaid licensing and supervision standards for psychiatric services could potentially raise FCA concerns
  - o Supreme Court rejected blanket distinction between "conditions of participation" and "conditions of payment." Rather, look to the "materiality" of the alleged noncompliance.

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### Value Based Reimbursement – Fraud and Abuse Risks

- History
- Goal
- ACA – Patient Protection and Affordable Care Act (PPACA)
  - AHCA ? American Health Care Act

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### MACRA

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
- Quality Payment Program (QPP)
- Rewards based on quality rather than volume of care
- Merit-Based Incentive Payment System (MIPS)
- Advance Alternative Payment Models (APMs)

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### Clinical Care Risks

- Quality of Care cases brought pursuant to FCA that seek to hold providers liable for substandard care.
- Submission of false claims when knowing failure to meet standards of care.

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### Tips for Ensuring Compliance

- Use of meaningful metrics – quality metrics
- Use of multidisciplinary groups to manage performance of the metrics
- Revisions to contracts
- Policies, training, reporting, monitoring, auditing – Bread and Butter Compliance

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### HIPAA Security

#### *Risks*

- Phishing Attacks
- Malware and Ransomware
- Encryption Blind Spots
- Cloud Threats
- Employees

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### HIPAA Security

#### *OCR Settlements*

#### Memorial HealthCare System

- \$5.5 Million
- Failure to implement procedures for reviewing / modifying / terminating user access
- Affiliated physician offices with an Organized Healthcare Arrangement

#### Children's Medical Center in Dallas

- \$3.2 Million
- Failure to implement risk management plans and deploy encryption
- Unencrypted ePHI

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## HIPAA Security

### Collaboration between Privacy and Security Teams

- Annual security and privacy awareness training
- Coordinated Large Scale Breach Plans with mock testing
- Jointly create policy and procedures
- Daily Security Operations Center (SOC) reports
- Joint committee and workgroups



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## HIPAA – Privacy

- Case study
- IDN, Integrated networks (OCHA 1, OCHA 2, Affiliated Corporate Entity)
- Business Associates and monitoring 3<sup>rd</sup> parties
- Access audits (proactive and reported)
- Breach reporting
- Privacy Impact Assessments (PIA)

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## Intermountain Healthcare

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- Intermountain Healthcare**
- Serves Utah and southeastern Idaho
  - Not-for-profit healthcare system
  - 22 hospitals
  - >185 clinics
    - 24 community clinics for low-income, homeless and uninsured; 6 owned, 18 receiving financial support
  - 1,400 physician multi-specialty Intermountain Medical Group
  - Health insurance – SelectHealth
    - 1 million covered lives
  - Homecare and Hospice
  - Clinical Quality Board Goals
  - 40,000 employees
  - Total assets of \$10 billion



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## Dignity Health

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### Dignity Health

- Founded in 1986, we've made it our goal to create environments that meet each patient's physical, mental, and spiritual needs.
- Dignity Health is made up of more than 60,000 caregivers and staff who deliver excellent care to diverse communities in 21 states.
- 39 acute care hospitals located in California, Arizona, and Nevada
- Headquartered in San Francisco, Dignity Health is the fifth largest health system in the nation and the largest hospital provider in California.
- Total assets of \$17 billion



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## Compliance Program Start Up: What are the Basics Needed for your Infrastructure?

Debbie Troklus, CHC-F, CHRC, CCEP-F, CHPC, CCEP-I  
Managing Director, Aegis Compliance & Ethics Center

Sheryl Vacca, CHC-F, CHRC, CHPC, CCEP-F, CCEP-I  
SVP/Chief Risk Officer  
Providence St. Joseph Health



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## Why are Compliance Programs Important?

- Raise Awareness
- Mitigation Factor
- Communicate Commitment
- Reduce Threat of Qui-Tams (Whistleblower)
- Makes Good Business Sense
- Minimizes impact of CIA



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## How Comprehensive Should a Compliance Program Be?

- Medicare Billing Compliance
- Medicaid
- Third Party Payors
- Employment/Labor Law
- Therapy Centers
- Safety
- EMTALA (Emergency Medical Treatment & Active Labor Act)
- HIPAA Privacy & Security
- Research
- Stark
- Anti-kickback
- Sarbanes-Oxley
- Quality
- Accreditation
- Other Federal &/or State Laws



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## OIG Guidance

- Voluntary Disclosure
- Hospital & Supplement
- Laboratory
- Home Health
- Third Party Billing
- DME
- Hospice
- Medicare + Choice
- Nursing Facilities & Supplement
- Ambulance
- Pharma
- Research (draft)
- Physician Practice

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## Compliance Program Development

**What are the top 3 obstacles to Effective Compliance Program Implementation?**

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## What is a Compliance Program

- A program which:
- Utilizes tools to prevent and/or detect violations of law or policy
  - Defines expectation for employees for ethical and proper behaviors when conducting business
  - Demonstrates the organization's commitment to "doing the right thing"
  - Encourages problems to be reported
  - Provides a mechanism for constant monitoring
  - Promotes an ethical culture

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### United States Sentencing Guidelines

- Effective November 1, 1991
- Revised November 2004 and 2010
- Control sentencing of organizations for most federal criminal violations
- Sentencing credit for “effective programs to prevent and detect violations of law”

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### Nov. 2010: FSG Amendment 744

- 1<sup>st</sup>: the organization must respond appropriately to the criminal conduct, including restitution to the victims, self-reporting and cooperation with authorities.
- 2<sup>nd</sup>: the organization must assess its program and modify it to make the program more effective. They seem to encourage the use of an independent monitor to ensure implementation of the changes.

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### Nov. 2010: FSG Amendment 744

**You can get credit for having an effective program, provided you meet the new criteria:**

- the head of the compliance program must report directly to the governing authority or appropriate subgroup,
- the compliance program must discover the problem before discovery outside the organization was reasonably likely,
- the organization must promptly report the problem to the government, and
- no person with operational responsibility in the compliance program participated in, condoned or was willfully ignorant of the offense.

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## Organizations Steps to an Effective Compliance Program



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## Organizational Relationships and Support

- Board
- Senior Leadership
- Management
- Providers
- Staff
- Budget



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## Seven Essential Elements of a Compliance Program

"The Seven Elements of a compliance program are important individually, but are most effective on an interdependent basis." CMS



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Seven Elements of an Effective Compliance Program

1. Standards and Procedures
2. Education and Training
3. Oversight
4. Monitoring and Auditing
5. Reporting
6. Enforcement and Discipline
7. Response and Prevention

Risk Assessment and Effectiveness Assessments are not considered part of the elements for FSG but are critical to a program's success

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Standards and Procedures

- Code of Conduct
  - Simple, short and separate from policies and procedures
  - Provide to all new employees, staff and vendors and during annual compliance training
  - Outline employee expectations in 'plain' English
  - Post prominently – posters and/or intranet
  - Use of attestations
  - Consider putting code in other languages

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Standards and Procedures

- Policies and Procedures
  - Assure that you are not writing policies that should be in the management arena
  - Senior leadership endorsed/approved including Board
  - Follow institutional template
  - Periodically reviewed and revised
  - Responsible party is defined. COMPLIANCE DOES NOT OWN ALL POLICIES
  - Education is provided to all affected staff
  - Ongoing evaluation/revision
  - Do not duplicate what might be already in place

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### Oversight (Authority and Resources)

- Board's Role
- Governing Board Committee, ie: Audit and Finance, Compliance and Audit (whatever is appropriate title)
- Compliance Officer
- Compliance Committee
- Other Committees
- Distributed Compliance Positions
- Subject Matter Experts

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### Compliance Independence

"OIG believes an organization's Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner. While independent, an organization's counsel and compliance officer should collaborate to further the interests of the organization. OIG's position on separate compliance and legal functions reflects the independent roles and professional obligations of each function."

Practical Guidance for Health Care Governing Boards on Compliance Oversight, OIG, April 2015

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### OIG: Practical Guidance for Health Care Governing Boards on Compliance Oversight

- **The Compliance Function** – prevention, detection, and assuring resolution of actions.
- **The Legal Function** – advises the organization on legal and regulatory risks, defends the organization.
- **The Internal Audit Function** – provides an objective evaluation through the existing risk and internal controls and framework.
- **The HR function** – manages recruiting, screening, and hiring, provides training and development.
- **Quality Improvement** – promotes consistent, safe, and high quality practices.

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### Education and Training

- Role of Compliance Officer in developing
- Specific to roles and responsibilities
- Use training to focus on key risk areas
- Mandatory vs. Voluntary
- General annual education
- Focused/specific education
- Physician training most effective with timely, personal approach
- Essential to reinforcing importance of your compliance program

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### Group Discussion

- Describe what is currently being done in your organization related to Oversight, Reporting Structure, Structure for Compliance Program and Education and Training.
- Identify 3 practices from the discussion which you thought would be good ideas for implementation and report these back to the session participants.

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### Compliance is management of risk

- Federal Sentencing Guidelines (US)
  - An organization "shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement [of its compliance and ethics program] to reduce the risk of criminal conduct identified through this process."
  - Risk management elements: standards and procedures (internal controls), monitoring, auditing, periodic evaluation
- (§8B2.1(b)(1)(5))
- Federal agencies
  - Department of Labor
  - HHS OIG
  - National Institute of Health

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### Conducting a Risk Assessment

1. Defining your Risk Assessment Methodology
2. Identification of risks
3. Evaluation/Analysis of risks
4. Prioritization of risks
5. Management action plans for mitigation
6. Reporting/documentation
7. Auditing and monitoring mitigation plans

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### Group Discussion

- Discuss your risk assessment process.
- Discuss how your risk assessment process helps identify auditing and monitoring plan.
- Discuss budget you have specifically for this process.

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### Monitoring and Auditing

- Define for your institution the difference between auditing and monitoring
- Leverage existing resources on auditing and monitoring activities
- Annual Plan is developed from a risk assessment and includes reviewing previous audits, monitors and other pertinent internal and external information
- Addition of "ad hoc" projects
- Concurrent vs. Retrospective
- Sharing results across the organization

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## Reporting and Investigation

- Mechanism to report matters anonymously, ie: hotline
- Internal vs. external
  - Caller knows how to receive updates and information related to their matter
  - Tracking of investigations and results
  - Reporting to leadership
  - Non-retaliation and participation in investigation policies
  - Confidentiality and Anonymity
  - Use of performance reviews and exit interviews for identifying potential areas of concern



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## Reporting and Investigation (cont)

- Process for triaging investigations should be defined
- Considerations for attorney client privilege should be given to high risk and/or sensitive matters
- Team to conduct investigations should be defined
- Investigators should be trained in procedures related to interviews, objective methodologies and forensics, where applicable
- Investigations are confidential
- Tracking of investigations and results
- Reporting to leadership



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## Response and Prevention

- Internal Investigation
- Are there enough facts to investigate?
  - Consider "fact finding" as a first step before deciding to investigate
  - Consult appropriate area for potential methodologies, ie: audit, legal, etc.
  - Contact Legal Counsel if fact finding warrants advice and/or privilege
- Considerations:
- Who will conduct interviews?
  - Discovery possibilities
  - Determine from facts as to substantiation of allegations
  - Monitor management's actions to resolve issue
  - Possible follow up audit
  - Document retention/destruction policy



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### Group Discussion

- How do you decide when an investigation should be done?
- Who conducts the investigation.
- Share 3 practices with the session participants on ideas to implement at your home organization.

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### Enforcement and Discipline

- Sanctions for non-compliant behaviors
- Fair and Consistent
- OIG Sanctions
- SAM/OIG/SDN Sanctions

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### Attorney Client Privilege

- Protect process and initial data gathering
- Provides for internal assessment before determining actions
- "Waiver of the privilege for the government acts as a waiver for all purposes"

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### Evaluating for Effectiveness

- Annual review of compliance program
- Continual review of policies and procedures
  - Are policies being followed?
  - Revisions necessary?
  - Awareness
  - Who is responsible?
- On-going risk assessment
  - Assure risks are being mitigated
- A dynamic process

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### Key Points for a Compliance Officer to Remember

1. It is important that the program be scalable to the resources available to your organization
2. Risk Assessments are your "help" in identifying the organization's vulnerabilities and prioritizing them.
3. The program will be in evolution from day 1 so each key element of the program will mature based on the time, skill and effort given as you go.
4. Rome was not built in one day...compliance programs are also not built in one day.
5. Build your framework and design, before responding to issues (which incidentally were probably around long before you were).
6. DON'T DO THIS ALONE. Find an organization champion to be the management voice to support your efforts.
7. Network for "sanity"...Identify peers in the profession who can be safe and independent sounding boards for you.

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### In summary....

- Independence for the Compliance Officer Role is critical to the success of the role.
- Current models of compliance programs vary but regardless of design, it is important that you have a direct reporting structure to the governing board and/or CEO.
- The Federal Sentencing Guidelines and the 7 elements are a good start for developing compliance programs. However, it is important to conduct a risk assessment which is the basis for your focus within each of the elements, ie: education and training, auditing and monitoring
- Measures for success for the new compliance program in the first 2 years are mainly related to your process and design...is it working as it should be. As the program evolves, outcome measurements will be able to be obtained.

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# Questions

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**KEEP THEM TALKING TO YOU: A CULTURE OF TRUST AND INTEGRITY IMPROVES QUALITY, SAFETY AND ORGANIZATIONAL OUTCOMES**

**MARCH 26, 2017**

**9:00 AM – 12:00PM**

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**KEY COMPONENTS OF COMPLIANCE PROGRAM**

- Responsibility of the program assigned to a high level official and a designated Compliance Officer:
  - These must be individuals who can report directly to the Board of Directors as needed.
- Standards established that clearly define expected ethical behavior that all who work at and for the organization must follow.
  - Code of Conduct
  - Policies and Procedures

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**KEY COMPONENTS (CONT'D)**

- Monitor and Audit high risk areas:
  - Assure corrective action is taken whenever we do not meet the standards/regulation/expectation
  - This includes plans of improvement, billing corrections, re-education etc.
- Develop disciplinary guidelines to use for those who do not follow the standards:
  - Discipline may include anything from re-education up to termination

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### KEY COMPONENTS (CONT'D)

- Education and Training are essential to assure that everyone who works here understands our standards and knows the regulations that affect to their job:
  - This includes orientation and on going education.
- Communication is essential to assure that all who work for our organization are knowledgeable about the avenues they have to report compliance related issues.
  - In person communication is always best but we also have a system for anonymous reporting.
- Evaluation of the program on an annual basis to assure that the program is effective.

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### PROGRAM GOALS

- Creating a culture of compliance
  - Zero tolerance may not be best route
- Training
  - Effectiveness
  - Targeted
- Hotline
  - Accessibility
  - Anonymity




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### UNDERLYING THEME?




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**LEGAL PARAMETERS**



How to encourage reporting by way of non-retaliation policy, while also maintaining compliance?

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**WHY INVESTIGATE A COMPLAINT?**



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**COMPLAINT CHANNELS FOR EMPLOYEES**

- Establish well-publicized, readily accessible complaint procedures.
- Establish multiple avenues/individuals to whom employees can report complaints.
  - Minimizes discomfort in reporting complaints.
  - Minimizes later arguments by that failure to report arose from fear of retaliation.

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### COMPLAINT CHANNELS FOR EMPLOYEES (CONT'D)

- Consider anonymous reporting procedures.
- Experts will critique policies:
  - Clear explanation of prohibited conduct;
  - Assurance of no retaliation;
  - Assurance of immediate/corrective action.

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### NON-COOPERATIVE COMPLAINANT, WRONGDOER, OR WITNESS?

- Remind of the obligation to cooperate; failure to do so may result in potential discipline.
- Refusal to cooperate may impugn credibility, or inference of wrongdoing.
- Confirm no retaliation policy.
- Confirm refusal to cooperate and disclosure of consequences of failure to cooperate.

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### WHAT TRIGGERS A DUTY TO INVESTIGATE?

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### WHEN MUST YOU INVESTIGATE?

- Former Employee Complains? YES
- Attorney for former employee sends settlement demand? YES
- Designated person receives complaint? YES

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### EMPLOYEES WHO ASK EMPLOYER NOT TO RESPOND TO COMPLAINT

- Once employee complains:
  - employer must take prompt, reasonable, preventative and corrective action.
  - employee relinquishes control over the employer's response.

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### CONDUCTING THE INVESTIGATION



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**CONDUCTING THE INVESTIGATION**

- Respond promptly to a complaint.
- Take immediate remedial measures, if appropriate.

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**CONDUCTING THE INVESTIGATION  
(CONT'D)**

- "Preserve Evidence" when complaint is received.
- Outline Policy Issues; Structure Interviews.
- Be fair and impartial during investigation.
- Make your best judgment about policy violation (not legal conclusion).
- Communicate outcome to affected employees (at a minimum the complainant and the alleged wrongdoer).

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**PROBLEM ISSUE: REFUSAL TO  
INTERVIEW WITHOUT ATTORNEY**

- Advise employee that attorney may become a witness and cannot interfere with investigation or interview.
- Refusing to allow attorney may affect perception of "reasonable investigation".
- Reassess who should do the interview.

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### WHAT CONSTITUTES A THOROUGH INVESTIGATION?

**Thorough: Tailor to circumstances.**

- Identify issues and interview all relevant witnesses.
  - Complainant and alleged wrongdoer.
  - Witnesses identified by complainant and alleged wrongdoer.
  - Employees in relevant work group.

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### WHAT CONSTITUTES A THOROUGH INVESTIGATION? (CONT'D)

- Identify and gather relevant documents.
- Confirm training; attendance logs.
- Survey workplace.
- Watch the alleged wrongdoer.
- Form conclusions in view of POLICIES.
- Suggest remedial measures.

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### WHAT CONSTITUTES A THOROUGH INVESTIGATION? (CONT'D)

**Not Thorough:**

- Interviewing only complainant and alleged wrongdoer.
- Not interviewing those people listed by complainant or alleged wrongdoer.

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### WHAT CONSTITUTES A THOROUGH INVESTIGATION? (CONT'D)

- Consider witness interviews AND review relevant documents.
- **Form conclusions** re: policy violations: *“corroborated,” “unfounded,” “inconclusive with training.”*
- Always suggest remedial measures. Even if inconclusive it can be a learning opportunity.

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### WHAT CONSTITUTES A THOROUGH INVESTIGATION? (CONT'D)

- **KEEP AN ACCURATE, PRESENTABLE RECORD** – don’t let the passage of time dilute the thoroughness of the investigation.

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### WHAT TO DOCUMENT

- Witness/Documents Investigation Log.
- Witness Disclosure Forms.
- Documents reviewed.
- Conclusions.
- Remedial Measures.
- FINAL: Integrated, stand alone document summarizing all of the above.

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### BEST PRACTICES FOR DOCUMENTING INTERVIEWS

- Date/time/individuals present.
- Length of interviews.
- Confirm Opening/Closing Statement.
  - instructions to witnesses, i.e., truthful cooperation, non-retaliation.
  - why they are being interviewed.
- Ask for corroborating or contradictory evidence, notes, records, etc.

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### BEST PRACTICES FOR DOCUMENTING INTERVIEWS (CONT'D)

- Include supportable observations about witnesses such as:
  - Demeanor – how did they appear/physical.
  - Credibility – why credible or not credible.

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### BEST PRACTICES FOR DOCUMENTING INTERVIEWS (CONT'D)

- Interview notes should not include:
  - Speculative statements
  - Generalizations
  - Irrelevant information "floosy" "Communist"
  - Editorial comments that may indicate not neutral
  - Legal conclusions

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### COLLECTING DOCUMENTS

- Personnel files.
- Emails.
- Surveillance video/Attendance records.
- Training/handbook documentation.
- Phone records (anonymous complaint line records).
- Expense account records.

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### WORST INVESTIGATORY PRACTICES

- Poor documentation—Unclear Context.
- Notes with conclusory/irrelevant information.
- Ignoring damaging information.
- No remedial measures because results are inconclusive.
- Discouraging reporting to governmental agency.

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### TAKING APPROPRIATE REMEDIAL ACTION

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- Prompt remedial action must be adequately remedial and effective.
- Action proportionate to the seriousness and frequency of the harassment.

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### REASONABLE REMEDIAL ACTION

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- Training.
- Counseling.
- Dissemination of policy.
- Oral or written warnings.
- Demotion.
- Discharge.
- Consider discipline/remedial measures for those other than wrongdoer (supervisor who failed to catch issue).

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### BARRIERS TO A SUCCESSFUL COMPLIANCE PROGRAM

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### BARRIERS/CHALLENGES

- One of the seven elements of an effective Compliance Program is to develop **effective lines of communication**.
- For most healthcare organizations, effective lines of communication entail multiple venues, allowing both employees and non-employees, to reach the Compliance Officer/Department at all times to report suspected noncompliance with the Code of Conduct, policies and procedures, laws and regulations.
- To help promote and encourage individuals to contact the Compliance Department, most healthcare organizations have a third party company manage a 1-800 number where people can call in and report anonymously.
- Even with the availability to remain anonymous, what barriers do Compliance Programs face to promote trust and integrity to improve reporting and decrease misconduct?

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### PHYSICAL & CULTURAL BARRIERS

- Putting a face to Compliance.
- Establishing credibility with the caller.
- Changing perception that Compliance is the “bad guy”.
- Making Compliance part of the “team”.
- Finding/achieving the balance of employees respecting Compliance but not fearing Compliance.
- Engaging Departmental leaders with investigations.
- Ensuring individuals continue to call their concerns into the hotline.
- Assuring accessibility to compliance reporting resources.

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### INDIVIDUAL BARRIERS

- Preventing both unintentional and intentional “retaliation” against someone who called in the hotline, for example:
  - Unintentionally revealing the caller’s identity throughout the course of the investigation causing their coworkers or manager to treat them differently.
  - Ensuring that post investigation the employee who called the hotline is not treated differently.
  - Being required to discipline the caller because of information discovered in the investigation (or due to the caller’s own admission) and the caller feeling retaliated against.

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### “TONE AT THE TOP” BARRIERS

- Ensuring that the message of Compliance, ethics, etc. gets from the top down.
  - Obtaining “buy in” at the highest level.
  - Does the Board and Executive team receive the latest compliance information? (And absorb it).
  - Ensuring that the message isn’t inadvertently lost or changed as it goes through multiple layers.
  - Visibility of enforcement efforts while not conflicting with risk management strategy.
  - As leaders, don’t forget to reward or acknowledge the good compliance “stuff” happening everyday.

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### INVESTIGATION BARRIERS

- Setting realistic expectations with the caller.
- How can Compliance provide assurance to a hotline caller that their issue will be reviewed and responded to while at the same time not promising an outcome prior to obtaining the facts?
- Conducting an investigation with extremely broad and/or vague allegations.
- Conducting anonymous investigations.
- Conducting an investigation when the caller requests to remain anonymous.
  - Can honoring anonymity become a barrier to initiating an investigation? Can honoring anonymity not always be honored?
- Misuse of the hotline – reporting a facially legitimate complaint against an employee that is actually false.




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### RESOURCE BARRIERS

- Challenged by fewer compliance resources/personnel in smaller organizations.
- “Multiples hats” worn by compliance personnel dilutes effectiveness.
- Conflicts arise when compliance personnel become “operations”.
- Employees less inclined to report an issue if from small organization.
- Delays lead to poor perceptions of the compliance program.
- Lack of resources prevents “proactive” compliance program.
- Poor visibility of the compliance program promotes fear and lack of trust (only come around when something is wrong!).

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## ADDITIONAL BARRIERS

- Perceptual
- Language Barriers
  - Jargon
  - Contextual Meaning
  - Insensitive/Discriminatory
- Physiological Barriers
  - Hunger
  - Fatigue
  - Emotional Distress
- Psychological Barriers
  - Negativity
  - Boredom
  - External pressures



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## BREAKING DOWN THE BARRIERS

- Discuss how to break down the barriers; questions to ask; actions to take.



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## COMMUNICATION

What's Your Style....



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### HOW EFFECTIVE IS YOUR COMMUNICATION?

Who is the Compliance Officer's Audience?

- Board Members
- Executive Management Team
- Legal Counsel
- Risk Management
- Field staff
- Patients/Residents/Tenants
- Government Investigators
- External Auditors
- Family Members
- Complainant

How does the compliance officer prioritize?




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### HOW EFFECTIVE IS YOUR COMMUNICATION? (CONT'D)

When is the Compliance Officer the Audience?

- Hotline Complaints
- Reports of Policy Violations
- Fielding questions from employees/customers/public
- First Contact for Government Investigators/Oversight
- Co-worker uses Compliance Officer as "sounding board" or for "venting"
- Trusted advisor in an organization
- Serves as mentor



How should the compliance officer respond?

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### BOOSTING COMPLIANCE COMMUNICATION EFFECTIVENESS

- Are you depending on "e-learning" as the only mode of communication to employees or other stakeholders?
- What communication channels do you currently use?
- What communication channels are you potentially overlooking?
  - Kiosks
  - Monthly Staff Meetings
  - Bulletin Boards
  - Newsletters, Blogs or other internal publications
  - Other?

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### BOOSTING THE COMPLIANCE MESSAGE

- Does your communication appeal to all learning styles?
  - Visual
  - Auditory
  - Reader/Writer, and
  - Kinesthetic
- How long is your message?
  - Once a year for 30 or 40 minutes vs. 6 times a year for 5-8 minutes
  - Compelling, to the point, and reinforce previous messages

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### BOOSTING THE COMPLIANCE MESSAGE (CONT'D)

- Presenting information for positive change by presenting the negative outcomes of non-compliance vs. the positive outcomes of compliance
- Repetition affects change
  - Focus on a change in behavior, not just a change in what employees know
- Recognize that others see things differently
- Get feedback
- Speak face to face whenever possible
- Use language that fits the audience
- Have integrity and honesty in communications
- Make your communication like a conversation
  - Clarity and Brevity

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### HYPOTHETICAL # 1

An employee notifies a Compliance Officer of perceived unethical billing practices of a regional leader. The compliance Officer listens to the employee and assures the employee that the concern will be fully investigated. Weeks pass and the employee hears nothing about the investigation nor does she observe any changes in the regional leader's business practices. The employee is concerned about what actions the Compliance Officer/company has taken. The employee reaches out to the Compliance Officer and inquires where the company is with the investigation. The Compliance Officer knows that they have been diligently investigating but (1) isn't sure what she should/can disclose to the employee; (2) knows that there is no actual evidence of unethical billing practices; and (3) that the regional leader is a "high performer" within the company and that without actual evidence, no corrective action will be taken.

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## HYPOTHETICAL # 2

Medicare Home Health requires as a condition of payment a face to face meeting between the treating physician/nurse practitioner and patient in order to determine that home health is appropriate. Thereafter, the practitioner must provide a written narrative on a specific form, identifying the need for home health, and must sign that form.

These forms are frequently filled out in a skilled nursing facility when discharging a resident – many times they will require home health services in order to permit safe discharge.

A social worker fills out the approval form and readies it for the practitioner's signature, however, she cannot locate the practitioner to get his or her signature. In order to not delay the resident's discharge and to speed the arrangement for home health services, the social worker decides to create blank "forms" with various treating practitioners' signatures on the forms so she can use them instead of finding the appropriate practitioner before discharging the resident.

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## HYPOTHETICAL # 2(CONT'D)

Some months later, the social worker quits and is responsible for hiring her replacement, who she trains to perform the home health approval process in the way she had been doing it – by using the copied "pre-signed" forms. Her replacement, who is a nurse by trade, doesn't feel that using the "pre-signed" form is correct and asks the social worker department supervisor if this is how the process is supposed to be completed. The supervisor assures her that this is the way they have done it for several years and when you cannot find the treating practitioner to sign the form, you should just use the "pre-signed" form instead.

Not wanting to be a tattle tale on her first weeks on the job, the new social worker declines to report her concern to the Compliance Officer and there is no hotline at her facility.

Years later the facility is audited and the mistakes uncovered. The facility has called to ask you how to handle the situation including whether to terminate the social worker who questioned the practice, but failed to report it to the Compliance Officer.

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## HYPOTHETICAL # 3

Nurses at a skilled nursing facility staff self-segregates into cliques along racial lines. Both white nurses and black nurses are engaging in a medication-diverting scheme. White nurse learns that a black nurse is stealing a resident's oxytocin and calls the hotline and reports it.

An investigation is conducted during which all of the nurses who work with the alleged wrongdoer are interviewed. None of the black nurses report having seen or being aware of the wrongdoer stealing oxytocin, which is incorrect. Moreover, none of the white nurses reporting or having seen or being aware of anyone else (like their white counterparts) stealing oxytocin, which is also incorrect. White nurses who have personal knowledge of the wrongdoer's actions reveal it in the interviews, but do not inaccurately report knowledge of misconduct.

It is later revealed during a medication audit that several of the white nurses and several of the black nurses are stealing oxytocin and you suspect that several of their coworkers were aware of the practice at the time of the investigation

The facility has called to ask how to handle the situation.

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### HYPOTHETICAL # 4

Employee ("Caller") uses the compliance hotline to report a "Compliance" concern. The Caller speaks directly with a member of the Compliance department and is cooperative and responsive to a number of interview questions. The caller asks to remain anonymous. However, the Caller demands immediate action be taken or he/she will contact other authorities (for example, the State Survey Agency). The Compliance department representative seeks the "who, what, when and where" details from the Caller to determine the nature of the "Compliance" concern(s). During the course of the call, Caller alleges multiple issues related to quality of care, HIPAA violation and harassment/discrimination by co-workers. Caller also accuses the facility leadership of ignoring past complaints from staff or being the cause of the complaints. The Caller adds that he/she is calling "on behalf of many other staff members who are fed up and ready to quit". Most of the reported matters are alleged to have occurred weeks or months ago.

Prior to ending the call, the Caller states that he/she is fearful of retaliation from his/her supervisor for calling the compliance hotline. The Caller adds that he/she is aware of others from this facility that contacted the compliance hotline and were terminated as a result of their call. Caller is unwilling to provide details of those prior instances.

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### HYPOTHETICAL # 5

Important characteristics of Compliance Officers and Compliance staff should include trustworthiness, integrity and respect for confidentiality. Often times close working relationships lead to the sharing of a number of topics with colleagues. Compliance team members can be viewed as a resource to "bounce things off". They can also be a sounding board for personnel, including high-level leaders, to "vent" frustrations about colleagues or discuss potential wrongdoing.

The challenge for the Compliance Officer is to maintain a respectful and fair relationship with all levels of personnel while remaining true to the duties owed to the organization. While there is a challenge some times to keep people talking, there may also be a challenge when people talk too much. When does a Compliance Officer have a duty to inform a colleague that "venting" has moved to an actionable compliance matter that must be investigated? Much like the anonymous hotline caller, the Compliance Officer may be faced with having the knowledge of a potential compliance matter that deserves investigation yet the reporter requests nothing be done.

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### HYPOTHETICAL # 6

The Organization conducts an audit of in-house therapy services under Medicare Part B. The audit identifies a 58% error rate over a 3 year period. The Director of Therapy Services has been in place for 10 years and a review of the direct therapy staff indicates that there have not been any staffing changes for the last 8 years. The Compliance Officer does an investigation to determine the underlying issues and the scope of the potential repayment. In an interview, a therapist states that they had stopped getting certifications signed by the physicians about 3 years ago because the physicians were complaining about too much paperwork and so they had just stopped the process without knowledge of management. Other contributing factors include that there has not been a process to monitor and audit therapy documentation on a regular basis since and there was not a triple check process in place prior to billing.

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### HYPOTHETICAL # 6 (CONT'D)

It was established through interviews that staff were aware that this practice was not acceptable however, they did not feel an obligation to report this to management, the Compliance Officer or the hotline.

The Compliance Officer has recommended to Senior Leadership that disciplinary action should be taken for the therapist who had stopped obtaining the physician documentation and for the Director or Therapy Services. Senior Leadership is balking at these recommendations for fear of upsetting long-term employees. The Compliance Officer is concerned about the credibility of the Compliance program if no actions are taken to address the actions or lack of actions of the staff.

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### SPEAKER CONTACT INFO

- **Karla Dreisbach, CHC, CHPC**
  - VP of Compliance, Peace Church Compliance Program
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- **Kelly Lipcomb, JD**
  - Attorney, Lane Powell
  - [lipcombk@lanepowell.com](mailto:lipcombk@lanepowell.com)

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

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**HIPAA COMPLIANCE THAT  
ADDRESSES THE RISKS OF  
TODAY AND WILL GROW WITH  
YOU IN THE FUTURE**

Ben Burton, Consultant (First Class Solutions, Inc.)  
Kevin Dunnahoo, Senior Manager (Protiviti)  
Matt Jackson, Director (Protiviti)

**27th Annual  
Compliance Institute**  
MARCH 26-29, 2017  
NATIONAL HARBOR, MD | CHARLOTTED NATIONAL

Internal Audit, Risk, Business & Technology Consulting

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WELCOME

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**AGENDA**

Introduction & Industry Buzz (Protiviti)
Seven Elements & HIPAA Compliance (First Class Solutions, Inc.)
Break (15 minutes)
Cybersecurity Considerations & Risk Analysis Processes (Protiviti)
Trending Risk Areas (Protiviti)
Closing Remarks
Q&A

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INTRODUCTION & INDUSTRY BUZZ

Horizontal lines for notes under the Introduction & Industry Buzz section.

CERTAINTIES...



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Horizontal lines for notes under the CERTAINTIES... section.

IN THE NEWS



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Horizontal lines for notes under the IN THE NEWS section.

**ENFORCEMENT IS HERE**

- Covered Entities and Business Associates
- Address confirmation letters sent out from an @hhs.gov email account (beware of phishing)
- Pre-audit questionnaires have been sent out verifying demographics of the organization and requesting a list of BAs
- 20,000+ BAs identified
- 10 business days to respond with the requested information, be ready!
- On-site comprehensive audits start in 2017



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## Standards and Procedures

- Written Policies
  - Start with the Rule
  - How will you comply
- Procedures
  - Reflect what you are doing
  - Include appropriate operational departments
- Will need to revise regularly – annually or biennially and when there is a change

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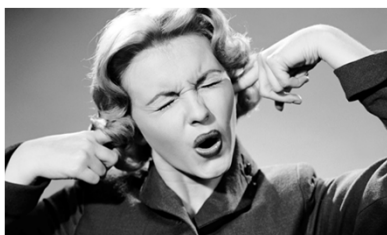
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## 2012 Alaska Medicaid



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HHS.gov U.S. Department of Health & Human Services  
Health Information Privacy

I'm looking for...

HHS A-Z Index

HIPAA for Individuals | Filing a Complaint | HIPAA for Professionals | Newsroom

HHS > HIPAA Home > For Professionals > Compliance Enforcement > Audit > Audit Protocol

Text Resize A A A Print Share

### Audit Protocol – Updated April 2016

The Phase 2 HIPAA Audit Program reviews the policies and procedures adopted and employed by covered entities and business associates to meet selected standards and implementation specifications of the Privacy, Security, and Breach Notification Rules. These analyses are conducted using a comprehensive audit protocol that has been updated to reflect the Omnibus Final Rule. The audit protocol is organized by Rule and regulatory provision and addresses separately the elements of privacy, security, and breach notification. The audits performed assess entity compliance with selected requirements and may vary based on the type of covered entity or business associate selected for review. You may submit feedback about the audit protocol to OCR at [OSOCR.Audit@hhs.gov](mailto:OSOCR.Audit@hhs.gov).

The protocol is available for public review and searchable by keyword(s) in the table below; export options will be made available soon.

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Audit Type	Section	Key Activity	Established Performance Criteria	Audit Inquiry	Required/Addressable
Privacy	§164.502 (a)(5)(i)	Prohibited uses and disclosures - Use and disclosure of genetic information for underwriting purposes	§ 164.502(a)(5)(i) Use and disclosure of genetic information for underwriting purposes: Notwithstanding any other provision of this subpart, a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of health plan, shall not use or disclose protected health information that is genetic information for underwriting purposes. For purposes of paragraph (a)(5)(i) of this section, underwriting purposes means, with respect to a health plan: (A) Except as provided in paragraph (a)(5)(i)(B) of this section: (1) <i>Disc for re-determination</i>	Does the health plan use or disclose for underwriting purposes, "Genetic Information" as defined at § 160.103, including family history? Inquire of management. Obtain and review all underwriting policies and procedures (for example, published and unpublished underwriting guidelines currently used by underwriting staff, including manuals and training materials). Evaluate whether the underwriting policies	

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### Education and Training

- New Employees
  - Must train within a “reasonable amount of time”
  - Must be documented
  - Related to job
- Existing staff
  - Periodic security updates
  - Anytime there is a material change

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### Monitoring and Auditing

- RISK ANALYSIS (security and privacy)
  - Comprehensive
  - Living
  - Include everyone that touches PHI
- Talk about findings
  - HIPAA does not exist in a box
  - Refine standards and procedures
- On going event monitoring
- Regular privacy audits

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Too Many Trees



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Do Something



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Response and Prevention

- BREACHES (45 CFR § 164 Subpart D— Notification in the Case of Breach of Unsecured Protected Health Information
  - Exceptions
  - Risk Assessment
- Mitigation and Prevention
- Requirements to disclose

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### Enforcement and Discipline

- Sanctions
  - Workforce members
  - Document
- Punishment needs to match the crime

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### Reporting

- Report to the Board
- Include in your annual training

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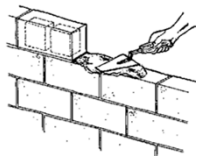
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### Fill in the Gaps



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**NIST Cybersecurity Framework**

- HHS crosswalk
- Added support to your Standards and Procedures

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**Stay Current**

- Review your professional resources
- Visit Governmental Websites
  - OIG
  - HHS

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**Conclusion**

- Risks to Organization
- Use the basic structure to create a base and augment
- Tools and Resources
- Engage others for help
- Keys to HIPAA compliance
  - Risk Analysis
  - Document, document, document,

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### Rules Tools

- 45 CFR 160 HIPAA General Administrative Requirements <http://162.140.57.127/cgi-bin/text-idx?SID=f93fdec29fbd880fe0e2bfb252bad46&mc=true&n ode=sp45.1.160.a&rgn=div6>
- 45 CFR 164 PART 164—SECURITY AND PRIVACY <http://www.ecfr.gov/cgi-bin/text-idx?SID=fe60fe4d138c1ac86e2e81f99b4908a6&mc=true&n ode=pt45.1.164&rgn=div5>
- HHS HIPAA Audit Protocol <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/index.html?language=es>
- Cornell University Law School, Legal Information Institute <https://www.law.cornell.edu/>

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### Guidance and Information

- HIPAA/NIST crosswalk <https://www.hhs.gov/sites/default/files/nist-csf-to-hipaa-security-rule-crosswalk-02-22-2016-final.pdf>
- HIPAA Privacy, Security & Breach Notification Compliance Audits phase 2, INFORMATIONAL WEBINAR, July 13, 2016 <https://www.hhs.gov/sites/default/files/OCRDeskAuditOpeningMeetingWebinar.pdf?language=en>
- NIST Special Publication 800-53, rev. 4, Security and Privacy Controls for Federal Information Systems and Organizations <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf>
- Office of Inspector General (various HIPAA reports, investigation results, and guidance) <https://oig.hhs.gov/>
- HealthIT.gov Security Risk Assessment <https://www.healthit.gov/providers-professionals/security-risk-assessment>

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### Professional Resources

- HCCA <http://www.hcca-info.org/>
- American Health Information Management Association <http://www.ahima.org/>
- Healthcare Information and Management Systems Society <http://www.himss.org/>
- AMA <https://www.ama-assn.org/practice-management/hipaa-compliance>
- AHA <http://www.aha.org/advocacy-issues/hipaa/index.shtml>

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### Other Information

- HcPro HIPAA Update  
<http://blogs.hcpro.com/hipaa/>
- HIPAA COW (Collaborative of Wisconsin)  
<http://hipaacow.org/>
- HIPAA News.org <http://hipaanews.org/>
- (NCHICA) North Carolina Healthcare Information & Communications Alliance, Inc.  
<http://nchica.org/>

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### References

- Becker's Health IT and CIO review "10 largest HIPAA settlement fines"  
<http://www.beckershospitalreview.com/healthcare-information-technology/10-largest-hipaa-settlement-fines.html>
- Becker's Health IT and CIO review "Missouri mom accused of violating HIPAA by taking son's photo is suing Mercy Hospital"  
<http://www.beckershospitalreview.com/healthcare-information-technology/missouri-mom-accused-of-violating-hipaa-by-taking-son-s-photo-is-suing-mercy-hospital.html>
- Six people fired from Cedars-Sinai over patient privacy breaches, July 12, 2013 By Anna Gorman and Abby Sewell  
<http://articles.latimes.com/2013/jul/12/local/la-me-hospital-security-breach-20130713>
- Administrative Law Judge rules in favor of OCR enforcement, requiring Lincare, Inc. to pay \$239,800 <http://wayback.archive-it.org/3926/20170127185543/https://www.hhs.gov/about/news/2016/02/03/administrative-law-judge-rules-favor-ocr-enforcement-requiring-lincare-inc-pay-penalties.html>

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#### My Information

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 Fax: 314-209-1911  
 Cell: 207-420-5811




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Questions?



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Health Care Compliance Association

protiviti  
THE PROTECTIVE SERVICES COMPANY

## CYBERSECURITY CONSIDERATIONS & RISK ANALYSIS PROCESSES

**27th Annual Compliance Institute**  
MARCH 26-29, 2017  
NATIONAL HARBOR, MD | CHARLOTTED NATIONAL

*Protiviti's Portion of the joint session:*  
**"HIPAA COMPLIANCE THAT ADDRESSES THE RISKS OF TODAY AND WILL GROW WITH YOU IN THE FUTURE"**

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### THE THREAT IS REAL

89% of healthcare organizations surveyed have suffered **at least one** data breach in the **last 2 years**

- 45% of CEs have experienced more than five data breaches over the past 2 years
- 61% of BAs experienced data breaches
- Data breaches could be costing the U.S. healthcare industry an average of \$6.2 billion annually
- The average economic impact of data breaches per organization is \$2.2 million.

Source: Sixth Annual Study on Patient Privacy & Security of Healthcare Data. Ponemon Institute, May 2016.

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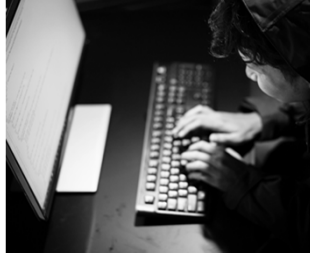
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THE THREAT IS REAL

Criminal attacks are now the number-one cause of data breaches (cyber-attacks, malicious insiders, and/or paper medical file theft)

Attacks are targeting medical files and billing / insurance records

CEs say 48% of medical identity theft's root cause was an unintentional employee action (phishing, social engineering, etc.).



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THE THREAT IS REAL

Medical Information is sold on the black market typically at a premium, reports range widely on the actual cost, but they go for well above the cost of stolen credit card info. An interactive map of healthcare breaches by number of occurrence can be found at the World Privacy Forum website.

Healthcare IT News

Privacy & Security

Cybercriminals to launch more ransomware attacks as black market price of health data drops

Executives at the World Privacy Forum and Institute for Critical Infrastructure Technology said that the availability of EHR data is outpacing demand, which means that cybercriminals have to undertake more attacks to steal the same amount of money.



By Jessica Davis | October 10, 2016 | 9:27 AM

SHARE 217

Source: <http://www.worldprivacyforum.org/medicalidentitytheft.html>

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AREA OF SCRUTINY



Deficient Risk Analysis!

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**ENFORCEMENT**

Phase II will mostly consist of "desk audits," but some will be selected for an on-site more comprehensive audit, starting in 2017

All entities are eligible for selection for the on-site audits EVEN those who have already gone through a "desk audit"

A report of the summarized findings will be created and made available sometime after the conclusion of the planned audits in 2017

**Desk Audit Scope**

- Privacy – Notice of Privacy Practices (does not apply to BAs)
- Breach Notification – Timing and Content of Breach Notifications or Breach Risk Assessments
- Security – Risk Analysis and Risk Management

**Audit Protocols – Updated and available now**

- <http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol-current/index.html>

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**ENFORCEMENT**

Add @hhs.gov as a known address to avoid losing emails in spam

Covered Entities - make sure you have a list of your Business Associates ready

Your documentation should be able to stand on its own because the main interaction with OCR is uploading your documents:

- Can they be understood by an auditor?
- Would they benefit from a narrative that explains them?

Assess against the protocols

- Desk audit focus
- Comprehensive

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**ENFORCEMENT**

HIPAA compliance reviews and complaint investigations are even more thorough than the Phase II audits

Complaint Investigation – complaint driven

Compliance Review – breach driven

**HIPAA Penalties vs. Settlements**

- OCR most often "settles" and creates "corrective action plans"
- These amounts are vastly reduced compared to what they could enforce through actual civil monetary penalties under the HITECH Act

**Trending Issues**

• Lack of BAA	• Lack of transmission security	• Insider threat
• BAA not updated after HITECH	• Patching of software	• Improper disposal
• Incomplete or inaccurate Risk Analysis	• Audit logs	• Insufficient backup and contingency planning

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EVALUATION VS. RISK ANALYSIS

<p><b>Evaluation</b></p> <ul style="list-style-type: none"> <li>Gap assessment comparing compliance practices against the individual standards/requirements</li> <li>Guidance may be found at: <a href="http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html">http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html</a></li> </ul>
<p><b>Risk Analysis / Risk Management</b></p> <ul style="list-style-type: none"> <li>Identify and assess risks to all of your ePHI</li> <li>Take action to reduce risks and vulnerabilities to a reasonable and appropriate level</li> <li>Guidance may be found at: <a href="http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html">http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html</a></li> </ul>

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EVALUATION VS. RISK ANALYSIS

Standard	Requirement	Specification	Detail
Evaluation §164.308(a)(8)	§164.308(a)(8) Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.	N/A	N/A

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EVALUATION VS. RISK ANALYSIS

Standard	Requirement	Specification	Detail
Security Management Process §164.308(a)(1)	§164.308(a)(1)(i) Implement policies to prevent, contain, and correct security violations.	Risk Analysis	§164.308(a)(1)(i)(A) Conduct an accurate and thorough <b>assessment of the potential risks and vulnerabilities</b> to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.
		Risk Management	§164.308(a)(1)(i)(B) <b>Implement security measures</b> sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level.

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**AREA OF SCRUTINY**

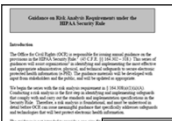

While high-level guidance has been issued, there are no baseline standards from the federal government in support of "risk analysis" efforts.

OCR issued "Guidance on Risk Analysis Requirements under the HIPAA Security Rule" on July 14, 2010

- Definitions
- Elements of a Risk Analysis
- 9 pages

NIST SP 800-30 – Guide for Conducting Risk Assessments

- 41 pages

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**ELEMENTS OF A RISK ANALYSIS**

**1. Scope of Analysis**

- An organization's risk analysis should include the potential risks and vulnerabilities to the confidentiality, availability and integrity of all ePHI that an organization creates, receives, maintains, or transmits. (45 C.F.R. § 164.306(a))
  - All ePHI, regardless of the particular electronic medium in which it is created, received, maintained or transmitted or the source or location of its ePHI.
    - o Hard Drives/USB Drives/Floppy Disks
    - o CD/DVD
    - o Cell Phones/PDAs
    - o Backup Media/Transmission Media
    - o Etc.

**2. Data Collection**

- Identify and document where the ePHI is stored, received, maintained or transmitted. (45 C.F.R. §§ 164.308(a)(1)(ii)(A) and 164.316(b)(1))
  - Questionnaires, Interviews, Automated Scanning Tools

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**AREA OF SCRUTINY**

Scope of your Risk Analysis is a big area for OCR

**Audit protocol**

- Does the entity...conduct an accurate and thorough assessment of the potential risks...to the confidentiality, integrity, and availability of all the ePHI it creates, receives, maintains, or transmits?
- Obtain and review the written risk analysis documentation for:
  - A defined scope that identifies all of its systems that create, transmit, maintain, or transmit ePHI
- The word "all" appears four different times in this one protocol

**Resolution Agreements**

- Failure to conduct risk analysis and implement risk management plans (MAPFRE 1/18/17 \$2.2m)
- Failure to conduct a thorough risk analysis of all of its ePHI (Lahey Hospital 11/24/2015, \$850k)
- Neither entity had conducted an accurate and thorough risk analysis (New York Presbyterian and Columbia University 5/7/2014, \$4.8m)

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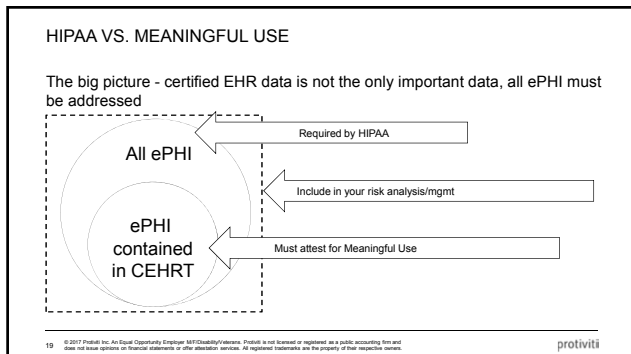
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### SCOPE – EXAMPLES

Applications	Asset Types
EHR	<ul style="list-style-type: none"> <li>• Desktops/Laptops</li> <li>• Server</li> <li>• SAN/Disk Array</li> <li>• Backup Tapes</li> <li>• USBs</li> <li>• Medical Devices</li> <li>• Printers</li> <li>• Mobile Devices</li> </ul>
Email	<ul style="list-style-type: none"> <li>• Vendor Cloud</li> <li>• Desktops/Laptops</li> <li>• Mobile Devices (smartphones/tablets/etc.)</li> </ul>
Network Shares	<ul style="list-style-type: none"> <li>• Server</li> <li>• Backup Tapes</li> </ul>
Electronic Voicemail	<ul style="list-style-type: none"> <li>• Server</li> <li>• Backup Tapes</li> <li>• Desktops/Laptops</li> </ul>

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### ELEMENTS OF A RISK ANALYSIS

**3. Identify and Document Potential Threats and Vulnerabilities**

- Identify and document reasonably anticipated threats and vulnerabilities to ePHI. (45 C.F.R. §§ 164.306(a)(2), 164.308(a)(1)(ii)(A), and 164.316(b)(1)(ii))
  - Threat – “[t]he potential for a person or thing to exercise (accidentally trigger or intentionally exploit) a specific vulnerability.”
    - o Natural – Floods, Earthquakes, Tornadoes, etc.
    - o Human – Inadvertent data entry, malicious software upload, unauthorized access to confidential data
    - o Environmental – Long term power failure, pollution, chemicals, liquid leaks
  - Vulnerability – “[a] flaw or weakness in system security procedures, design, implementation, or internal controls that could be exercised (accidentally triggered or intentionally exploited) and result in a security breach or a violation of the system’s security policy.”

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THREAT & VULNERABILITY – EXAMPLES

Assets	Threat	Vulnerability
Desktops, Laptops, Servers, etc.	Malware – theft of sensitive data	Lack of sufficient anti-malware (installed/updated)
Desktops, Laptops, Servers, SAN, etc.	Hacker – theft of sensitive data	Unpatched vulnerabilities in network systems
Desktops, Laptops, Smartphones, USBs, etc.	Burglar/Thief – theft of equipment	Media is not handled and guarded properly
Desktops, Laptops, Smartphones, USBs, etc.	Careless IT personnel – improper destruction/disposal or reuse of media	Media is not properly disposed of
Desktops, Laptops, Servers, SAN, etc.	System Cracker – social engineering	Employees are overly trusting and uneducated/unaware of social engineering tactics

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ELEMENTS OF A RISK ANALYSIS

4. Assess Current Security Measures

- Assess and document the security measures an entity uses to safeguard ePHI (45 C.F.R. §§ 164.306(b)(1), 164.308(a)(1)(ii)(A), and 164.316(b)(1))
  - Documentation – Policy, Procedure, Process, etc.
  - Practice – Physical or logical controls in place

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SECURITY MEASURES – EXAMPLE

Assets	Threat	Vulnerability	Security Measures (Controls)
Desktops, Laptops, Smartphones, USBs, etc.	Burglar/Thief – theft of equipment	Media is not handled and guarded properly	1) Employees are educated to protect the physical security of the device on a yearly basis
Desktops, Laptops, Servers, SAN, etc.	System Cracker – social engineering	Employees are overly trusting and uneducated/unaware of social engineering tactics	1) Employees are educated on social engineering threats yearly 2) Social engineering tests are performed twice a year to assess employee awareness

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ELEMENTS OF A RISK ANALYSIS

5. Determine the Likelihood of Threat Occurrence

- Document all threat and vulnerability combinations with associated likelihood estimates that may impact the confidentiality, availability and integrity of ePHI of an organization. (45 C.F.R. §§ 164.306(b)(2)(iv), 164.308(a)(1)(ii)(A), and 164.316(b)(1)(ii))
  - Threat-source motivation and capability
  - Nature of the vulnerability

Likelihood Level	Likelihood Definition
High	The threat-source is highly motivated and sufficiently capable, and controls to prevent the vulnerability from being exercised are ineffective.
Medium	The threat-source is motivated and capable, but controls are in place that may impede successful exercise of the vulnerability.
Low	The threat-source lacks motivation or capability, or controls are in place to prevent, or at least significantly impede, the vulnerability from being exercised.

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ELEMENTS OF A RISK ANALYSIS

6. Determine the Potential Impact of Threat Occurrence

- Assess the magnitude of the potential impact resulting from a threat triggering or exploiting a specific vulnerability. (45 C.F.R. §§ 164.306(a)(2), 164.308(a)(1)(ii)(A), and 164.316(b)(1)(ii))
  - Quantitative vs. Qualitative Assessment
  - Loss of Integrity, Confidentiality, Availability

Magnitude of Impact	Impact Definition
High	Exercise of the vulnerability (1) may result in the highly costly loss of major tangible assets or resources, (2) may significantly violate, harm, or impede an organization's mission, reputation, or interest, or (3) may result in human death or serious injury.
Medium	Exercise of the vulnerability (1) may result in the costly loss of tangible assets or resources, (2) may violate, harm, or impede an organization's mission, reputation, or interest, or (3) may result in human injury.
Low	Exercise of the vulnerability (1) may result in the loss of some tangible assets or resources or (2) may noticeably affect an organization's mission, reputation, or interest.

Source: OCR's "Guidance on Risk Analysis Requirements under the HIPAA Security Rule"

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ELEMENTS OF A RISK ANALYSIS

7. Determine the Level of Risk

- Assign a risk level based on the average of the assigned likelihood and impact levels. (45 C.F.R. §§ 164.306(a)(2), 164.308(a)(1)(ii)(A), and 164.316(b)(1))
  - Inherent Risk = Likelihood \* Impact
  - Residual Risk = Inherent Risk - Safeguards (Controls)

Risk Level	Risk Description and Necessary Actions
High	If an observation or finding is evaluated as a high risk, there is a strong need for corrective measures. An existing system may continue to operate, but a corrective action plan must be put in place as soon as possible.
Medium	If an observation is rated as medium risk, corrective actions are needed and a plan must be developed to incorporate these actions within a reasonable period of time.
Low	If an observation is described as low risk, the system's DAA must determine whether corrective actions are still required or decide to accept the risk.

Source: OCR's "Guidance on Risk Analysis Requirements under the HIPAA Security Rule"

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RISK DETERMINATION – EXAMPLES

Assets	Threat	Vulnerability	Security Measures (Controls)	Likelihood	Impact	Risk Rating
Desktops, Laptops, Smartphones, USBs, etc.	Burglar/ Thief – theft of equipment	Media is not handled and guarded properly	1) Employees are educated to protect the physical security of the device on a yearly basis	High (5)	High (5)	Critical (25)
Desktops, Laptops, Servers, SAN, etc.	System Cracker – social engineering	Employees are overly trusting and uneducated or unaware of social engineering tactics	1) Employees are educated on social engineering threats yearly 2) Social engineering tests are performed twice a year to assess employee awareness	Moderate (3)	High (5)	High (15)

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ELEMENTS OF A RISK ANALYSIS

**8. Finalize Documentation**

- The Security Rule requires the risk analysis to be documented but does not require a specific format. (45 C.F.R. § 164.316(b)(1))

**9. Periodic Review and Updates to the Risk Assessment**

- Conduct continuous risk analysis to identify when updates are needed. (45 C.F.R. §§ 164.306(e) and 164.316(b)(2)(iii))

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ELEMENTS OF RISK MANAGEMENT

Risk management is the **implementation of security measures** to sufficiently reduce an organization's risk of losing or compromising its ePHI and to meet the general security standards.

**Example Risk Management Steps**

- Develop and implement a risk management plan [This plan describes what will be done to further mitigate the identified risk.]
- Implement security measures.
- Evaluate and maintain security measures."

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**RISK MANAGEMENT – EXAMPLES**

Assets	Threat	Vulnerability	Controls	Likelihood	Impact	Risk Rating
Desktops, Laptops, Smartphones, USBs, etc.	Burglar/ Thief – theft of equipment	Media is not handled and guarded properly	1) Employees are educated to protect the physical security of the device on a yearly basis	High (5)	High (5)	Critical (25)
Risk Management Plan: Encrypt all devices that may receive ePHI. Implement a MDM Solution to manage these devices. Use the MDM solution to perform monthly inventory checks to see if any devices have gone missing and investigate. Remotely wipe any devices that cannot be located.				Responsible Party: CIO Remediation Date: Est. 10/1/2017		

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**RISK MANAGEMENT – EXAMPLES**

Assets	Threat	Vulnerability	Controls	Likelihood	Impact	Risk Rating
Desktops, Laptops, Servers, SAN, etc.	System Cracker – social engineering	Employees are overly trusting and uneducated or unaware of social engineering tactics	1) Employees are educated on social engineering threats yearly 2) Social engineering tests are performed twice a year to assess the employees awareness	Moderate (3)	High (5)	High (15)
Risk Management Plan: Increase education to occur quarterly through a variety of different avenues. Communicate the results of the social engineering tests to reaffirm the issue with the workforce. Use real-life examples to further enhance awareness.				Responsible Party: Education Team Remediation Date: Est. 12/31/2017		

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**AREA OF SCRUTINY** 

OCR will be looking for evidence that you took action on the identified risks in some form or fashion

**Audit Protocol**

- Obtain and review documentation demonstrating the security measures implemented and/or in the process of being implemented as a result of the risk analysis or assessment. Evaluate and determine whether the implemented security measures appropriately respond to the threats and vulnerabilities identified in the risk analysis according to the risk rating and that such security measures are sufficient to mitigate or remediate identified risks to an acceptable level.
- Have this info documented

**HIPAA Penalty Enforcement**

- February 1, 2017 – OCR levied a \$3.2 million civil money penalty against Children’s Medical Center of Dallas for lack of addressing known security risks.
  - Encryption was identified as a risk in 2007, was not remediated until 2013
  - Children’s suffered 2 breaches during this time that encryption would have protected against

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**TRENDING RISK AREAS**  
*RISKS TO LOOK FOR IN YOUR ENVIRONMENT*

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**TRENDING RISK AREAS – VENDOR MANAGEMENT**

- Vendors are a key part of many healthcare organization's business processes, but have also been an avenue for compromising of PHI/ePHI.
- Threat: Vendor's are not diligent in their security measures.
- Vulnerability: Vendor's lack of controls may put your data at risk.
- Recommended Controls:
  - Robust contracts and BAAs that specify the requirements to protect the data and implications for failure to do so
  - Vendor management and assessment process up-front and ongoing to assess the controls the vendor has in place. Could be accomplished through:
    - Reviewing SSAE16 SOC Reports (Third party's assessment of controls)
    - Questionnaire to vendor
    - Audits of vendor to test controls effectiveness
  - Process to monitor for new vendor's, working with Contracting/AP/Supply Chain, etc.

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**TRENDING RISK AREAS – MEDICAL DEVICES**

- Threats: Hackers, Patients, Malware, etc.
- Vulnerabilities: Unpatched vulnerabilities, out of date operating systems, default user/admin credentials, weak wireless encryption, etc.
- Recommend Controls:
  - Physically secure devices
  - Segment these devices network segments
  - Regular vulnerability scans
  - Implement a life cycle management program for devices
- Need to be managed throughout the entire life cycle:
  - Planning & Requirements
  - Procurement & Contracting
  - Implementation
  - Maintenance
  - Decommission

**FDA RECALLED:**

- Hospira Symbiq Infusion System – Cybersecurity vuln.
- Alaris Medley Large Volume Pump – Defective part



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TRENDING RISK AREAS – SOCIAL ENGINEERING

PAYMENT NOTIFICATION

**Online Payment Confirmation**

You have a payment of \$100.00 USD to account: [Account@protivity.com](#)

From our site you can download the file and view your account. If you don't see the details for the transaction please contact our support.

Item	Qty	Unit Price	Tax	Amount
SECURE MESSAGE	1	\$100.00	0.00	\$100.00
<b>TOTAL</b>				<b>\$100.00</b>

SECURE MESSAGE: In order to receive the file you are viewing this message by email, please click the link below.

Transaction Board (Email) - [View Details](#)

SECURE EMAIL

You have received a secure email from Secure Messages Inc. that may contain confidential information.

Click here to login and view your secure email by 2014-05-27 11:26 PDT.



Secured by Encryption Copyright 1999 Secure Messages, Inc. All rights reserved.

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TRENDING RISK AREAS – RANSOMWARE

- Threats: Malware, Attackers External and Internal, Social Engineers/Phishing
- Vulnerabilities: Users not aware of threats, poor network security measures, lack of data backups
- Recommended Controls:
  - Education of workforce
  - Testing of network security controls through penetration testing
  - Testing of data backups and disaster recovery readiness
  - Block unnecessary tasks/privileges from users (block office macros, block executable file coming from external domains, restrict administrator tasks on workstations, etc.)
  - Have a plan




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CLOSING REMARKS

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WHAT YOU SHOULD BE DOING TODAY

Take action on the following:

Monitor Phase 2 audit developments and apply lessons-learned.

Ensure sufficient Gap Evaluation and Risk Analysis efforts have been completed.

Periodically test the operating effectiveness of compliance/control activities (not just design).

Remediate identified gaps/risks in a timely manner.

Create documentation/evidence that can stand on its own.

Continue building a "culture of compliance" at your organization!

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Horizontal lines for notes or additional information.

Q&A

Horizontal lines for Q&A responses.

CONTACT US

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Phone: 469-374-2479



Matt is a founding member of Protiviti and is a Director in the Dallas office with more than 17 years professional experience providing operational, technology, and regulatory consulting and internal audit services to the healthcare industry. Matt serves as Protiviti's National Healthcare Information Technology Leader as well as Protiviti's HIPAA Solutions Leader. He is a frequent speaker on, and has published various articles related to, internal audit, compliance, and information technology improvement initiatives.

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Senior Manager  
kevin.dunnahoo@protiviti.com

Phone: 972-788-8529



Kevin is a Senior Manager with Protiviti's Dallas office and has more than 9 years of professional experience providing IT consulting and auditing services to the Healthcare industry. Kevin is a member of Protiviti's National Healthcare Practice and is a key lead for HIPAA Security Compliance services. In the Healthcare industry, Kevin has provided value to his clients through his insights and understanding of the HIPAA Security regulations, information security practices, business continuity, and IT audit. Kevin is a certified HCISPP, CISSP, ABCEP, and HITRUST CSF Practitioner, and has also co-authored various Protiviti thought leadership whitepapers specifically related to HIPAA compliance and enforcement.

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Horizontal lines for contact information or notes.



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Compliance That Addresses the Risks of Today and Will Grow with You in the Future

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### Objectives

- Identify industry trends and risk for governmental audit/investigation
- Understand the basics of how the seven elements apply to HIPAA compliance
- Become Familiar with basic HIPAA rules and tools
- Be able to speak "HIPAA" Privacy and Security
- Know when you need to engage others for help

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Still thinking about HIPPOs



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### Applies to All Organizations

- Don't have a plan (overwhelmed by HIPAA or still thinking about HIPPOs)
  - Use the 7 elements of an effective compliance plan
  - Supplement with other tools
- You have a plan
  - Make it stronger
  - Areas for improvement
    - risk analysis
    - training

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### HIPAA is Fun for Everyone



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### HIPAA Regulations



- Required by LAW
- Penalties for non-compliance
- We see all

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### HIPAA Regulations



- Privacy/Security is Priority #1
- Breaches
  - Direct to the appropriate staff
  - Candid and Open

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### HIPAA (applicability)

Covered Entities (CE) and Protected Health Information (PHI)

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### The Rule (who)

- 45 CFR 160 General Administrative Requirements
- 45 CFR 164 Security and Privacy
- 45 CFR 160.102 and 164.104 – applies to everyone in health care
  - Covered Entity (CE)
    - Health plans
    - Health Clearinghouses
    - Health providers that transmit electronically
  - Business Associates (BA) - certain sections only

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**Electronic CFR**  
(code of federal regulations)

**§160.102 Applicability.**  
 (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:  
 (1) A health plan.  
 (2) A health care clearinghouse.  
 (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.  
 (b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.  
 (c) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).  
 [65 FR 82796, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 78 FR 5687, Jan. 25, 2013]

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**Legal Information Institute**

**§ 160.102 Applicability.**  
 (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:  
 (1) A health plan.  
 (2) A health care clearinghouse.  
 (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.  
 (b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.  
 (c) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).  
 [65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 78 FR 5687, Jan. 25, 2013]

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**The Rule (what)**

- 45 CFR 160.103 *Protected health information* means individually identifiable health information
- 45 CFR 164 Subpart C—Security Standards for the Protection of **Electronic** Protected Health Information

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## Protected Health Information

- Is
  - Transmitted by electronic media;
  - Maintained in electronic media; or
  - Transmitted or maintained in any other form or medium.
- Is not
  - Covered by the Family Educational Rights and Privacy Act (FERPA);
  - “Education Records”
  - Employment records held by a covered entity in its role as employer; and
  - Regarding a person who has been deceased for more than 50 years.

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## HHS Audits and Investigations

- 200-250 Desk Audits
- Few comprehensive on-site audits (start in 2017)
- Wide range of CEs
- May lead to investigations

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### Audit Phase 2

#### Alert: Phishing Email Disguised as Official OCR Audit Communication - November 28, 2016

It has come to our attention that a phishing email is being circulated on mock HHS Departmental letterhead under the signature of OCR's Director, Jocelyn Samuels. This email appears to be an official government communication, and targets employees of HIPAA covered entities and their business associates. The email prompts recipients to click a link regarding possible inclusion in the HIPAA Privacy, Security, and Breach Rules Audit Program. The link directs individuals to a non-governmental website marketing a firm's cybersecurity services. In no way is this firm associated with the U.S. Department of Health and Human Services or the Office for Civil Rights. We take the unauthorized use of this material by this firm very seriously.

OCR would like to further share that this phishing email originates from the email address OSOCRAudit@hhs.gov and directs individuals to a URL at <http://www.hhs.gov.us>. This is a subtle difference from the official email address for our HIPAA audit program, OSOCRAudit@hhs.gov, but such subtlety is typical in phishing scams.

Covered entities and business associates should alert their employees of this issue and take note that official communications regarding the HIPAA audit program are sent to selected auditees from the email address OSOCRAudit@hhs.gov. In the event that you or your organization has a question as to whether it has received an official communication from our agency regarding a HIPAA audit, please contact us via email at OSOCRAudit@hhs.gov

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## Structure

Think of HIPAA Compliance like a house

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## Not all houses are the same



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## Basic Structure (7 elements)

- Standards and Procedures
- Oversight
- Education and Training
- Monitoring and Auditing (**Risk Assessment**)
- Reporting
- Enforcement and Discipline
- Response and Prevention

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### Basic Materials/Tools

- HHS HIPAA Audit Protocol (in the rules tools)
- 45 CFR 160 and 164
- OIG Guidance
- NIST Standards (National Institute of Standards and Technology)
- Professional Resources
  - HCCA Library
  - HCCA Weekly News
  - Other Professional Organizations (HIMSS, AHIMA, AIHC, etc.)

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### Start Building



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### Foundation (Oversight)

- Establish the need
  - Compliance reasons
  - Business Reasons
- Get formal approval from the Governing Board
  - Privacy Officer
  - Security Officer

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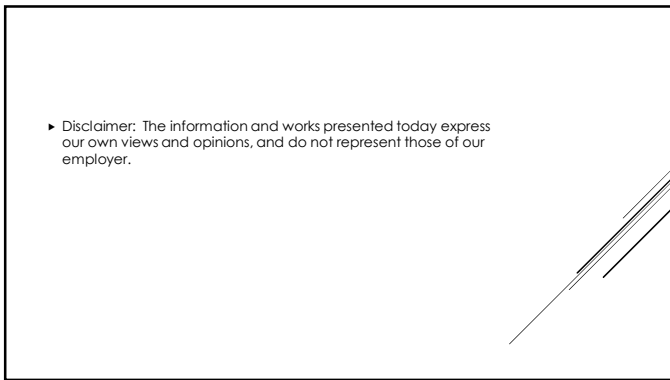
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"I WALK DOWN THE STREET.  
THERE IS A DEEP HOLE IN THE SIDEWALK.  
I FALL IN.  
I AM LOST... I AM HELPLESS.  
IT ISN'T MY FAULT.  
IT TAKES FOREVER TO FIND A WAY OUT.

I WALK DOWN THE SAME STREET.  
THERE IS A DEEP HOLE IN THE SIDEWALK.  
I PRETEND I DON'T SEE IT.  
I FALL IN AGAIN.  
I CAN'T BELIEVE I AM IN THE SAME PLACE.  
BUT, IT ISN'T MY FAULT.  
IT STILL TAKES ME A LONG TIME TO GET OUT.

I WALK DOWN THE SAME STREET.  
THERE IS A DEEP HOLE IN THE SIDEWALK.  
I SEE IT IS THERE.  
I STILL FALL IN. IT'S A HABIT.  
MY EYES ARE OPEN.  
I KNOW WHERE I AM.  
IT IS MY FAULT. I GET OUT IMMEDIATELY.

WALK DOWN THE SAME STREET.  
THERE IS A DEEP HOLE IN THE SIDEWALK.  
I WALK AROUND IT.  
I WALK DOWN ANOTHER STREET."

— DORTA NIELSON: THERE'S A HOLE IN MY SIDEWALK: THE ROMANCE OF SELF-DISCOVERY

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**BENCHMARKING**

Group exercise: Audience benchmarking

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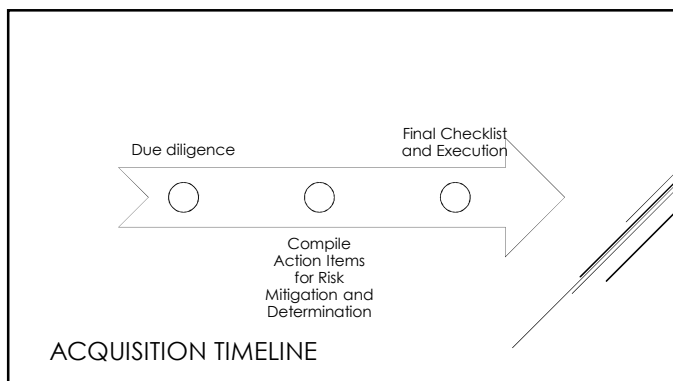
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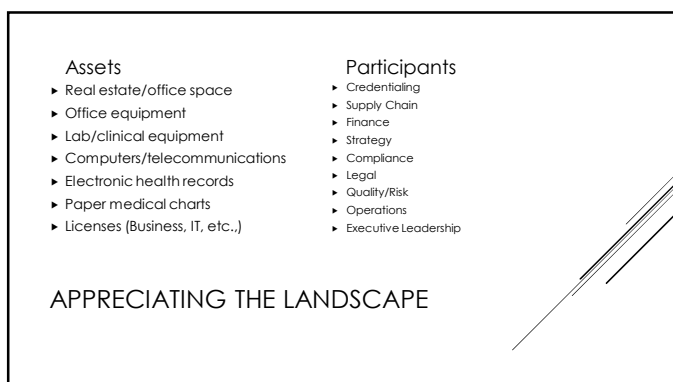
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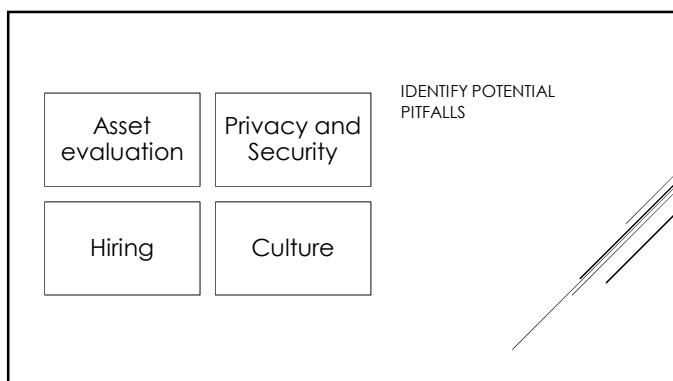
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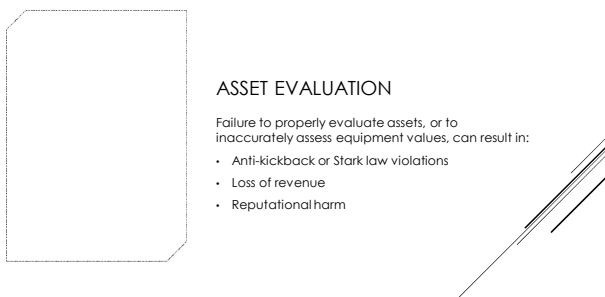
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**ASSET EVALUATION**

Failure to properly evaluate assets, or to inaccurately assess equipment values, can result in:

- Anti-kickback or Stark law violations
- Loss of revenue
- Reputational harm



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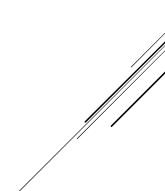
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► Case example                      Case example

**EVALUATING ASSETS:  
WHAT CAN GO WRONG?**



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► Location

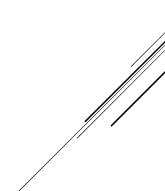
- Healthcare real estate ≠ commercial real estate
- Use vendors with experience in healthcare laws and real estate transactions
- Avoid leases at sub-optimum locations and consider reputational damage from prior location

► Relationships

- Commercially reasonable
- Need legitimate business purpose for renting from a provider-owned building
- Need arms length transactions
- Fair Market Value applies at all times

**TRAIL GUIDE FOR ASSETS**

Real Estate / Office Space:



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▶ Include the use of fair market value (FMV) when appraising equipment, space and other items recognized in the Asset Purchase Agreement.

▶ Use vendors who are experienced in appraising equipment in a healthcare environment

- ▶ Avoid inaccurate assessments due to liens or no consideration of depreciation, etc.

▶ Consider costs to purchase and refurbish/re-image to match the organization's security standards v. replace devices/network infrastructure

▶ Consider license, maintenance, archiving costs for the transition and integration periods

**TRAIL GUIDE FOR ASSETS**

Office equipment  
Lab/diagnostic/clinical equipment  
Business Licenses

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**PRIVACY AND SECURITY RISKS**

Failure to properly assess privacy and security risks can result in:

- HIPAA, SAMSHA, and state privacy law violations
- Loss of data from Ransom ware and other malware attacks
- Loss of patient and community trust and other reputational harm
- Loss of revenue

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▶ Case example

▶ Case example

**PRIVACY AND SECURITY:  
WHAT CAN GO WRONG?**

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- ▶ Avoid purchasing legacy systems
- ▶ Need gap analysis on security standards for IT devices/systems
- ▶ Identify ownership for risk mitigation plan, archiving steps. Pull such costs into Asset Purchase Price.
- ▶ Consider a full 're-boot' on Privacy expectations and education, especially in rural settings
- ▶ Consider active and automated monitoring of user access logs, especially in rural settings
- ▶ Physical walk-through of privacy and security safeguards is essential to capture risks to which current operations may be desensitized

**TRAIL GUIDE FOR PRIVACY AND SECURITY**

Know your technology systems  
Privacy culture and awareness  
Physical safeguards

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**HIRING PROVIDERS AND STAFF**

Failure to properly vet providers and staff can result in:

- Patient harm from bad actors
- Decreased quality/performance scores
- False Claim Act violations
- Loss of revenue from CMS ineligibility (conditions of participation)
- Reputational harm

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▶ Case example

▶ Case example

**HIRING PROVIDERS:  
WHAT CAN GO WRONG?**

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- ▶ Licensure issues:
  - ▶ Contract Language: must have active license in good standing
  - ▶ Inquire of provider: Are you currently under investigation?
- ▶ Balance the load of primary care v. specialists/sub-specialists with the organization's strategy (Think: growth and stability)
- ▶ Avoid costly promises: excessive sign-on bonuses, guarantees of jobs for family/friends, selecting payer panels, etc.
- ▶ Conflicts of interest: vetted before closing the deal. Have a Management Plan in place before contract is executed
- ▶ Medical necessity reviews must be performed for specialists
- ▶ Coding concerns must be addressed in a timely manner

**TRAIL GUIDE FOR HIRING**  
Check-points for Physicians and other clinical providers




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▶ Case example                      ▶ Case example

**HIRING STAFF (NON-CLINICAL):  
WHAT CAN GO WRONG?**




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- ▶ Work with human resources to make sure the staff retained in the purchase are placed in the correct classification and have the skill sets needed for their roles
- ▶ Qualifications and licenses:
  - ▶ Review qualifications for ALS/BLS, other certifications
  - ▶ Review scope of license v. historical practice
  - ▶ Meaningful use requirements related to CMA, RMA roles in EHR and attestations
- ▶ Offers of employment should contain contingency language where applicable
  - ▶ Drug screens, certifications, licenses, COI management plans, etc.

**TRAIL GUIDE FOR HIRING**  
Check-points for Staff and non-providers




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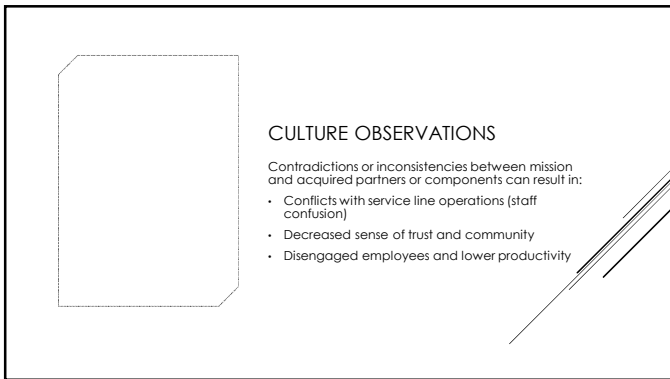
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**CULTURE OBSERVATIONS**

Contradictions or inconsistencies between mission and acquired partners or components can result in:

- Conflicts with service line operations (staff confusion)
- Decreased sense of trust and community
- Disengaged employees and lower productivity

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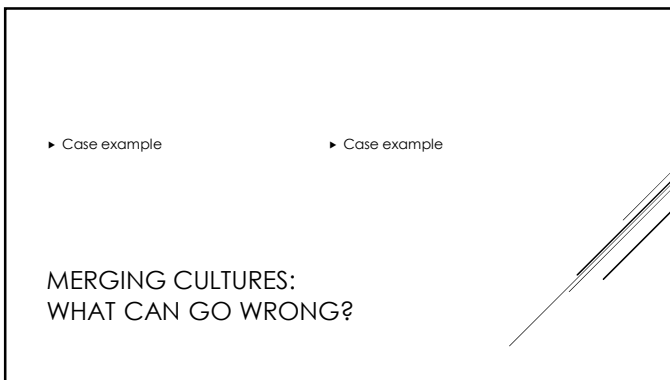
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► Case example                      ► Case example

**MERGING CULTURES:  
WHAT CAN GO WRONG?**

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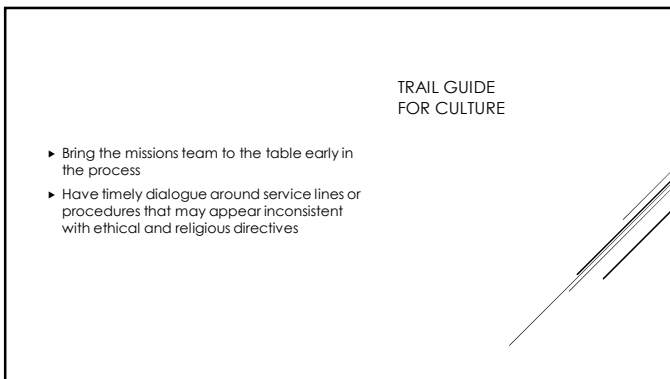
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**TRAIL GUIDE  
FOR CULTURE**

- Bring the missions team to the table early in the process
- Have timely dialogue around service lines or procedures that may appear inconsistent with ethical and religious directives

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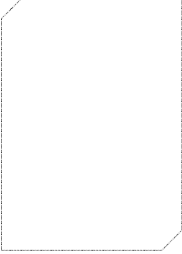
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**DUE DILIGENCE IS VITAL**  
What to do when the due diligence recommendation is not heeded?



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- ▶ The purpose of due diligence process is to ask the questions and document the responses and observations
- ▶ When effective, the due diligence process will identify potential risks, justify or quantify the level of risk based upon laws, regulations, mission, etc., and to return a recommendation to the stakeholders.
- ▶ Make sure legal counsel (in addition to stakeholders/strategy team) is aware of the recommendations from due diligence efforts.

**TRAIL GUIDE FOR REJECTION OF DUE DILIGENCE RECOMMENDATION**  
Manage expectations



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- ▶ Due Diligence Game Time!

**GROUP EXERCISE**



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RECAP / Q&A

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CONTACT INFORMATION

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# HCCA Compliance Institute

March 26, 2017

## Exploring CMS's Final Rule on Reporting and Refunding Overpayments

Gary W. Eiland, Partner

King & Spalding LLP

Houston, Texas

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KING & SPALDING

## Overpayments and Self-Disclosures



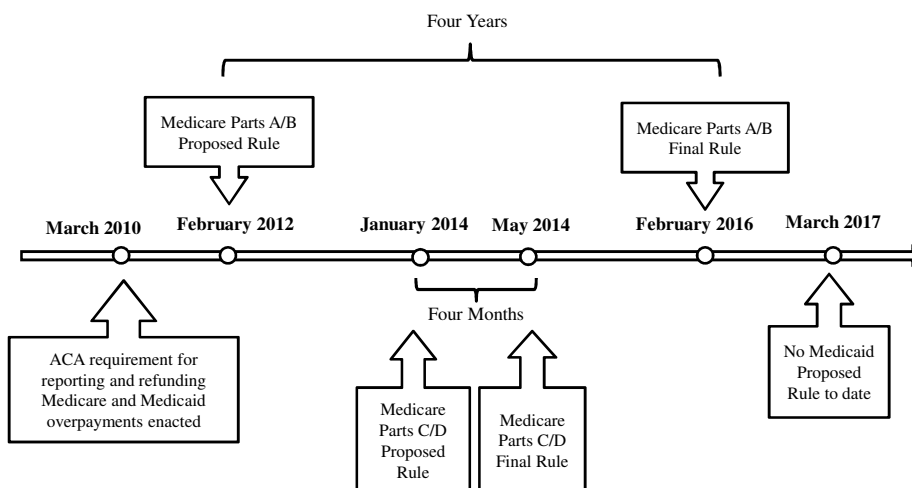
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## The Affordable Care Act Law

- March 23, 2010: Enactment of the Affordable Care Act (ACA)
- Section 6402(a) of the ACA (now codified at 42 U.S.C. § 1320a-7k(d)):
  - A person who has received an overpayment must report and return the overpayment within either 60 days after the date on which the overpayment was **identified** or on the date any corresponding cost report is due, whichever is later.
  - The term “overpayment” means any **Medicare** or **Medicaid** funds that a person receives or retains to which the person, after **applicable reconciliation**, is not entitled.

## Timeline of Significant Overpayment Developments



## “Identification” Defined: A/B Final Rule

- Medicare Parts A /B Final Rule: New regulatory definition in 42 C.F.R. § 401.305(a)(2)
  - An overpayment is identified “when the person **has, or should have** through the **exercise of reasonable diligence, determined** that the person has received an overpayment and **quantified** the amount of the overpayment.”
- This definition includes two key concepts:
  1. Concept of reasonable diligence
  2. Quantification

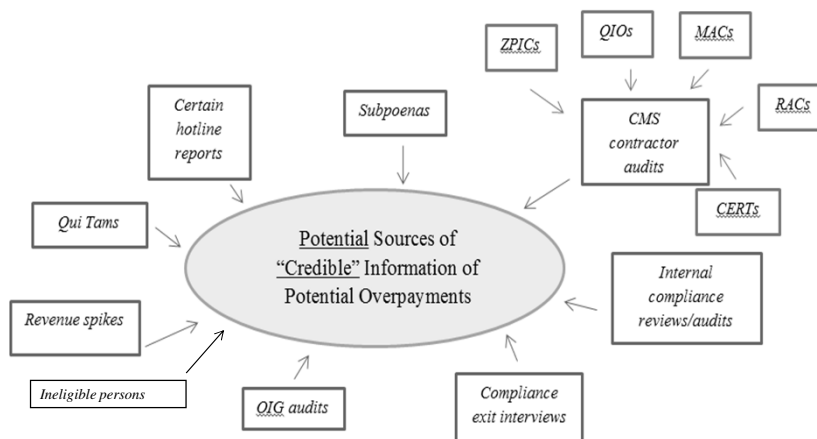
## Concept of Reasonable Diligence

- The finalized definition of “identification” incorporates concept of “**reasonable diligence**.”
- In the Final Rule, CMS stated that reasonable diligence includes both **proactive** compliance activities and **reactive** investigative activities.
  - Size and scope of compliance programs will vary, but having no compliance activities may expose the provider to liability.
- When does the 60-day clock begin to tick?
  1. When the exercise of reasonable diligence is completed, *or*
  2. If there is a failure to exercise reasonable diligence, on the day *when the person received credible information of a potential overpayment*.

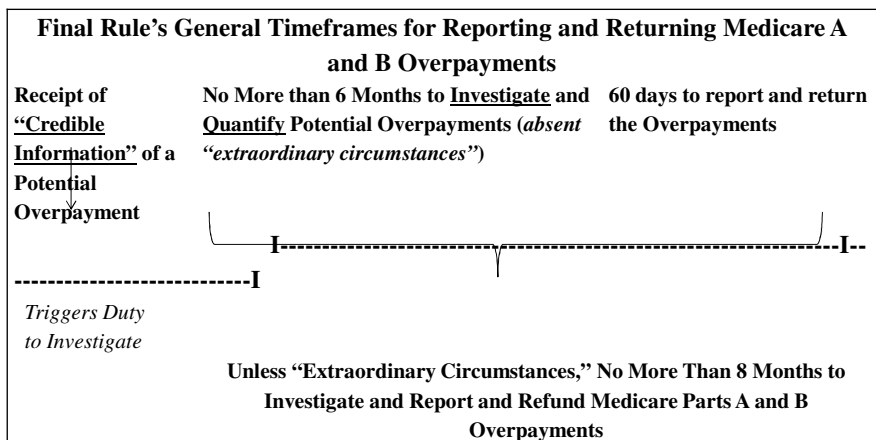
## Credible Information of Potential Overpayments

- Keyword—Potential Overpayments.
- Receipt of “credible information” triggers a duty to investigate.
  - “Credible information” is not specifically defined, but includes information that **“supports a reasonable belief that an overpayment may have been received.”**
  - CMS specifically rejected an evidentiary standard— instead adopted credible “information” standard.

## Potential Sources of “Credible” Information (Not Exhaustive)



## Medicare Parts A/B Overpayment Final Rule: Parts A/B Overpayment Final Rule: Timeline



## Lookback Period

- Pursuant to the Medicare Parts A/B Final Rule, Medicare Parts A/B overpayments must be reported and returned “only if a person identifies the overpayment within **six years** of the date the overpayment was received.”
- **Maximum Threshold** - providers should not be foreclosed from using a more limited lookback period if justified by the relevant circumstances (coverage change or EHR system conversion).
- Practical challenges of lookback period:
  - Recordkeeping difficulties
  - Evolving regulatory standards
  - Audit resources
  - Potential need for statistical sampling resources



## FCA Enforcement of 60-Day Rule

- *Kane ex rel. New York v. Healthfirst, Inc.*, 11 CIV. 2325 (ER) (S.D.N.Y. Aug. 3, 2015)
  - Healthcare provider erroneously submitted claims to Medicaid for payment due to a software error. The provider failed to fully investigate and identify all overpayments until two years later.
  - The court interpreted “identification” to include situations where *“a person is put on notice that a certain claim may have been overpaid.”*
- Parties settled for **\$2.95 million** on August 23, 2016

## Retained Overpayments

- *U.S. ex rel. Odumosu v. Pediatric Servs. of Am. Healthcare (PSA)*; *U.S. ex rel. McCray v. PSA*
  - Home healthcare provider to pay \$6.88 M to settle allegations that it failed to refund overpayments from TRICARE and 20 state Medicaid programs between 2007 and 2013
 

*“First of its kind” settlement stemming from a provider’s failure to “actively investigate whether they have received overpayments and, if so, promptly return the overpayments”*

John Horn, U.S. Attorney  
Northern District of Georgia  
(Aug. 4, 2015)

No. 1:11-cv-1007 (N.D. Ga.); No. 4:13-cv-127 (S.D. Ga.), (settlements announced Aug. 3, 2015)

# Questions

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**Health Care Compliance Association  
2017 Compliance Institute**

**Recent Developments  
Under the Federal False Claims Act**

**March 2017**

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Washington, D.C.  
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John T. Boese is Of Counsel in the Washington, D.C. office of Fried, Frank, Harris, Shriver & Jacobson LLP, where he was a partner for over thirty years. He continues to represent a broad spectrum of defendants in civil, criminal, debarment, and exclusion cases arising from federal fraud investigations of government contractors and grantees, health care providers, and other organizations. Mr. Boese is the author of the treatise CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (Wolters Kluwer Law & Business) (4th ed. & Supp. 2017-1). It is routinely cited by courts at all levels on issues arising under the civil False Claims Act. The statements herein do not necessarily present the position of the author's Firm or clients of the Firm, and should not be imputed to them.

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2017

## INTRODUCTION

The False Claims Act (“FCA”) was enacted in 1863 in response to allegations of fraud that arose in the context of Civil War procurements, but the FCA became a significant enforcement tool only after Congress enacted watershed amendments in 1986, including stiffer damages and penalties, and the expansion of the rights of private citizens, known as *qui tam* relators, to bring suits on behalf of the government. The Department of Justice recovered more than \$4.7 billion under the FCA in fiscal year 2016, bringing total FCA recoveries to more than \$53 billion since 1986.<sup>1</sup> Nearly \$3 billion recovered in 2016 was in *qui tam* cases initiated or brought by relators, whose “relator’s share” totaled \$519.6 million that year. The number of *qui tam* suits filed in fiscal year 2016 was 702, roughly five times the number of non-*qui tam* suits that the government filed that year. There are no signs that *qui tam* actions are going to decline.

The Affordable Care Act strengthened the government’s focus on health care fraud, allocating an additional \$350 million to that effort over the next ten years, but the single most effective weapon in the government’s arsenal continues to be the civil False Claims Act. Of the \$4.7 billion in FCA recoveries in 2016, nearly \$2.6 billion was from the health care industry (broadly defined to include pharmaceutical and medical device companies).<sup>2</sup> As the Justice Department has noted, the government’s focus on healthcare-related actions has consistently produced large FCA recoveries. Increasingly, DOJ is demanding “nonmonetary remedial measures,” such as expensive corporate integrity agreements, in FCA settlements. Also, DOJ has announced that it intends to follow the new policy memorandum known as the “Yates Memo” that takes a more aggressive approach toward pursuing individuals as FCA defendants in addition to corporations.<sup>3</sup>

Substantive areas of particular concern to health care providers and the health care industry include upcoding, off-label promotion, failure to document patient care, deficient compliance training, worthless services, and the expanded use of the Antikickback statute as bases for FCA liability. In addition, the knowing nonpayment of an “obligation”—defined to include “knowingly and improperly” retaining an “overpayment” from a government health care program—is a basis for the FCA’s treble damages and penalties under the “reverse false claim” theory of liability. Provisions linking the FCA to government health care program requirements ensure that the FCA’s role in health care fraud enforcement will only increase.

Substantive and procedural FCA amendments enacted in 2009 and 2010—in the Fraud Enforcement and Recovery Act of 2009 (“FERA”), the Affordable Care Act (“ACA”), and the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank”)—make it easier for the government and *qui tam* relators to conduct investigations and obtain recoveries under the FCA.<sup>4</sup> The full impact of FERA’s and the ACA’s amendments is now being felt, and it is clear

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<sup>1</sup> See Press Release, Dep’t of Justice, Justice Department Recovers Over \$4.7 Billion from False Claims Cases in Fiscal Year 2016 (Dec. 14, 2016) (“DOJ’s 2016 Press Release”). See also DOJ’s 2016 FCA Statistics (attached as Appendix4)

<sup>2</sup> See DOJ’s 2016 Press Release.

<sup>3</sup> See Memorandum from Deputy Att’y Gen. Sally Quillian Yates, Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015) (“Yates Memo”), <https://www.justice.gov/dag/file/769036/download>; Press Release, Dep’t of Justice, Principal Deputy Assistant Att’y Gen. Benjamin C. Mizer Delivers Remarks at the 16th Pharm Compliance Cong. and Best Practices Forum (Oct. 22, 2015), <https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-16th>.

<sup>4</sup> See FERA, Pub. L. No. 111-21 (2009); ACA, Pub. L. No. 111-148, 124 Stat. 119 (2010); Dodd-Frank Act, Pub. L. No. 111-203, §3301, 124 Stat. 1376, 2079 (2010).

that these amendments will be the basis for attempts to recover more funds, cover more potential defendants, and narrow defenses to FCA suits in the years to come. Now that twenty-nine states plus the District of Columbia, New York City, Chicago, and Philadelphia have false claims laws, false claims litigation often takes place at the federal, state, multi-state, and municipal levels. The considerable resources of the government—federal and state—coupled with the seemingly limitless supply of whistleblowers willing to litigate FCA claims on behalf of the government, assure that the civil False Claims Act will remain one of the government’s most powerful weapons against fraud.

The key changes under FERA, the ACA, and Dodd-Frank discussed below are:

- FERA’s amendments to FCA liability
- FERA’s amendments to the FCA’s procedural provisions
- FERA’s retroactive application to pending FCA cases
- The ACA’s amendments to the “public disclosure” bar
- The Dodd-Frank Act’s amendments to the FCA’s whistleblower provisions.

Important recent FCA developments discussed include:

- Materiality and false certification liability after the Supreme Court’s *Escobar* decision
- Falsity
- Causation
- The FCA’s knowledge and intent standards—including *Escobar*’s scienter requirement
- Reverse false claims
- Damages and penalties
- Public disclosure and first-to-file
- Retaliation

For a full discussion of the FCA and decisional law under it, please refer to JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (Wolters Kluwer Law & Business) (4th ed. & Supp. 2017-1) (“BOESE”). A redline showing the current FCA, as amended, is attached as Appendix 1.

## **A. FCA Fundamentals**

Some important features that are present in both versions of the FCA—before and after FERA—should be noted at the outset:

- Violations of the FCA give rise to potentially enormous economic liability. The law provides that all damages are trebled. Each false claim submitted is subject to a mandatory penalty of \$5,500 and \$11,000 per violation.
- The FCA can be enforced not only by the powerful resources of the federal government, but also through the use of private plaintiffs, referred to as *qui tam* relators. The term "*qui tam*" is derived from a Latin phrase, "*qui tam pro domino rege quam pro se ipso*," or “who pursues this action on our Lord the King’s behalf as

well as his own.” As this phrase indicates, the *qui tam* action arose in early English common law as a device for permitting private individuals to litigate claims on the sovereign's behalf. Like relators in modern FCA actions, early *qui tam* litigants not only gained standing they otherwise would lack, but also a share of any recovery obtained on the sovereign's behalf as a result of the *qui tam* action. Significant amendments to the False Claims Act in 1986 strengthened the rights of relators, and increased the bounties that may be awarded to successful relators, thus dramatically increasing the incentives to filing suit. There are unique procedural steps involved when a *qui tam* relator initiates FCA litigation, including the requirement that the complaint must be filed under seal, and the United States may intervene and take over the action.

- Whether an FCA suit is initiated by the government or by a *qui tam* relator, the liability, damages and penalties provisions remain the same. Defendants are also liable for the attorneys' fees and costs of relators.
- A number of state and local governments have adopted their own versions of false claims acts, with *qui tam* enforcement. Although in the past these laws have varied considerably from the federal FCA, most of them no longer do because they must follow the federal model in order to receive an economic incentive under the Deficit Reduction Act of 2005.<sup>5</sup>

It is also important to note what the False Claims Act does not cover. Although false tax returns are almost certainly the most common false claim filed with the federal government, the False Claims Act expressly excludes such claims from the scope of its coverage.<sup>6</sup> This FCA “tax bar” has been held to apply broadly whenever a false claim is made or a benefit is procured under the Internal Revenue Code, and is not limited to false income tax claims.<sup>7</sup> Recently, however, New York amended its state FCA to allow *qui tam* enforcement of tax law violations.<sup>8</sup>

## **B. The 1986 Law**

Prior to the 2009 and 2010 amendments, liability under the civil False Claims Act has arisen primarily under the provisions of 31 U.S.C. §§ 3729(a)(1) - (7). The government (or the *qui tam* relator) bears the burden of proving each element of a False Claims Act violation, including damages, by the preponderance of the evidence.<sup>9</sup> The four most commonly-invoked liability provisions of the 1986 FCA are:

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<sup>5</sup> Pub. L. No. 109-171, §§ 6031-6033, 120 Stat. 4, 72-74 (2006) (to be codified at 42 U.S.C. §§ 1396a(a), 1396b(i), 1396h(a)).

<sup>6</sup> 31 U.S.C. § 3729(e) provides that “This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1954.”

<sup>7</sup> *United States ex rel. Lissack v. Sakura Global Capital Mkts., Inc.*, 377 F.3d 145 (2d Cir. 2004). Congress has enacted a “tax *qui tam*” statute which provides a bounty to anyone who brings tax underpayments by certain corporations and high-income individuals to the attention of the IRS. *See Tax Relief and Health Care Act of 2006*, Pub. L. No. 109-432, §406, 120 Stat. 2922, 2958 (Dec. 20, 2006). *See also* BOESE, §1.07[A][1].

<sup>8</sup> *See* N.Y. State Fin. Law §189.4(a). *See also* FraudMail Alert No. 10-08-26, New York State FCA: New York’s False Claims Act Now Equals or Exceeds Federal Fraud Law—False State Tax Returns Are Now Privately Enforceable under State FCA,

<http://friedlive.icvmgroup.net/siteFiles/Publications/Fried%20Frank%20FraudMail%20Alert.pdf>.

<sup>9</sup> 31 U.S.C. § 3731(c).

- Section 3729(a)(1) establishes liability for so-called “direct” false claims to the government;
- Section 3729(a)(2) imposes liability for making false records or false statements to support a false claim;
- Section 3729(a)(3) involves conspiracy to get a false claim paid; and
- Section 3729(a)(7), the so-called “reverse false claims provision,” imposes liability for false records or statements made to reduce or avoid an obligation to the government.

The remaining three subsections of Section 3729(a), subsections (a)(4), (a)(5) and (a)(6), tend to be either redundant or to apply to situations that occur infrequently under modern government contracting procedures. These sections of the FCA are seldom invoked, and therefore have not been the subject of significant case law analysis.<sup>10</sup>

The 1986 amendments lowered the intent needed for an FCA violation to the “recklessness” standard, established the burden of proof at a preponderance of the evidence, and expanded the *qui tam* enforcement mechanism by:

- increasing the relators’ share to up to 30 % of the government’s recovery;
- removing the government knowledge bar and replacing it with public disclosure/original source provisions;
- adding a retaliation provision;
- allowing *qui tam* participation after U.S. intervention; and
- encouraging *qui tam* intervention if the U.S. declined to intervene.

### **C. The 2009 Amendments—FERA**

Although Congress stated that its purpose in enacting FERA was to expand the FCA’s liability provisions in order to reach frauds by financial institutions and other recipients of TARP and economic stimulus funds, the 2009 amendments were not needed for that purpose because financial institutions and stimulus funds were already covered by the existing FCA. FERA was simply the vehicle for FCA amendments that had been languishing in Congress since well before the financial crisis in 2008. The broader purpose of a general expansion of the FCA is reflected in the amendments: they are not limited to mortgage and financial fraud, they have nothing to do with financial markets, and they apply across the board to all recipients and payers of government money or property, including health care providers and the health care industry.

The amendments expand FCA liability beyond previous limits by revising all seven of the statute’s liability provisions and redefining key terms such as “claim,” “material,” and “obligation.” While the key liability provisions of the FCA remain those addressing false claims, false statements supporting false claims, conspiracy, and reverse false claims, FERA renumbered and expanded these provisions to cover additional conduct. The new Sections 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G), extend liability to any person who:

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<sup>10</sup> For a review of the limited case law arising under subsections (a)(4), (a)(5), and (a)(6), see BOESE, §§ 2.01[G] - [J].

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

[ . . . ] or

- (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

A red-line version of the False Claims act is attached as Appendix 1, and use of this red-line is critical to understanding the revisions. Many of the important details of the 2009 amendments are discussed in a contemporaneously issued FraudMail Alert (attached as Appendix 2). A few key illustrations of the expansion in FCA liability under FERA include the following:

- Section 3729(a)(1)(B) amended Section 3729(a)(2) to remove the phrase “to get,” on which the unanimous Supreme Court relied in *Allison Engine Co. v. United States ex rel. Sanders*<sup>11</sup> to limit FCA liability to false statements or claims made by defendants for the purpose of getting the government to pay the claim. FERA expressly applied this amendment retroactively to “claims” pending on or after June 7, 2008 (which was two days before the Supreme Court’s decision in *Allison Engine*). This attempt to apply the amendment retroactively to prior conduct has been challenged, and courts are divided on its retroactive application in pending cases.<sup>12</sup>
- The language in Section 3729(a)(3) had been properly interpreted to limit liability for conspiracy to violations of then-Section 3729(a)(1). Section 3729(a)(1)(C) amended this provision to extend liability for conspiracy to commit a violation of any other substantive section of the FCA.

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<sup>11</sup> 553 U.S. 662 (2008).

<sup>12</sup> Compare *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1327 (11<sup>th</sup> Cir. 2009) (defining “claim” as a demand for payment as under Section 3729(b)(2)(A) and finding that no such claims were pending as of June 7, 2008), and *Allison Engine Co. v. United States ex rel. Sanders*, No. 1:95CV970, 2009 WL 3626773 (S.D. Ohio Oct. 27, 2009) (defining “claim” as a demand for payment, and finding that applying the amendment retroactively would violate the Ex Post Facto Clause), and *United States v. Science Applications Int’l Corp.*, No. 04-1543, 2009 WL 2929250 (D.D.C. Sept., 14, 2009), with *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010) (applying amendment retroactively because relator’s claim was pending as of June 7, 2008), and *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (same). See also *New York v. Sprint Nextel Corp.*, No. 103917/2011 (N.Y. Sup. Ct. July 1, 2013) (slip op.) (ruling that the New York FCA’s tax liability amendment was not sufficiently punitive in nature or effect to preclude its retroactive application under the *Ex Post Facto* Clause); *United States ex rel. Romano v. New York-Presbyterian Hosp.*, No. 00 Civ. 8792(LLS), 2008 WL 612691 (S.D.N.Y. Mar. 5, 2008) (ruling that the relator could not add state FCA claims to federal claims that were based on Medicaid claims submitted more than six years prior to the New York FCA’s effective date).



- Section 3729(a)(1)(G) expanded the scope of reverse false claims liability in the prior law under Section 3729(a)(7) to include retention of an overpayment.

More key changes to FCA liability are included in FERA's statutory definitions of "claim," "obligation," and "material" in Section 3729(b), which are discussed below.

The Department of Justice has authority to conduct broad pre-intervention discovery through civil investigative demands ("CIDs") that allow it to demand production of documents, oral testimony, and answers to interrogatories. This CID discovery power augments DOJ's pre-existing power to obtain documentary evidence through subpoenas and authorized investigative demands, and it is stronger than standard civil discovery because the Federal Rules of Civil Procedure do not apply to it. FERA expanded DOJ's power to issue CIDs and to use the information received in response to CIDs for an "official use."<sup>13</sup> Under this expanded authority, the Attorney General's authority to issue CIDs was delegated to the Assistant Attorney General for the Civil Division,<sup>14</sup> who then re-delegated this authority to certain senior enforcement officials in the Civil Division as well as to U.S. Attorneys in certain cases.<sup>15</sup> After this expansion, use of CIDs by both DOJ and U.S. Attorneys' Offices has increased dramatically.<sup>16</sup>

FERA also amended the FCA to permit the government's complaint-in-intervention and amendments to the complaint to relate back to the original *qui tam* complaint for statute of limitations purposes.<sup>17</sup> FERA revised the FCA's retaliation provision so that it protects contractors and agents in addition to employees, although the conduct and remedies under this provision are still employment-based.<sup>18</sup>

Key FCA provisions unchanged by FERA include: (1) the FCA's standard of scienter, which is "knowing" or "knowingly," (2) the FCA's definition of damages, and (3) the public disclosure/original source jurisdictional bar provisions. FERA made no change in the law on the question of whether government employees can be *qui tam* relators, and on the application of Rule 9(b)'s pleading requirements to FCA complaints. As discussed below, the Affordable Care Act amended the FCA's public disclosure bar in 2010, and a further revision of the FCA's retaliation provision was made by the Dodd-Frank Act.

#### **D. Recent Developments in FCA Liability, *Qui Tam* Enforcement, and Retaliation**

The dominant development this year is the Supreme Court's unanimous, watershed decision in *United States ex rel. Escobar v. Universal Health Services, Inc.*, which held that the false certification theory of liability may be applied in FCA cases, and established critical limits on the

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<sup>13</sup> See Appendix 2 at 5 (discussing CID amendment).

<sup>14</sup> See Order No. 3134-2010 (Jan. 15, 2010).

<sup>15</sup> See Dep't of Justice, Directive No. 1-10, Redlegation of Authority of Assistant Attorney General, Civil Division, to Branch Directors, Heads of Offices and United States Attorneys in Civil Division Cases (Mar. 8, 2010) (to be codified at 28 C.F.R. Part 0).

<sup>16</sup> In fiscal year 2011, DOJ authorized the issuance of 888 CIDs—more than ten times the number issued during the two years before re-delegation combined. See Press Release, Dep't. of Justice, Acting Assistant Attorney General Stuart F. Delery Speaks at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 7, 2012), <http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html>.

<sup>17</sup> See Appendix 2 at 5 (discussing relation-back amendment).

<sup>18</sup> See *id.* at 4 (explaining FERA's retaliation amendments).

scope of this theory for all false certification cases (express and implied).<sup>19</sup> This decision is discussed in the materiality section below. The Supreme Court also ruled this term in *State Farm Fire & Casualty Co. v. United States ex rel. Rigsby* that a relator's violation of the FCA's seal requirement does not mandate dismissal of the relator's complaint.<sup>20</sup> Other recent developments include the Eighth Circuit's conclusion that the defendant's objectively reasonable interpretation of the term "emergence" in an ambiguous regulation precluded a "knowing" FCA violation,<sup>21</sup> and the Sixth Circuit's dismissal of a *qui tam* case at the pleadings stage for failure to state a reverse false claim that met the FCA's scienter requirement.<sup>22</sup>

Given the number of important developments this year, only a few of the most significant can be briefly touched upon in these pages. For a more exhaustive analysis of recent FCA developments, see JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (Wolters Kluwer Law & Business) (4th ed. & Supp. 2017-1).

## 1. Claims and Presentment

Prior to FERA, Section 3729(a)(2) liability was limited to false statements supporting false claims for money or property that the government "provides" or "will reimburse." Some courts read this language to require the false claim to be subjected to a government payment or approval process, but the circuits were split on the underlying question of whether "presentment" of the false claim to the government was required under Section 3729(a)(2). In a unanimous decision, in *Allison Engine Co. v. United States ex rel. Sanders*,<sup>23</sup> the Supreme Court resolved this split by holding that presentment was not required under Section 3729(a)(2), but that was limited to false statements that were designed "to get" a false claim paid or approved "by the Government." The Court found that this limitation was necessary because, without a clear link to payment or approval by the government, the FCA would be "boundless" and become an "all-purpose antifraud statute."<sup>24</sup>

FERA, however, eliminated both the "to get" language and the "by the Government" limitation in Section 3729(a)(2) as well as comparable language in Sections 3729(a)(3) and (a)(7). Now Section 3729(a)(1)(B) liability is limited by a nexus to the government requirement in the definition of "claim" in Section 3729(b)(2)(ii), which covers requests for funds to a contractor, grantee, or other recipient, if the money or property requested "is to be spent or used on the Government's behalf or to advance a Government program or interest." FERA does not define the key terms "used on the Government's behalf" or "to advance a Government program or interest," and therefore their meaning is left to the courts to determine on a case-by-case basis.

The presentment requirement remains in Section 3729(a)(1)(A), however, and the definition of "claim" in Section 3729(b)(2)(A)(i) makes clear that presentment must be directly to the government. The Fourth Circuit's decision in *United States ex rel. Nathan v. Takeda Pharm. N.A., Inc.* emphasizes that this requirement is still of primary importance under Section

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<sup>19</sup> 136 S. Ct. 1986 (2016).

<sup>20</sup> No. 15-513, 2016 WL 7078622 (U.S. Dec. 6, 2016).

<sup>21</sup> *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874 (8th Cir. 2016). See *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C.Cir. 2015) (reaffirming that there can be no FCA liability where the law or regulation is ambiguous, the defendant's interpretation of the language is reasonable, and the agency issued no formal guidance indicating the defendant's interpretation was wrong).

<sup>22</sup>

<sup>23</sup> 553 U.S. 662 (2008).

<sup>24</sup> 553 U.S. at 669, 672.

3729(a)(1)(A) and must be pled with particularity under Rule 9(b) even when a fraudulent scheme is alleged:

[T]he critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.”<sup>25</sup>

The Fourth Circuit compared the *Nathan* relator’s allegations with those in *United States ex rel. Grubbs v. Kanneganti*,<sup>26</sup> and *United States ex rel. Duxbury v. Ortho Biotech Products*,<sup>27</sup> and drew clear distinctions between allegations of fraudulent conduct that necessarily lead to an inference that false claims were presented to the government and the allegations made by the *Nathan* relator, which did not lead to the same inference. The relator in *Nathan* asked the Supreme Court to review the Fourth Circuit’s decision, and the Court invited the Solicitor General to submit a brief expressing the views of the United States on the question of whether Rule 9(b) requires an FCA complaint to allege with particularity that specific false claims actually were presented to the government. After the Solicitor General submitted a brief opposing a per se rule but noting that this *qui tam* suit would be dismissed under either standard, the Court denied *certiorari* in *Nathan*.

## 2. Requirements under Rule 9(b)

Rule 9(b) provides:

In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind may be averred generally.

Courts have explained that the purposes of this “heightened” requirement to plead the circumstances of the fraud with particularity are to deter meritless claims of fraud, to protect defendants’ reputations, to give particularized notice to defendants of plaintiffs’ claims, and to prevent fraud suits in which the dispositive facts are learned through discovery.<sup>28</sup> To satisfy this requirement, the complaint must set forth specifics as to the who, what, when, where, and how of the fraud alleged.<sup>29</sup> Courts universally apply this heightened pleading requirement to FCA complaints because the allegations sound in fraud, and there is no conflict between the FCA’s lower intent requirements and Rule 9(b), which provides that intent may be averred generally. Courts use a case-by-case approach in applying Rule 9(b) to substantive claims that have various

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<sup>25</sup> 707 F.3d 451, 456 (4th Cir. 2013) (internal citations omitted).

<sup>26</sup> 565 F.3d 180 (5th Cir. 2009).

<sup>27</sup> 579 F.3d 13 (1st Cir. 2009). It should be noted that the scope of the claims in *Duxbury* were strictly limited when the First Circuit affirmed the district court’s order limiting discovery to the claims that survived dismissal and precluding the relator from discovery on “nationwide” fraud that was outside the time frame and geographic location of the original relator’s employment. See *United States ex rel. Duxbury v. Ortho Biotech Prods., LP*, 719 F.3d 31 (1st Cir. 2013).

<sup>28</sup> See, e.g., *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1<sup>st</sup> Cir. ), *cert. denied*, 125 S. Ct. 59 (2004); *United States ex rel. Clausen v. Lab. Corp. of Am.* 290 F.3d 1301, 1313, 1316-17 (11th Cir. 2002); *United States v. Rogan*, No. 02-C-3310, 2002 WL 31433390, at \*3 (N.D. Ill. 2002).

<sup>29</sup> See, e.g., *United States ex rel. Cafasso v. General Dynamics C4 Sys.*, 637 F.3d 1047, 1057 (9th Cir. 2011); *United States ex rel. Lacy v. New Horizons, Inc.*, 348 F. App’x 421 (10th Cir. 2009); *Corsello v. Lincare, Inc.* 428 F.3d 1008, 1014 (5th Cir. 2005).

proof requirements, and this approach helps to define the contours of FCA liability. However, some erosion in the heightened standard is occurring in certain *qui tam* cases where the details of a fraudulent scheme have been alleged with particularity but no actual false claim was pled.

As the *Nathan* case discussed above reflects, the False Claims Act was not designed to punish every type of fraud committed upon the government. Instead, because liability under the FCA attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme, “the critical question is whether the defendant caused a false claim to be presented to the government.”<sup>30</sup> Despite this key requirement for FCA liability, a clear circuit split has developed over whether Rule 9(b) requires FCA complaints to allege the details of a false claim that actually was submitted. Some recent decisions from the First, Third, Fifth, Sixth, Seventh, Eighth, Ninth, and Eleventh Circuits have found that detailed allegations of a particular fraudulent scheme that produce a strong inference that false claims were submitted may meet Rule 9(b)’s requirement for specificity,<sup>31</sup> although even within those circuits there is some confusion over the proper standard. Other decisions in the Second, Fourth, and Sixth Circuits have applied a stricter standard under which not just the existence of the fraudulent scheme, but false claims that actually were submitted as a result, must be pled with particularity.<sup>32</sup> The fact that the lower standard is still in flux within individual circuits that have applied it,<sup>33</sup> and the subsequent dismissals in cases where the inference that false claims were submitted was not borne out following discovery,<sup>34</sup> indicate that the limits to its application are still being delineated.

### 3. Falsity and False Certification

The terms “false” and “fraudulent” are not specifically defined in the FCA. They have been construed and interpreted by the courts with reference to their construction and interpretation in other contexts, most notably in criminal cases brought under 18 U.S.C. §§ 287 and 1001. Establishing falsity under both the FCA and the criminal False Claims or False Statements Act requires proof of “actual falsity.”<sup>35</sup> Matters that are the subject of legitimate scientific dispute are not a basis for a “false” claim within the meaning of the FCA.<sup>36</sup> In the

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<sup>30</sup> 707 F.3d 451, 456 (4th Cir. 2013).

<sup>31</sup> *See, e.g.*, United States *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13 (1st Cir. 2009); United States *ex rel.* Foglia v. Renal Ventures Management, LLC, 754 F.3d 153 (3d Cir. 2014); United States *ex rel.* Grubbs v. Kanneganti, 565 F.3d 180 (5th Cir. 2009); United States *ex rel.* Prather v. Brookdale Senior Living Communities, Inc., 838 F.3d 750 (6th Cir. 2016); United States *ex rel.* Presser v. Acacia Mental Health Clinic, LLC, 836 F.3d 770 (7th Cir. 2016); United States *ex rel.* Thayer v. Planned Parenthood, No. 13-1654, 2014 WL 4251603 (8th Cir. Aug. 29, 2014); Ebeid v. Lungwitz, 616 F.3d 993 (9th Cir. 2010); United States *ex rel.* Mastej v. Health Mgmt. Assocs., Inc., 591 F. App’x 693, 708 (11th Cir. 2014).

<sup>32</sup> *See, e.g.*, United States *ex rel.* Nathan v. Takeda Pharms. N. Am., Inc., 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 81 U.S.L.W. 3650 (U.S. Mar. 31, 2014) (No. 12-1349); United States *ex rel.* SNAPP, Inc. v. Ford Motor Co., 618 F.3d 505 (6th Cir. 2010). *See also* United States *ex rel.* Siegel v. Roche Diagnostics Corp., 988 F. Supp. 2d 341 (E.D.N.Y. 2013) (applying a heightened standard that requires an actual false claims to be pled).

<sup>33</sup> *See, e.g.*, United States *ex rel.* Grenadyor v. Ukrainian Village Pharmacy, Inc., 772 F.3d 1102 (7th Cir. 2014); United States *ex rel.* Dunn v. North Mem’l Health Care, 739 F.3d 417 (8th Cir. 2014); United States *ex rel.* Ge v. Takeda Pharm. Co., 737 F.3d 116 (1st Cir. 2013); United States *ex rel.* Nunnally v. W. Calcasieu Cameron Hosp., 519 F. App’x 890, 892-95 (5th Cir. 2013) (unpublished decision).

<sup>34</sup> *See, e.g.*, United States *ex rel.* Lusby v. Rolls-Royce Corp., No. 1:03CV680-SEB-WGH, 2012 WL 4357438 (S.D. Ind. Sept. 24, 2012) (granting summary judgment to defendant because relator had no proof that Rolls-Royce made a false claim for payment to the government); United States *ex rel.* Duxbury v. Ortho Biotech Prods., LP, 719 F.3d 31 (1st Cir. 2013) (“*Duxbury II*”) (granting summary judgment to defendant).

<sup>35</sup> *See* United States v. Diogo, 320 F.2d 898 (2d Cir. 1963); United States v. Lange, 528 F.2d 1280 (5th Cir. 1976).

<sup>36</sup> *See, e.g.*, United States *ex rel.* Hill v. University of Medicine & Dentistry of N.J., No. 10-4364, 2011 WL 5008427 (3d Cir. Oct. 20 2011) (finding that scientific judgments or conclusions on which reasonable minds may

FCA context, resolving disputed questions of falsity often involves the interpretation of a law, regulation, contract, or agreement.

**False certification liability.** Two types of false claims have been recognized as actionable under the FCA—“factually false” claims and “legally false” claims. Proving falsity in a run-of-the-mill “factually false” claim case is a relatively straight forward matter of showing that the defendant submitted “an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.”<sup>37</sup> For example, a hospital that bills Medicare for a “phantom” patient it has never treated may be liable under the FCA—without the need to determine “materiality” or false certification issues. Those issues are similarly irrelevant in a case where a doctor treats a Medicare patient and then codes the treatment at a higher reimbursement level. In such cases, where the defendant has billed the government for a service that it has not provided, which is the essence of a false claim, the falsity of the claim is obvious and materiality is assumed. Of course, plaintiffs may not simply allege factual falsity to avoid proving that the basic requirements for liability have been met. Courts have rejected such attempts where the proper predicate for liability has been lacking.

Many FCA cases are based not on facially or factually false claims, but on an alleged false certification of compliance with a law, regulation or contract provision. Some of the most significant FCA developments each year arise in “false certification” or “legally false” claim cases that involve something quite different from direct overbilling or factually false claims. FCA plaintiffs are using the statute to litigate alleged regulatory and statutory violations, most of which lack a private right of action, on the theory that the defendant falsely certified compliance with the regulatory scheme and the government would not have paid the claim had it known about the noncompliance. In a “false certification” claim, the defendant has provided the goods or services to the government or government beneficiary for the agreed upon price. For example, a hospital has provided medically necessary services to a Medicare eligible beneficiary and billed the government the proper amount, but the hospital has not complied with some other regulation, statute, or contract term in the course of delivering those services. The hospital may have violated one or more “conditions of participation” in the course of delivering the necessary services to the eligible beneficiary. The hospital may have expressly certified compliance with the conditions, or its certification may be implied.

**Prerequisite to payment analysis.** With FERA’s adoption of the more lenient test for materiality, under which a false statement only has to “be capable of influencing” the

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differ cannot be “false”); *United States ex rel. Morton v. A Plus Benefits, Inc.*, No. 04-4148, 139 F. App’x 980 (10th Cir. July 19, 2005) (unpublished decision); *United States ex rel. Polukoff v. St. Mark’s Hosp.*, No. 2:16CV00304-JNP-EJF, 2017 WL 237615 (D. Utah Jan. 19, 2017) (physician’s medically reasonable and necessary representation could not be proven false because it was a medical judgment about which reasonable minds may differ); *United States ex rel. Milam v. Regents of the Univ. of California*, 912 F. Supp. 868, 886 (D. Md. 1995).

<sup>37</sup> See *United States ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153 (3d Cir. 2014) (finding that relator’s allegation that Renal’s overfill claim misrepresented goods provided and overcharged the government was a “factually false claim”); *United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) (distinguishing factually false from legally false claims); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (same); *United States ex rel. Sanchez-Smith v. AHS Tulsa Reg’l Med. Ctr.*, 754 F. Supp. 2d 1270, 1288 (N.D. Okla. 2010) (finding no evidence that services were so deficient that claims were factually false and rejecting relators’ allegations that “would stretch FCA ‘factual’ falsity liability too far beyond its intended purpose of preventing misrepresentations of fact on claim forms”).

government's decision to pay the claim, courts began to rely more heavily on a "prerequisite to payment" analysis of falsity as a limit on liability under the false certification theory. Under that analysis, technical or minor violations of federal laws and regulations that are "conditions of participation" but not prerequisites to payment do not render a claim "false" for purposes of the FCA. Some courts limited liability to situations in which the government explicitly conditioned its payment on compliance with the regulations or laws violated,<sup>38</sup> but this "express condition of payment" is not dispositive following the Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*,<sup>39</sup> as explained in the materiality section below. Other courts have affirmed the imposition of liability in the absence of express false certifications of compliance.<sup>40</sup> Prior to *Escobar*, most circuit courts held that FCA liability turned on falsity, and that the determining factor in that analysis was the prerequisite to payment requirement.<sup>41</sup>

For example, in *United States ex rel. Steury v. Cardinal Health, Inc.*,<sup>42</sup> the relator claimed that by submitting claims for payment to the Veterans Administration for allegedly defective intravenous fluid pumps, Cardinal Health falsely and implicitly certified compliance with an

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<sup>38</sup> See, e.g., *United States ex rel. Bishop v. Wells Fargo & Co.*, No. 15-2449, 2016 WL 2587426 (2d Cir. May 5, 2016) (stating that the *Mikes* express test holding is not limited to the healthcare industry, and concluding that some of the same concerns raised in the Medicare fraud context in *Mikes* are also relevant to the banking industry); *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."); *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (relator's implied certification theory was "doomed by the rule, adopted by all courts of appeals to have addressed the matter, that a false certification of compliance with a statute or regulation cannot serve as the basis for a qui tam action under the FCA unless payment is conditioned on that certification."); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999).

<sup>39</sup> 136 S. Ct. 1989 (2016).

<sup>40</sup> See, e.g., *Augustine*, *supra* note 19; *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519 (10th Cir. 2000) (affirming the imposition of liability for allegedly false implied certifications of contractual compliance). See also *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011) (rejecting the argument that, in the absence of an express legal representation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation, finding that the non-defendant hospital's claims to Medicare could be rendered false by alleged underlying kickback violations of other defendants, and ruling that the alleged kickbacks violated preconditions to Medicare's payment in the physicians' and hospital's provider agreements and in the hospital's cost reports).

<sup>41</sup> See, e.g., *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir.), *cert. denied*, 135 S. Ct. 85 (2014) (holding that claims for drugs re-packaged in violation of FDA processing regulations were not "false"); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (ruling that an "underlying claim for payment is not 'false' within the meaning of the FCA if the contractor was not required to certify compliance in order to receive payment"); *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707 (6th Cir. 2013) (holding that "approved physician" and updating enrollment information requirements were not conditions of Medicare payment); *United States ex rel. Hill v. City of Chicago*, 772 F.3d 455 (7th Cir. 2014) (affirming dismissal of relator's false certification allegation that program as implemented differed from the City's grant application for lack of falsity); *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825 (8th Cir. 2013) ("[t]he absence of a clear requirement that a written report must underlie or support each claim for surgical pathology services means that Relators pleaded a claim of regulatory noncompliance, not a plausible claim that Mayo submitted false or fraudulent claims for Medicare payment."). See also FraudMail Alert No. 10-11-03, Fifth Circuit Holds "Prerequisite to Payment" is a Fundamental Requirement in Establishing "Falsity" in a False Certification Case (Nov. 3, 2010), <http://www.friedfrank.com/siteFiles%2FPublications%2FFried%20Frank%20FraudMail%20Alert%20No.%2010-11-03.pdf>; FraudMail Alert No. 11-08-31, Sixth Circuit Joins Second and Fifth Circuits in Holding That FCA Claims Based on Implied False Certifications Must Allege and Prove That the Alleged Violation Was a Prerequisite to Payment (Aug. 31, 2011), <http://www.friedfrank.com/siteFiles%2FPublications%2FFried%20Frank%20FraudMail%20Alert%20C2%AE%20No.%2011-08-31.pdf>.

<sup>42</sup> 625 F.3d 262 (5th Cir. 2010).

implied warranty of merchantability. Without deciding whether it would adopt the implied false certification theory, the Fifth Circuit found that Cardinal Health did not make an implied false certification simply because the FAR included warranty of merchantability provisions. The court concluded that the claim could not be “false” within the meaning of the FCA if compliance with this warranty was not required in order to receive payment, and held that “a false certification, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.”<sup>43</sup> As the Third Circuit explained in *United States ex rel. Chesbrough v. Visiting Physicians Ass’n*,<sup>44</sup> the FCA should not be interpreted to “enforce compliance with all medical regulations” such as those that require resolving medical issues that are not requirements for reimbursement.

More recently, in *United States ex rel. Bishop v. Wells Fargo & Co.*, the Second Circuit affirmed the dismissal of a *qui tam* suit alleging that the defendants falsely certified compliance with various banking laws and regulations when they borrowed money at favorable rates from the Federal Reserve’s discount window.<sup>45</sup> The court specifically looked to the Second Circuit’s prior policy statements in *Mikes v. Straus* that the FCA “was not designed for use as a blunt instrument to enforce compliance with all . . . regulations,” and that to construe the implied false certification theory expansively “would improperly broaden the Act’s reach.”<sup>46</sup> In *Mikes*, the Second Circuit affirmed dismissal of *qui tam* allegations that a medical practice violated the FCA by submitting Medicare reimbursement claims for procedures that did not meet the requisite standard of care. The *Mikes* decision clarified that the FCA was not intended to police general regulatory noncompliance, and that “it does not encompass those instances of regulatory noncompliance that are irrelevant to the government’s disbursement decisions.” To keep the expansive implied false certification theory in check, and to prevent it from being used “to resolve medical issues concerning levels of care” that are more appropriately monitored by medical agencies, the court held in *Mikes* that this theory “is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid.”<sup>47</sup> The Second Circuit reaffirmed that holding and applied the express statement rule to the false certification claims in *Bishop*, concluding that the *Mikes* rule is not limited to health care cases, and that the rationale for applying the rule in the health care context also supports its application to the banking industry<sup>48</sup>

**The Supreme Court’s validation of the implied false certification theory in *Escobar*.** In *Universal Health Services, Inc. v. United States ex rel. Escobar*,<sup>49</sup> the Supreme Court validated the implied false certification theory as a basis for FCA liability. Using the common law of fraudulent misrepresentation by omission as the template for this liability, the Court opted to apply a “demanding” materiality standard, derived from its common law antecedents in fraudulent misrepresentation, rather than narrowly circumscribing the meaning of a “false or fraudulent” claim using an express condition of payment requirement. The Court concluded that stringent limitations were necessary, however, to keep the false certification theory from improperly expanding the FCA’s punitive sanctions and using the FCA as an “all-purpose antifraud statute.”<sup>50</sup> These limitations are discussed below.

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<sup>43</sup> 625 F.3d at 269.

<sup>44</sup> 655 F.3d 461 (6th Cir. 2011).

<sup>45</sup> No. 15-2449, 2016 WL 2587426 (2d Cir. May 5, 2016).

<sup>46</sup> *Id.* at \*10, (quoting *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001)).

<sup>47</sup> 274 F.3d at 700.

<sup>48</sup> 2016 WL 2587426, at \*12.

<sup>49</sup> 136 S. Ct. 1989 (2016).

<sup>50</sup> *Id.* at 2003 (quoting *Allison Engine*).

#### 4. Materiality

Three different concepts of materiality are reflected in FCA case law—a pre-FERA concept, a post-FERA concept, and the separate “rigorous materiality requirement” that the Supreme Court adopted in *Universal Health Services, Inc. v. United States ex rel. Escobar*. The first concept developed as a necessary, although implicit, element that was applied to prevent FCA liability from extending to noncompliance with a multitude of regulatory requirements. Under FERPA, the statutory definition of “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property”<sup>51</sup> was adopted on the Justice Department’s recommendation based on DOJ’s statement that it was consistent with the interpretation of the majority of courts in the FCA context. In adopting this materiality standard, FERPA made explicit a previously implicit requirement under the prior law. The standard itself was not new. Many courts have interpreted it as strongly limiting FCA liability to false statements that directly affect the government’s payment decision, and several courts have held that violations of “conditions of participation” in a federal healthcare program did not result in FCA violations. For example, in *United States ex rel. Conner v. Salina Regional Health Center*,<sup>52</sup> the Tenth Circuit found that sweeping, general certifications were not specific conditions of payment. Similarly, in *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*,<sup>53</sup> the court found that there was no evidence showing that noncompliance with Medicare’s conditions of participation would make the defendants ineligible for Medicare payments or lead to nonpayment of the claims.

Under FERPA, a false record or statement on which liability is premised under Sections 3729(a)(1)(B) and (a)(1)(G) must be “material” to a false claim or obligation. However, the absence of the word “material” in new Section 3729(a)(1)(A)—the fundamental provision for false claim liability on which liability in every other false claim provision is based—supports the view that FERPA’s “capable of influencing” concept of “materiality” is relevant only to link a “false record or statement” to a false claim under subsection (a)(1)(B) or to an obligation to pay money to the government under subsection (a)(1)(G). That is, while subsection (a)(1)(B) requires a false record or statement to be “material” to a false claim, this requirement assumes that there is a false claim. Thus liability under subsection (a)(1)(B), as under subsection (a)(1)(A), depends on first finding the claim false.

As the Supreme Court explained in *Escobar*, when a defendant makes specific representations in submitting a claim but omits violations of material statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided. Such claims can be “false or fraudulent” under the FCA. Claims that do not make any specific representations or that omit noncompliance with lesser requirements do not meet *Escobar*’s demanding materiality standard and do not result in a false claim under the FCA.<sup>54</sup> This demanding materiality standard—some call it “*Escobar* materiality”—is the third materiality concept that now operates to limit the scope of false certification liability in FCA cases.

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<sup>51</sup> See 31 U.S.C. § 3729(b)(4).

<sup>52</sup> 543 F.3d 1211 (10th Cir. 2008).

<sup>53</sup> 525 F. Supp. 2d 972 (W.D. Tenn. 2007). The reader should note that the author was one of the attorneys representing the defendants in this case.

<sup>54</sup> *Escobar*, 136 S.Ct. 1989, 1995, 1999.



In addition, a False Claims Act plaintiff must prove that an alleged falsity actually caused the government to pay claims it otherwise would not have paid.<sup>55</sup> The evolving case law on the need to prove materiality, causation, and reliance in False Claims Act cases is discussed in detail in BOESE, §§ 2.04 and 2.05.

Many government and relator lawyers hoped that FERA's definition of "material" would undermine the interpretations in *Conner* and *Landers*, or dictate a different interpretation. While that has not happened, a recurring problem with the natural tendency test of materiality has been that, in determining whether the government could have refused to pay or approve a claim, it is rarely deemed necessary under that standard to consider the government's actual responses to the alleged false claims.<sup>56</sup> That approach leaves out the key interest of the government officials involved in the transaction, who have the public interest in mind when deciding whether or not to pay the claim. For this reason, the author proposed that courts would find a legal way to reinstate the "prerequisite to payment" requirement,<sup>57</sup> which is precisely what happened in the *Chesbrough* and *Steury* line of cases discussed above. In *Escobar*, however, instead of relying on the prerequisite to payment analysis to determine falsity, the Supreme Court opted to apply stringent new, additional materiality and scienter requirements, which do take the government's payment decisions into account.

***Escobar's Materiality and Knowledge Requirements.*** In *Escobar*, the Supreme Court unanimously validated the implied false certification theory's application in appropriate cases, and drew the contours of the analysis required to apply it. The relators in *Escobar*—parents of a teenage girl who suffered a fatal reaction to medication after receiving treatment at defendants' mental health facility—alleged that the facility's noncompliance with state staffing and licensing requirements rendered false the defendant's claims for payment to Medicaid. Prior to bringing their *qui tam* suit, the relators initiated a state administrative action against the clinic, which resulted in one individual's agreement to pay a \$1,000 fine and the clinical director's agreement to a supervised probationary period of two years. The state agency ultimately concluded that the evidence was insufficient to find that there had been "abuse" by the caregiver. In short, the state never asked for its money back, yet the relators sought millions of dollars in FCA damages and penalties.

First, the Supreme Court validated the implied false certification theory as a basis for FCA liability "at least where two conditions are satisfied":

first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the

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<sup>55</sup> See, e.g., *Blackstone*, 647 F.3d 377 (1st Cir. 2011) (noting that "[o]nly persons who knowingly submit or cause the submission of a false or fraudulent claim can be held liable for violating the FCA," that "[t]he term 'causes' is hardly boundless," and that "it has been richly developed as a constraint in various areas of the law"); *United States ex rel. Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003) (en banc); *United States ex rel. Tessitore v. Infomedics, Inc.*, 847 F. Supp. 2d 256 (D. Mass. 2012) (rejecting relator's theory—that drug manufacturer's failure to report adverse events kept FDA from requiring warnings sooner, causing more prescriptions for Paxil to be written by physicians and more claims for reimbursement to the government—as an unsupported hypothetical that called for inferences that went against the evidence); *Massachusetts v. Shering-Plough Corp.*, No. 03-11865-PBS, 2011 WL 4436969, at \*3 (D. Mass. Sept. 23, 2011) (finding that pharmacists' claims were factually false, but that defendants had "no role in causing that independent falsehood").

<sup>56</sup> See, e.g., *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008) (applying the "capable of influencing" test of materiality and finding that testimony of a government official showing that it would not have paid was not a required component of materiality).

<sup>57</sup> See John T. Boese, *The Past, Present, and Future of "Materiality" Under the False Claims Act*, 3 ST. LOUIS U.J. OF HEALTH L. & POL'Y 291 (2010).

defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.<sup>58</sup>

The Court specifically rejected the contention that *all* claims for payment implicitly certify compliance with all ancillary regulatory, statutory, and contractual provisions.<sup>59</sup> Rather, the Court looked to the common law for classic examples of actionable half-truths, such as the seller who discloses that there may be two new roads near the property he is selling, but fails to disclose a third potential road that might bisect it. Instead of adopting a narrow construction of what it means to be false or fraudulent, the Court opted to apply heightened materiality and scienter standards, with the requirement that they be strictly enforced, to address concerns about fair notice and open-ended FCA liability.

Second, the Court described its materiality requirement as “demanding.”<sup>60</sup> Like the classic examples in the common law from which it derives, *Escobar* materiality “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation,” and clearly does not encompass “minor or insubstantial” noncompliance.<sup>61</sup> The Court emphasized that, if the government “pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.”<sup>62</sup>

Third, the Court adopted an additional scienter requirement, holding that plaintiffs cannot prove an implied certification claim without showing that the defendant knew that compliance with the obligation underlying the certification was material to the government's payment.<sup>63</sup> Fourth, the Court indicated that FCA allegations relying on the implied certification theory will not withstand a motion to dismiss if the complaint does not plead facts supporting these requirements.<sup>64</sup>

Courts have begun applying *Escobar*'s materiality and scienter standards to allegations in false certification cases, both express and implied. These decisions indicate that the courts are taking the new standards seriously. For example, in *United States ex rel. Nelson v. Sanford-Brown, Ltd.*,<sup>65</sup> the Seventh Circuit focused on two of the four requirements described above in granting summary judgment for the defendant, a for-profit higher education institution. First, the court took for granted that *Escobar*'s two-part test—the specific representations, and the failure to disclose noncompliance with material statutory requirements—is a mandatory, threshold requirement that any false certification claim must satisfy, and the court found that the college made no representations, let alone false or misleading representations, in connection with its claims for payment.<sup>66</sup> Second, the court concluded that the relator failed to establish materiality given that he offered no evidence that the government's “likely or actual behavior” would have been different had it known of the college's alleged noncompliance with Title IV regulations.

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<sup>58</sup> *Escobar*, 136 S. Ct. 1989, 2001.

<sup>59</sup> *Id.* at 2000.

<sup>60</sup> *Id.* at 2003.

<sup>61</sup> *Id.* at 2002, 2003.

<sup>62</sup> *Id.* at 2003.

<sup>63</sup> *Id.* at 1996.

<sup>64</sup> *Id.* at 2004 n.6.

<sup>65</sup> 840 F.3d 445 (7th Cir. 2016).

<sup>66</sup> *Id.* Cf. *Rose v. Stephens Inst.*, No. 09-cv-5966-PJH, 2016 WL 6393513 (N.D. Cal. Oct. 28, 2016) (certifying for interlocutory appeal whether *Escobar* created a two-part mandatory threshold test that applies to every implied false certification claim).

The most that the relator could show was that the purported noncompliance would have entitled the government to decline payment, which is not enough under *Escobar*.

On remand in *Escobar II*, on the other hand, the First Circuit had little difficulty in concluding that the relators sufficiently alleged that: (1) MassHealth's licensing and supervision requirements for staff go to the "very essence of the bargain" of MassHealth's contracts with providers under Medicaid and is strong evidence that noncompliance would influence the government's payment, (2) regulatory compliance with these requirements was a condition of payment, and (3) there was no evidence that MassHealth paid the claims knowing of the noncompliance. In assessing the paying agency's knowledge of noncompliance, the First Circuit ignored the earlier complaints against defendants' mental health facility at Arbor in 2009 and 2010 and instead focused on the fact that the agency paid the Escobars' claims before the state began its investigation of Arbor in 2011.<sup>67</sup> While the decision in *Escobar II* may give the impression that the analysis of the government's knowledge is a truncated one, the First Circuit's later decision in *D'Agostino v. EV3, Inc.*, better illustrates this concept:

The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so. The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.<sup>68</sup>

And while the government and relators have continued to assert the "natural tendency to influence" test as if nothing has really changed with respect to materiality after *Escobar*, this argument no longer suffices in view of *Escobar's* creation of a heightened materiality standard.<sup>69</sup>

## 5. Causation

Section 3729(a)(1) of the FCA imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval." (emphasis added). Liability under this provision specifically requires a causal link between the defendant's actions and the submission of a false claim to the government, but the Act does not include a definition of causation. Principles of causation from tort law have been applied by some courts, but their application to FCA allegations could stretch these principles beyond their legal foundation. In view of the FCA's punitive nature, and because the provisions of the civil FCA and the criminal false claims statute were historically the same until relatively recently, a strong argument can be made for strictly construing undefined or ambiguous provisions such as causation under the FCA as under criminal statutes. FERA amended the predicate of the "causes to be presented" language in Section 3729(a)(1)(A), but neither the

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<sup>67</sup> *Escobar II*, No. 14-1423, 2016 WL 6872650 (1st Cir. Nov. 22, 2016).

<sup>68</sup> *D'Agostino*, No. 16-1126, 2016 WL 7422943 (1st Cir. Dec. 23, 2016).

<sup>69</sup> See, e.g., *United States ex rel. Kelly v. Serco, Inc.*, No. 14-56769, 2017 WL 117154 (9th Cir. Jan. 12, 2017) (finding cost formatting standard minor and ancillary to contract's purpose under *Escobar*); *Carlson v. DynCorp Int'l LLC*, No. 14-1281, 2016 WL 4434415 (4th Cir. Aug. 22, 2016) (finding alleged violations of accounting regulations or best practices insufficient under *Escobar* standard).

meaning of causation nor its role was changed. Similar amendments to Section 3729(a)(1)(B) did not change its requirement for causing a false record or statement in support of a false claim. The courts are developing standards for these causal requirements.

In *United States ex rel. Franklin v. Parke-Davis*, the court held that common law tort causation principles required two questions to be considered in determining whether the defendant's allegedly improper promotion of off-label uses caused the submission of false claims: (1) whether the defendant's conduct was a "substantial factor" in producing the harm; and (2) whether the outcome was foreseeable.<sup>70</sup> The court concluded that the relator provided sufficient evidence to show that the defendant "played a key role in setting in motion a chain of events that led to false claims," and that it was foreseeable that the defendant's actions would "ineluctably result in false Medicaid claims."<sup>71</sup> In *United States ex rel. Drescher v. Highmark, Inc.*, however, the court cautioned the government that basing causation on medical insurers' incorrect denial or incorrect payment of claims and subsequent submission of false claims by a secondary insurer was a "novel" theory that required evidence of direction and control on the medical insurers' part and few options on the part of secondary insurers.<sup>72</sup> More recently, in *Allison Engine*, the Supreme Court applied a common law principle underlying proximate cause in interpreting Section 3729(a)(2) liability to ensure that "a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct."<sup>73</sup> And while FERA's amendments in Section 3729(a)(1)(B) eliminated the purpose-based "to get" limitation which was the focus of the Court's analysis in *Allison Engine*, there is no indication of congressional intent to extend liability beyond these natural, ordinary, and reasonable consequences.

In *United States ex rel. Hutchesson v. Blackstone Med., Inc.*, the relator alleged that Blackstone paid kickbacks to physicians to get them to use its medical devices in surgeries performed in a hospital, causing the physicians and the hospital to submit false claims to Medicare for reimbursement of services using those devices as well as for the devices themselves. Referring to the Supreme Court's rulings in *United States ex rel. Marcus v. Hess* and *United States v. Bornstein* that a non-submitting entity could be liable for knowingly causing a submitting entity to submit a false claim, the First Circuit found that FCA liability was not conditioned on whether the submitting entity knew or should have known about the non-submitting entity's unlawful conduct.<sup>74</sup> The First Circuit reasoned that the *qui tam* complaint could state a claim under the "causes to be presented" or "causes to be made or used" language

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<sup>70</sup> No. Civ. A. 96-11651PBS, 2003 WL 22048255, at \*4 (D. Mass. Aug. 22, 2003). See also *United States ex rel. Freedman v. Suarez-Hoyos, MD*, No. 8:04CV933-T-24 EAJ, 2012 WL 4344199 (M.D. Fla. Sept. 21, 2012) (citing *Parke-Davis* and ruling that liability could attach to a kickback arrangement that was a substantial factor in causing presentment of a false claim); *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395 (D. Mass. 2010) (finding allegations that defendant's literature compared its drug favorably with other drugs approved for off-label outpatient use and failed to reflect unfavorable information about the drug were sufficient to pass the "substantial factor" test for causation of claims to Medicare for off-label use); *United States ex rel. DeCesare v. Americare In Home Nursing*, No. 1:05CV696, 2010 WL 5313315, at \*13 (E.D. Va. Dec. 16, 2010) (finding that it was a "necessary, foreseeable, and obvious consequence of VNSN's referrals that Medicare and Medicaid claims would be filed," and therefore that the complaint alleged that VNSN caused false claims to be submitted under the "substantial factor" test); *United States ex rel. Strom v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) (finding that the causation requirement of Rule 9(b) had been met by the allegation that "Defendants' marketing activities created the market for the outpatient use of [the drug], and . . . encouraged such a use even though they had no credible evidence that [the drug] was effective in that context").

<sup>71</sup> 2003 WL 22048255, at \*6.

<sup>72</sup> 305 F. Supp. 2d 451 (E.D. Pa. 2004).

<sup>73</sup> 553 U.S. 662, 672 (2008).

<sup>74</sup> *Id.* at 390 (citing *Hess*, 317 U.S. 537 (1943), and *Bornstein*, 423 U.S. 303 (1976)).

in Sections 3729(a)(1) and (a)(2) if it identified a materially false or fraudulent claim—including a claim that was false due to an implied representation of compliance with a precondition of payment, such as the prohibition on kickbacks in the provider agreement.

After the Affordable Care Act amended the Antikickback Statute to provide that Medicare or Medicaid claims that include “items or services resulting from” a kickback violation are false claims under the FCA, defendants have argued that the phrase “resulting from” requires the government to plead that the kickback scheme actually caused false claims to be submitted on a claim-by-claim basis. One court rejected that argument as calling for “a strict ‘but for’ causation requirement” that would narrow the scope of the word “false.”<sup>75</sup>

## **6. Knowledge and Intent**

Under Section 3729(b) of the FCA, “knowing” and “knowingly” are defined as:

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

FERA made no substantive change in this definition.

### **a. Allison Engine Intent**

In *Allison Engine Co. v. United States ex rel. Sanders*, the Supreme Court found that the “presentment” requirement that limits liability under Section 3729(a)(1) was not a requirement under Section 3729(a)(2). In order to prevent the FCA from being used as an “all-purpose antifraud statute,”<sup>76</sup> however, the Court imposed another intent element, in addition to the FCA’s “knowing” standard, that limited a defendant’s liability under Sections 3729(a)(2) and (a)(3) to the “natural, ordinary, and reasonable consequences of his conduct.” The Court found that the purpose of a false statement under Section 3729(a)(2) must be “to get” a false claim paid or approved by the government, and that a conspiracy to defraud under Section 3729(a)(3) must be for the purpose of “getting” a false claim allowed or paid. FERA’s FCA amendments removed these references to purpose, substituting a materiality requirement for the “to get” language in Section 3729(a)(1)(B) that the Supreme Court in *Allison Engine* relied upon in imposing the additional intent requirement, and making a similar substitution in Section 3729(a)(1)(G). These substantive alterations to the statute complicate FCA litigation and raise retroactivity issues in some cases, as already noted above. FERA did not alter Section 3729(b)(1), which defines the statutory intent standards for “knowing” and “knowingly,” discussed below.

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<sup>75</sup> See *United States ex rel. Kester v. Novartis Pharma. Corp.*, No. 11CV8196(CM), 2014 WL 4230386 (S.D.N.Y. Aug. 7, 2014) (ruling that the government sufficiently pled an AKS violation against Novartis under the express false certification theory without requiring the government to allege that the kickback scheme actually caused the pharmacy’s sale to a particular patient). However, the district court subsequently modified its ruling in *Kester* based on finding that the AKS could not be a basis for implied false certification liability prior to March 2010 because the AKS did not expressly precondition payment of federal claims prior to that date and Second Circuit precedent in *Mikes v. Straus* requires an express precondition to payment. *Kester*, 43 F. Supp. 3d 332 (S.D.N.Y. 2014).

<sup>76</sup> 553 U.S. 662, 672 (2008).

## b. The “Reckless Disregard” Standard

The FCA’s actual knowledge and deliberate ignorance standards are rarely used by the government to prove intent because the defendant’s specific state of mind is the determining factor under them. Reckless disregard, on the other hand, has been described as aggravated gross negligence, gross negligence-plus, or conduct that runs an unjustifiable risk of harm.<sup>77</sup> The government has also argued that the FCA’s knowledge standard can be met with “collective knowledge,” but that argument was soundly rejected by the D.C. Circuit in a recent decision, as discussed below.

In *Safeco Insurance Co. of America v. Burr*, the Supreme Court held that the reckless disregard standard was an objective one in a case interpreting a similar standard in the Fair Credit Reporting Act (“FCRA”).<sup>78</sup> Under this objective standard, the Court found that a defendant’s incorrect interpretation of an ambiguous statutory provision, if reasonable, does not provide a basis for liability unless there was an unjustifiably high risk of violating the statute. In *United States ex rel. K & R Ltd. Partnership v. Massachusetts Housing Finance Agency*, the D.C. Circuit applied the definition of reckless disregard from the Supreme Court’s *Safeco* decision to an FCA case.<sup>79</sup> *Safeco* and *K & R Ltd.* make examinations of subjective intent unnecessary in FCA cases involving reasonable interpretations of ambiguous requirements where the government has not provided formal guidance.<sup>80</sup>

More recently, in *United States ex rel. Purcell v. MWI Corp.*, the D.C. Circuit ruled that no jury could properly find that MWI acted “knowingly” in certifying that it paid “regular commissions”—an ambiguous term—to its sales agents in connection with a transaction funded by an Ex-Im Bank loan.<sup>81</sup> This decision reinforced the important principles that the FCA does not reach “an innocent, good-faith mistake about the meaning of an applicable rule or regulation” or extend to claims made based on “reasonable but erroneous interpretations of a defendant’s legal obligations,” and that informal guidance on the interpretive issue is insufficient to warn a regulated defendant away from its otherwise reasonable interpretation.<sup>82</sup> The D.C. Circuit also recognized that the outcome avoided the potential due process problems posed by “penalizing a

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<sup>77</sup> See *United States v. Krizek*, 859 F. Supp. 5 (D.D.C. 1994), *aff’d*, 111 F.3d 934 (D.C. Cir. 1997).

<sup>78</sup> 551 U.S. 47 (2007).

<sup>79</sup> 530 F.3d 980 (D.C. Cir. 2008).

<sup>80</sup> See, e.g., *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874 (8th Cir. 2016); *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825 (8th Cir. 2013) (“Mayo’s reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA”); *United States ex rel. Farmer v. City of Houston*, 523 F.3d 332 (5th Cir. 2008) (finding that relator could not show that the defendants “knew” of the falsity of the claims because the regulations governing the program were unclear). See also *Chapman Law Firm v. United States*, No. 09-891C, 2012 WL 256090 (Fed. Cl. Jan. 18, 2012) (applying the doctrine of *contra proferentem* to the ambiguous contract provision that was drafted by the government, accepting the contractor’s reasonable interpretation, and denying the government’s motion for partial summary judgment on the FCA claim). Cf. *United States ex rel. Chilcott v. KBR, Inc.*, No. 09CV4018, 2013 WL 5781660 (C.D. Ill. Oct. 25, 2013) (finding both interpretations facially reasonable, but drawing from the allegations the “reasonable inference that [Relator’s] interpretation is the correct one” and inferring that “Defendants did not simply choose, in good faith, a reasonable interpretation among equal alternatives”).

<sup>81</sup> 807 F.3d 281 (D.C. Cir. 2015). See *FraudMail Alert No. 17-01-10*, Supreme Court Denial of Certiorari in *U.S. ex rel. Purcell v. MWI Lets Stand DC Circuit Decision Limiting FCA Liability Based on Ambiguous Agency Regulation* (Jan. 10, 2017) (attached as Appendix 3).

<sup>82</sup> 807 F.3d at 287-90.

private party for violating a rule without first providing adequate notice of the substance of the rule.”<sup>83</sup>

The government has argued that corporate “collective knowledge” is appropriate under the False Claims Act because the Act is remedial rather than penal in nature. This fundamentally misconstrues the nature of the statute, particularly in light of rulings characterizing FCA damages and penalties as punitive. In *United States v. Science Applications International Corp.*, the D.C. Circuit forcefully and definitively rejected the government’s argument that collective knowledge can be used to prove intent under the False Claims Act.<sup>84</sup> Exhibiting a clear grasp of the high stakes involved in FCA liability, the panel unanimously held that collective knowledge was “an inappropriate basis for [FCA] scienter” because

it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act’s language, structure, and purpose.<sup>85</sup>

As a result, the court found that the FCA’s scienter standard must be strictly enforced, and it interpreted this standard to allow liability based on constructive knowledge only when defendants act with “reckless disregard” or “deliberate ignorance,” noting that innocent mistakes or negligence remain defenses to liability. Collective knowledge conflicts with this statutory standard, the court concluded, because it lacks balance and precision, noting that it would allow

“a plaintiff to prove scienter by piecing together scraps of ‘innocent’ knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.” *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 452 F.2d 908, 918 n.9 (4th Cir. 2003). In other words, even absent proof that corporate officials acted with deliberate ignorance or reckless disregard for the truth by submitting a false claim as the result of, for instance, a communication failure, the fact-finder could determine that the corporation knowingly submitted a false claim.<sup>86</sup>

The court held that the proper standard for knowledge under the FCA excludes collective knowledge. Because the district court’s instruction to the jury allowed it to find that SAIC submitted false claims “knowingly” where no individual at SAIC had all of the knowledge necessary for FCA liability, the court found that the district court’s instruction was erroneous and prejudicial, and ordered a new trial.

The *SAIC* case included one more knowledge element that limits false certification liability:

Establishing knowledge . . . on the basis of implied certification requires the plaintiff to prove that the defendant knows (1) that it violated a contractual obligation, and (2) that its compliance with that obligation was material to the government’s decision to pay.<sup>87</sup>

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<sup>83</sup> *Id.* at 287.

<sup>84</sup> 626 F.3d 1257 (D.C. Cir. 2010).

<sup>85</sup> *Id.* at 1274.

<sup>86</sup> *Id.* at 1275.

<sup>87</sup> *Id.* at 1271.

This knowledge requirement is a critical limit on the use of the false certification theory of liability because it means that the government or the relator will have to prove the defendant knew that the government's paying agent considered the violation to be material. As noted in the discussion of materiality above, the Supreme Court explicitly adopted this additional knowledge requirement in *Escobar*.<sup>88</sup>

## 7. Reverse False Claims

The FCA's "reverse false claim" provision, 31 U.S.C. § 3729(a)(1)(G), formerly Section 3729(a)(7), is intended to provide a potential remedy to the government when the flow of money or property is from a person with an obligation to the government, rather than the more common situation, in which money flows from the government to a recipient. Under the reverse false claim provision, liability extends to any person who knowingly and improperly avoids or decreases an "obligation" to pay the government.

What constitutes an "obligation" to pay or transmit money or property to the government was once hotly disputed, but it became relatively settled prior to FERA. This was largely due to the Sixth Circuit's decision declining to adopt the DOJ's position in *American Textile Manufacturers Institute, Inc., v. The Limited, Inc.* ("ATMI"), holding instead that liability could arise under Section 3729(a)(7) only if the defendant "made a false record or statement at a time that the defendant owed to the government an obligation sufficiently certain to give rise to an action of debt at common law."<sup>89</sup> The Sixth Circuit emphasized that the obligation must exist before the false claim or statement was made in order for liability to arise under Section 3729(a)(7).<sup>90</sup>

Post-FERA, reverse false claim theory is undergoing further development, with renewed attempts to extend this liability to potential obligations to repay the government. Under FERA, "obligation" is defined in Section 3729(b)(3) as:

an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

Using this definition, reverse false claims liability under Section 3729(a)(1)(G) may be based on an "established duty" to pay the government—one that arises from a contractual, grant, license, or other fee-based relationship—although the amount owed may be unfixed. The legal obligations arising under these relationships are relatively clear and easy to define. The word "contingent" was specifically stricken from the duties listed in the legislation prior to passage, and the general understanding has been that this definition is not intended to encompass

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<sup>88</sup> *Escobar*, 136 S. Ct. 1989, 1996.

<sup>89</sup> 190 F.3d 729, 736 (6th Cir. 1999). The reader should note that the author represented the defendants in the ATMI case.

<sup>90</sup> *Id.* at 742. Other courts reaching similar conclusions include the Eighth Circuit, in *United States v. Q International Courier, Inc.*, 131 F.3d 770 (8th Cir. 1997), the District of Colorado, in *United States ex rel. Bahrani v. Conagra, Inc.*, 338 F. Supp. 2d 1202 (D. Colo. 2004), and the District of Maine, in *United States ex rel. S. Prawer & Co. v. Verrill & Dana*, 962 F. Supp. 206 (D. Me. 1997). Court decisions that have found an existing "obligation" in cases alleging reverse false claims violations include *United States v. Pemco Aeroplex, Inc.*, 195 F.3d 1234 (11th Cir. 1999) (en banc), *United States ex rel. Ervin & Associates v. Hamilton Securities Group*, 370 F. Supp. 2d 18 (D.D.C. 2005), and *United States v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436 (S.D.N.Y. 1999).



contingent duties such as penalties and fines.<sup>91</sup> A considerable body of case law supports the view that the government's ability to pursue reimbursement does not transform the potential reimbursement into an "obligation" under the FCA.<sup>92</sup> But relators have seized on the 2009 amendment as an opportunity to revisit these limitations, arguing that the amendment opened the door to FCA liability based on the failure to pay contingent fines and penalties, and that the duty arising from a "statute or regulation" covers a potential penalty, a view that, if followed, could create extensive and unforeseen reverse false claim liability.<sup>93</sup>

For example, in *United States ex rel. Simoneaux v. E.I. DuPont De Nemours & Co.*,<sup>94</sup> the relator alleged that DuPont violated Section 3729(a)(1)(G) by failing to report to EPA certain Toxic Substances Control Act ("TSCA") violations and, in so doing, concealed or avoided the obligation to pay penalties that could be assessed for such violations. The Fifth Circuit rejected the relator's assertion that FERA's definition of "obligation" covers contingent penalties, and that by imposing liability "at the statutory level," the TSCA makes assessment of a penalty mandatory. The court agreed with defense and government (as amicus) arguments that "established" is the key word and that (a) the FERA amendments did not change the overarching requirement that the obligation must be one "to pay or transmit money or property to the Government," and (b) "[a] statute enforceable through an unassessed monetary penalty . . . creates an obligation to obey the law, not an obligation to pay money."<sup>95</sup> That is, "established" refers to whether there is a duty to pay, while "fixed" refers to the amount owing. The Fifth Circuit specifically rejected the relator's broad construction of the term "obligation," noting the harsh consequences that would result:

For example, 45 C.F.R. § 3.42(e) prohibits roller-skating at the National Institutes of Health, and a person violating that regulation "shall be fined under title 18, United States Code, imprisoned for not more than 30 days, or both." 40 U.S.C. 1315(c). Under [the relator's] reasoning, roller-skating at the NIH results in a penalty "of not less than \$5,000" and three times the fine assessed under Title 18. And any private person who saw the roller-skater could bring a *qui tam* action against him. The statutory definition of "obligation" cannot bear the weight of that interpretation.<sup>96</sup>

The Fifth Circuit also analyzed the applicable regulations and held that the TSCA penalties at issue are discretionary, not mandatory. As a result, since EPA had not assessed any penalty against DuPont for the supposed violations, and had not even commenced any penalty

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<sup>91</sup> See 155 Cong. Rec. S4539 (daily ed. Apr. 22, 2009) (statement of Sen. Kyl). At one point in the legislative process, there was an intent to overturn the Sixth Circuit's decision in *ATMI*, but whether the law as enacted actually did so is questionable because the court found the penalties and duties in *ATMI* "contingent," and the definition of "obligation" in Section 3729(b)(3) excludes "contingent" duties.

<sup>92</sup> See, e.g., *United States ex rel. Guth v. Roedel Parsons Koch Blache Balhoff & McCollister*, No. 15-30043, 2015 WL 5693302 (5th Cir. Sept. 29, 2015) (approving district court's reasoning in dismissing claim that was predicated on potential or contingent obligation to pay amounts not levied or assessed) (per curiam) (unpublished op.); *United States ex rel. Mason v. State Farm Aut. Ins. Co.*, 398 F. App'x 233, 235 (9th Cir. 2010); *United States ex rel. Landis v. Tailwind Sports Corp.*, No. 1:10-cv-00976 (CRC), 2016 WL 141615 (D.D.C. Jan. 12, 2016); *United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 811-12 (E.D. La. 2009).

<sup>93</sup> See *Simoneaux v. E.I. DuPont DeNemours & Co.*, No. 12-219-SDD-SCR, 2014 WL 4352185 (M.D. La. Sept. 2, 2014), *rev'd*, No. 16-30141, 2016 WL 7228813 (5th Cir. Dec. 13, 2016).

<sup>94</sup> No. 16-30141, 2016 WL 7228813 (5th Cir. Dec. 13, 2016).

<sup>95</sup> *Id.* at \*3.

<sup>96</sup> *Id.* at \*6.

proceedings, there was no “established” duty to pay within the meaning of the reverse false claim provision.

While the Justice Department’s clear statement against the excesses urged by the *Simoneaux* relator should discourage most relators from continuing to pursue reverse false claim liability based on contingent obligations of this type, the application of the *Simoneaux* decision to reverse false claim cases arising in the customs arena remains uncertain. For instance, the Fifth Circuit distinguished allegations of failure to pay duties on mismarked goods (such as found in *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*<sup>97</sup>), on the basis that “the customs law imposes a duty to pay,” whereas most regulatory statutes, such as the TSCA, “impose only a duty to obey the law, and the duty to pay regulatory penalties is not ‘established’ until the penalties are assessed.”<sup>98</sup> Extension of Section 3729(a)(1)(G) liability to breaches of contract also is in flux.<sup>99</sup>

A final note—it is not clear precisely how a duty arises from the retention of an overpayment and when that duty becomes “established.” The Senate Report accompanying FERA explained that the statutory language was not intended “to create liability for a simple retention of an overpayment that is permitted by a statutory or regulatory process for reconciliation.”<sup>100</sup> However, under the Affordable Care Act of 2010 (“ACA”), an overpayment retained beyond the deadline for reporting and returning it is an “obligation” as defined in the FCA,<sup>101</sup> which links reverse false claim liability for an overpayment to the ACA’s 60-day rule for reporting and returning “identified” overpayments. This link between FCA liability and the ACA’s overpayment deadline raised a plethora of questions from health care providers.<sup>102</sup> CMS addressed the ACA’s overpayment requirements for Medicare Parts C and D in a 2014 final rule, and more recently, in 2016, CMS issued a final rule on the overpayment requirements for Medicare Parts A and B.<sup>103</sup> In an intervened case, the defendant challenged one of the first *qui tam* cases brought using the FCA to enforce the ACA’s overpayment requirements under Medicaid.<sup>104</sup>

## 8. Damages and Penalties

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<sup>97</sup> 839 F.3d 242 (3d. Cir. 2016).

<sup>98</sup> 2016 WL 7228813, at \*6.

<sup>99</sup> See, e.g., *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2014 WL 43388726 (S.D. Tex. Sept. 5, 2014) (ruling that a fine under a corporate integrity agreement could be an “obligation” under the FCA); *Ruscher*, 2015 WL 517807 (S.D. Tex. Sept. 3, 2015) (on summary judgment, finding no evidence of a reportable event under Omnicare’s corporate integrity agreement and dismissing reverse false claim); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 4461793 (E.D. Pa. July 21, 2015) (agreeing with relators that Cephalon’s contractual obligation to pay the government upon breach of its corporate integrity agreement was an “established duty”).

<sup>100</sup> S. Rep. No. 111-10, at 15 (2009).

<sup>101</sup> See ACA, Pub. L. No. 111-148, 124 Stat. 119, § 6402 (2010) (amending 42 U.S.C. §1128J).

<sup>102</sup> The ACA established the deadline for reporting and returning an overpayment as the later of either 60 days after an overpayment has been “identified” or the date of a corresponding cost report, without defining the term “identified,” for example.

<sup>103</sup> See Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014); Medicare Program: Reporting and Returning of Overpayments, 81 Fed. Reg. 7654-7684 (Feb. 12, 2016) (to be codified at 421 C.F.R. pts. 401, 405).

<sup>104</sup> See *United States ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015) (defining “identified” as when a provider is put on notice of a potential overpayment). See also *United States ex rel. Ortiz v. Mount Sinai Hosp.*, No. 13 Civ. 47335 (RMB), slip op. (S.D.N.Y. Nov. 9, 2015) (finding that relators sufficiently pled wrongful overpayment retention with illustrative examples).

FCA violations result in liability for:

a civil penalty of not less than \$5,000 and not more than \$10,000, . . . plus 3 times the amount of damages which the Government sustains *because of* the [person's] act.”<sup>105</sup>

The measure of damages in a False Claims Act case is dependent on the nature of the alleged fraud, but the test is always the same: the difference between what the government actually paid and what it should have paid absent the FCA violation.

In false certification cases, courts of appeals appear to be divided regarding whether a broad “but for” test or an actual loss test of causation is the proper measure of damages. In *United States v. Science Applications International Corp.*,<sup>106</sup> the D.C. Circuit vacated the damages portion of the decision below because of a flawed jury instruction that required the jury to assume that SAIC’s services had no value. That assumption was particularly egregious in this case because the jury had already decided that actual damages to the government, as measured for purposes of the alternative breach of contract claim, were \$78, yet the district court imposed FCA damages of \$6.49 million. Reversing that portion of the lower court’s decision, the circuit court held that there is no irrebuttable presumption that expert services and advice are worthless if an organizational conflict of interest provision has been violated, and ruled that the damages must take into account the value of the goods and services. The panel pointed out that, under the benefit of the bargain framework that applied in this case, damages should be calculated by determining the amount the government paid minus the value of the goods or services provided, which is the standard measure under the FCA. Indeed, the evidence showed that the government agency, NRC, continued to use SAIC’s work product after its contract with SAIC was terminated in 1999, and an NRC project manager testified that SAIC’s “actual work product ‘constituted the opposite of a conflict,’ . . . due to its transparency and fairly conservative results.” The jury instruction erroneously removed this calculation from the case, and established an irrebuttable presumption that the services of an expert are worthless where a violation of a conflict of interest requirement has occurred. Because the district court’s instruction to the jury required them to assume that SAIC’s services had no value, the court vacated and remanded the damages for a new trial. This case ultimately settled for \$1.5 million.

In *United States v. Rogan*,<sup>107</sup> on the other hand, the district court did not apply a benefit of the bargain analysis in evaluating damages in the context of Stark Act and AKS violations. The court noted that the violations were “myriad” and “overwhelming,” and found that the government would not have paid anything for the claims of patients referred by physicians that had prohibited financial relationships with the hospital, citing the Stark Act. Rather than engaging in a benefit analysis, the court measured the damages as the entire federal share of these claims to Medicare and Medicaid.<sup>108</sup> After they were trebled, the damages were more than \$50 million. In addition, the court found that there were 18,000 penalties, bringing the total damages and penalties to over \$64 million. The Seventh Circuit affirmed the damages award in *Rogan*, adopting the lower court’s decision that placed no value on the medical services provided during the period of the unlawful payments for referrals and agreeing that “when the conditions [of the government’s payment] are not satisfied, nothing is due.”

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<sup>105</sup> 31 U.S.C. § 3729(a)(1) (emphasis supplied).

<sup>106</sup> 626 F. 3d 1257 (D.C. Cir. 2010).

<sup>107</sup> 459 F. Supp. 2d 692 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

<sup>108</sup> *Id.* at 726-27.

More recently, in *United States ex rel. Wall v. Circle C Construction, LLC*,<sup>109</sup> the Sixth Circuit rejected the government’s claim that its entire payment for electrical work on dozens of warehouses was “tainted” by a subcontractor’s underpayment of some of the electricians who worked on the project (a Davis-Bacon Act violation). The court applied the benefit of the bargain analysis and emphasized that FCA damages are focused on actual damages, not the “hypothetical scenario” advanced by the government.<sup>110</sup> Exposing the incongruity between the government’s theory and its actual losses, the court observed that, in all of those warehouses, “the government turns on the lights every day.”<sup>111</sup> Applying the concrete question of whether the government “in fact got less value than it bargained for,” the court readily determined that the government received all of the value of the electrical work on all of the warehouses minus the wage shortfall.

As the decisions above reflect, a key feature of FCA liability is its treble damages provision. An important development on the application of this multiplier is the Seventh Circuit’s revisit of the question of whether net or gross damages are trebled when deducting the value of goods or services received by the government. Historically, the Justice Department advocated and employed the “gross trebling” method—which trebles the claim amount first and afterward deducts the value of goods and services provided—but that method distorts the government’s actual damages by severely diminishing the value of any benefit received. In *United States v. Anchor Mortgage Corp.*,<sup>112</sup> the Seventh Circuit held that the proper approach was “net trebling”—which subtracts the value of goods or services provided before multiplying the damages and thus accounts for the actual benefit that the government received. The Seventh Circuit based its holding on the finding that no FCA language or policy supported departure from the norm in civil litigation, where damages are based on net loss, and it rejected the Justice Department’s misreading of the Supreme Court’s decision in *United States v. Bornstein*.<sup>113</sup> Given the Ninth Circuit’s decision that applied gross trebling in *United States v. Eghbal*,<sup>114</sup> a circuit split has emerged on this issue.

Without question, one of the most feared remedies under the False Claims Act is the per claim penalty. In 2016, the Justice Department announced that the FCA penalty range would nearly double—from \$5,500 - \$11,000 to \$10,781 - \$21,563 per claim—in response to legislation passed by Congress requiring government agencies to increase civil monetary penalties to account for inflation.<sup>115</sup> Drafted in the innocent-sounding verbiage of inflation adjustments tied to the Consumer Price Index, Congress required the first “catch up adjustment,” implemented through rulemaking, to take effect by August 1, 2016. Further, automatic annual

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<sup>109</sup> No. 14-6150, 2016 WL 423750 (6th Cir. Feb. 4, 2016). *See also* FraudMail Alert No. 16-02-10, Sixth Circuit Rejects Government’s “Fairyland” FCA Damages Theory (Feb. 10, 2016), <http://www.friedfrank.com/siteFiles%2FPublications%2F021016-FINALVERSION-FRAUDMAIL-Civil%20False%20Claims%20Act%20Sixth%20Circuit.pdf>.

<sup>110</sup> *Id.* at \*2.

<sup>111</sup> *Id.* at \*1.

<sup>112</sup> 711 F.3d 745 (7th Cir. 2013).

<sup>113</sup> *Id.* at 750. In *Bornstein*, the Court supported using the traditional market value approach to measure actual damages—and thus net trebling—but found that this approach did not apply to a *third party*’s settlement payments to the government, which were deducted after damages were multiplied. 423 U.S. 303, 317 n.13 (1976).

<sup>114</sup> 548 F.3d 1281 (9th Cir. 2008).

<sup>115</sup> *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599-600 (2015) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note).

adjustments are authorized without any agency assessment of the need for an increase. This annual adjustment provision raises the potential for an Administrative Procedure Act challenge. The impact of this legislation on civil fraud defendants is substantial because it may unfairly enhance the enormous settlement leverage the Justice Department already has against many defendants in the civil fraud enforcement arena. Increases in FCA penalties will exacerbate constitutional concerns in penalties-heavy FCA cases, particularly where there are large numbers of relatively small monetary claims.

FCA penalties are assessed on a per-claim basis regardless of the amount of the damages, except when the court finds that the result is an excessive civil penalty. A recent decision by the U.S. Court of Appeals for the Fourth Circuit in *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, unwittingly may have opened the door to a new and unsettling era in *qui tam* litigation.<sup>116</sup> Dispensing with decades of Supreme Court jurisprudence—including one case argued by Chief Justice Roberts before he took the federal bench—the Fourth Circuit ordered the trial court to impose \$24 million in FCA penalties against the defendants following a trial at which the relator pointedly sought no FCA damages and no proof of economic harm to the United States was ever established. This result is squarely at odds with a number of constitutional protections, particularly the Eighth Amendment’s Excessive Fines Clause, as well as decisions applying that constitutional provision to FCA penalty awards.<sup>117</sup> The Fourth Circuit’s sole reliance on intangible and non-economic factors such as “deterrent effects” and public policy considerations to override the traditional excessive fines analysis lacks precedent. The Supreme Court declined to review this decision, however, and on remand, the trial court imposed the \$24 million *qui tam* award that it previously found excessive.

## 9. Public Disclosure, Original Source, and First-to-File

In 2010, Congress amended the FCA’s public disclosure bar as part of the comprehensive health care reform initiative in the Affordable Care Act,<sup>118</sup> adding new limitations to the public disclosure provision in Section 3730(e)(4)(A) and expanding the original source exception in Section 3730(e)(4)(B). Section 3730(e)(4) now provides:

(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
- (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

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<sup>116</sup> 741 F.3d 390, 408 (4th Cir. 2013), *cert. denied*, 83 U.S.L.W. 3184 (2014). The reader should note that the author represented one of the other defendants in the *Bunk* case, but was not involved in the trial or appeal.

<sup>117</sup> See FraudMail Alert No. 13-12-20, Fourth Circuit Holds That a \$24 Million FCA Penalty is Not an “Excessive Fine” Even Where the Relator Fails to Prove That the United States Suffered Any Economic Harm (Dec. 12, 2013), <http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%20FraudMail%20Alert%20-%202012-20-13%20-%20Fourth%20Circuit%20Holds%20That%20a%20%2424%20M%20FCA%20Penalty%20is%20Not%20an%20%2E%80%9CExcessive%20Fine%2%80%9D.pdf>.

<sup>118</sup> ACA, Pub. L. No. 111- 148, 124 Stat. 119, 901-02 (2010) (amending 31 U.S.C. § 3730(e)(4)). See FraudMail Alert No. 10-03-24, Here They Go Again—Newly Enacted Comprehensive Health Care Reform Law Contains More FCA Amendments, <http://www.friedfrank.com/siteFiles/Publications/774D87395C8E15E59B979BCB2E52F5C0.pdf>.

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, “original source” means an individual who has either—

(i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or

(ii) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Under the 2010 bar, if “substantially the same” allegations or transactions were publicly disclosed, then the *qui tam* relator must be an “original source,” unless the government opposes dismissal. While the 1986 public disclosure bar was considered a threshold *jurisdictional* determination,<sup>119</sup> the 2010 amendments eliminate the word “jurisdiction,” and replace it with the requirement that “the court shall dismiss an action or claim . . . unless opposed by the Government.” Until recently, the government had not exercised this veto, but it has begun to do so.<sup>120</sup>

In addition, the amendments narrow the definition of public disclosures to disclosures in *federal* sources—that is, disclosures in federal criminal, civil, or administrative hearings under Section 3730(e)(4)(A)(i), and in federal hearings, reports, audits, or investigations under Section 3730(e)(4)(A)(ii). These revisions effectively overrule the Supreme Court’s ruling in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, (“*Graham County II*”)<sup>121</sup> that *qui tam* allegations could be publicly disclosed by state and local sources, and eliminate defenses based on disclosures from state and local government sources unless the information is also disclosed in the news media or otherwise publicly disclosed. The defense to public disclosures in federal hearings is further narrowed to hearings in which the government or its agent is a party, thus excluding disclosures made in purely private litigation such as retaliation or negligence actions.

The amendments also revise the original source exception. Rather than requiring the original source to have both “direct” and “independent” knowledge of the alleged fraud, the original source exception is met by knowledge that is “independent” of and “materially adds” to the publicly disclosed allegations, which must be voluntarily disclosed to the government before filing suit. The courts have begun to apply this new statutory language. For example, in *United States ex rel. Paulos v. Stryker Corp.*, the Eighth Circuit rejected the relator’s claim that he had knowledge that materially added to the publicly disclosed allegations despite his claim that he was among the first to link the defendant’s medical device to the resulting disease, because, even if he discovered the link to chondrolysis *first*, Section 3730(e)(4)(B) does not provide an exception for “early discoveries or suspicions.”<sup>122</sup>

Because of the ACA’s silence on the issue of an effective date for these *qui tam* amendments, the Supreme Court applied the presumption against retroactivity in *Graham County*

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<sup>119</sup> See *Rockwell Int’l Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397, 1406 (U.S. 2007).

<sup>120</sup> See, e.g., *United States ex rel. Szymoniak v. Am. Home Mortgage Serv. Inc.*, No. 0:10-cv-01465-JFA, 2014 WL 1910845 (D.S.C. May 12, 2014).

<sup>121</sup> 130 S. Ct. 1396 (U.S. 2010). The reader should note that the author filed an amicus brief on behalf of the Washington Legal Foundation and the Allied Educational Foundation in support of Petitioners in *Graham County II*.

<sup>122</sup> 762 F.3d 688, 694 (8th Cir. 2014).

II, limiting the impact of the ACA’s public disclosure amendments in cases pending at the time of enactment and leaving open the question of whether the amendments apply retroactively to prior conduct where no *qui tam* case was pending.<sup>123</sup>

Under a separate bar in Section 3730(b)(5) known as the “first-to-file” bar, when a relator brings a *qui tam* action, “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” The primary purpose of this bar—the text of which has remained unchanged since its inclusion in the 1986 amendments—is to prevent multiple *qui tam* suits based on the same underlying conduct. Recently, a circuit court split developed on whether the phrase “pending action” is a timing requirement, as the Fourth Circuit interpreted it in *United States ex rel. Carter v. Halliburton Co.*,<sup>124</sup> or whether it is a shorthand reference to the first-filed action that distinguishes the first action from subsequent actions, as the D.C. Circuit decided in *United States ex rel. Shea v. Cellco P’ship*.<sup>125</sup> In May 2015, the Supreme Court resolved this issue in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*.<sup>126</sup> The Court saw no reason to interpret the term “pending” other than by reference to its ordinary meaning, which Black’s and Webster’s defined as “remaining undecided.” Courts are divided on other interpretive questions not answered by the Court in *Carter*, such as what happens *after* dismissal of the original complaint that was pending when a subsequent related action was filed.<sup>127</sup>

## 10. Whistleblower Retaliation

In 1986, a whistleblower’s cause of action for retaliation was enacted in Section 3730(h) of the FCA, which provided that an employee who was discharged or otherwise discriminated against in the terms or conditions of employment by an “employer” because of lawful acts done by the “employee” in furtherance of an action under Section 3730 “shall be entitled to all relief necessary to make the employee whole.” FERA revised the definition of both protected persons and protected conduct in Section 3730(h) by (1) removing the specific reference to the “employer” (and thus the requirement of an employee-employer relationship) so that independent contractors could bring retaliation actions,<sup>128</sup> and (2) replacing lawful acts “in furtherance of an action under this section” with the phrase “in furtherance of other efforts to

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<sup>123</sup> See *Graham County II*, 130 S. Ct. 1396, 1400 n.1 (2010). To the extent that it is not effectively foreclosed under *Schumer*, this will be a disputed issue, with defendants arguing, as they did in *Schumer*, that the *qui tam* amendments should not be given retroactive effect because they would enlarge liability and eliminate defenses in *qui tam* suits, and relators arguing in favor of retroactivity. See *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 948 (1997).

<sup>124</sup> 701 F.3d 171 (4th Cir. 2013), *cert. granted sub nom.* *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 134 S.Ct. 2899 (U.S. 2014).

<sup>125</sup> 748 F.3d 338 (D.C. Cir. 2014).

<sup>126</sup> No. 12-1497, 2015 WL 2456621 (U.S. May 26, 2015). See *FraudMail Alert No. 15-05-26, Supreme Court Squarely Rejects Justice Department’s Use of Wartime Suspension of Limitations Act in Civil FCA Actions, but Offers Hope to Relators with Its First-to-File Ruling* (May 26, 2015), [http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%202015-26-15%20-%20Fraudmail%20Alert%20-%20Supreme\\_Court\\_Squarely\\_Rejects\\_Justice\\_Dept.pdf](http://www.friedfrank.com/siteFiles%2FPublications%2FFINAL%20-%202015-26-15%20-%20Fraudmail%20Alert%20-%20Supreme_Court_Squarely_Rejects_Justice_Dept.pdf).

<sup>127</sup> Compare *United States ex rel. Chovanec v. Apria Healthcare Group, Inc.*, 606 F.3d 361, 362 (7th Cir. 2010) (ruling that subsequent related action must be dismissed if it was brought when related first-filed action was pending), and *United States ex rel. Carter v. Halliburton Co.*, No. 1:11cv602, 2015 WL 7012542 (E.D. Va. Nov. 12, 2015) (same), with *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. 2015) (ruling that Rule 15(d) allows second relator to amend complaint brought during pendency of a related first-filed action, which was subsequently dismissed, rather than “expose the relator to the vagaries of filing a new action”).

<sup>128</sup> See BOESE, § 4.11[B][2][b] (discussing the term “employer” and the independent contractor issue).

stop 1 or more violations.” The new definition of protected conduct seemed to require the person to actually try to stop the fraud itself rather than simply take steps toward filing a *qui tam* action.

The following year, Congress provided a new definition of protected conduct under Section 3730(h) in the Dodd-Frank Wall Street Reform and Consumer Protection Act.<sup>129</sup> This revision restores the original protection of lawful acts in furtherance of a *qui tam* action in addition to FERA’s “other efforts to stop 1 or more violations.” As amended, Section 3730(h) now provides:

Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor or agent, or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

The Dodd Frank amendments also provided, for the first time, a statute of limitations for retaliation that requires the action to be brought within three years of the date when the retaliation occurred.<sup>130</sup>

Courts are beginning to grapple with whether the new definitions in Section 3730(h) apply to a variety of employment relationships and conduct. In most cases, the term “employee” has been limited to persons in an employment-like relationship with the defendant, which does not include applicants or non-employer corporations.<sup>131</sup> Recently, protected conduct has been interpreted to include reporting the fraud within the organization, such as informing a board member or the company’s corporate compliance arm in some cases.<sup>132</sup> However, if the plaintiff was not reporting fraud to a supervisor in furtherance of an FCA claim and never said that the defendant committed fraud on the government, the retaliation claim has been dismissed.<sup>133</sup>

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<sup>129</sup> Pub. L. No. 111-203, § 3301, 124 Stat. 1376 (2010). See FraudMail Alert No. 10-06-29, Here They Go Again, Round III: Financial Reform Bill Contains More FCA Amendments, <http://www.friedfrank.com/siteFiles/Publications/E81F1748D2D2912B1C54CB77388F98CA.pdf>.

<sup>130</sup> 31 U.S.C. §3730(h)(3). See *Weslowski v. Zugibe*, 14 F. Supp.3d 295 (S.D.N.Y. Mar. 31, 2014) (rejecting plaintiff’s attempt to bring an action against his employer more than three years after his resignation and ruling that this “continuing violation” theory of liability could not be used because the FCA’s retaliation provision only applies to retaliatory conduct that occurred during the plaintiff’s employment).

<sup>131</sup> See, e.g., *Boegh v. Energysolutions, Inc.*, 772 F.3d 1056, 1064 (6th Cir. 2014) (finding that the “FCA’s legislative history and case law from other courts reinforce that “employee” is limited to employment-like relationships); *United States ex rel. Abou–Hussein v. Science Applications Int’l Corp.*, No. 2:09-1858-RMG, 2012 WL 6892716, at \*3-4 (D.S.C. May 3, 2012) (reasoning that Congress intended to extend protection to “individuals who [a]re not technically employees within the typical employer[-]employee relationship, but nonetheless have a contractual or agent relationship with an employer”), *aff’d*, 475 Fed. App’x. 851 (4th Cir. 2012) (per curiam). Cf. *Tibor v. Michigan Orthopedic Inst.*, No. 14-10920, 2014 WL 6871320 (E.D. Mich. Dec. 5, 2014) (noting that the amended provision prohibits retaliation against independent contractors or “doctors without traditional employment relationships with hospitals” who are not technically “employees”).

<sup>132</sup> See, e.g., *United States ex rel. Si v. Laogai Research Found.*, No. 09CV2388 (KBJ), 2014 WL 5446487 (D.D.C. Oct. 14, 2014); *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34 (D. Mass. 2014). 9 F. Supp. 3d 34 (D. Mass. 2014).

<sup>133</sup> See *Lee v. Computer Scis. Corp.*, No. 1:14cv581 (JCC/TCB), 2015 U.S. Dist. LEXIS 21998 (E.D. Va. Feb 24, 2015).



Refusing to participate in the fraud alone has not been deemed protected activity.<sup>134</sup>

### III. State False Claims Acts

As a result of the Medicaid fraud provisions in the Deficit Reduction Act of 2005 ("DRA") and an economic incentive in the DRA that encourages every state without a state false claims act with *qui tam* provisions to adopt one, state legislatures have enacted state false claims laws with provisions that mirror, or exceed, the federal FCA.<sup>135</sup> There are now 30 of these state laws, and they are increasing false claims visibility, enforcement actions, and recoveries.<sup>136</sup> The states that have *qui tam* false claims statutes are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. The District of Columbia, New York City, Philadelphia, and Chicago also have false claims laws with *qui tam* enforcement. Many states have amended their state false claims laws to include the far more onerous provisions in the FERA, ACA, and Dodd-Frank amendments in order to qualify for the DRA incentive.

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<sup>134</sup> See *United States ex rel. Tran v. Computer Scis. Corp.*, No. 11-cv-0852 (KBJ), 2014 WL 2989948 (D.D.C. July 3, 2014).

<sup>135</sup> See Deficit Reduction Act of 2005, Pub. L. 109-171, § 6031 (2006). Updated guidelines for evaluating whether state FCAs conform to the current federal FCA were issued by HHS OIG in 2013. See Dep't of Health & Human Servs., Office of Inspector Gen., *OIG Guidelines for Evaluating State False Claims Acts* (Mar. 15, 2013), available at <http://oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf>.

<sup>136</sup> See BOESE, Chapter 6 (discussing individual state and municipal false claims laws).

## Appendix 1

# THE FEDERAL FALSE CLAIMS ACT

## 31 U.S.C. §§ 3729-3733

### As amended by:

The Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009) (signed by the President on May 20, 2009)

The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1303, 124 Stat. 119, 168 (2010) (signed by the President on Mar. 23, 2010)

The Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A, 124 Stat. 1376, 2077 (2010) (signed by the President on July 21, 2010).

### § 3729. False claims

(a) LIABILITY FOR CERTAIN ACTS.—~~Any~~

(1) IN GENERAL.—Subject to paragraph (2), any person who—

- (1A) knowingly presents, or causes to be presented, ~~to an officer or employee of the United States Government or a member of the Armed Forces of the United States~~ a false or fraudulent claim for payment or approval;
- (2B) knowingly makes, uses, or causes to be made or used, a false record or statement material to ~~get~~ a false or fraudulent claim ~~paid or approved by the Government~~;
- (3C) conspires to ~~defraud the Government by getting a false or fraudulent claim allowed or paid~~ commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
- (4D) has possession, custody, or control of property or money used, or to be used, by the Government and, ~~intending to defraud the Government or willfully to conceal the property,~~ knowingly delivers, or causes to be delivered, less ~~property than the amount for which the person receives a certificate or receipt~~ than all of that money or property;
- (5E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to

defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

- (6F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge ~~the~~ property; or
- (7G) knowingly makes, uses, or causes to be made or used, a false record or statement material to ~~conceal, avoid, or decrease~~ an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person, ~~except that if,~~

(2) REDUCED DAMAGES.—If the court finds that—

- (A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
- (B) such person fully cooperated with any Government investigation of such violation; and
- (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of ~~the~~that person.

(3) COSTS OF CIVIL ACTIONS.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) ~~KNOWING AND KNOWINGLY DEFINED~~ DEFINITIONS.—For purposes of this section, ==

(1) the ~~terms~~terms “knowing” and “knowingly””—

(A) mean that a person, with respect to information—

- (1) has actual knowledge of the information;
- (2) acts in deliberate ignorance of the truth or falsity of the information; or
- (3) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud~~is required~~;

~~(e) CLAIM DEFINED. For purposes of this section,~~(2) the term “claim” includes”—

(A) means any request or demand, whether under a contract or otherwise, for money or property ~~which and whether or not the United States has title to the money or property, that—~~

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government —

(I) provides or has provided any portion of the money or property ~~which is requested or demanded;~~ ~~or if the Government~~

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property;

(3) the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(d) EXEMPTION FROM DISCLOSURE.—Any information furnished pursuant to ~~subparagraphs (A) through (C) of~~ subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(e) EXCLUSION.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

### **§ 3730. Civil actions for false claims**

(a) RESPONSIBILITIES OF THE ATTORNEY GENERAL.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) ACTIONS BY PRIVATE PERSONS.—

- (1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.
- (2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.
- (3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.
- (4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—
  - (A) proceed with the action, in which case the action shall be conducted by the Government; or

- (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.
  - (5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.
- (c) RIGHTS OF THE PARTIES TO QUI TAM ACTIONS.—
- (1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).
  - (2)
    - (A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.
    - (B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.
    - (C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—
      - (i) limiting the number of witnesses the person may call;
      - (ii) limiting the length of the testimony of such witnesses;
      - (iii) limiting the person's cross-examination of witnesses; or
      - (iv) otherwise limiting the participation by the person in the litigation.
    - (D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the

defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

- (3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.
- (4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.
- (5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) AWARD TO QUI TAM PLAINTIFF.—

- (1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or



transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

- (2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.
- (3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.
- (4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) CERTAIN ACTIONS BARRED.—

- (1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.
- (2) (A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.
  - (B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).
- (3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) ~~No~~The court shall ~~have jurisdiction over~~dismiss an action or claim under this section ~~based upon the public disclosure of, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--~~  
(i) in a Federal criminal, civil, or administrative hearing, in which the Government or its agent is a party;  
(ii) in a congressional, administrative, or Government Accountability Office, or other Federal report, hearing, audit, or investigation; or  
(iii) from the news media,  
 unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who ~~has direct and independent knowledge of~~either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which the allegations are basedallegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section ~~which is based on the information.~~

- (f) GOVERNMENT NOT LIABLE FOR CERTAIN EXPENSES.—The Government is not liable for expenses which a person incurs in bringing an action under this section.
- (g) FEES AND EXPENSES TO PREVAILING DEFENDANT.—In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

~~(h) — Any employee who~~ (h) Relief From Retaliatory Actions. —

(1) IN GENERAL. — Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or, contractor, agent, or associated others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief or other efforts to stop 1 or more violations of this subchapter.

(2) RELIEF. —Relief under paragraph (1) shall include reinstatement with the same seniority status such that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An employee may bring an action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

(3) LIMITATION ON BRINGING CIVIL ACTION. —A civil action under this subsection may not be brought more than 3 years after the date when the retaliation occurred.

**§ 3731. False claims procedure**

- (a) A subpoena [subpoena] requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.
- (b) A civil action under section 3730 may not be brought—
  - (1) more than 6 years after the date on which the violation of section 3729 is committed, or
  - (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but

in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

(c) If the Government elects to intervene and proceed with an action brought under 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

~~(e)~~(d) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

~~(d)~~ Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

### **§ 3732. False claims jurisdiction**

(a) ACTIONS UNDER SECTION 3730.—Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) CLAIMS UNDER STATE LAW.—The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

(c) SERVICE ON STATE OF LOCAL AUTHORITIES.—With respect to any State or local government that is named as a co-plaintiff with the United States in an action brought under subsection (b), a seal on the action ordered by the court under section 3730(b) shall not preclude the Government or the person bringing the action from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence and information possessed by the person bringing the action on the law enforcement authorities that are authorized under the law of that State or local government to investigate and prosecute such actions on behalf of such governments, except that such seal applies to the law enforcement authorities so served to the same extent as the seal applies to other parties in the action.

### **§ 3733. Civil investigative demands**

(a) IN GENERAL.—

(1) ISSUANCE AND SERVICE.—Whenever the Attorney General, or a designee (for purposes of this section), has reason to believe that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation, the Attorney General, or a designee, may, before commencing a civil proceeding under section 3730(a) or other false claims law, or making an election under section 3730(b), issue in writing and cause to be served upon such person, a civil investigative demand requiring such person—

- (A) to produce such documentary material for inspection and copying,
- (B) to answer in writing written interrogatories with respect to such documentary material or information,
- (C) to give oral testimony concerning such documentary material or information, or
- (D) to furnish any combination of such material, answers, or testimony.

The Attorney General may ~~not~~ delegate the authority to issue civil investigative demands under this subsection. Whenever a civil investigative demand is an express demand for any product of discovery, the Attorney General, the Deputy Attorney General, or an Assistant Attorney General shall cause to be served, in any manner authorized by this section, a copy of such demand upon the person from whom the discovery was obtained and shall notify the person to whom such demand is issued of the date on which such copy was served. Any information obtained by the Attorney General or a designee of the Attorney General under this section may be shared with any qui tam relator if the Attorney General or designee determine it is necessary as part of any false claims act investigation.

(2) CONTENTS AND DEADLINES.—

- (A) Each civil investigative demand issued under paragraph (1) shall state the nature of the conduct constituting the alleged violation of a false claims law which is under investigation, and the applicable provision of law alleged to be violated.
- (B) If such demand is for the production of documentary material, the demand shall—
  - (i) describe each class of documentary material to be produced with such definiteness and certainty as to permit such material to be fairly identified;

- (ii) prescribe a return date for each such class which will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying; and
  - (iii) identify the false claims law investigator to whom such material shall be made available.
- (C) If such demand is for answers to written interrogatories, the demand shall—
  - (i) set forth with specificity the written interrogatories to be answered;
  - (ii) prescribe dates at which time answers to written interrogatories shall be submitted; and
  - (iii) identify the false claims law investigator to whom such answers shall be submitted.
- (D) If such demand is for the giving of oral testimony, the demand shall—
  - (i) prescribe a date, time, and place at which oral testimony shall be commenced;
  - (ii) identify a false claims law investigator who shall conduct the examination and the custodian to whom the transcript of such examination shall be submitted;
  - (iii) specify that such attendance and testimony are necessary to the conduct of the investigation;
  - (iv) notify the person receiving the demand of the right to be accompanied by an attorney and any other representative; and
  - (v) describe the general purpose for which the demand is being issued and the general nature of the testimony, including the primary areas of inquiry, which will be taken pursuant to the demand.
- (E) Any civil investigative demand issued under this section which is an express demand for any product of discovery shall not be returned or returnable until 20 days after a copy of such demand has been served upon the person from whom the discovery was obtained.

- (F) The date prescribed for the commencement of oral testimony pursuant to a civil investigative demand issued under this section shall be a date which is not less than seven days after the date on which demand is received, unless the Attorney General or an Assistant Attorney General designated by the Attorney General determines that exceptional circumstances are present which warrant the commencement of such testimony within a lesser period of time.
- (G) The Attorney General shall not authorize the issuance under this section of more than one civil investigative demand for oral testimony by the same person unless the person requests otherwise or unless the Attorney General, after investigation, notifies that person in writing that an additional demand for oral testimony is necessary. ~~The Attorney General may not, notwithstanding section 510 of title 28, authorize the performance, by any other officer, employee, or agency, of any function vested in the Attorney General under this subparagraph.~~

(b) PROTECTED MATERIAL OR INFORMATION.—

- (1) IN GENERAL.—A civil investigative demand issued under subsection (a) may not require the production of any documentary material, the submission of any answers to written interrogatories, or the giving of any oral testimony if such material, answers, or testimony would be protected from disclosure under—
  - (A) the standards applicable to subpoenas or subpoenas duces tecum issued by a court of the United States to aid in a grand jury investigation; or
  - (B) the standards applicable to discovery requests under the Federal Rules of Civil Procedure, to the extent that the application of such standards to any such demand is appropriate and consistent with the provisions and purposes of this section.
- (2) EFFECT ON OTHER ORDERS, RULES, AND LAWS.—Any such demand which is an express demand for any product of discovery supersedes any inconsistent order, rule, or provision of law (other than this section) preventing or restraining disclosure of such product of discovery to any person. Disclosure of any product of discovery pursuant to any such express demand does not constitute a waiver of any right or privilege which the person making such disclosure may be entitled to invoke to resist discovery of trial preparation materials.

(c) SERVICE; JURISDICTION.—

- (1) BY WHOM SERVED.—Any civil investigative demand issued under subsection (a) may be served by a false claims law investigator, or by a United States marshal or a deputy marshal, at any place within the territorial jurisdiction of any court of the United States.
  - (2) SERVICE IN FOREIGN COUNTRIES.—Any such demand or any petition filed under subsection (j) may be served upon any person who is not found within the territorial jurisdiction of any court of the United States in such manner as the Federal Rules of Civil Procedure prescribe for service in a foreign country. To the extent that the courts of the United States can assert jurisdiction over any such person consistent with due process, the United States District Court for the District of Columbia shall have the same jurisdiction to take any action respecting compliance with this section by any such person that such court would have if such person were personally within the jurisdiction of such court.
- (d) SERVICE UPON LEGAL ENTITIES AND NATURAL PERSONS.—
- (1) LEGAL ENTITIES.—Service of any civil investigative demand issued under subsection (a) or of any petition filed under subsection (j) may be made upon a partnership, corporation, association, or other legal entity by—
    - (A) delivering an executed copy of such demand or petition to any partner, executive officer, managing agent, or general agent of the partnership, corporation, association, or entity, or to any agent authorized by appointment or by law to receive service of process on behalf of such partnership, corporation, association, or entity;
    - (B) delivering an executed copy of such demand or petition to the principal office or place of business of the partnership, corporation, association, or entity; or
    - (C) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to such partnership, corporation, association, or entity at its principal office or place of business.
  - (2) NATURAL PERSONS.—Service of any such demand or petition may be made upon any natural person by—
    - (A) delivering an executed copy of such demand or petition to the person; or
    - (B) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to the person at the person’s residence or principal office or place of business.



(e) PROOF OF SERVICE.—A verified return by the individual serving any civil investigative demand issued under subsection (a) or any petition filed under subsection (j) setting forth the manner of such service shall be proof of such service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such demand.

(f) DOCUMENTARY MATERIAL.—

(1) SWORN CERTIFICATES.—The production of documentary material in response to a civil investigative demand served under this section shall be made under a sworn certificate, in such form as the demand designates, by—

(A) in the case of a natural person, the person to whom the demand is directed, or

(B) in the case of a person other than a natural person, a person having knowledge of the facts and circumstances relating to such production and authorized to act on behalf of such person.

The certificate shall state that all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the false claims law investigator identified in the demand.

(2) PRODUCTION OF MATERIALS.—Any person upon whom any civil investigative demand for the production of documentary material has been served under this section shall make such material available for inspection and copying to the false claims law investigator identified in such demand at the principal place of business of such person, or at such other place as the false claims law investigator and the person thereafter may agree and prescribe in writing, or as the court may direct under subsection (j)(1). Such material shall be made so available on the return date specified in such demand, or on such later date as the false claims law investigator may prescribe in writing. Such person may, upon written agreement between the person and the false claims law investigator, substitute copies for originals of all or any part of such material.

(g) INTERROGATORIES.—Each interrogatory in a civil investigative demand served under this section shall be answered separately and fully in writing under oath and shall be submitted under a sworn certificate, in such form as the demand designates, by—

(1) in the case of a natural person, the person to whom the demand is directed, or

(2) in the case of a person other than a natural person, the person or persons responsible for answering each interrogatory.

If any interrogatory is objected to, the reasons for the objection shall be stated in the certificate instead of an answer. The certificate shall state that all information required by the demand and in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted. To the extent that any information is not furnished, the information shall be identified and reasons set forth with particularity regarding the reasons why the information was not furnished.

(h) ORAL EXAMINATIONS.—

- (1) PROCEDURES.—The examination of any person pursuant to a civil investigative demand for oral testimony served under this section shall be taken before an officer authorized to administer oaths and affirmations by the laws of the United States or of the place where the examination is held. The officer before whom the testimony is to be taken shall put the witness on oath or affirmation and shall, personally or by someone acting under the direction of the officer and in the officer's presence, record the testimony of the witness. The testimony shall be taken stenographically and shall be transcribed. When the testimony is fully transcribed, the officer before whom the testimony is taken shall promptly transmit a copy of the transcript of the testimony to the custodian. This subsection shall not preclude the taking of testimony by any means authorized by, and in a manner consistent with, the Federal Rules of Civil Procedure.
- (2) PERSONS PRESENT.—The false claims law investigator conducting the examination shall exclude from the place where the examination is held all persons except the person giving the testimony, the attorney for and any other representative of the person giving the testimony, the attorney for the Government, any person who may be agreed upon by the attorney for the Government and the person giving the testimony, the officer before whom the testimony is to be taken, and any stenographer taking such testimony.
- (3) WHERE TESTIMONY TAKEN.—The oral testimony of any person taken pursuant to a civil investigative demand served under this section shall be taken in the judicial district of the United States within which such person resides, is found, or transacts business, or in such other place as may be agreed upon by the false claims law investigator conducting the examination and such person.
- (4) TRANSCRIPT OF TESTIMONY.—When the testimony is fully transcribed, the false claims law investigator or the officer before whom the testimony is taken shall afford the witness, who may be accompanied by counsel, a reasonable opportunity to examine and read the transcript, unless such examination and reading are waived by the witness. Any changes in form or substance which the witness desires to make shall be entered and identified upon the transcript by the officer or the false claims law investigator, with a statement of the reasons given by the witness for making such changes. The transcript shall then be signed by the witness,

unless the witness in writing waives the signing, is ill, cannot be found, or refuses to sign. If the transcript is not signed by the witness within 30 days after being afforded a reasonable opportunity to examine it, the officer or the false claims law investigator shall sign it and state on the record the fact of the waiver, illness, absence of the witness, or the refusal to sign, together with the reasons, if any, given therefor.

- (5) CERTIFICATION AND DELIVERY TO CUSTODIAN.—The officer before whom the testimony is taken shall certify on the transcript that the witness was sworn by the officer and that the transcript is a true record of the testimony given by the witness, and the officer or false claims law investigator shall promptly deliver the transcript, or send the transcript by registered or certified mail, to the custodian.
- (6) FURNISHING OR INSPECTION OF TRANSCRIPT BY WITNESS.—Upon payment of reasonable charges therefor, the false claims law investigator shall furnish a copy of the transcript to the witness only, except that the Attorney General, the Deputy Attorney General, or an Assistant Attorney General may, for good cause, limit such witness to inspection of the official transcript of the witness' testimony.
- (7) CONDUCT OF ORAL TESTIMONY.—
  - (A) Any person compelled to appear for oral testimony under a civil investigative demand issued under subsection (a) may be accompanied, represented, and advised by counsel. Counsel may advise such person, in confidence, with respect to any question asked of such person. Such person or counsel may object on the record to any question, in whole or in part, and shall briefly state for the record the reason for the objection. An objection may be made, received, and entered upon the record when it is claimed that such person is entitled to refuse to answer the question on the grounds of any constitutional or other legal right or privilege, including the privilege against self-incrimination. Such person may not otherwise object to or refuse to answer any question, and may not directly or through counsel otherwise interrupt the oral examination. If such person refuses to answer any question, a petition may be filed in the district court of the United States under subsection (j)(1) for an order compelling such person to answer such question.
  - (B) If such person refuses to answer any question on the grounds of the privilege against self-incrimination, the testimony of such person may be compelled in accordance with the provisions of part V of title 18 [18 USCS §§ 6001 et seq.].

- (8) WITNESS FEES AND ALLOWANCES.—Any person appearing for oral testimony under a civil investigative demand issued under subsection (a) shall be entitled to the same fees and allowances which are paid to witnesses in the district courts of the United States.
- (i) CUSTODIANS OF DOCUMENTS, ANSWERS, AND TRANSCRIPTS.—
- (1) DESIGNATION.—The Attorney General shall designate a false claims law investigator to serve as custodian of documentary material, answers to interrogatories, and transcripts of oral testimony received under this section, and shall designate such additional false claims law investigators as the Attorney General determines from time to time to be necessary to serve as deputies to the custodian.
- (2) RESPONSIBILITY FOR MATERIALS; DISCLOSURE.—
- (A) A false claims law investigator who receives any documentary material, answers to interrogatories, or transcripts of oral testimony under this section shall transmit them to the custodian. The custodian shall take physical possession of such material, answers, or transcripts and shall be responsible for the use made of them and for the return of documentary material under paragraph (4).
- (B) The custodian may cause the preparation of such copies of such documentary material, answers to interrogatories, or transcripts of oral testimony as may be required for official use by any false claims law investigator, or other officer or employee of the Department of Justice, ~~who is authorized for such use under regulations which the Attorney General shall issue~~. Such material, answers, and transcripts may be used by any such authorized false claims law investigator or other officer or employee in connection with the taking of oral testimony under this section.
- (C) Except as otherwise provided in this subsection, no documentary material, answers to interrogatories, or transcripts of oral testimony, or copies thereof, while in the possession of the custodian, shall be available for examination by any individual other than a false claims law investigator or other officer or employee of the Department of Justice authorized under subparagraph (B). The prohibition in the preceding sentence on the availability of material, answers, or transcripts shall not apply if consent is given by the person who produced such material, answers, or transcripts, or, in the case of any product of discovery produced pursuant to an express demand for such material, consent is given by the person from whom the discovery was obtained. Nothing in this subparagraph is intended to prevent disclosure to the Congress, including any committee or subcommittee of the

Congress, or to any other agency of the United States for use by such agency in furtherance of its statutory responsibilities. ~~Disclosure of information to any such other agency shall be allowed only upon application, made by the Attorney General to a United States district court, showing substantial need for the use of the information by such agency in furtherance of its statutory responsibilities.~~

(D) While in the possession of the custodian and under such reasonable terms and conditions as the Attorney General shall prescribe—

(i) documentary material and answers to interrogatories shall be available for examination by the person who produced such material or answers, or by a representative of that person authorized by that person to examine such material and answers; and

(ii) transcripts of oral testimony shall be available for examination by the person who produced such testimony, or by a representative of that person authorized by that person to examine such transcripts.

(3) USE OF MATERIAL, ANSWERS, OR TRANSCRIPTS IN OTHER PROCEEDINGS.—Whenever any attorney of the Department of Justice has been designated to appear before any court, grand jury, or Federal agency in any case or proceeding, the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony received under this section may deliver to such attorney such material, answers, or transcripts for official use in connection with any such case or proceeding as such attorney determines to be required. Upon the completion of any such case or proceeding, such attorney shall return to the custodian any such material, answers, or transcripts so delivered which have not passed into the control of such court, grand jury, or agency through introduction into the record of such case or proceeding.

(4) CONDITIONS FOR RETURN OF MATERIAL.—If any documentary material has been produced by any person in the course of any false claims law investigation pursuant to a civil investigative demand under this section, and—

(A) any case or proceeding before the court or grand jury arising out of such investigation, or any proceeding before any Federal agency involving such material, has been completed, or

(B) no case or proceeding in which such material may be used has been commenced within a reasonable time after completion of the

examination and analysis of all documentary material and other information assembled in the course of such investigation,

the custodian shall, upon written request of the person who produced such material, return to such person any such material (other than copies furnished to the false claims law investigator under subsection (f)(2) or made for the Department of Justice under paragraph (2)(B)) which has not passed into the control of any court, grand jury, or agency through introduction into the record of such case or proceeding.

(5) APPOINTMENT OF SUCCESSOR CUSTODIANS.—In the event of the death, disability, or separation from service in the Department of Justice of the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony produced pursuant to a civil investigative demand under this section, or in the event of the official relief of such custodian from responsibility for the custody and control of such material, answers, or transcripts, the Attorney General shall promptly—

- (A) designate another false claims law investigator to serve as custodian of such material, answers, or transcripts, and
- (B) transmit in writing to the person who produced such material, answers, or testimony notice of the identity and address of the successor so designated.

Any person who is designated to be a successor under this paragraph shall have, with regard to such material, answers, or transcripts, the same duties and responsibilities as were imposed by this section upon that person's predecessor in office, except that the successor shall not be held responsible for any default or dereliction which occurred before that designation.

(j) JUDICIAL PROCEEDINGS.—

(1) PETITION FOR ENFORCEMENT.—Whenever any person fails to comply with any civil investigative demand issued under subsection (a), or whenever satisfactory copying or reproduction of any material requested in such demand cannot be done and such person refuses to surrender such material, the Attorney General may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person a petition for an order of such court for the enforcement of the civil investigative demand.

(2) PETITION TO MODIFY OR SET ASIDE DEMAND.—

- (A) Any person who has received a civil investigative demand issued under subsection (a) may file, in the district court of the United States for the judicial district within which such person resides, is

found, or transacts business, and serve upon the false claims law investigator identified in such demand a petition for an order of the court to modify or set aside such demand. In the case of a petition addressed to an express demand for any product of discovery, a petition to modify or set aside such demand may be brought only in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending. Any petition under this subparagraph must be filed—

- (i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or
- (ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the demand to comply with the provisions of this section or upon any constitutional or other legal right or privilege of such person. During the pendency of the petition in the court, the court may stay, as it deems proper, the running of the time allowed for compliance with the demand, in whole or in part, except that the person filing the petition shall comply with any portions of the demand not sought to be modified or set aside.

(3) PETITION TO MODIFY OR SET ASIDE DEMAND FOR PRODUCT OF DISCOVERY.—

(A) In the case of any civil investigative demand issued under subsection (a) which is an express demand for any product of discovery, the person from whom such discovery was obtained may file, in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending, and serve upon any false claims law investigator identified in the demand and upon the recipient of the demand, a petition for an order of such court to modify or set aside those portions of the demand requiring production of any such product of discovery. Any petition under this subparagraph must be filed—

- (i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

- (ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.
  - (B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the portions of the demand from which relief is sought to comply with the provisions of this section, or upon any constitutional or other legal right or privilege of the petitioner. During the pendency of the petition, the court may stay, as it deems proper, compliance with the demand and the running of the time allowed for compliance with the demand.
- (4) PETITION TO REQUIRE PERFORMANCE BY CUSTODIAN OF DUTIES.—At any time during which any custodian is in custody or control of any documentary material or answers to interrogatories produced, or transcripts of oral testimony given, by any person in compliance with any civil investigative demand issued under subsection (a), such person, and in the case of an express demand for any product of discovery, the person from whom such discovery was obtained, may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian, a petition for an order of such court to require the performance by the custodian of any duty imposed upon the custodian by this section.
- (5) JURISDICTION.—Whenever any petition is filed in any district court of the United States under this subsection, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry out the provisions of this section. Any final order so entered shall be subject to appeal under section 1291 of title 28. Any disobedience of any final order entered under this section by any court shall be punished as a contempt of the court.
- (6) APPLICABILITY OF FEDERAL RULES OF CIVIL PROCEDURE.—The Federal Rules of Civil Procedure shall apply to any petition under this subsection, to the extent that such rules are not inconsistent with the provisions of this section.
- (k) DISCLOSURE EXEMPTION.—Any documentary material, answers to written interrogatories, or oral testimony provided under any civil investigative demand issued under subsection (a) shall be exempt from disclosure under section 552 of title 5.
- (l) DEFINITIONS.—For purposes of this section—
- (1) the term “false claims law” means—
    - (A) this section and sections 3729 through 3732; and



- (B) any Act of Congress enacted after the date of the enactment of this section [enacted Oct. 27, 1986] which prohibits, or makes available to the United States in any court of the United States any civil remedy with respect to, any false claim against, bribery of, or corruption of any officer or employee of the United States;
- (2) the term “false claims law investigation” means any inquiry conducted by any false claims law investigator for the purpose of ascertaining whether any person is or has been engaged in any violation of a false claims law;
- (3) the term “false claims law investigator” means any attorney or investigator employed by the Department of Justice who is charged with the duty of enforcing or carrying into effect any false claims law, or any officer or employee of the United States acting under the direction and supervision of such attorney or investigator in connection with a false claims law investigation;
- (4) the term “person” means any natural person, partnership, corporation, association, or other legal entity, including any State or political subdivision of a State;
- (5) the term “documentary material” includes the original or any copy of any book, record, report, memorandum, paper, communication, tabulation, chart, or other document, or data compilations stored in or accessible through computer or other information retrieval systems, together with instructions and all other materials necessary to use or interpret such data compilations, and any product of discovery;
- (6) the term “custodian” means the custodian, or any deputy custodian, designated by the Attorney General under subsection (i)(1); ~~and~~
- (7) the term “product of discovery” includes—
- (A) the original or duplicate of any deposition, interrogatory, document, thing, result of the inspection of land or other property, examination, or admission, which is obtained by any method of discovery in any judicial or administrative proceeding of an adversarial nature;
- (B) any digest, analysis, selection, compilation, or derivation of any item listed in subparagraph (A); and
- (C) any index or other manner of access to any item listed in subparagraph (A); and
- (8) the term “official use” means any use that is consistent with the law, and the regulations and policies of the Department of Justice, including use in connection with internal Department of Justice memoranda and reports;

communications between the Department of Justice and a Federal, State, or local government agency, or a contractor of a Federal, State, or local government agency, undertaken in furtherance of a Department of Justice investigation or prosecution of a case; interviews of any qui tam relator or other witness; oral examinations; depositions; preparation for and response to civil discovery requests; introduction into the record of a case or proceeding; applications, motions, memoranda and briefs submitted to a court or other tribunal; and communications with Government investigators, auditors, consultants and experts, the counsel of other parties, arbitrators and mediators, concerning an investigation, case or proceeding.

\* \* \*

S. 386 Section 4(f):

EFFECTIVE DATE AND APPLICATION.—The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that—

(1) subparagraph ( B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date; and

(2) section 3731(b) of title 31, as amended by subsection (b); section 3733, of title 31, as amended by subsection (c); and section 3732 of title 31, as amended by subsection (e); shall apply to cases pending on the date of enactment.

## Appendix 2

# FraudMail Alert<sup>®</sup>



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## CIVIL FALSE CLAIMS ACT: The False Claims Act is Amended for the First Time in More Than Twenty Years as the President Signs the Fraud Enforcement and Recovery Act of 2009

Last night, the Fraud Enforcement and Recovery Act of 2009 ("FERA") was signed into law by the President, marking only the second time in the history of the civil False Claims Act ("FCA") that all-embracing amendments have been made to this 1863 law. After its first large-scale revision in 1986, the FCA became the government's most successful weapon in its fight against suspected fraud on the United States, but it also became a weapon that competitors, disappointed bidders, disgruntled employees, and antagonistic agencies could use to punish and destroy those who opposed them. Congress's stated purpose in passing the FERA was to expand the FCA's liability provisions to reach frauds by financial institutions and other recipients of TARP and economic stimulus funds, but those funds were already covered by the FCA. The real purpose of these amendments is to overturn many decisions—like the unanimous Supreme Court decision last year in *Allison Engine Co. v. United States ex rel. Sanders*—which set logical and reasonable limits on the scope of the FCA, a punitive statute that has the power to destroy any individual, institution, municipal entity, or company subject to its provisions.

The new amendments will adversely affect everyone—all government contractors and subcontractors, all healthcare providers, every public and private grantee and sub-grantee, and every other person, company, and entity that pays money to the government or receives Federal funds—by making it far easier to conduct FCA investigations and to win FCA recoveries. Quite simply, many logical defenses have been eliminated, and those who deal in any way with the Federal government are entering a whole new world in which FCA liability is much broader and easier to prove.

Prior FraudMail Alerts have commented on the FCA amendments in the FERA throughout the legislative process. See FraudMail Alert Nos. [09-05-19](#); [09-05-15](#); [09-05-13](#); [09-05-06](#); [09-04-30](#). Here is a comprehensive look at these FCA amendments. A red-line version of the changes that have now become final is available [here](#). Attached is the [final version of the FCA](#) that is effective as of May 20, 2009.

### Major FCA Amendments Expanding Liability

Under the FERA, the key liability sections of the FCA remain the provisions addressing false claims, false statements supporting false claims, conspiracy, and the reverse false claims and obligation provisions. These provisions have been renumbered as well as expanded to cover additional conduct. The new sections 3729(a)(1)(A), (B), (C), and (G) extend liability to any person who:

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);  
[ . . . ] or
- (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Many of the key changes are in the definitions, found in section 3729(b).

**Elimination of *Allison Engine's* Intent Requirement:** Under the Supreme Court's unanimous decision in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008), FCA liability was limited to fraudulent statements that were designed "to get" false claims paid or approved "by the Government." See [FraudMail Alert No. 08-06-09](#). See also John. T. Boese, Civil False Claims and Qui Tam Actions §2.06[G] (3d ed. 2006 & Supp. 2009-1). The Supreme Court's interpretation in *Allison Engine* no longer applies after the FERA because the new law removes both the "to get" language and the "by the Government" limitation in section 3729(a)(2)—as well as comparable language in sections 3729(a)(3) and (a)(7). Further, it attempts to make those changes in section 3729(a)(1)(B) effective as of June 7, 2008—the date *Allison Engine* was decided.

The Court in *Allison Engine* found that, without a clear link between a false claim and payment or approval by the government, the FCA would be "boundless" and become an "all-purpose antifraud statute." 128 S. Ct. at 2128, 2130. To replace this rational limitation, the FERA adds a new definition of "claim," and FCA liability will be limited only by requiring some sort of nexus to the government. The FCA now covers requests for funds to a contractor, grantee, or other recipient, if the money or property requested "is to be spent or used on the Government's behalf or to advance a Government program or interest." The legislation does not define the key terms "used on the Government's behalf" or "to advance a Government program or interest," and presumably courts will have to decide their meaning on a case by case basis. No one knows the scope. Are government funds invested in GM or AIG "advanc[ing] a Government program" so that a false

claim to those entities will violate the FCA and be enforced by *qui tam* relators? Recognizing that this new language is not very clear, Senator Kyle attempted to limit its scope:

[p]revious understanding, as well as commons sense, dictate that a particular transaction does not “advance a Government program or interest” unless it is predominantly federal in character—something that at least would require . . . that the claim ultimately results in a loss to the government . . . [rather than] any garden-variety dispute between a general contractor and a subcontractor simply because the general receives some federal money.

155 Cong. Rec. S4540 (daily ed. Apr. 22, 2009) (statement of Sen. Kyl). One hopes that Senator Kyle’s interpretation is accepted. Future FCA case law will determine whether and to what extent Congress succeeded in overturning *Allison Engine* through the FERA.

**Materiality Requirement:** In addition to the nexus to the government requirement, the FERA, at long last, specifically incorporates a materiality requirement in the False Claims Act (a position the government and relators fought, without success, for over 15 years), but it defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,” which is the “weaker” materiality standard that has been applied in some FCA cases. See John T. Boese, *Civil False Claims and Qui Tam Actions* §2.04 (Aspen Publishers) (3d ed. & Supp. 2009-2). How much of a difference will this make? That depends entirely on how literally courts will read this provision. Almost every violation or mistake is arguably “capable of influencing” a payment decision by the government, but many courts in the past have read this test as strongly limiting the application of the FCA. For example, despite applying this “weaker” materiality standard, at least two courts have held that violations of “conditions of participation” in a Federal healthcare program do not result in FCA violations. See *United States ex rel. Conner v. Salina Reg’l Health Ctr.*, 543 F.3d 1211 (10th Cir. 2008); *United States ex rel. Landers v. Baptist Mem’l Health Care Corp.* 525 F. Supp. 2d 972 (W.D. Tenn. 2007).

**Conspiracy:** Under the prior FCA, the conspiracy section was drafted to cover only a conspiracy “to get a false claim paid or approved.” Courts had properly interpreted this language to limit the conspiracy section to apply only to violations of then-subsection 3729(a)(1), and not to violations of the reverse false claim provision. Moreover, the conspiracy section required that the government pay the false claim. The new conspiracy section, 31 U.S.C. § 3729(a)(1)(C), expands the conspiracy section to include a conspiracy to commit a violation of any other substantive section of the FCA. The amendment also eliminates the need for the false claim to be paid or approved, and assesses liability for conspiring to commit the violation. Importantly, the word “knowingly” still does not appear in the language of the new conspiracy section, so the argument remains that a common law liability, including specific intent, is still required to prove a conspiracy under the FCA.

**Liability for Overpayments:** The amended reverse false claims liability provision in section 3729(a)(1)(G) quoted above extends new liability to “knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government.” Under this provision, there is no need for a person to have taken an affirmative act—a false statement or record—in order to conceal, avoid, or decrease the obligation to the government. This new

provision is even more dangerous because an "obligation" is specifically defined to include within the scope of FCA liability the retention of an overpayment from the government. The term "improperly" is intended to limit this liability, and would presumably exclude overpayments such as those under Medicaid that undergo a reconciliation process. Practitioners will be required, almost immediately after passage, to begin to advise clients whether they have received "overpayments" and the potential liability that could result from retention of such overpayments. Moreover, even though this provision is not retroactive, an overpayment is an overpayment, whether it occurred before or after May 20, 2009. The government and relators are almost certain to argue that this provision applies to overpayments made before the date of the legislation.

**Expanded Definition of "Obligation":** The definition of "obligation" that triggers reverse false claims liability is expanded to encompass "an established duty, whether or not fixed" that arises from a contractual, grantee, licensee, or fee-based relationship, from a statute or regulation, or from the retention of any overpayment. According to government statements, this is intended to overturn, among other cases, the Sixth Circuit's decision 10 years ago in *United States ex rel. American Textile Manufacturers Institute, Inc. v. The Limited, Inc.*, 190 F.3d 729 (6<sup>th</sup> Cir. 1999) ("*ATMI*"), which defined "obligation" to include only established obligations to pay money to the government. In addition to extending new liability to the retention of overpayments, this expanded definition seeks to extend liability to duties to pay fees that were not covered previously because they were not fixed in all particulars. Whether much of an expansion is actually achieved under this provision remains to be seen because even the DOJ concedes that the new language is not intended to extend FCA liability to penalties or fines. (The reader should note that the author represented many of the defendants in the *ATMI* case.)

**Effective Date:** Under the effective date provision in the FERA, the FCA liability amendments would apply prospectively, with one important exception. The amendment to section 3729(a)(2) takes effect on the date that *Allison Engine* was decided—June 7, 2008—making that amendment retroactive. The retroactivity of this amendment will raise a host of practical problems in pending cases, and is almost certain to be challenged as unconstitutional because conduct which the Supreme Court defined as outside the scope of FCA liability is, retroactively, now a violation. Were this a normal civil statute, such retroactivity would be allowable. But the Supreme Court has already defined the FCA as an "essentially punitive" statute. *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000). Whether a clearly punitive statute can be applied retroactively is a completely different question.

#### **Additional FCA Amendments**

In addition to amending the FCA's liability provisions, the FERA includes four other amendments that make recoveries and investigations under the FCA easier. These amendments are as follows:

**Retaliation:** The prohibition against retaliation is expanded to include a "contractor, or agent," in addition to an employee—without requiring prohibited retaliatory acts to be taken by an "employer." Under this unusually broad definition, a retaliation action could be based on many different types of relationships that do not involve an employment contract, which could lead to unintended consequences.

**Civil Investigative Demands:** Under the FCA as passed in 1986, the Attorney General had to personally approve a CID, which can require deposition testimony under oath, clearly a power and a potentially abusive power. Under FERA, the Attorney General is now authorized to appoint a designee to approve a civil investigative demand, and the Attorney General or designee may share the information obtained with "any *qui tam* relator if the Attorney General or designee determine it is necessary as part of any false claims act investigation." In addition, "official use" is broadly defined, allowing the Justice Department to use the information in communications with government personnel, consultants, and counsel for other parties in matters concerning an investigation, case, or proceeding. The expanded use and sharing of CID responses with any *qui tam* relator, consultant, and counsel is potentially harmful to businesses and individuals, and in recognition of this, one hopes it will be narrowly and carefully circumscribed by the Justice Department to curb abuses.

**Relation Back:** The government's complaint in intervention or amendment to a relator's complaint relates back to the date of the original complaint. Under this amendment, the government could delay its intervention in ways that could dramatically undermine a defendant's ability to defend itself. See, e.g., *United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263 (2d Cir. 2006); *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc.*, 409 F. Supp. 2d 43 (D. Mass. 2006).

**Service on State or Local Authorities:** The seal provision would not prevent the government or relator from serving the written disclosure, a *qui tam* complaint, or other pleading on state and local law enforcement authorities that investigate the case.

#### Author

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## Appendix 3

# FraudMail Alert®



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## CIVIL FALSE CLAIMS ACT: Supreme Court Denial of Certiorari in *U.S. ex rel. Purcell v. MWI* Lets Stand DC Circuit Decision Limiting FCA Liability Based on Ambiguous Agency Regulation

On January 9, 2017, the Supreme Court denied certiorari in *United States ex rel. Purcell v. MWI Corp.*, No. 16-361, ending one of the longest running False Claims Act ("FCA") cases in history. In so doing, the Supreme Court let stand a significant decision by the D.C. Circuit that severely limits FCA liability where the allegations are dependent on violations of ambiguous agency regulations. See *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015).

As described in detail in one of our prior alerts, the FCA case against Moving Water Industries Corp. ("MWI") involved an Export-Import Bank loan that funded Nigeria's purchase of MWI irrigation equipment and the *qui tam* relator's claim (adopted by the Justice Department after intervention) that MWI falsely certified that it paid "regular commissions" to agents in connection with the transaction. On appeal, the D.C. Circuit found that the term "regular commissions" was ambiguous, that MWI's interpretation was objectively reasonable, and that no published guidance supported the government's *post hoc* claim that the term referred to the supposed commission rate within the industry as a whole rather than to commission rates MWI regularly paid its agents. Based on these findings, the D.C. Circuit unanimously reversed the jury verdict, and remanded the action to the district court with instructions to enter final judgment for MWI. See [FraudMail Alert No. 15-11-25](#).

Then, notwithstanding its years of active and vigorous post-intervention prosecution of the case—including petitioning the D.C. Circuit for rehearing and rehearing en banc—the Justice Department suddenly reversed course. Not only did it decline to seek a writ of certiorari, but it went a step further and filed a brief opposing Supreme Court review (after the *qui tam* relator petitioned for certiorari). In its opposition, the Justice Department sought to justify its stance by positing a self-serving interpretation of the D.C. Circuit's decision, its continuing relevance, and its precedential value, while at the same time urging the Supreme Court not to weigh in. The Justice Department's self-serving—and as yet untested—interpretation would undermine the D.C. Circuit's decision in *Purcell* and conflicts with a growing body of FCA case law. See [Br. of Nat'l Ass'n of Mfrs. as Amicus Curiae in Support of Defendant-Appellee/Cross-Appellant and in Support of Reversal of the Decisions Finding Liability under the False Claims Act, United States ex rel. Purcell v. MWI Corp.](#), No. 14-5210 (D.C. Cir. filed Mar. 2, 2015) (the reader should note that some authors of this Alert filed the referenced amicus brief).

With its denial of certiorari, the Supreme Court did not adopt (or even acknowledge) the Justice Department's interpretation, but instead let stand the D.C. Circuit's decision in *Purcell*. However, FCA defendants and their counsel should not be surprised if the Justice Department continues to press this interpretation in future cases.

\* \* \*

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. If you have any questions about the contents of this memorandum, please call your regular Fried Frank contact or the attorney listed below:

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## Appendix 4

**FRAUD STATISTICS - OVERVIEW**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sub>1</sub>		SETTLEMENTS AND JUDGMENTS <sub>2</sub>					RELATOR SHARE AWARDS <sub>3</sub>		
	NON QUITAM	QUITAM	NON QUITAM	QUITAM			TOTAL QUITAM AND NON QUITAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
1987	343	30	86,479,949	0	0	0	86,479,949	0	0	0
1988	210	43	173,287,863	2,309,354	33,750	2,343,104	175,630,767	88,750	8,438	97,188
1989	224	87	197,202,180	15,111,719	1,681	15,113,400	212,315,580	1,446,770	200	1,446,970
1990	243	72	189,564,367	40,483,367	75,000	40,558,367	230,122,734	6,590,936	20,670	6,611,606
1991	234	84	270,530,467	70,384,431	69,500	70,453,931	340,984,398	10,667,537	18,750	10,686,287
1992	285	114	137,958,206	133,949,447	994,456	134,943,903	272,902,109	24,121,648	259,784	24,381,432
1993	304	138	181,945,576	183,643,787	6,603,000	190,246,787	372,192,363	27,576,235	1,766,902	29,343,137
1994	280	218	706,022,897	379,018,205	2,822,323	381,840,528	1,087,863,425	69,453,350	838,897	70,292,246
1995	233	260	269,989,542	239,024,292	1,635,000	240,659,292	510,648,934	45,162,296	465,800	45,628,096
1996	185	341	247,357,271	124,361,203	13,522,433	137,883,636	385,240,908	22,119,619	3,731,978	25,851,597
1997	186	547	465,568,061	621,919,274	6,021,200	627,940,474	1,093,508,535	65,857,419	1,658,485	67,515,904
1998	120	468	151,435,794	438,834,846	30,248,075	469,082,921	620,518,715	70,264,372	8,486,645	78,751,017
1999	140	493	195,390,485	492,924,785	5,067,503	497,992,288	693,382,773	63,018,064	1,374,487	64,392,552
2000	95	363	367,887,197	1,208,370,688	1,688,957	1,210,059,645	1,577,946,841	183,679,377	375,143	184,054,520
2001	85	311	494,496,974	1,215,525,916	128,587,151	1,344,113,067	1,838,610,042	187,550,470	30,701,881	218,252,350
2002	61	318	119,598,292	1,078,174,023	25,786,140	1,103,960,162	1,223,558,454	161,377,822	4,582,319	165,960,141
2003	92	334	711,098,299	1,534,862,352	5,185,911	1,540,048,263	2,251,146,563	337,307,857	1,382,741	338,690,598
2004	105	432	115,656,023	561,717,502	9,261,879	570,979,382	686,635,404	110,224,220	2,376,128	112,600,348
2005	105	405	276,914,983	1,149,047,524	7,481,593	1,156,529,117	1,433,444,099	166,580,543	2,031,695	170,612,237
2006	71	385	1,712,459,257	1,491,105,499	22,711,363	1,513,816,862	3,226,276,119	219,976,072	5,647,836	225,623,908
2007	129	365	564,826,844	1,251,726,955	160,246,894	1,411,973,849	1,976,800,693	192,886,212	4,616,899	197,503,111

**FRAUD STATISTICS - OVERVIEW**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sup>1</sup>		SETTLEMENTS AND JUDGMENTS <sup>2</sup>					RELATOR SHARE AWARDS <sup>3</sup>		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED				
2008	161	379	312,193,480	1,042,582,229	12,678,936	1,055,261,165	1,367,454,645	201,382,144	2,997,615	204,379,759
2009	132	433	469,334,681	1,959,856,256	33,776,480	1,993,632,735	2,462,967,417	249,567,135	9,684,147	259,251,282
2010	140	576	647,383,493	2,280,378,123	108,890,899	2,389,269,023	3,036,652,516	363,349,351	30,649,677	393,999,028
2011	125	635	241,365,995	2,648,195,115	173,888,703	2,822,083,818	3,063,449,813	510,631,604	49,041,606	559,673,210
2012	144	652	1,608,112,862	3,342,216,074	44,673,343	3,387,189,418	4,995,302,260	435,679,630	12,640,243	448,319,873
2013	101	755	169,126,772	2,838,439,485	127,348,056	2,965,787,541	3,134,914,313	522,362,640	30,449,937	552,812,577
2014	97	715	1,676,564,226	4,371,182,653	81,378,451	4,452,561,104	6,129,125,330	694,250,967	14,868,000	709,118,968
2015	110	639	731,342,286	1,879,431,785	1,174,568,901	3,054,000,386	3,785,342,672	330,344,878	336,706,994	667,051,872
2016	143	702	1,856,329,432	2,800,043,469	104,984,335	2,905,028,403	4,761,357,835	491,202,979	28,402,836	519,605,815
<b>TOTAL</b>	<b>4,863</b>	<b>11,304</b>	<b>15,347,423,655</b>	<b>35,394,820,358</b>	<b>2,290,532,213</b>	<b>37,685,352,572</b>	<b>53,032,776,227</b>	<b>5,766,722,698</b>	<b>585,786,731</b>	<b>6,352,509,628</b>

NOTES:

1. "New Matters" refers to newly received referrals, investigations, and qui tam actions.
2. Non qui tam settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.
3. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims, which may be less than the total settlement or judgment. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U. S. C. § 3730(h).

**FRAUD STATISTICS - HEALTH AND HUMAN SERVICES**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sub>2</sub>		SETTLEMENTS AND JUDGMENTS <sub>3</sub>					RELATOR SHARE AWARDS <sub>4</sub>		
	NON QUITAM	QUITAM	NON QUITAM TOTAL	QUITAM			TOTAL QUITAM AND NON QUITAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
1987	12	3	11,361,826	0	0	0	11,361,826	0	0	0
1988	7	5	2,182,675	355,000	0	355,000	2,537,675	88,750	0	88,750
1989	19	16	350,460	5,099,661	0	5,099,661	5,450,121	50,000	0	50,000
1990	27	11	10,327,500	903,158	0	903,158	11,230,658	119,474	0	119,474
1991	19	12	8,670,735	5,420,000	0	5,420,000	14,090,735	861,401	0	861,401
1992	26	15	9,821,840	2,192,478	0	2,192,478	12,014,118	446,648	0	446,648
1993	22	38	12,523,165	151,760,404	0	151,760,404	164,283,569	22,946,101	0	22,946,101
1994	43	76	381,470,015	6,280,815	240,000	6,520,815	387,990,830	1,113,597	72,000	1,185,597
1995	27	87	96,290,779	84,061,789	1,620,000	85,681,789	181,972,568	14,337,982	465,800	14,803,782
1996	20	177	63,059,873	49,236,698	2,340,000	51,576,698	114,636,572	6,707,168	667,400	9,374,568
1997	48	269	351,440,027	578,987,061	92,500	579,079,561	930,519,608	58,852,605	20,250	58,872,855
1998	35	276	40,107,920	251,824,167	2,526,075	254,350,242	294,458,162	46,863,357	187,015	47,050,372
1999	27	315	38,000,792	406,761,680	1,366,599	408,128,379	446,129,171	45,174,556	317,829	45,492,385
2000	35	212	208,899,015	723,152,746	333,457	723,486,203	932,385,218	115,397,403	87,343	115,484,746
2001	34	178	435,649,179	931,262,922	14,991,554	946,254,475	1,382,103,654	143,864,700	3,735,501	147,600,200
2002	22	193	74,454,427	937,841,186	23,407,571	961,248,757	1,035,703,184	150,280,717	4,008,686	154,289,403
2003	26	215	541,929,810	1,304,920,314	2,880,785	1,307,801,099	1,849,730,909	284,074,366	722,233	284,796,601
2004	28	273	34,816,447	470,335,061	5,775,062	476,110,142	510,926,589	95,920,149	1,625,129	97,545,278
2005	34	270	204,821,548	906,656,836	6,671,593	913,328,429	1,118,149,977	120,969,296	1,900,095	122,869,393
2006	18	216	1,050,520,714	1,227,114,221	16,229,540	1,243,343,761	2,293,864,475	163,167,984	3,921,996	167,089,981
2007	25	199	465,052,993	929,615,846	152,456,540	1,082,072,486	1,547,125,480	156,285,623	2,497,177	158,782,799



**FRAUD STATISTICS - HEALTH AND HUMAN SERVICES**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sup>2</sup>		SETTLEMENTS AND JUDGMENTS <sup>3</sup>					RELATOR SHARE AWARDS <sup>4</sup>		
	NON QUI TAM	QUI TAM	NON QUI TAM TOTAL	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2008	60	231	162,972,022	962,461,088	6,852,571	969,313,659	1,132,285,682	185,933,162	1,522,164	187,455,327
2009	34	279	238,061,424	1,364,911,522	30,283,452	1,395,194,974	1,633,256,368	155,440,550	8,669,822	164,110,372
2010	42	385	546,963,733	1,955,805,336	15,478,518	1,971,283,854	2,518,247,587	335,084,132	4,373,489	339,457,621
2011	38	417	178,287,545	2,182,785,375	88,291,393	2,271,078,768	2,449,364,313	446,646,645	24,055,593	470,702,208
2012	25	414	557,273,967	2,504,096,869	37,563,868	2,541,660,538	3,098,934,505	280,816,748	10,527,293	291,344,041
2013	27	504	81,354,329	2,523,689,075	119,260,369	2,642,949,443	2,704,303,773	465,027,975	28,526,451	493,554,426
2014	32	470	88,054,490	2,271,159,011	66,322,326	2,337,481,337	2,425,535,827	382,745,316	10,877,186	393,622,502
2015	26	425	154,658,714	1,472,783,885	472,604,555	1,945,388,440	2,100,047,154	258,821,659	132,218,688	391,040,347
2016	69	501	97,579,302	2,427,980,533	71,931,554	2,490,912,087	2,597,491,389	431,263,484	19,254,883	450,518,367
<b>TOTAL</b>	<b>907</b>	<b>6,583</b>	<b>6,127,167,067</b>	<b>26,639,454,777</b>	<b>1,139,519,860</b>	<b>27,778,974,658</b>	<b>33,906,131,725</b>	<b>4,371,321,550</b>	<b>260,253,992</b>	<b>4,631,575,542</b>

NOTES:

- The information reported in this table covers matters in which the Department of Health and Human Services is the primary client agency.
- "New Matters" refers to newly received referrals, investigations, and qui tam actions.
- Non qui tam settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.
- Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims, which may be less than the total settlement or judgment. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U. S. C. § 3730(h).

**FRAUD STATISTICS - DEPARTMENT OF DEFENSE**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sub>2</sub>		SETTLEMENTS AND JUDGMENTS <sub>3</sub>					RELATOR SHARE AWARDS <sub>4</sub>		
	NON QUITAM	QUITAM	NON QUITAM	QUITAM			TOTAL QUITAM AND NON QUITAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
1987	237	20	27,897,128	0	0	0	27,897,128	0	0	0
1988	122	28	149,136,213	0	33,750	33,750	149,169,963	0	8,438	8,438
1989	122	31	154,588,297	10,002,058	0	10,002,058	164,590,355	1,394,770	0	1,394,770
1990	74	41	117,115,978	21,630,713	69,000	21,699,713	138,815,691	3,776,850	18,870	3,795,720
1991	78	44	227,898,245	57,200,000	42,000	57,242,000	285,140,245	8,625,800	10,500	8,636,300
1992	73	61	62,603,695	127,700,000	994,456	128,694,456	191,298,151	23,540,000	259,784	23,799,784
1993	93	53	83,742,840	24,000,000	5,707,641	29,707,641	113,450,481	3,280,425	1,671,498	4,951,923
1994	62	81	222,799,421	369,136,206	1,530,000	370,666,206	593,465,627	67,712,679	451,200	68,163,879
1995	54	88	110,459,386	140,548,237	15,000	140,563,237	251,022,623	26,348,711	0	26,348,711
1996	44	75	78,085,099	55,908,927	5,924,726	61,833,653	139,918,752	10,825,550	1,696,923	12,522,473
1997	48	79	30,734,273	35,090,213	1,513,700	36,603,913	67,338,186	6,018,810	379,435	6,398,245
1998	30	61	71,063,139	122,463,185	27,717,000	150,180,185	221,243,324	12,213,171	8,298,630	20,511,801
1999	33	65	30,522,711	15,114,509	745,137	15,859,646	46,382,357	2,684,186	179,750	2,863,936
2000	9	40	53,007,693	95,607,325	505,500	96,112,825	149,120,518	15,668,259	122,800	15,791,059
2001	10	41	17,472,751	30,030,696	88,083,098	118,113,794	135,586,545	5,955,566	19,451,866	25,407,432
2002	16	41	15,017,365	18,057,658	1,350,000	19,407,658	34,425,022	2,576,196	381,000	2,957,196
2003	10	35	107,337,000	204,884,468	0	204,884,468	312,221,468	46,592,795	0	46,592,795
2004	16	49	10,098,491	21,581,366	0	21,581,366	31,679,857	3,031,610	0	3,031,610
2005	16	49	19,049,935	101,125,200	0	101,125,200	120,175,135	21,428,085	0	21,428,085
2006	12	68	586,550,385	52,480,219	1,520,203	54,000,421	640,550,806	11,128,675	299,986	11,428,661
2007	25	50	16,400,000	36,230,796	496,909	36,727,705	53,127,705	4,983,718	126,419	5,110,137

**FRAUD STATISTICS - DEPARTMENT OF DEFENSE**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sub>2</sub>		SETTLEMENTS AND JUDGMENTS <sub>3</sub>					RELATOR SHARE AWARDS <sub>4</sub>		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED				
2008	27	43	70,756,834	60,468,116	5,701,365	66,169,481	136,926,315	11,891,101	1,439,451	13,330,552
2009	17	51	22,388,261	416,852,869	140,000	416,992,869	439,361,130	64,468,853	26,600	64,496,453
2010	23	56	26,251,482	231,354,446	9,473,700	240,828,146	267,079,628	12,335,365	2,833,839	15,169,204
2011	19	45	29,484,345	113,130,570	0	113,130,570	142,614,915	9,420,127	0	9,420,127
2012	16	59	2,000,000	166,386,739	307,000	166,693,739	168,893,739	20,777,673	70,000	20,847,673
2013	12	78	4,869,169	47,118,462	154,000	47,272,462	52,141,631	7,248,939	41,580	7,288,519
2014	9	44	14,102,250	46,234,251	9,014,000	55,248,251	69,350,501	8,448,658	2,693,500	11,143,158
2015	7	35	109,591,660	145,989,076	26,572,197	172,561,273	282,552,933	24,600,368	2,561,920	27,162,288
2016	8	31	60,625,089	47,924,527	13,615,000	61,539,527	122,164,617	9,833,706	3,888,000	13,731,706
<b>TOTAL</b>	<b>1,322</b>	<b>1,545</b>	<b>2,532,049,136</b>	<b>2,814,250,830</b>	<b>201,225,362</b>	<b>3,015,476,212</b>	<b>5,547,525,347</b>	<b>450,810,645</b>	<b>46,921,989</b>	<b>497,732,634</b>

NOTES:

1. The information reported in this table covers matters in which the Department of Defense is the primary client agency.
2. 'New Matters' refers to newly received referrals, investigations, and qui tam actions.
3. Non qui tam settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.
4. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator's claims, which may be less than the total settlement or judgment. Relator share awards do not include amounts recovered in subsection (n) or other personal claims. See 31 U. S. C. § 3730(h).

**FRAUD STATISTICS - OTHER (NON-HHS, NON-DOD)<sup>1</sup>**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

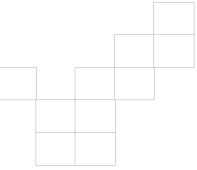
FY	NEW MATTERS <sup>2</sup>		SETTLEMENTS AND JUDGMENTS <sup>3</sup>					RELATOR SHARE AWARDS <sup>4</sup>		
	NON QUITAM	QUITAM	NON QUITAM TOTAL	QUITAM			TOTAL QUITAM AND NON QUITAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
1987	94	7	47,220,995	0	0	0	47,220,995	0	0	0
1988	81	10	21,968,775	1,954,354	0	1,954,354	23,923,129	0	0	0
1989	83	40	42,263,423	10,000	1,681	11,681	42,275,104	2,000	200	2,200
1990	142	20	62,120,889	17,949,496	6,000	17,955,496	80,076,385	2,694,612	1,800	2,696,412
1991	137	28	33,961,487	7,764,431	27,500	7,791,931	41,753,418	1,180,336	8,250	1,188,586
1992	186	38	65,532,871	4,056,969	0	4,056,969	69,589,840	135,000	0	135,000
1993	189	47	85,679,571	7,883,383	895,359	8,778,742	94,458,313	1,349,709	95,404	1,445,113
1994	175	61	101,753,461	3,601,184	1,052,323	4,653,507	106,406,968	627,074	315,697	942,771
1995	152	94	63,239,477	14,414,266	0	14,414,266	77,653,743	2,475,603	0	2,475,603
1996	121	89	106,212,299	19,215,578	5,257,707	24,473,285	130,685,584	2,586,902	1,367,655	3,954,557
1997	90	199	83,393,761	7,841,980	4,415,000	12,256,980	95,650,741	986,005	1,258,800	2,244,805
1998	55	131	40,264,735	64,547,494	5,000	64,552,494	104,817,229	11,187,844	1,000	11,188,844
1999	60	112	126,666,982	71,048,596	2,955,567	74,004,263	200,671,245	15,159,323	876,908	16,036,231
2000	51	111	105,980,489	389,610,617	850,000	390,460,617	496,441,106	52,613,715	165,000	52,778,715
2001	41	92	41,175,045	254,232,298	25,512,500	279,744,798	320,919,843	37,730,204	7,514,514	45,244,718
2002	23	84	30,126,500	122,275,179	1,028,569	123,303,748	153,430,248	6,620,908	192,633	6,813,542
2003	56	83	61,631,489	25,057,571	2,305,126	27,362,697	89,194,186	4,640,694	660,508	5,301,202
2004	61	110	70,741,084	69,801,056	3,486,818	73,287,873	144,028,957	11,272,462	750,999	12,023,461
2005	55	87	53,043,500	141,265,468	810,000	142,075,468	195,118,968	26,163,159	131,600	26,294,759
2006	41	101	75,388,158	211,511,060	4,961,620	216,472,680	291,860,838	45,679,413	1,425,854	47,105,266
2007	79	116	83,373,851	285,880,313	7,293,345	293,173,657	376,547,508	31,616,672	1,993,303	33,612,175

**FRAUD STATISTICS - OTHER (NON-HHS, NON-DOD)<sup>1</sup>**  
**October 1, 1987 - September 30, 2016**  
**Civil Division, U.S. Department of Justice**

FY	NEW MATTERS <sup>2</sup>		SETTLEMENTS AND JUDGMENTS <sup>3</sup>					RELATOR SHARE AWARDS <sup>4</sup>		
	NON QUI TAM	QUITAM	NON QUI TAM TOTAL	QUITAM			TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
				WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL				
2008	74	105	78,464,624	19,653,025	125,000	19,778,025	98,242,649	3,557,680	36,000	3,593,680
2009	81	103	208,884,996	178,091,864	3,353,028	181,444,892	390,329,888	29,656,732	967,725	30,644,457
2010	75	135	74,168,279	93,218,341	83,938,681	177,157,022	261,325,301	15,929,854	23,442,348	39,372,202
2011	68	173	33,594,105	352,279,170	85,597,310	437,876,480	471,470,585	54,564,832	24,966,043	79,550,875
2012	103	178	1,048,838,895	671,732,467	7,102,675	678,835,142	1,727,674,036	134,085,210	2,042,949	136,128,159
2013	62	173	102,903,274	267,631,949	7,933,887	275,565,636	378,468,910	50,087,725	1,881,906	51,969,631
2014	56	201	1,574,407,486	1,752,719,796	6,042,125	1,758,761,521	3,333,169,407	254,895,554	1,297,314	256,192,868
2015	77	177	466,691,913	260,658,824	675,391,850	936,050,674	1,402,742,566	46,922,851	201,926,387	248,849,238
2016	66	170	1,698,125,040	323,943,159	19,438,381	343,381,540	2,041,506,580	50,076,503	5,249,953	55,326,455
<b>TOTAL</b>	<b>2,654</b>	<b>3,075</b>	<b>6,688,217,453</b>	<b>5,639,849,905</b>	<b>949,786,951</b>	<b>6,589,636,856</b>	<b>13,277,854,309</b>	<b>896,400,976</b>	<b>278,610,750</b>	<b>1,175,011,726</b>

NOTES:

1. The information reported in this table covers matters in which the primary client agency is neither the Department of Health and Human Services nor the Department of Defense.
2. 'New Matters' refers to newly received referrals, investigations, and qui tam actions.
3. Non qui tam settlements and judgments do not include matters delegated to United States Attorneys' offices. The Civil Division maintains no data on such matters.
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**Immediately Address  
IT Access Compliance Challenges  
with These Techniques,  
Using Tools You Already Have**

Active Learning on how to Deter and Detect  
Patient Privacy Violations  
and Data Breaches by Insiders

Alan Norquist & John Vastano  
Veriphyr, Inc.

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Agenda: IT Compliance Deters and Detects Insider Breaches

- What is IT Access Compliance?
- Insiders more dangerous than outside hackers
  - Insiders = Employees, Contractors, 3<sup>rd</sup> Parties, Providers
- Characteristics of insider theft and privacy violations
- Why insiders bigger legal issue than hackers or lost/stolen hardware
- How IT access compliance can do what traditional IT security can't
- Practical approaches to IT access compliance you can use immediately

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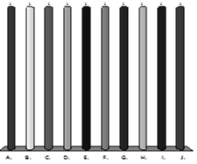
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Survey - Your Organization's Focus?

- A. Healthcare
- B. Insurance
- C. Pharma
- D. Medical Devices
- E. Legal Services
- F. Government
- G. Other
- H. Other/All



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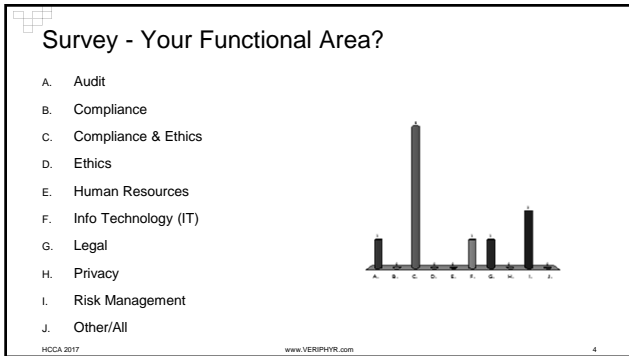
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### IT Access Compliance

- Only have access rights as required to achieve job objectives
  - user access to systems and applications is reviewed on a periodic basis.
- Only act on data as required to achieve job objectives
  - regularly review records of information system activity

Insider = Employee, Contractor, Provider, 3<sup>rd</sup> Party or Anyone with Valid Credentials (Username and Password) including hackers with stolen credentials

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**But Not Employees, Contractors, Providers, etc.**

#1 Means of Insider Breach  
Privilege Abuse  
*"Misusing privileges granted by a company to commit nefarious acts"*  
 aka - Non-compliant user access

Cartoon by P. Daly  
 HCCA 2017 www.VERIPHYR.com

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**Selling Data Instead of Drugs?**

Quotes from FBI Press Release

- "A confidential source (CS) initially approached [criminal] and inquired about purchasing narcotics.
- [Criminal] told the CS that he did not have any narcotics but that he did have personal identity information (PII) that he was willing to sell to the CS....
- [Criminal] provided the CS with specific instructions on what information to enter into the web pages of the Internet-based tax services to obtain a tax refund.
- An examination of the PII revealed that it was from a medical services provider."

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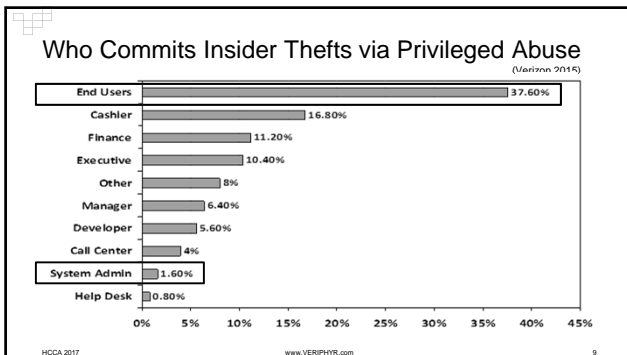
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**Data Theft via Privilege Abuse by Insiders**

- Months and Years Before Discovered
  - 31.25% - stole for months
  - 18.75% - stole for years (source: Verizon)
- No Technical Skills Required
  - Already issued logins and passwords
- Walk Out of Your Organization with Stolen Data on Phone
  - No need to email or upload data to the cloud
  - Just take a photo on smart phone and walk out of the building
  - Print out or e-mail stolen data from home



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**Hackers vs. Privilege Abuse by Insiders – “Injury in Fact”**

- Hacker Steals Patient Data
  - Did customer suffer “injury in fact”?
  - Cases dismissed due to lack of “injury in fact”
    - No clear connection between data theft and identity theft
- Employee Steals Data via Privilege Abuse
  - Local Law Enforcement Bust Local Identify Theft Ring

*“Among the paperwork were computer screen-shot printouts displaying patients’ personal information from a local hospital” – indictment*

- Did patient suffer “injury in fact”?



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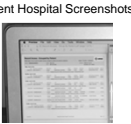
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**Stolen/Lost Computer vs Insider Theft - “Injury in Fact”**

- \$4 Billion Lawsuit against Healthcare Org.
  - Computer with PHI stolen
  - Dismissed due to lack of “injury in fact”
    - “No proof unauthorized person accessed stolen material.”
- Lawsuit - Insider Theft for Identity Theft Ring
  - Police find hospital data and credit statements
  - Would this be “proof unauthorized person accessed stolen material”?
  - Would suit be dismissed?




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### Traditional IT Security is for Outsiders/Hackers

- Focus on the network and not designed for insider privilege abuse

**IT Security Technology**

- Data Loss Protection (DLP)
- Security Event Mgmt (SEM/SIEM)
- Firewalls
- Intrusion Prevention (IDS/IPS)
- Security Intelligence
- Anti-Phishing
- Anti-Virus
- Anti-Malware

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### Focusing on Exfiltration is Insufficient

Must detect impermissible use at the source and not depend on infiltration or exfiltration on the network or computer?

- Just Viewing is a problem
  - Geological survey results
  - M&A insider information
- Just Creating is a problem
  - Fraudulent vendors
- Just Altering is a problem
  - Company financials

Insider Privilege Abuse + Phone w/ Camera = Information Compromise

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### Access Compliance is for Data Breach by Insiders

- Addresses privilege abuse of applications and data

**Answer: Access Compliance**

- Restrict access rights to job objectives
- Monitor access activity vs. job objectives

Insider Privilege Abuse + Smartphone w/ Camera = Data Theft

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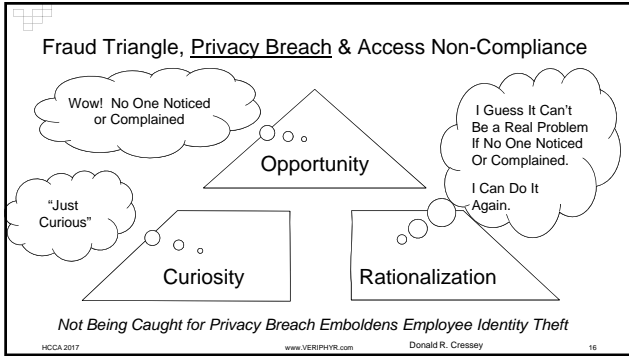
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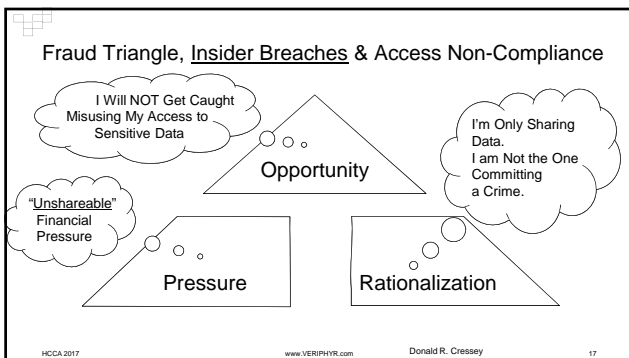
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**IT Access Compliance**

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Insider – Employee, Contractor, Provider, 3<sup>rd</sup> Party or Anyone with Valid Credentials (Username and Password) including hackers with stolen credentials

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**Detect Malicious Insiders by Understanding Compliant Use**

<p>To Detect <b>Malicious Access &amp; Use</b></p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p>Access Data or Take Actions <b>OUTSIDE <u>job objectives</u></b></p> </div>	<p><b>=!</b></p>	<p>Understand <b>Compliant Access &amp; Use</b></p> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p>Access <b>ONLY</b> the Data and Take <b>ONLY</b> the Action <b>required for <u>job objectives</u></b></p> </div>
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Key - Use true peer groups of workers with similar job objectives  
 - Can't use peer groups based on title and departments or other static label

Group workers by "job"  
 If workers access or activities are anomalous for the "job"  
 Then anomalous actions are impermissible use

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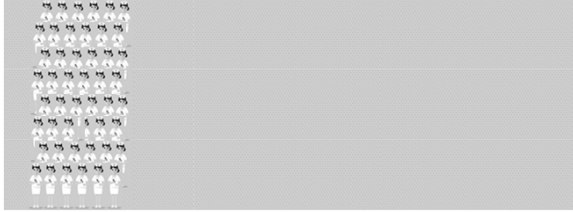
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**Worker Jobs – Not Titles and Departments**  
 All Outpatient Nurses are **NOT** All the Same!



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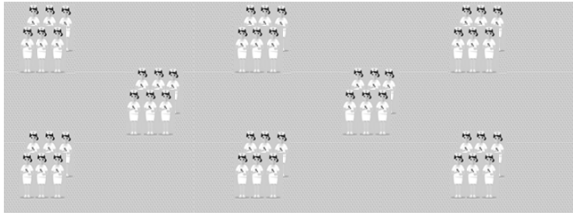
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**Worker Jobs – Not Titles and Departments**  
 All Outpatient Nurses are **NOT** All the Same!  
 Different Jobs Reflected in Differences in What Activities are Permissible Use



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**Worker Jobs – Not Titles and Departments**  
All Outpatient Nurses are **NOT** All the Same!  
Different Jobs Reflected in Differences in What Activities are Permissible Use  
**Understanding “Jobs” Reveals Impermissible Use by Nurses**

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**IT Compliance to Proactively Detect Privacy Violations and Data Theft**

- Employees Doing Similar Jobs Behave Similarly
  - Compare Employee Access Rights to Job Peers to Find Anomalies
  - Compare Employee Activity to Job Peers to Find Anomalies
    - Uses Existing Application Logs of Employee Access to Identity Data
- Investigate Anomalies with Managers and Employee
  - Employees Know They are Being Effectively Monitored
  - Deters Identity Theft (Reducing “Opportunity” in Triangle)
  - Detect Identity Theft in Early Stages
    - Intervene Before Employee Breaks the Law

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**Walk through examples, then hands on**

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**Attestation of User Access Rights**

Manager: ZEBRA, ZACKARY

**Access Rights Grouped by User**

Worker	Department	Title	Application	Access Level
ALFA, ALICE	Inpatient	RN	BILLING	3
			Data Warehouse	1
			EHR	2
			FINANCE	2
			HR	4
ALPHA, ALPHA	Inpatient	RN	Imaging	4
			Pediatrics	1
			Scheduling	3
			EHR	4
			Imaging	5
BETA, BETA	Inpatient	RN	Pediatrics	6
			Scheduling	4
			EHR	4
			Imaging	5
			Pediatrics	6
BRAVO, BETTY	Inpatient	RN	Scheduling	4
			EHR	3
			FINANCE	3
			HR	5
			Imaging	5
CHARLIE, CHARLIE	Inpatient	RN	Pediatrics	2
			Scheduling	4
			EHR	4
			Imaging	4
			Pediatrics	6

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- What Rights are Inappropriate?
- Insufficient context for manager to make an informed decision

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**Attestation of User Access Rights**

Manager: ZEBRA, ZACKARY

**Access Rights Grouped by Job Objective Peer Groups and by Application**

Application	Worker	Department	Title	Access Level		
BILLING	ALFA, ALICE	Inpatient	RN	3		
	BRAVO, BETTY	Inpatient	RN	3		
	DELTA, DEBBIE	Inpatient	RN	3		
	ECHO, EDWARD	Inpatient	RN	3		
	FOXTROT, FRANK	Inpatient	RN	3		
	GAMMA, GEORGE	Inpatient	RN	3		
	KILO, KAREN	Inpatient	RN	3		
	Data Warehouse	ALFA, ALICE	Inpatient	RN	1	
		EHR	ALFA, ALICE	Inpatient	RN	2
			BRAVO, BETTY	Inpatient	RN	2
DELTA, DEBBIE			Inpatient	RN	2	
ECHO, EDWARD			Inpatient	RN	2	
FOXTROT, FRANK			Inpatient	RN	2	
GAMMA, GEORGE			Inpatient	RN	2	
KILO, KAREN			Inpatient	RN	2	
FINANCE			ALFA, ALICE	Inpatient	RN	2
			BRAVO, BETTY	Inpatient	RN	2
	DELTA, DEBBIE		Inpatient	RN	2	
	ECHO, EDWARD	Inpatient	RN	2		
	FOXTROT, FRANK	Inpatient	RN	2		
	GAMMA, GEORGE	Inpatient	RN	2		
	KILO, KAREN	Inpatient	RN	2		
	HR	ALFA, ALICE	Inpatient	RN	4	
		BRAVO, BETTY	Inpatient	RN	4	
		DELTA, DEBBIE	Inpatient	RN	4	
ECHO, EDWARD		Inpatient	RN	4		
FOXTROT, FRANK		Inpatient	RN	4		

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- Groups of workers who have the same job objective
- Truly similar as opposed to grouping by title or department
- What Rights are Inappropriate?

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**User Access Rights Review**

Manager: ZEBRA, ZACKARY

Application: (All)

JOPG: (All)

**Access Rights Grouped by User**

Are they all true peers? What is inappropriate?

Access Level	Worker	Department	Title	Scheduling	Pediatrics	Imaging	HR	FINANCE	EHR	Data Warehouse	BILLING
Blank	ALFA, ALICE	Inpatient	RN	3	1	1	4	4	2	1	2
	ALPHA, ALPHA	Inpatient	RN	4	6	5			4		
	BETA, BETA	Inpatient	RN	4	6	5			4		
	BRAVO, BETTY	Inpatient	RN	4	2	1	5	5	3		3
	CHARLIE, CHARLIE	Inpatient	RN	4	6	5			4		
	DELTA, DEBBIE	Inpatient	RN	4	2	2	5	5	3		3
	DELTA, DELTA	Inpatient	RN	4	6	5			4		
	ECHO, EDWARD	Inpatient	RN	4	2	2	5	5	3		3
	ECHO, ECHO	Inpatient	RN	4	6	5			4		
	FOXTROT, FRANK	Inpatient	RN	4	2	2	5	5	3		3
	FOXTROT, FOXTROT	Inpatient	RN	4	6	4			3		3
	GAMMA, GEORGE	Inpatient	RN	4	2	2	5	5	3		3
	GOLF, GOLF	Inpatient	RN	4	6	5			4		4
	KILO, KAREN	Inpatient	RN	4	2	2	4	5	3		3

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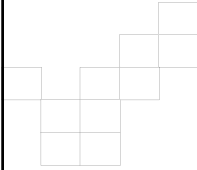
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**Immediately Address  
IT Access Compliance Challenges  
with These Techniques,  
Using Tools You Already Have**

Alan Norquist & John Vastano  
anorquist@veriphys.com  
jvastano@veriphys.com  
www.VERIPHYR.com

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# EMR, CTMS and the Clinical Trial Billing Audit

## How Tools Can Help You As An Internal Auditor

**Cynthia Lawson, BS, CHRC, CPC**

Consultant, Kelly Willenberg & Associates

**Kelly M. Willenberg, DBA, MBA, BSN, CCRP, CHRC, CHC**

Owner, Kelly Willenberg & Associates

HCCA Compliance Institute

March 26-29, 2017

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## Objectives

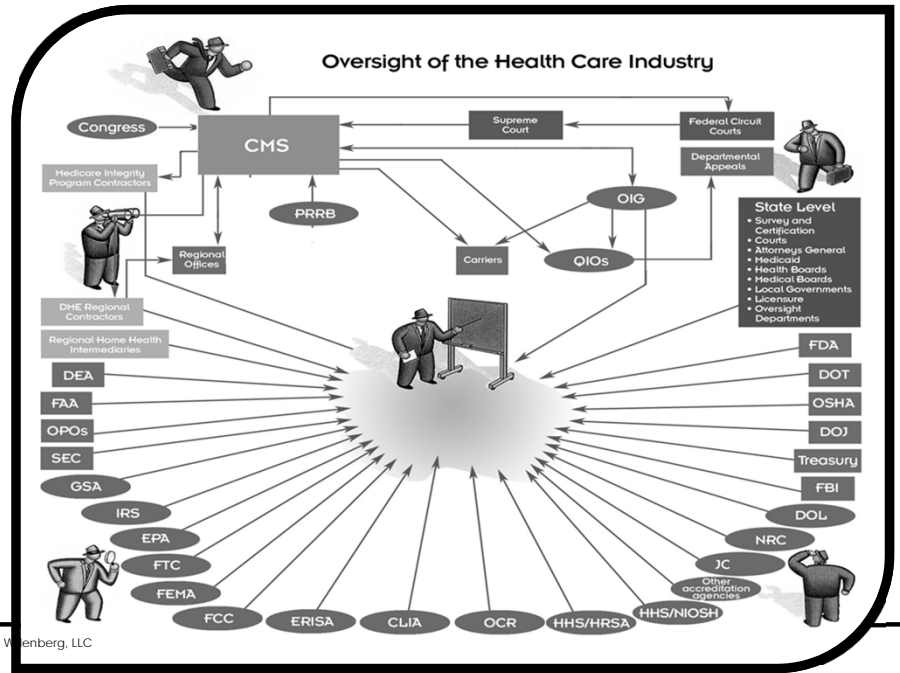
- ▶ EMR and billing audits
- ▶ CTMS and billing audits
- ▶ Clinical trial review and revenue cycle integrity

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## Healthcare Regulatory Environment



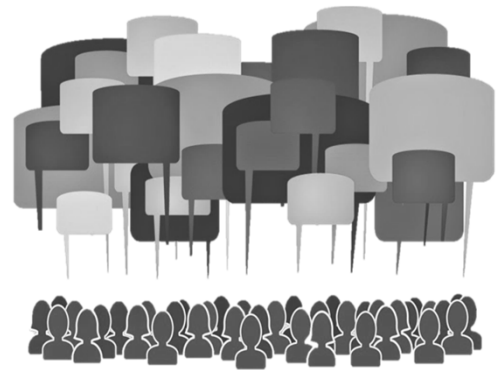
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## Clinical Trial Billing Village

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Project Accounting/Grant administration
- Health Information Management/IT
- Registration/Scheduling/Authorizations/Denials
- Medical center billing and coding
- Physician professional fee billing and coding
- Offsite facilities providing Clinical Trial services
- Managed care contract negotiators
- Others



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## Risk Assessments and Audits

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## What Does Effective Mean?

- Federal Sentencing Guidelines standard –

1. The organization exercises due diligence to prevent and detect inappropriate conduct by the Medicare & Medicaid provider;
2. The organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and
3. The compliance program is reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.

Failure to prevent or detect specific offenses does not necessarily mean that the program is not generally effective in preventing and detecting such conduct.

Federal Sentencing Guidelines amendment effective 11/1/2010 Section 8B2.1(a)

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## Auditing and Risk Analysis

- An audit begins with risk analysis
  - Identify institutional priorities – could be from special concerns
  - Assess system and user groups for weak links
  - Seek agreement of higher administration
- Select audit elements in relation to risk analysis
  - Prepare and plan for each sub-set of the audit
  - Consider potential sub-sets: complex studies? easy-to-correct studies? biggest billers? a particular document/stage of process? a particular department or investigator?
  - Evidence of flawed system?
- Design audit documents to reflect audit elements

## Risk Analysis Can Prevent

- Billing for services that have been provided free by the sponsor
- Billing for services that have been promised free in the Informed Consent
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial (this is a complicated issue)
- Billing for device trials without CMS centralized review and approval
- Billing Medicare Advantage plans for drug studies

## Risk Assessment Response

- Responsible parties should identify the procedures for responding and mitigating risk uncovered based on risk assessment
- Consult compliance, counsel, or consultants when addressing assessment/audit findings to determine the proper course of action to mitigate findings
- Establish reasonable and achievable standards for making enhancements and/or supporting change needed to address risk assessment/audit results
- Correct deficiencies, address opportunities, and mitigate the events identified through assessment/auditing

## Risk Assessment Response

- Test charge capture, segregation of charges and bill review methods for research related services and regularly select a sample of protocols and participants and trace a sample of bills through the process continuum to identify where (if any) control weaknesses may exist
- Keep an account of lost revenue both on payer side and in research
- Keep an account of residual balances and follow institutional policy
- Ensure your Coverage Analyses are being properly reviewed, approved and utilized
- Ensure healthy communication avenues exist between departments relative to research, avoid siloes
- Review CTMS system for maximum efficacy and ensure integration with billing system if available
- Optimize tracking process from registration forward for clinical trial participants
- Test process for resolving billing inquiries
- Ensure operating procedures include billing compliance responsibilities so it is clear who is responsible.

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## Consequences of Non-Compliance

- ▶ Loss of community trust and reputation
- ▶ Potential loss of federal grant funding
- ▶ Potential loss of participation in Medicare/Medicaid
- ▶ Fines and penalties
- ▶ Enforcement actions and fines
- ▶ Corporate Integrity Agreements
- ▶ Lost revenue both on payer side and in research
- ▶ Staff time lost on correcting billing errors
- ▶ Residual balances

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## Measuring Success

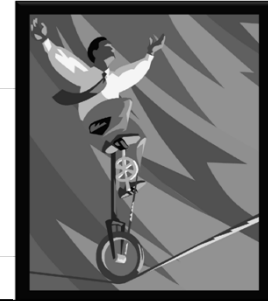
- ▶ How effective are you?
  - ▶ Are you asking the right questions?
  - ▶ Are you documenting these questions?
  - ▶ Are you the sought after subject matter expert within organization?
  - ▶ Do you step outside of your comfort zone?
- ▶ Internal scorecard for Compliance
- ▶ Feedback from external audits
- ▶ Number/ amounts of re-payments
- ▶ Transparency as an organizational culture

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## Ignorance is Not Bliss

- ▶ For identified risk, exposure or non-compliance, possessing the information puts the institution at risk
- ▶ Knowing of non-compliance and not acting to mitigate the event also adds to the risk exposure



## Why Auditing is Important

- ▶ Properly directed, internal audit programs can help an organization stay focused and uncover educational opportunities
- ▶ Clinical trials billing is an area of considerable complexity, uncertainty, and curiosity
- ▶ Move beyond collecting findings to providing insight
  - ▶ Collect complaints or feedback from audit program "customers"
  - ▶ Understand the objectives of the stakeholders who "own" the process being audited
  - ▶ Identify and report completed corrective actions
  - ▶ Verify improvements and train



## An Effective Audit Plan

- Is an educational activity
- Promotes understanding of errors found
- Effectively uses resources
- Raises standards of billing compliance in clinical trials through overall revenue integrity
- Prompts change
- Provides a source of truth in the information
- Reacts to problem areas in clinical trial billing
- Provides sources of information and educational moments
- Ensures that all study accounts are debited for research-related tests and procedures and bill third party payers for routine costs

## How to Get Buy-in for Auditing

- Requiring operation teams' self monitor allows greater wider and deeper compliance assurance
  - Stakeholders (CR teams, billing team, IRB, sponsored projects office) working separately cover lots of ground
  - Whenever possible, compare notes to prevent conflict of approaches, to ensure results reach relevant parties
  - Set schedule for collaboration of different primary stakeholders
- Compliance office(r) should also plan for self-monitoring
  - Review billing compliance for completeness
  - Target hottest spots or biggest risk areas

## Audit Types

- ▶ Retrospective – after billing
  - ▶ Advantages: Simple, documentation is complete, refined sample
  - ▶ Disadvantages: Processing findings, may not be timely, billing adjustments may be required
  
- ▶ Prospective – before billing
  - ▶ Advantages: Timely, avoid billing adjustments
  - ▶ Disadvantages: May hold up billing, sample may be limited
  - ▶ More difficult to complete

## Audit Timing

- ▶ Retrospective – after claim is submitted and reimbursed
  - ▶ Advantages: Simple, documentation is complete, refined sample
  - ▶ Disadvantages: Processing findings may not be timely, billing adjustments may be required which can lead to alerting the payers of issues
  
- ▶ Prospective – before claim is submitted
  - ▶ Advantages: Timeliness, avoids billing adjustments
  - ▶ Disadvantages: May hold up billing, sample may be limited

## Audit Elements

- Once the elements of an audit are determined, and higher administration has agreed, the percentage of X to audit must be determined.
  - Generally, audit percentage for adequate representation is minimum of 10%
  - Depending upon resources and volume of studies, more or less may be necessary
  - Some audit elements may not be conducive to representation percentage
    - Flawed system element
    - Audit for cause or special concern

## Audit Process

- Set up schedule of rotation of audit (by department, by doctor, by highest accrual?)
- Contact study teams and department; provide schedule (and document templates?)
  - Pre-audit meeting: document request, questions answered
  - Audit (Was it routine? For cause? Or started with earlier with issue?)
  - Draft for Discussion Purposed Only with Key Leaders
  - Corrections due date
- Final audit review
- Final audit meeting, with corrective action plan for systemic error
- Follow schedule; follow documents

## Areas for Compliance Attention

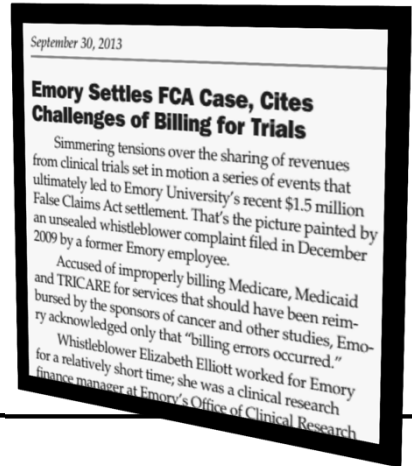
- Software and technology
- Financial operations including billing compliance
- Clinical operations intersect with financial
- Human subject protection
- Coordinating, collaborating and communicating with physicians

## Areas of Risk and Why

Area of Risk	Why this is a Risk
Budget development and approval	Lack of consistency
Registration of research subjects	Lack of subject tracking mechanism, billing errors
Charge capture/billing for research related services	No process for tracking or reporting
Document Concordance	Inconsistent documents lead to billing errors
Process for resolving billing inquiries	Follow through not performed

## Areas to Watch

Inadequate financial accounting	Poor budget process, lack of proper accounting and invoicing to Sponsors
Research subjects not identified	Claims lack proper research coding, dx, modifiers, CCs, and NCT # on claim
Charge capture/billing for research related services and routine costs, study drugs & devices	Charge segregation occurring between research and payer or Medicare and Medicare Advantage
No monitoring of billing inquiries	Communication on denials management not thorough or lack of attention to detail



## Suggested Focus Areas

- Medicare Secondary Payer/Other Insurance Coverage
- Documentation of visit with orders
- Hospital Outpatient, Ambulatory Surgery Centers
- Coding of Evaluation and Management Services
- EHR cookie-cutter medical history
- Payments for Evaluation and Management Services
- Evaluation and Management Services during Global
- Test done prior to consent
- Excessive Payments for Diagnostic Tests (Medical Necessity)
- Medicare Billings without research modifiers then research is clearly occurring

## Before You Begin Your Audit

- ▶ Understand your institution
  - ▶ Risk tolerance
- ▶ Know your research universe
  - ▶ All legal entities involved
- ▶ Know how to find all the studies
- ▶ Know how to find all the study-related documents
  - ▶ Protocol, CTA/budget, Coverage analysis, Informed Consents, research order forms or alerts, summary of sponsor payment
- ▶ Know how to find all the study subjects
- ▶ Know how to get to all the bills (tech and pro), EOBs, external vendor invoices

## The Process Tools

- ALL Claims – BOTH Technical and Professional
- Claims BEFORE the Informed Consent Date and Inclusive up to the Current Date of the Audit
- The EOBs
- Codes, Modifiers, CC's, Drugs, Devices, and NCT#'s on claims
- Medicare Advantage
- Coverage Analysis
- Grant/Budget Reconciliation

## What Documents Do I Need?

- Select a sample of two to three research participants for each of the selected clinical trials
- For each clinical trial, collect all versions of:
  - CTA, budget
  - Coverage analysis (CA)
  - Research Protocol, may not be needed if the CA is verified to match the Protocol
  - Informed consent form (ICF) , may not be needed if the CA is verified to match the ICF

## The Sample

- Select a sample of 2 to 3 research participants for each of the clinical trials selected for testing
  - For each patient, you need:
    - UB-04 (i.e., CMS 1450), CMS 1500, EOB, any billing activity
      - Revenue accounting from Sponsor
  - On and off study dates and study calendar with visit dates
  - Verification whether the participant is a screen failure
  - Signed informed consent
  - Medical Record

## IT Systems Roundup

- Do an accounting of what you have
- IRB system if any
- Grants accounting and financials
- Payroll
- Clinical Trial Management System (CTMS) used for patient and administrative tracking
- Professional billing system
- Facility billing system

## Utilize Tools You Currently Have

- ▶ Understanding legacy systems and how they can help or hurt
- ▶ CTMS
  - ▶ Use a CTMS to better enhance your patient management, financial management and billing compliance management
- ▶ EMR
  - ▶ EPIC, Cerner, Meditech, GE Centricity, Athena, ARIA, MOSAIQ, NextGen, Allscripts and EClinicalWorks, McKesson



## Consequences of Not Utilizing Tools

- More costly IT and infrastructure bill annually in FTEs or consultants
- Overworked personnel leading to a decrease in organizational productivity
- Inability to solve problems quickly
- Loss of revenue across the spectrum of operations in clinical trials due to inefficient billing of payers and sponsors



## Preparing For a Billing Audit

## Findings Leading to an Audit

- Billing for services that have been provided free by the sponsor or promised free or invoiceable
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial (this is a complicated issue)
- Billing for device trials without M/C approval
- Billing Medicare Advantage Plans for drug studies

## Further Findings Leading to an Audit

- ▶ Physician Errors
  - ▶ Lack of a signed proper order for conventional care
  - ▶ Inadequate documentation of medical necessity for the item or service
  - ▶ Lack of documentation of study participation, as required
- ▶ Coding Errors
  - ▶ Billing without proper codes, modifiers, IDE # or NCT #
- ▶ Waiving/paying/reimbursing subject co-pay or deductible obligations

## Which Studies

- Studies with the most risk
  - All services paid for by the sponsor
  - Mixed visits with both research and conventional care
  - Inpatient studies
  - Studies with large number of patients enrolled
  - Studies with numerous visits
  - Studies with drugs/devices where there can be increased number of adverse events
  - Department with a large volume of studies
  - Investigator initiated with off label drugs
  - Problem PI

## Which Subjects

- Is there a central database with all subjects registered
- Does the billing system have a flag or an identifier where you can run a report
- Does the coordinator keep a spreadsheet
- Is there a CTMS where all information is stored
- Pull a report from the sponsor's EDC
- Screen failures

## The Coverage Analysis (CA)

*Systematic review of research related documents to determine the billing status of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study*

Based on thorough research, supported by industry guidelines which meet the “generally accepted in the medical community” standard and compliant with government regulations

## Billing Errors May Start with the Coverage Analysis

This Coverage Analysis is intended as a general guideline for use in determining which items and services are billable to a 3rd Party Payer. All items and services that are billable to a 3rd Party Payer must be supported by medical necessity.

Protocol Related Items and Services	CPT / HCPCS	Active Monitoring Phase										Comments and Justification	
		≤ 60 days prior to	At time of registration	Surgery	Adjuvant Chemotherapy	Radiation Therapy	Observation (6)	Year 1.5	Year 2.5	Year 3.5	Year 4.5		
CBC with Diff. & Platelets	85025	M											NCCN guidelines for Breast Cancer (v2.2015) state that CBC with differential and platelets is generally supported under NCCN guidelines. Medical records must document medical necessity.
Bilateral Mammogram	77056, 770561	M					M	M	M	M	M		NCCN guidelines for Breast Cancer (v2.2015) state that bilateral mammogram is supported during the work-up and surveillance period. Medical records must document medical necessity.
Bilateral MRI of Breasts	77059, A9952, 96374	M											NCCN guidelines for Breast Cancer (v2.2015) state that bilateral MRI is supported during the work-up period. May be used to define extent of cancer or presence of multifocal disease in the ipsilateral breast, or as screening of the contralateral breast, or as screening of the chest wall at the time of initial diagnosis (category 2B). There is evidence to demonstrate that the use of MRI to facilitate local control improves local recurrence or survival. Medical records must document medical necessity.
Biopsy of each suspicious breast lesion	88307, 88305, 19101, 19100, 19081, 19186	M											NCCN guidelines for Breast Cancer (v2.2015) state that biopsy of each suspicious breast lesion is supported during the work-up for breast cancer. Medical records must document medical necessity.
Optional research blood sample	36415, 36591, 36592, 99000		S										Research purposes only; bill to sponsor

## The Coverage Analysis

- Does the Coverage Analysis document credible sources, such as
  - National Guideline Clearinghouse – AHRQ / NIH
  - National Comprehensive Cancer Network
  - American College of Cardiology
  - JAMA, NEJM
  - Attestation of PI

### Does the Coverage Analysis

- Use the Protocol as foundation
- Record the services analysis on a billing grid
- Document the QCT analysis
- Cite sources
- CPTs and HCPCS?

## Billing Compliance Rules

- Routine Costs Analysis:
  - Items and Services that are
  - Ordinarily provided to beneficiaries and covered by Medicare
  - Typically provided absent a clinical trial (conventional care)
  - Required solely to administer the investigational drug
  - Provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item
  - Needed to deal with the diagnosis or treatment of complications.
- **Does not** include items and services that are:
  - Provided solely to satisfy data collection
  - Provided free of charge.
  - Statutorily excluded or for which there is non-coverage decision.

## Moving Towards Billing Compliance

- Identify governance & project management team
- Implement formal feasibility process to improve linear process in collaboration with Principal Investigators and impacted areas
- Ensure a complete Coverage Analysis (CA) is in place on all studies with billable items/service
- Always be audit ready!



## Identify Potential Risk Areas When Auditing

- ▶ Evaluation and management codes
- ▶ Medical necessity
- ▶ Documentation of referrals
- ▶ Designated health services
- ▶ Inadequately educated billers
- ▶ Insufficient documentation
- ▶ Use of incorrect codes or no modifiers
- ▶ Coding not supported by the medical record

## How Do Errors Occur?

- ▶ Technological errors: A “research flag” (i.e., unique study number, a hold on an encounter or claim, or some other indicator) is not recognized by information systems , not interfaced with all systems or not provided to outside vendors
- ▶ Human errors: Multitude of errors can occur
  - ▶ Registration or scheduling unaware of research participants
  - ▶ Technicians in ancillary service areas are unaware of trial
  - ▶ Work queue not handled appropriately

## Questions to ask Prior to Starting the Audit

- Protocol, all protocol amendments
- CTA, Budget, Coverage Analysis and ALL amendments
- Informed Consent, all versions
- Confirm anything that was provided by the Sponsor
- Patient records including visit dates
- System access (paper claims if not access available including EOBs)

## Obstacles to Auditing

- Clinical trials involve multiple departments that are not communicating
- EMR/Billing systems do not automatically manage research rules
- Lack of coordination and collaboration of the study intelligence
- Inability to distinguish research subjects and research-related services at the time of visit

## EMR

### Clinical Trial Billing Audits



## EMR Functionality

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Flagging patient

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Bill queue or hold

Medication and Problem Lists

Blinding of drug and other items/services

Break the Glass feature when necessary

Documentation of study events

CMS requirement of EMR medical record documentation

Helps with coding notification for billers

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Can assist with direction of charges

## Questions to Ask EMR Auditing

- Patient Master Index Level
  - Are study subjects identifiable at the patient level?
  - Is there an easy way to “flag” or “link” a patient to a research study at the patient level?
- Registration
  - Are study subjects identifiable in registration (or scheduling) systems?
  - Is there an easy way for check-in personnel to validate a patient’s status as a research participant?
  - Are all points of entry for your facility equipped to deal with various research patient scenarios?
- Medical Record Documentation and Ordering
  - Are CMS guidelines met?
  - Are JCAHO guidelines met?
  - Are visit names/#’s included in the notes?
  - Are orders entered appropriately?
  - Are notes copy/paste?

## Clinical Trial Required Documentation

### 69.3 - Medical Records Documentation Requirements (Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

CMS Claims Processing Manual,  
Chapter 32

Documentation that during this hospital stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied.

- There must be a signed consent form for clinical trial.
- There must be documentation on the signed consent form that during this hospital stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied.

**Specifications Manual for Joint Commission National Quality Measures (v2013A1)**

## Tracking Subjects

- CTMS
- Billing Systems
- Bill Hold or Sieve (Work Queue), Report
- The old fashioned way – by paper!

## Tracking Subjects By Digging Deeper

- Identify the patient electronically both in the Master Patient Index file (MPI) and by encounter
- Establish methodology for identifying patient when a research encounter is occurring
- Establish ability to order research related items or services that are both routine care and research related

## How Do EMR Errors Occur?

- Lack of a “research flag” (i.e., unique study number, a letter on an encounter form, or some other indicator)
- Examples:
  - Research participants are not identified
  - Registration or schedulers are not aware of the research participants
  - Lack of knowledge on EMR can do for research billing
  - Not building EMR customization for research documentation requirements
- Lack of documentation in medical record
- Lack of automation

# Clinical Trial Research Order Form

Date of Service: \_\_\_\_\_ Visit # / Cycle & Day: \_\_\_\_\_

Research Participant Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Research Participant MRN/MRUN: \_\_\_\_\_ Diagnosis: \_\_\_\_\_

Title: \_\_\_\_\_

Location of Ordered Services: (Place X)


PI: \_\_\_\_\_

IRB #: \_\_\_\_\_

Sponsor: \_\_\_\_\_

Protocol Number /Version: \_\_\_\_\_

Project #: \_\_\_\_\_

IND/IDE #: \_\_\_\_\_

ClinicalTrials.gov #: \_\_\_\_\_

Services listed below include all services identified by the research protocol for the clinical trial

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# Clinical Trial Research Order Form

Services Ordered	Procedures	CPT Code	Bill to Study	Services Ordered	Lab Services	CPT Code
<input type="checkbox"/>	Data Collection only - no protocol stipulated interventions			<input type="checkbox"/>		
<input type="checkbox"/>				<input type="checkbox"/>		

Note: All charges related to services provided for research related injury are to be forwarded to Study Team. Do not bill participant's insurance for research related injuries.

This document serves as an expense invoice if signed below. If you have questions regarding this form or need further assistance, please contact Study Team

Date/Time	Physician / Prescriber Signature	MD ID#
Date/Time	RN Signature/Print: Validation of Correct Transcription	

Date/Time	Read Back: <input type="checkbox"/> VO <input type="checkbox"/> TO
Date/Time	Initials:
Date/Time	12/24 Hour Chart Check RN Print/Initial

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## CTMS

Billing Compliance Audits

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## Advantages Of A CTMS

- Improves metrics
- Standardizes training
- Easier management of CRC workload
- Easier access to study data
- Provide benchmarking capability
- Assists with calendar build for billing compliance
- Enables a better way to track patient management
- Study financial tracking

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## Utilize a CTMS During An Audit

- ▶ Study Inventory
- ▶ Study Calendars
- ▶ Patient Inventory
- ▶ Patient Visit Tracking
- ▶ Budget and Contract Tracking

## Clinical Trial Review

Revenue Cycle integrity

Coverage Analysis Performed

Audit and Review

Budget with research pricing, Contract, Consent Review

## Clinical Trial Billing Process

Medicare, Medicaid, MAP and Commercial Payers

Subject Registration and Tracking

Charge Capture, Segregation, Research Pricing

Medical Documentation for Medical Necessity

# CLINICAL TRIAL BILLING PROCESS

### The Clinical Trial Billing Process Cycle

#### Coverage Analysis Review "Front End" Cycle

#### Document Review "Middle" Cycle

#### Patient On Study Review "Back End"

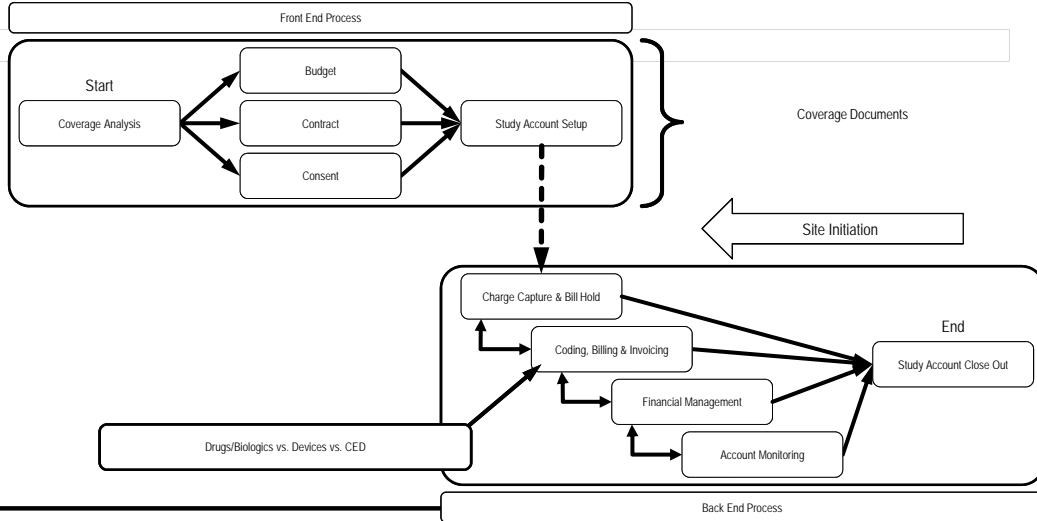


- Review protocol for feasibility
- Do a Qualifying Clinical Trial status
- Perform Coverage Analysis with validation
- Review draft budget, contract and consent
- National Guidelines for disease
- NCD's and LCD's review
- Review draft budget against CA
- Provide consent language based on CA

- Ensure Coverage Analysis guides other documents especially the consent language in the expected costs section
- Budget negotiation detailed to coverage analysis level
- Contract language matches financial piece and consent
- Consistency checklist confirming all pieces match in language prior final IRB approval
- Document review ends with final IRB approval and study start up

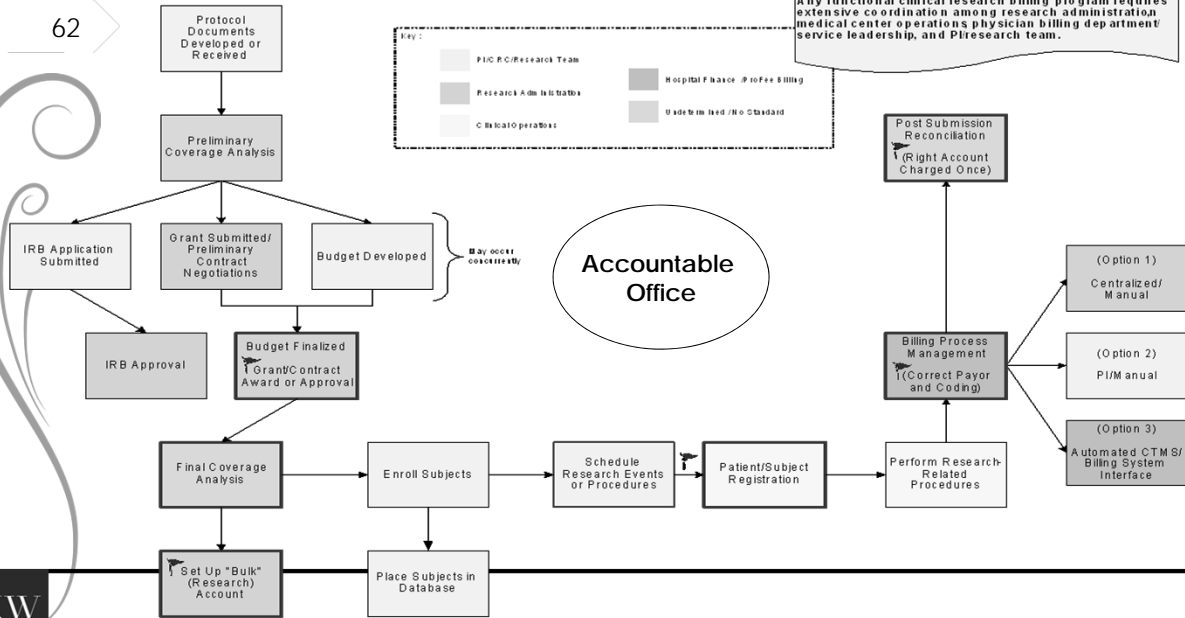
- Patient signs consent understanding financial implications
- Patient Flagged in billing systems
- Identification of Study Specific Visit
- Charge review against Coverage Analysis and medical documentation
- Coding rules applied
- NCT# applied
- Medicare Advantage review for drug clinical trials

# The Clinical Trial Revenue Continuum



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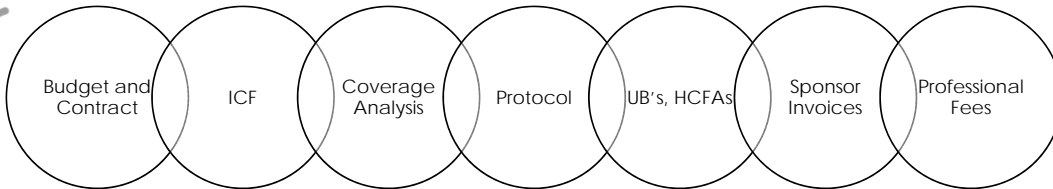
# Clinical Research Billing Process Flow



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## Fragmented Billing Information



## Hypothetical Scenario

	Total # of Claims Reviewed	# of Claims Billed To Correct Payer	# of Claims Billed to Incorrect Payer	Total Dollars in Overpayments	Claim Error Rate %
Medicare & Medicare Advantage	200	97	103	\$256,345.00	52%

## Operational Questions

- Master Patient Index Level
  - Encounter level vs MPI
- Registration and Scheduling
  - Are all points of entry for your facility equipped to deal with various research patient scenarios?
- Charge Capture
  - Who is entering charges?
  - Know you bill "scrub" system
  - Who is working the "queue"

## Revenue Cycle Impact

- Verify items charged to a payer on UB or 1500 agree with allowable items per the MCA
- Verify coverage analysis
  - Follow first patient through to look for missing items/services or coding
- Verify that bills match the revenue that was paid
  - Look for denials
  - Look for partial payments on remittances
- Calculate excess charges and then calculate excess reimbursement

## Medicare & Clinical Trials: Coding Concepts

- Clinical Trial Number – NCT# from [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Revenue Codes - Devices, Supplies, and Drugs
  - 0624 - Investigational Device
  - 0278 - Medical/Surgical Supplies: Other implants
  - 0256 - Investigational Drugs
- Condition Codes
  - 30 - Qualified clinical trial
  - 53 - Initial placement of a medical device provided as part of a clinical trial or a free sample
  - Diagnosis Code
  - ICD 10 - Z00.6 - Encounter for examination for normal comparison and control in clinical research program
- HCPCS Modifiers
  - Q0 - Investigational clinical service
  - Q1 - Routine clinical service

**Must have Medical Record Documentation:**  
 Trial name, trial sponsor & protocol number (assigned by sponsor)

## Routine Costs vs. Research

- Routine Costs
  - Ordinarily provided to beneficiaries and covered by Medicare
  - Typically provided absent a clinical trial (conventional care)
  - Provision of the investigational drug
  - Provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item
  - Diagnosis or treatment of complications
- Routine Costs do not include items and services that are:
  - Provided solely to satisfy data collection
  - Provided free of charge
  - Statutorily excluded or for which there is non-coverage decision

## Look at the Claims

### ► Charge Segregation

- Verify that the patient received the services per the clinical trial protocol
- With the Coverage Analysis as your guide, review orders and medical documentation
  - Verify that the charges for each item or service associated with conventional care were posted to the patient account
  - Verify that the charges for each item or service, including incidentals, considered “research related” were posted to the research account

## Check Bills for Appropriate Coding

- Diagnosis Code: Z00.6
- NCT #
- Condition Codes: 30 for QCT, 53 for devices provided at discount or free
- Modifiers:
  - The Centers for Medicare & Medicaid Services (CMS) has discontinued the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007.
  - Effective for dates of service on and after January 1, 2008, CMS has created the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services:
    - Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
    - Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.

## The Rules on Modifiers

- Depends on the type of claim
- Know when to use the IDE# and how to get it correctly on the claim
- Inpatient: No
  - Use Z00.6 (i.e., Examination of a participant in a clinical trial)
  - Condition Code 30 only. This indicates that you are working with a "qualified clinical trial." When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study
- Outpatient: Yes - Q1
  - Routine clinical service provided in a clinical research study that is in an approved clinical research study
  - Use it to identify routine services provided in the trial/study
- Outpatient: Yes - Q0
  - Investigational clinical item or service provided in a clinical research study that is in an approved clinical research study
  - Use it to designate the item or service under investigation in the trial/study

## What Else Should I Review?

- For conventional care procedures that are payable by Medicare but performed outside the normal allowable time limit, refer to the ICF to determine if they should be billed to a research participant's payor
- Verify items charged to a payer on UB-04 & 1500 agree with allowable items per the MCA
- Verify that bills match the revenue that was paid.
  - Look for denials and write offs
  - Look for partial payments on remittances.
- Calculate excess charges and calculate excess reimbursement received.

## The Final Step

- ▶ Look at the study accounts
- ▶ Confirm signed ICF is in medical record
- ▶ Confirm summary of protocol is in medical record

## The Clinical Trial Billing Plan and What to Avoid

- Billing for services paid for by the sponsor
- Split billing great
- Hospital bill and physician billing inconsistency
- Lack of reconciliation with sponsor payments
- Study teams not aware of denials or write offs
- No post-study analysis
- No communication, coordination and collaboration

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## Case Study

Clinical Trial Process Review - When is There Cause to Audit

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## Hospital Case Study to Analyze Hospital's Internal Process Review



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## Community Hospital with 200 Open Studies Open

- Oncology, neuro and cardiology largest areas of research
- No centralized office for billing compliance
- No staff identified to ensure that coding is being handled appropriately
- A report out of billing system shows limited Z00.6 on any claims although it is believed that about 800 patients are either on study with interventions, in follow up, or in registry studies

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## Review Active List to Prioritize Studies

- Verify items against consents that were promised at no charge
- Review coverage analysis against all other documents for consistency
- Validate study calendar against visits
- Review claims for proper coding
- Analyze reimbursement to determine if payback is warranted

KW

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## The Audit

- Talk to the people involved in the process
- Review protocol and schedule of events
- Review Coverage Analysis including Qualifying Status
  - If there is not a Coverage Analysis available, create one based on protocol, CTA/Budget and Informed Consent
  - If there is a Coverage Analysis, how robust is the documentation to support billing?
- Review Medical Records to ensure proper documentation for items and services determined to be “conventional care” or research only
- Verify subject received services that were billed and posted to the correct account – research or third party payer

## The Audit

- Verify claims that were submitted to Medicare or Medicare Advantage were properly coded with research codes and modifiers including the clinicaltrials.gov number
- Verify claims for drug studies were redirected to Medicare for Medicare Advantage subjects
- Verify that there is corresponding professional fee claim for every technical fee claim where appropriate
- Verify that ancillary charges for an item or service that should be billed to a sponsor are posted to the appropriate study account
  - Example – sedation for MRI in pediatric study or BUN/Cr for a contrast-enhanced CT or pathology for a Bone Marrow Biopsy

## The Audit

- ▶ Look for denials or partial payments
  - ▶ There may be Local Coverage Determinations that were not accounted for when the study was started
  - ▶ Also important in drug studies
- ▶ Look at study accounts in relation to the budgets and reconciliation
  - ▶ Check for high residuals
- ▶ Confirm that a signed copy of the ICF is in the Medical Records and in the pharmacy records if study drug is being used

## Findings from Review

- Billing had occurred for services paid for by the sponsor, promised at no costs or listed as an invoiceable with some patients getting the service for free
- Split billing not done for Medicare Advantage Patients on drug trials
- Lack of consistency between hospital bill and physician bill
- Lack of reconciliation with sponsor payments
- Study teams not aware of denials
- Lack of any type of post-study analysis
- Lack of medical necessity in medical records

## Lessons From the Audit

- ▶ There must be structure
  - ▶ Coverage Analysis for all studies regardless of sponsor MUST be completed, available and updated as studies are amended
  - ▶ Study-related documents should be stored in such a way that they are immediately retrievable
  - ▶ There must be a way to easily identify research subjects
    - ▶ Patient level flags
    - ▶ Visit level flags
    - ▶ Subject registration with different plan codes
    - ▶ CTMS and EMR
  - ▶ Monitoring and Auditing need to be ongoing processes
    - ▶ Errors can be difficult to eradicate

## Billing Compliance

- ▶ Financial and compliance risks must be considered
- ▶ Quality measures must be taken and reviewed by institution
- ▶ Understand that clinical trial billing is complex and must be a priority



## Summary

- ▶ To successfully conduct a Clinical Trial Billing audit, prior planning is essential
- ▶ Understand that the process can be long and it is not possible to do overnight
- ▶ Auditors must know all the billing rules in addition to the institutional policies
- ▶ The audit results can be used to enhance process improvement efforts

## Verify Improvements and Train

Training Objectives To Target Weaknesses

## Training

- ▶ Develop a research compliance curriculum for
  - ▶ Investigators
  - ▶ Coordinators
  - ▶ Billing personnel
  - ▶ Coverage analysts
  - ▶ Financial analysts
  - ▶ Coding team
- ▶ Develop standard policies and procedures and train as they are amended

## QUESTIONS?

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**KELLY WILLENBERG**  
**& ASSOCIATES**  
RESEARCH. COMPLIANCE. CONSULTING.



# SCREENING

## HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA <input type="checkbox"/>										PICA <input type="checkbox"/>														
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>										1a. INSURED'S I.D. NUMBER (For Program in Item 1)														
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5. PATIENT'S ADDRESS (No., Street)										6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>														
CITY					STATE					7. INSURED'S ADDRESS (No., Street)					CITY					STATE				
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b. RESERVED FOR NUCC USE										b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____														
c. RESERVED FOR NUCC USE										c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>														
d. INSURANCE PLAN NAME OR PROGRAM NAME										10d. CLAIM CODES (Designated by NUCC)														
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SIGNED _____ DATE _____										a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>														
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.										15. OTHER DATE MM DD YY QUAL.														
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE										16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY														
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A. _____ B. <u>Z00.6</u> C. _____ D. _____										23. PRIOR AUTHORIZATION NUMBER _____														
E. _____ F. _____ G. _____ H. _____										24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EPSCOT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #														
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					Dr. A					a. NPI					b. NPI									

CARRIER  
PATIENT AND INSURED INFORMATION  
PHYSICIAN OR SUPPLIER INFORMATION



# SCREENING

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APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

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CARRIER  
PATIENT AND INSURED INFORMATION  
PHYSICIAN OR SUPPLIER INFORMATION



# SCREENING

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				b. MED. REC. #															
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8 PATIENT NAME		a		9 PATIENT ADDRESS		a													
b				b		c		d		e									
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b																			
c																			
d																			

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63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME			
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74 PRINCIPAL PROCEDURE CODE		a. OTHER PROCEDURE CODE		b. OTHER PROCEDURE CODE		75		76 ATTENDING NPI		QUAL	
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C1D1

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA [ ] [ ] [ ] [ ] PICA [ ] [ ] [ ] [ ]

1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK LUNG <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	
CITY	STATE	7. INSURED'S ADDRESS (No., Street)	
ZIP CODE	TELEPHONE (Include Area Code) ( )	CITY	STATE
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>		b. OTHER CLAIM ID (Designated by NUCC)	
c. INSURANCE PLAN NAME OR PROGRAM NAME		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

SIGNED \_\_\_\_\_ DATE \_\_\_\_\_

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.	15. OTHER DATE MM DD YY QUAL.	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. _____	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY
17b. NPI _____		20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		22. RESUBMISSION CODE _____ ORIGINAL REF. NO. _____
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. _____		23. PRIOR AUTHORIZATION NUMBER _____
A. _____	B. <u>Z00.6</u>	
E. _____	F. _____	
I. _____	J. _____	

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. EPSCOT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 01 03 17			G0463 Q1	2				NPI	
2								NPI	
3								NPI	
4								NPI	
5								NPI	
6								NPI	

25. FEDERAL TAX I.D. NUMBER	SSN EIN [ ] [ ]	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>	28. TOTAL CHARGE \$	29. AMOUNT PAID \$	30. Rsvd for NUCC Use
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)		32. SERVICE FACILITY LOCATION INFORMATION		33. BILLING PROVIDER INFO & PH # ( )		
SIGNED _____ DATE _____		a. NPI	b. _____	a. NPI	b. _____	

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

# C1D3 - ARM B

1		2		3a PAT. CNTL #		4 TYPE OF BILL																		
				b. MED. REC. #																				
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH																
8 PATIENT NAME				9 PATIENT ADDRESS																				
b				b				c		d		e												
10 BIRTHDATE		11 SEX	12 DATE		ADMISSION 13 HR 14 TYPE 15 SRC		16 DHR		17 STAT		18		19		20		21		CONDITION CODES 22 23 24 25 26 27 28		29 ACDT STATE		30	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 CODE		OCCURRENCE SPAN FROM		THROUGH		36 CODE		OCCURRENCE SPAN FROM		THROUGH		37				
a		b		c		d		e		f		g		h		i		j		k		l		
38		39 CODE		VALUE CODES AMOUNT		40 CODE		VALUE CODES AMOUNT		41 CODE		VALUE CODES AMOUNT												
a		b		c		d		e		f		g		h		i		j		k		l		
D4		012345		67																				

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	OFFICE VISIT	G0463Q1	010317				
2	CHEMO ADMIN INITIAL	96413Q1	010517				
3	CHEMO ADMIN, ADDL HR	96415Q1	010517				
4	DRUG #2	J9045Q1	010517				
5	DRUG #3	J9264Q1	010517				
6							
7							
8							
9							
10							
11							
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21							
22							
23							
PAGE ____ OF ____			CREATION DATE	TOTALS			

50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ASG. BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI											
MEDICARE ADVANTAGE												57 OTHER PRV ID											
58 INSURED'S NAME		59 P.REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.															
63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME															
66 DX		67		A		B		C		D		E		F		G		H		I		68	
69 ADMIT DX		70 PATIENT REASON DX		a		b		c		71 PPS CODE		72 ECI		a		b		c		73			
74 PRINCIPAL PROCEDURE CODE		DATE		a. OTHER PROCEDURE CODE		DATE		b. OTHER PROCEDURE CODE		DATE		75		76 ATTENDING NPI		QUAL				LAST		FIRST	
c. OTHER PROCEDURE CODE		DATE		d. OTHER PROCEDURE CODE		DATE		e. OTHER PROCEDURE CODE		DATE				77 OPERATING NPI		QUAL				LAST		FIRST	
80 REMARKS		81CC a												78 OTHER NPI		QUAL				LAST		FIRST	
		b																					
		c												79 OTHER NPI		QUAL				LAST		FIRST	
		d																					

# C2D3 - ARM B

1		2		3a PAT. CNTL #		4 TYPE OF BILL	
				b. MED. REC. #			
				5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM	
						7 THROUGH	
8 PATIENT NAME			9 PATIENT ADDRESS				
a			a				
b			b			c	
b			d			e	
10 BIRTHDATE		11 SEX		12 DATE		ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR	
						17 STAT 18 19 20 21	
						CONDITION CODES 22 23 24 25 26 27 28 29 ACDT STATE 30	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE	
CODE		CODE		CODE		CODE	
a		a		a		a	
b		b		b		b	
35 OCCURRENCE SPAN FROM THROUGH				36 OCCURRENCE SPAN FROM THROUGH			
CODE				CODE			
a				a			
b				b			
38				39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT	
				CODE		CODE	
				a		a	
				b		b	
				c		c	
				d		d	

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	CHEST X-RAY	71020	020217				1
2	VENIPUNCTURE	36415	020217				2
3	CBC	85025	020217				3
4							4
5							5
6							6
7							7
8							8
9							9
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11							11
12							12
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21							21
22							22
23							23

PAGE \_\_\_\_ OF \_\_\_\_ CREATION DATE TOTALS

50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI	
A MEDICARE ADVANTAGE										57 OTHER PRV ID	
B										C	
C											
58 INSURED'S NAME			59 P.REL.	60 INSURED'S UNIQUE ID			61 GROUP NAME		62 INSURANCE GROUP NO.		
A									A		
B									B		
C									C		
63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME			
A								A			
B								B			
C								C			

66 DX		67		Z00.6		B		C		D		E		F		G		H		68	
A		I		J		K		L		M		N		O		P		Q		C	
69 ADMIT DX		70 PATIENT REASON DX		a		b		c		71 PPS CODE		72 ECI		a		b		c		73	
A																				A	
B																				B	
C																				C	
74 PRINCIPAL PROCEDURE CODE		a. OTHER PROCEDURE CODE		b. OTHER PROCEDURE CODE		75		76 ATTENDING NPI		QUAL		LAST		FIRST		77 OPERATING NPI		QUAL		LAST	
c. OTHER PROCEDURE CODE		d. OTHER PROCEDURE CODE		e. OTHER PROCEDURE CODE				78 OTHER NPI		QUAL		LAST		FIRST		79 OTHER NPI		QUAL		LAST	
80 REMARKS		81CC a		b		c		d													



# FINAL VISIT

## HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA <input type="checkbox"/>										PICA <input type="checkbox"/>														
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>										1a. INSURED'S I.D. NUMBER (For Program in Item 1)														
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)										3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>														
5. PATIENT'S ADDRESS (No., Street)										6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>														
CITY					STATE					7. INSURED'S ADDRESS (No., Street)					CITY					STATE				
ZIP CODE					TELEPHONE (Include Area Code) ( )					ZIP CODE					TELEPHONE (Include Area Code) ( )									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										10. IS PATIENT'S CONDITION RELATED TO:														
a. OTHER INSURED'S POLICY OR GROUP NUMBER										a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>														
b. RESERVED FOR NUCC USE										b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____														
c. RESERVED FOR NUCC USE										c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>														
d. INSURANCE PLAN NAME OR PROGRAM NAME										10d. CLAIM CODES (Designated by NUCC)														
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.										11. INSURED'S POLICY GROUP OR FECA NUMBER														
SIGNED _____ DATE _____										a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>														
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. _____										b. OTHER CLAIM ID (Designated by NUCC)														
15. OTHER DATE MM DD YY QUAL. _____										c. INSURANCE PLAN NAME OR PROGRAM NAME														
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE										d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.														
17a. _____										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.														
17b. NPI _____										SIGNED _____														
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)										16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY														
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. _____										18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY														
A. _____ B. <u>Z00.6</u> C. _____ D. _____										20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____														
E. _____ F. _____ G. _____ H. _____										22. RESUBMISSION CODE _____ ORIGINAL REF. NO. _____														
I. _____ J. _____ K. _____ L. _____										23. PRIOR AUTHORIZATION NUMBER _____														
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER										F. \$ CHARGES G. DAYS OR UNITS H. EPSCOT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #														
1 08 01 17 08 01 17 71260 Q1 2										NPI														
2										NPI														
3										NPI														
4										NPI														
5										NPI														
6										NPI														
25. FEDERAL TAX I.D. NUMBER					SSN EIN <input type="checkbox"/>					26. PATIENT'S ACCOUNT NO.					27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)										28. TOTAL CHARGE \$														
SIGNED _____ DATE _____										29. AMOUNT PAID \$														
32. SERVICE FACILITY LOCATION INFORMATION										30. Rsvd for NUCC Use														
a. NPI										b. NPI														
33. BILLING PROVIDER INFO & PH # ( )										a. NPI														
										b. NPI														

CARRIER  
PATIENT AND INSURED INFORMATION  
PHYSICIAN OR SUPPLIER INFORMATION

# FINAL VISIT

1		2		3a PAT. CNTL #		4 TYPE OF BILL																	
				b. MED. REC. #																			
5 FED. TAX NO.				6 STATEMENT COVERS PERIOD FROM		7 THROUGH																	
8 PATIENT NAME		a		9 PATIENT ADDRESS		a																	
b				c		d																	
10 BIRTHDATE		11 SEX		12 DATE		ADMISSION 13 HR 14 TYPE 15 SRC 16 DHR		17 STAT		18		19		20		21		CONDITION CODES 22 23 24 25 26 27 28		29 ACCT STATE		30	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 CODE		OCCURRENCE SPAN FROM		THROUGH		36 CODE		OCCURRENCE SPAN FROM		THROUGH		37			
a		b		c		d		e															
38		39 CODE		VALUE CODES AMOUNT		40 CODE		VALUE CODES AMOUNT		41 CODE		VALUE CODES AMOUNT											
a		D4																					
b																							
c																							
d																							

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	CT	7126026Q1	080117				1
2	CONTRAST	Q9967Q1	080117				2
3							3
4							4
5							5
6							6
7							7
8							8
9							9
10							10
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23							23

PAGE \_\_\_\_ OF \_\_\_\_ CREATION DATE TOTALS

50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI	
MEDICARE ADVANTAGE										57 OTHER PRV ID	
58 INSURED'S NAME		59 P.REL.	60 INSURED'S UNIQUE ID			61 GROUP NAME		62 INSURANCE GROUP NO.			
63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME			

66 DX		67		200.6		B		C		D		E		F		G		H		68	
69 ADMIT DX		70 PATIENT REASON DX		a		b		c		71 PPS CODE		72 ECI		a		b		c		73	
74 PRINCIPAL PROCEDURE CODE		DATE		a. OTHER PROCEDURE CODE		DATE		b. OTHER PROCEDURE CODE		DATE		75		76 ATTENDING NPI		QUAL					
														LAST		FIRST					
c. OTHER PROCEDURE CODE		DATE		d. OTHER PROCEDURE CODE		DATE		e. OTHER PROCEDURE CODE		DATE				77 OPERATING NPI		QUAL					
														LAST		FIRST					
80 REMARKS		81CC a												78 OTHER NPI		QUAL					
		b												LAST		FIRST					
		c												79 OTHER NPI		QUAL					
		d												LAST		FIRST					

# DRAFT

## M12-895

### A Randomized, Phase 2 Study of the Efficacy and Tolerability of Veliparib in Combination with Temozolomide or Veliparib in Combination with Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Subjects with BRCA1 or BRCA2 Mutation and Metastatic Breast Cancer

This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.

#### Study Identifying Information and Documents Received

Identifier	Information
Please list the Principal Investigator's (PI) Name:	Jane Dilys Skelton, M.D.
Please list protocol version and/or date:	Clinical Study Protocol M12-895; Amendment 1 18 September 2014 and Administrative Change 2 dated 12 October 2016
Please list the NCT (ClinicalTrials.gov) #:	NCT01506609
Please list the Sponsor:	AbbVie Inc.
Please list any additional funding sources:	N/A
Please list the Institutional Review Board (IRB) #:	SCHULMAN IRB #201105761
What is the version and/or date of the Main IRB approved Informed Consent Form (ICF)?	SCHULMAN APPROVED; DATE: November 5, 2015
What is the status / version and/or date of the Clinical Trial Agreement or Grant?	Executed Agreement with Budget 1/4/2012
What is the version and/or date of the sponsor budget?	Executed Agreement with Budget 1/4/2012
What is the version and/or date of the internal budget? (Grant applications)	Not provided
Please list the version of the Investigational Drug/Device Brochure:	Not provided
Additional Documents:	None
Is this a drug, device, or "other" study?	Drug Study (Proceed to QCT & Coverage Support Tab)

#### Notes:

Conditional payment clause on page 25 of the ICF, "The sponsor, AbbVie, may pay a portion of denied insurance claims not covered by your health plan for regular medical care related to the study."

**DRAFT**

**M12-895**

**A Randomized, Phase 2 Study of the Efficacy and Tolerability of Veliparib in Combination with Temozolomide or Veliparib in Combination with Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Subjects with BRCA1 or BRCA2 Mutation and Metastatic Breast Cancer**

**This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.**

**Investigational Item or Service Analysis**

Question	Answer
What is the name of the investigational item?	Veliparib
What is the FDA status of the investigational item?	Investigational
If FDA approved, is the investigational item being used off-label?	No
Is this study required by Medicare as a part of the "Coverage with Evidence Development" process? <small><a href="http://cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html">http://cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html</a></small>	No

**Qualifying Clinical Trial Analysis**

Requirement	Yes	No	Comment
Does the investigational item or service fall into a Medicare benefit category?  Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).	X		Drugs and Biologicals
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?	X		The primary objective of the study is to assess the PFS of oral veliparib in combination with TMZ or in combination with carboplatin and paclitaxel compared to placebo plus carboplatin and paclitaxel in subjects with BRCA1 or BRCA2 mutation and locally recurrent or metastatic breast cancer. Protocol page 42
Does the study enroll patients with diagnosed diseases?	X		Subjects will be adult men and women with metastatic breast cancer and a documented deleterious BRCA1 or BRCA2 germline mutation. Protocol page 48
Is the study a deemed trial? <small>(Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or Provided under BLA / BB IND / IND # or IND Exempt as verified by the FDA or IRB)</small>	X		IND = 77104
<b>Is the study a qualifying clinical trial?</b> <b>(All questions must be answered "Yes" to qualify)</b>	X		

**Sponsor Paid Items**

The sponsor agreement specifies payment for the following items and services:	Executed agreement Attachment 1 to Exhibit A indicates sponsor payment for all Physical Exams, ECGs, Central Labs, Serum Pregnancy, Bone Scans, CT or MRI Scans at Screening, Optional Biopsy at Screening and Follow Up; Pharmacogenomics, Archived Tumor Samples
---	--

**Informed Consent Form Items Promised Free of Charge**

The Informed Consent Form indicates that the patient and/or their insurer will not be billed for the following:	Approved ICF page 24: You will not be charged for the required study drug(s) (veliparib, carboplatin, paclitaxel, temozolomide or placebo) or procedures during the study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. All other tests and procedures that you would routinely have as part of your regular and outgoing medical care will be billed to you and/or your health plan. Examples of such tests and procedures may include: other drugs, blood and urine tests, x-rays, clinic visits, hospitalization and other care required to treat your underlying disease or other medical conditions. You should ask your study doctor if you have any questions about how to determine if a test or procedure is a study-related procedure (and covered by the study) or part of your routine medical care (and billed to you and/or your health plan).
---	---



DRAFT

XYZ Study

Phase II Breast Cancer Study with PO Drug and Drug #1 or PO Drug with Drug #2 and Drug #3 vs Placebo with Drug #2 and Drug #3

This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.

Protocol Related Items and Services	CPT / HCPCS (Sample codes)	Visit Schedule																		Comments			
		Screening/ Baseline Visit	C1D1	C1D3	C1D15 or 17	C1D22	C2D1	C2D3	C2D15 or 17	C2D22	C3D1	C3D3	C4D1	C4D3	C5D1	C5D3	C6D1	C6D3	Every 9 Weeks from C1D1		Final Visit	30 Day Follow Up Visit	Post- treatment Follow Up
Physical Exam - E&M	99201-99205; 99211-99215; G0463	S	S		S	S	S		S	S	S		S		S		S			S	S		Per CTA/budget, sponsor to pay.
12 Lead ECG	93000, 93005, 93010	S	S																	S			Per CTA/budget, sponsor to pay.
CT or MRI Scan of Chest, Abdomen and Pelvis	71260, 71250, 71270, 74160, 74150, 74170, 74177, 74176, 74178, 72193, 72192, 72194, 74182, 74181, 74183, 71551, 71550, 71552, 72196, 72195, 72197	S																	Q1	S			Per CTA/budget, sponsor to pay for Imaging at screening and any scan not considered conventional care which would be at the Final Visit. NCD 310.1 allows for the coverage of routine cost of conventional care. It would appear reasonable and necessary to perform routine imaging during treatment to monitor disease progression and response to treatment. Use supported by the NCCN Guidelines Version 2.2016 - Invasive Breast Cancer BINV-P; guidelines recommend imaging every 2-4 cycles during treatment. Coverage is generally provided under NCD 220.1 and NCD 220.2. CT Scans are also covered under LCD L33284 and L33285. Medical records must document medical necessity.
Contrast Agents for CT Scans	Q9951, Q9958, Q9959, Q9960, Q9961, Q9962, Q9963, Q9964, Q9965, Q9966, Q9967, A9576, A9577, A9578, A9579, J0152	S																	Q1	S			Contrast agents would not be billed separately from scans.
BUN/Creatinine	84520, 82565	S																	Q1	S			NCD 310.1 allows for the coverage of routine cost of conventional care. Assessing kidney function prior to contrast-enhanced scan would appear reasonable and necessary. Medical records must document medical necessity. Screening and end of study bill to study.
Full Body Bone Scan	78300, 78305, 78306, 78315, 78320, 78350, 78351, A9503 OR 78813, 78816, A9552, A9699, Q9965, Q9966, Q9967	S																					Per CTA/budget, sponsor to pay.
Drug #3 - Arm B only	J9264, J9265			S				S			S		S		S		S						Per ICF, all drugs provided for free. Bill to study.
Drug #2 - Arm B only	J9045			S				S			S		S		S		S						Per ICF, all drugs provided for free. Bill to study.
Chemo IV Administration - Arm B only	96413, 96415, 96365			Q1				Q1			Q1		Q1		Q1		Q1						IV Administration would be considered reasonable and necessary. Nominal charge would need to be included on claim for billing purposes.
Anti-emetics and Pre-meds	J8540, J1094, J1100, Q0166, S0091, J1626, J2405, S0119, Q0162, J1453, J2469, J2060, Q0163, J1200, S0028, J7030, J7040, J7050, J0131, J9150, J7510, J2650, J7506, J1626			Q1				Q1			Q1		Q1		Q1		Q1						Drugs should only be used when clinically indicated. NCD 310.1 allows for the coverage of routine cost of managing toxicities. It would appear reasonable and necessary to ameliorate the side effects of chemotherapy when indicated. Medical records must document medical necessity.
Drug #1	J8700	S					S			S		S		S		S							Oral medication given once a day on days 1-5. Per ICF, all drugs provided for free. Bill to study.
PO Drug	N/A	S					S			S		S		S		S							Oral medication given twice a day on days 1-7. Per ICF, all drugs provided for free. Bill to study.
Serum Pregnancy Test for Women of Child Bearing Potential	84702, 84703	S	S																				Per CTA/budget, sponsor to pay.
Samples for Pharmacogenetics	36415, 36416, 99000, 99001		S																				Per CTA/budget, sponsor to pay.
Biopsy - optional	11100	S																		S			Per CTA/budget, sponsor to pay.
Hematology	85025		M		M	M	M		M	M	M		M		M		M						Would only be done as clinically indicated. Coverage generally supported under NCD 190.15. Medical records must document medical necessity.
CMP	80053		M		M		M		M		M		M		M		M						Would only be done as clinically indicated. Medical records must document medical necessity.

S - Sponsor or Other Funding Source is responsible for coverage and payment of this item or service  
 Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study; Billable item or service to third party payer  
 Q0 - Item under investigation in the trial/study when billed to a third party payer  
 M - Regular Medicare billing rules apply

Principal Investigator or Institutional Representative Approval:

Date:

# Strategies to Build An Effective Compliance and Ethics Program

THAT STANDS THE TEST OF TIME, CHANGE AND SEASONS



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## Disclaimer

THE VIEWS SHARED TODAY ARE NOT NECESSARILY THE VIEW OF OUR ORGANIZATIONS AND ARE OUR PERSONAL VIEWS.

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## Discussion Goals

Discuss best practice strategies to establish a strong compliance and ethics program framework.

Provide and review essential materials and resources for our toolboxes to strengthen our proficiencies.

Engage participants in discussion regarding methodologies to reinforce our programs and key partnerships through defined accountabilities and metrics.

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# Federal Sentencing Guidelines

## § 8B2.1. Effective Compliance and Ethics Program

An organization shall— (1) exercise due diligence to prevent and detect criminal conduct; and (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

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## Compliance & Ethics (C&E) Elements Framework



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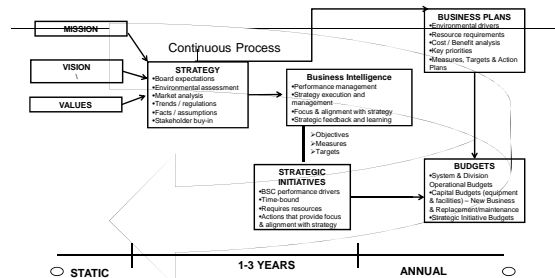
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## What Is Your C&E Strategy Plan & Process?



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### Alignment of Strategic Pillars C&E Program

- Safety
- Quality
- Patient Satisfaction
- People
- Finance
- Community
- Other?




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### The Compliance & Ethics Program Plan Strategic C & E Plan

- Strategy Language: Scorecard vs. Dashboard
  - Collection of data, monitoring, diagnostics, managing and have linkages
  - Balanced Scorecard focus: strategy, priorities, accountabilities, and targets
  - Dashboard: more tactical focused monitoring on critical process points (driver)
  - Key Performance Indicators
  - Business performance management
- **SWOT**
  - Regulations
  - Responsibilities
  - Relationships
  - Resources

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### Federal Sentencing Guidelines

- FSG for organizations introduced the concept of compliance programs to reduce criminal culpability for business organizations in 1991
- Sarbanes-Oxley Act required US Sentencing Commission to review and amend guidelines to enhance the compliance and ethics program effectiveness in 2004
- Amendments encourage business organizations to partner with the Federal government and promote self policing, reporting and cooperation in investigations of its own wrongdoing
- OIG Compliance Guidance 1998 – Hospital Guidance amended 2005

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## High-level Oversight Of C&E Program Board & The Leadership Framework Sets the Tone



- (2) (A) The organization's governing authority shall be: knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight
- (B) High-level personnel shall ensure the organization has an effective compliance and ethics program. Specific individual(s) within high-level personnel shall be assigned overall responsibility.
- (C) Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program.....

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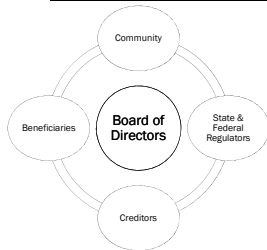
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## The Board's Core Obligations Compliance & Ethics Program – Duty of Care



(2) (A) The organization's governing authority shall be: knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight

- Director's fiduciary obligations include:
  - A good faith effort
  - Information regarding compliance with laws is brought to board's attention on a regular and timely basis

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## Executive Leadership Role Compliance & Ethics Program



"Incumbent upon a health system's corporate officers and managers to provide ethical leadership to the organization and to assure that adequate systems are in place to facilitate ethical and legal conduct."

- Office of Inspector General

A leader is one who knows the way, goes the way, and shows the way.

- John C. Maxwell

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**Compliance & Ethics Officer Influence**  
 "Successful leadership today is influence, not authority." *Kenneth Blanchard*

<b>Honest</b>	<b>Clear</b>	<b>Listener</b>
<b>Approachable</b>		<b>Reliable</b>
<b>Collaborative</b>		<b>Humble</b>
<b>Courageous</b>	<b>Respectful</b>	<b>Partner</b>

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**Promote a Compliance and Ethical Culture**  
 Accountability and Incentives

PROMOTING RESPONSIBLE & ETHICAL BEHAVIOUR

FSG: (6) The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program;

"Regardless of the type of reward, developing criteria for incentives, implementing it, and executing a plan of action will benefit the organization, demonstrate effectiveness, and create awareness of the compliance program in a positive manner." *Shawn DeGroot, Associate Director at Navigant Consulting*

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**C&E Program Strategic Alignment**  
 The C&E Plan Strategy To Influence Culture



- **Define C&E Documents:** The Compliance Plan vs. Annual Work Plan; Committee Charters; Other Committee overlaps for feedback loops; more...
- **Define the Strategy:** Address how C&E through assessment and risk prioritization assist with allocating resources to mitigate risk
  - **Establish Expectations and Accountability:** Develop incentives to meet goals and define roles, partnerships and requirements
  - **Performance Measurement and Effectiveness:** Track, maintain, evaluate and report and communicate routinely

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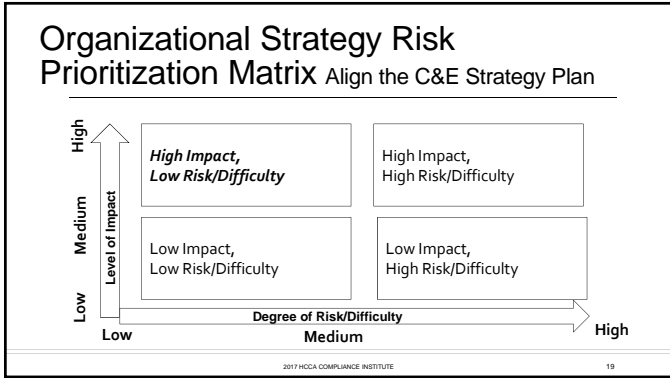
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### C&E Program Strategic Alignment

Pillar: Quality or Community or Finance?

**C&E Strategy:** Meet quality standards (P4P)  
**Risk** to achieve the goal: Quality outcomes, timely reports, HACs, and other  
**Goal:** Audit the monitor and report identified activities  
**Regulatory Reference:** CPGs & CIAs address quality  
**Performance Measure:** Define # of Audits (frequency, target performance to meet and timeline)  
**Incentive:** Number of points or % impacts bonus and/or performance reviews

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### Establish Written Standards for Conduct

Code of Conduct & Policies (communicated)

(b) Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law within the meaning of subsection (a) minimally require the following:

(1) The organization shall establish standards and procedures to prevent and detect criminal conduct.

"Honesty is the best policy."  
Benjamin Franklin

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### Education and Training Periodic, Role and Risk Specific, and Values Based

(4) (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.



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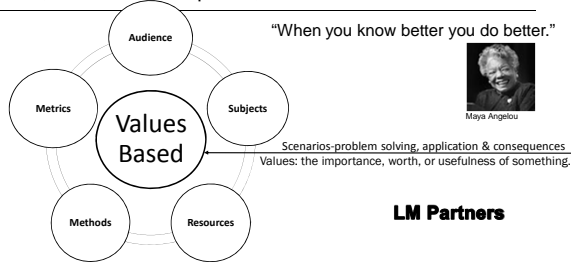
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### Education and Training Periodic, Role and Risk Specific, and Values Based



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### C&E Program Strategic Alignment Pillar: People

- C&E Strategy:** Maintain a qualified workforce
- Risk** to achieve the goal: Workforce knowledge of C&E Program and expectations to identify, prevent and report concerns
- Goal:** Audit and Monitor and report workforce participation or Establish monitoring of credentials
- Regulatory Reference:** FSG and OIG CPG
- Performance Measure:** Define % of timely completion of assigned training
- Incentive:** Number of points or % impacts bonus or performance reviews

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### Open Lines of Communication Confidential Message Line, Surveys & Exit Interviews

(5) The organization shall take reasonable steps— (C) to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.

#### Awareness Strategies



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### Detection/Remediation/Enforcement Screening, Response (Corrective Action Plans)



(3) ...use reasonable efforts not to include within the substantial authority personnel of the organization whom the organization knew, or *should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.*

(6) (B) appropriate disciplinary measures ...

(7) the organization shall take reasonable steps to respond to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.

#### HR Partners

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### C&E Program Strategic Alignment Pillar: People

**C&E Strategy:** Satisfied workforce through a C&E and just culture.

**Risk** to achieve goal: Inconsistent discipline, unreported issues, fear of retaliation and potential whistleblowers.

**Goal:** (1) Promote open lines of communication and how to identify and report compliance and ethics opportunities. (2) Develop and enforce disciplinary standards

**Regulatory Reference:** FSG, OIG CPG, DRA

**Performance Measure:** (1) *Define* % of participation to be met. (2) Developed and implemented standards within specified time.

**Incentive:** Number of points or % impacts bonus or performance reviews

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### C&E Program Strategic Alignment

Pillar: Community

**C&E Strategy:** Increase Corporate Responsibility and C&E Culture through screening and detection

**Risk to achieve goal:** Hire ineligible workforce (excluded), fines, reputation

**Goal:** Establish screening for excluded individuals and monitor activity

**Regulatory Reference:** FSG, OIG, OIG Advisory 2013, Social Security Act

**Performance Measure:** Policy and department procedures defined and implemented. Define roles and % of participation to be met

**Incentive:** Number of points or % impacts bonus or performance reviews

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### Corrective Action Plans

Oversight of Mitigation

- Root Cause(s) understood
- Participation of stakeholders and experts
- Assigned responsibilities
- Defined mitigation and timelines
- Leadership sponsor (oversight for accountability)
- Report completion
- Approval of Corrective Action Plan
- Ongoing monitoring and reporting (oversight for accountability)
- Compliance Monitor(verify its fixed)



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### C&E Program Strategic Alignment

Pillar: Community

**C&E Strategy:** Increase Corporate Responsibility and C&E Culture

**Risk to achieve goal:** Compliance opportunities not mitigated, fines, penalties, loss of reputation

**Goal:** Effective implementation of Corrective Action Plans (CAPs)

**Regulatory Reference:** FSG and OIG CPG

**Performance Measure:** # of CAPs completed timely and effectively CAPs may be associated with external/payer audits or internal audit activities and outcomes OR % of participation in role based training or policy acknowledgement

**Incentive:** Number of points or % impacts bonus or performance reviews

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### Assessment Activities

#### Risk Assessment, Auditing, Monitoring & Program Effectiveness

- (5) The organization shall take reasonable steps—
  - (A) to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct." Thus, auditing and monitoring activities must be in place for the organization's compliance program to be deemed effective.
  - (B) to evaluate periodically the effectiveness; and
- (c) shall periodically assess the risk (b) to reduce the risk of criminal conduct identified through this process

#### Assessment Partners

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### C&E Program Strategic Alignment

#### Pillar: Financial

- C&E Strategy:** Improve operating efficiency, integrity and efficiency
- Risk** to achieve the goal: Stark/AKS, overpayments....
- Goal:** Evaluate documentation, coding and billing controls, contracts, payments, procurement, overpayments.....
- Regulatory Reference:** FSG, OIG CPG
- Performance Measure:** Define %/# of repayments processed on time
- Incentive:** *Number of points impacts bonus and/or performance reviews*

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### Auditing Verses Monitoring

- Audits are evaluations that are conducted by an individual who is independent from the operations being assessed. Audits are periodic and typically retrospective and done through sample.
- Monitoring is an ongoing assessment that may be completed by either the compliance professional or by an individual within the operations area (who would then be responsible for ongoing reporting of the results). It is often automated and concurrent.

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## Thank you!

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**Contact Information:**

- Deann Baker: [bakerd3@sutterhealth.org](mailto:bakerd3@sutterhealth.org);  
707-864-4666
- Dwight Claustre: [dclaustre@aegis-compliance.com](mailto:dclaustre@aegis-compliance.com);  
623-866-9106

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## 2017 HCCA Compliance Institute Strategies to Build and Effective C&E Program Resource Page

### Board and Leadership Resources

- OIG 8/7/12 Focus on Compliance: The Next Generation of CIAs  
[https://oig.hhs.gov/compliance/compliance-guidance/docs/Focus\\_on\\_Compliance.pdf](https://oig.hhs.gov/compliance/compliance-guidance/docs/Focus_on_Compliance.pdf)
- CCOJD: <http://www.corporatecompliance.org/Resources/ResourceOverview/Library/LibraryDocument/ArticleId/1432/Corporate-Compliance-Officer-Role-and-Responsibilities.aspx>
- CEO & How they can make a difference: <http://www.corporatecompliance.org/Resources/ResourceOverview/Library/LibraryDocument/ArticleId/1720/How-Can-a-CEO-Make-a-Difference.aspx>
- Board responsibilities:  
<http://managementhelp.org/boards/>
- Corporate Responsibility and Corporate Compliance:  
<https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf>
- Corporate Responsibility and Health Care Quality:  
<https://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>
- 2015 Yates Memo:  
<https://www.dlapiper.com/~media/Files/Insights/Publications/2016/04/assessyourcomplianceprogram.pdf>

### Education

HCCA & SSCE Resources:

Expert Videos:

- <http://www.hcca-info.org/Resources/HCCAResources/ExpertVideos.aspx>
- [https://www.youtube.com/playlist?list=PLA\\_9sigAHJtNirLcl-VgzG21x2N0JwH47](https://www.youtube.com/playlist?list=PLA_9sigAHJtNirLcl-VgzG21x2N0JwH47)
- [https://www.youtube.com/playlist?list=PLA\\_9sigAHJtO70oskURwmWBB3j5C1sdr4](https://www.youtube.com/playlist?list=PLA_9sigAHJtO70oskURwmWBB3j5C1sdr4)

HCCA – Web-x, Pamphlets and whitepapers

Consider adding articles from HCCA to your internal organizational communications

Regulators and Oversight Agencies trainings and resources:

- MLN <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html?redirect=/MLNGENINFO>
- OIG <http://oig.hhs.gov/compliance/>

## 2017 HCCA Compliance Institute Strategies to Build and Effective C&E Program Resource Page

### Screening:

- DHSS, OIG Supplemental Compliance Program Guidance for Hospitals, Federal Register, Vol. 70, No. 19, January 31, 2005 “*employees, contractors and medical and clinical staff members checked routinely against government sanctions lists, including the OIG’s List of Excluded Individuals/Entities (LEIE) and the General Service’s Administrations’ Excluded Parties Listing System.*” (EPLS)
- OIG Special Advisory: <http://oig.hhs.gov/exclusions/files/sab-05092013.pdf>
- All state Medicaid directors need to **conduct their own search** for ineligible parties, both in- and out-of-state providers monthly, to capture exclusions and reinstatements that have occurred since the last search CMS issued a State Medicaid Director Letter (SMDL): <http://www.ahcancal.org/advocacy/Letters/CMSStateMedicaidDirectorLetter.pdf>

### Leadership Resources:

- “Leadership: The Power of Emotional Intelligence” by Daniel Coleman
- “Crucial Conversations” by Kerry Patterson
- The Just Culture Organization [www.justculture.org](http://www.justculture.org);
- Centers for Medicare and Medicaid (CMS) Root Cause Analysis <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceforRCA.pdf>



N O.	TRACK & REPORT THE COMPLIANCE ELEMENT/FOCUS	DATA COMPILATION, METRICS, & INCENTIVES	REPORT TO	REPORTING FREQUENCY	CORPORATE STRATEGY/INITIATIVES AND GOALS FOR COMPLIANCE
1	<b>EDUCATION AND TRAINING</b> Define Data Compilation Standards, Frequency, Goals, Metrics, Incentives		<b>Examples of tying to Strategy</b>		
	<b>Compliance Type of activities:</b> Required education and training - tracked by area	<b>Compliance Report pulled from On-line system</b> # Participants / # Total EE = % <b>Defined Performance</b> Met/didn't meet:% / #s;	<b>Compliance Committee BOD Committee</b>	<b>Define Periodic Reporting Quarterly and Annual</b>	<b>People - Invest in Our People and Maintain a Satisfied Workforce</b> 1. Maintain a qualified workforce and help connect them to purpose and benefits of the C&E Program. 2. Promote open lines of communication and how to identify and report C&E opportunities. <b>Reference: DRA &amp; FCA</b>
A	Annual Compliance: Refresher on DRA/FCA, Hotline/Reporting, COC, Privacy/Security, etc)	Online training maintained in system - Education/Org Development maintain data and pull reports.	Managers	Periodic	
B	New Hire Compliance Training: Initial DRA/FCA, Hotline/Reporting, COC, Privacy/Security, etc.)	Live training and/or on-line system - Education/Org Development maintain data and pull reports.	Managers	Periodic	
C	Target Education - such as position specific and education identified as part of a CAP	Live: maintained in system. Participation/signature sheets sent to upload in the system by Education/Org Development and generate reports monthly.	Managers	Periodic	
2	<b>DETECTION, REMEDIATION AND ENFORCEMENT (Response and prevention of a pattern of issues)</b>				
	<b>Compliance type of activities:</b> Identify if it is an investigations, response to payer audit or screening, exit interview, hotline, etc.	<b>Compliance Report pulled from data base</b> Timely response to mitigate non-compliance (# overpayments or # response to payers & results) <b>Defined Performance</b> Met/didn't meet:% / #s;	<b>Compliance Committee BOD Committee Other</b>	<b>Quarterly and Annual</b>	<b>Community - Increase Corporate Responsibility and Compliant and Ethical Culture</b> 1. Community Commitment (do the right thing & hire eligible workforce through exclusions screening); 2. Consistent Discipline creates satisfied workforce. 3. Timely response and mitigation of non-compliance. <b>Reference: OIG Screening; FSG, OIG CPG, ACA &amp; PPACA, Regs.</b>
A	<b>Method of Notification or Identification:</b>	# Hotline; Incident Report system; External agency; Payer; Direct report from employee; Customer; Exit interviews; Screening; etc.			
B	<b>Area:</b>	# Program, Dept. Division of occurrence/issue	Managers	Periodic	
C	<b>Types of issues:</b>	# Categories/Subcategories			
	<b>Track &amp; Report Priority/Risk Level at:</b>	# <b>High Med Low</b>			

N O.	TRACK & REPORT THE COMPLIANCE ELEMENT/FOCUS	DATA COMPILATION, METRICS, & INCENTIVES	REPORT TO	REPORTING FREQUENCY	CORPORATE STRATEGY/INITIATIVES AND GOALS FOR COMPLIANCE
D	Outcome:	# Not Substantiated; Substantiated; Deficiencies found or not found; Significant (widespread) or Isolated; Results of payers or external agencies; # repayments/overpayments and appeals.			

N O.	TRACK & REPORT THE COMPLIANCE ELEMENT/FOCUS	DATA COMPILATION, METRICS, & INCENTIVES	REPORT TO	REPORTING FREQUENCY	CORPORATE STRATEGY/INITIATIVES AND GOALS FOR COMPLIANCE
3	<b>AUDITING AND MONITORING (testing of controls and remediation)</b>				
	<b>Compliance Type of Activity:</b> Identify whether it's Auditing or Monitoring	<b>Compliance Report pulled from data base</b> # of Audits & monitoring by area, type, priority and results <b>Defined Performance</b> Met/didn't meet:% / #s;	<b>Compliance Committee</b> <b>BOD</b> <b>Committee</b> <b>Other</b>	<b>Quarterly and Annual</b>	<b>Finance-</b> Improve Operating Efficiency and Solvency or Process Improvement/Cost Containment 1. Evaluate Documentation, Coding and Billing Control Environment to assist in Financial Integrity and Accountability <b>Reference:</b> OIG CPG, FSG, Regs
A	<b>Type &amp; purpose of identifying Audit or Monitor:</b> Overpayments, Physician Arrangements, Documentation, Coding, Billing/Internal Controls.	Identify specific standard and/or process; identify controls			
B	<b>Area:</b>	Program, Dept. Division identified	Managers	Periodic	
C	<b>Purpose of Audit or monitor:</b>	Categories & Subcategories (Audit or Monitoring)			
	<b>Priority/Risk Level at:</b>	# <b>High Med Low</b>			
4	<b>STANDARDS OF WRITTEN CONDUCT &amp; POLICIES</b>				
	<b>Compliance Type of Activity:</b> Routine communication of written standards to workforce; Identify if it's response to a CAP.	<b>Compliance Report pulled from Policy, Procedure Management System (PPMS)</b> <b>Defined Performance</b> Met/didn't meet: % /#s;	<b>Compliance Committee</b> <b>BOD</b> <b>Committee</b> <b>Other</b>	<b>Quarterly and Annual</b>	<b>People -</b> Invest in Our People and Maintain a Satisfied Workforce 1. Maintain a qualified workforce. 2. Promote open lines of communication and how to identify and report C&E opportunities. <b>Reference:</b> DRA & FCA
A	<b>Compliance Policies and Procedures</b>	# of policies by area assigned # of policies attested to within timeline	Managers	Periodic	
B	<b>Code of Conduct acknowledgement</b>	Current workforce: # acknowledged/# of workforce; New workforce: # acknowledged/# of new workforce	Managers	Periodic	
C	<b>Confidentiality acknowledgement, FWA, COI, Etc.</b>	Current workforce: # acknowledged/# of workforce; New workforce: # acknowledged/# of new workforce	Managers	Periodic	

N O.	TRACK & REPORT THE COMPLIANCE ELEMENT/FOCUS	DATA COMPILATION, METRICS, & INCENTIVES	REPORT TO	REPORTING FREQUENCY	CORPORATE STRATEGY/INITIATIVES AND GOALS FOR COMPLIANCE
5	<b>RISK ASSESSMENT AND ANNUAL WORK PLAN</b>				
	Evaluate Compliance Risk to prioritize and allocate resources to mitigate risk	<b>Compliance Report Pulled from Data Base:</b> # projects defined for work plan (RA based) # completed (resourced) with Leader involvement <b>Defined Performance</b> Met/didn't meet:% / #s;	Compliance Committee BOD Committee Other	Quarterly and Annual	<b>Finance-</b> Improve Operating Efficiency and Solvency or Process Improvement/Cost Containment <u>OR</u> <b>Community</b> - Increase Corporate Responsibility 1. Evaluate and prioritize compliance risk to align the allocation of resources with the compliance program to successfully meet its mission for Accountability, Transparency and Integrity. <b>Reference:</b> FSG, OIG CPG
A	Purpose of Compliance Risk Assessment:	# Payer/External Agency activities; Internal significant control or isolated weaknesses; New or revised regulations or standards, CAP, etc.			
B	Area:	# Program, Dept. Div. Risk Areas evaluated	Managers	Periodic	
	Priority/Risk Level at:	# High Med Low			
	Define annual work plan	Evaluate completion of projects defined and participation and resource allocation to mitigate risk effectively.			
6	<b>EVALUATION OF EFFECTIVENESS OF C&amp;E PROGAM AND DEPARTMENT</b>				
	Evaluation of Compliance & Ethics Program Effectiveness	Evaluate workforce knowledge, compliance program activities and organizational C&E Culture	Compliance Committee BOD Committee Other	Periodic	<b>Community</b> - Increase Corporate Responsibility 1. Community Participation -2. Community Commitment;
A	Compliance & Ethics program effectiveness (Independent)	Assess: 1. Workforce understanding of their responsibility to C&E, level of comfort reporting and perception of organizational culture (surveys & exit interviews); 2. evaluation of effectiveness of elements above (evaluation of mitigation of risks through controls and identification of gaps). 3. Department resources, standards and experience.		Every three years	
B	Compliance & Ethics program effectiveness (Internal)	Same as above		Every year	

Designed by Deann Baker, Compliance Professional

# 60-Day Overpayment FCA Enforcement Action Results in \$2.95 Million Settlement

8/30/2016 by Stephanie Johnson | King & Spalding

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On August 23, 2016, a New York hospital system settled False Claims Act (FCA) allegations that it violated the 60-day overpayment rule by improperly retaining Medicaid overpayments. The whistleblower alleged that three of the system’s hospitals violated the reverse FCA provision, 31 U.S.C. § 3729(a)(1)(G), by improperly retaining Medicaid overpayments.

Specifically, the whistleblower and the New York Office of the State Comptroller allegedly informed the hospitals that certain claims had been improperly billed to Medicaid due to a software glitch caused by the State’s Medicaid managed care organization, Healthfirst. However, the whistleblower and the Government further alleged that the hospitals took approximately two years to fully reimburse the Medicaid program for overpayments identified by the Comptroller. The nearly \$3 million settlement is one of the first settlements related to a provider’s alleged failure to timely report and refund “identified” overpayments, as required by the 60-day overpayment rule.

There has been considerable uncertainty regarding the precise parameters of the Affordable Care Act's 60-day overpayment rule, which was enacted in 2010 and requires recipients of a Medicare or Medicaid overpayment to report and refund the overpayment within 60 days of "identification" of the overpayment (or the date the corresponding cost report is due, whichever is later). See 42 U.S.C. § 1320a-7k(d). One controversial aspect of this rule surrounds the interpretation of the term "identification," which is the trigger for the 60-day timer to report and refund the overpayment.

As previously [reported](#) in *Health Headlines*, the Southern District of New York was the first court to interpret and define the extent of a provider's obligations under the 60-day rule. See *Kane ex rel. New York v. Healthfirst, Inc.*, 11 CIV. 2325 (ER) (S.D.N.Y.). The court denied the hospitals' motion to dismiss and rejected the hospitals' argument that "identification" could be reasonably interpreted to require conclusive proof of an overpayment; instead, the court interpreted "identification" to include situations where ***"a person is put on notice that a certain claim may have been overpaid."***

In February of this year, after the August 3, 2015 *Kane* decision but before last week's settlement, CMS issued the Final Rule for Medicare Parts A/B overpayments. The Final Rule defines "identification," stating that a Medicare Parts A/B overpayment is identified "when the person has, or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." CMS has yet to issue a proposed or final rulemaking for Medicaid overpayments. However, providers are still subject to the ACA's 60-day overpayment rule for Medicaid payments even in the absence of rulemaking from CMS.

In a press release regarding the *Kane* settlement, DOJ highlighted the important role the Comptroller played in identifying the underlying software error that caused the initial overpayments, and the Comptroller's partnership with law enforcement to identify additional overpayments. The DOJ press release emphasized the length of time the hospitals allegedly took to repay claims, noting that the Defendants were "alerted to the software error by the New York State Comptroller" in 2010, and an

internal investigation by the whistleblower in 2011 revealed approximately 900 claims that may have been wrongfully submitted. “These claims were identified in the whistleblower’s list on February 4, 2011,” the press release claims, “yet Defendants did not fully repay these claims until March 2013, *i.e.*, nearly two years later.”

The settlement of nearly \$3 million represents more than three times the amount of alleged Medicaid overpayments. The settlement is also notable because the hospitals specifically “admit[ted], acknowledge[d] and accept[ed] responsibility” for conduct relating to failing to timely refund the Medicaid overpayments.

The DOJ Press Release is available [here](#).

---

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*DISCLAIMER: Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations.*

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## New Business/Service Compliance Checklist

### Dignity Health New Business/Service Compliance Checklist

Facility: \_\_\_\_\_ New Business/Service Line: \_\_\_\_\_

Target Opening/Start Date: \_\_\_\_\_ Has System Compliance Director been notified?  Yes  No

Element	Resources	Action Required	Comments	Date Complete
<b>Regulatory</b>				
Have Federal and State requirements (including program licensing) been assessed/reviewed for this program/service?				
Have Joint Commission requirements been assessed/reviewed for this program/service (if applicable)?				
Are Policies and Procedures required for Joint Commission or State Requirements completed & approved?				
Are any notifications required to CMS (Medicare/Medicaid) prior to start up of program/service?				
Has business license been obtained (if required)?				
Have physical plant requirements been met?				
Have the CMS Physician Supervision requirements for provider-based diagnostic and therapeutic services been evaluated and put in place as required?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
Is this a "Provider-Based" entity?		If yes, complete the applicable checklists.		
<b>Medical Staff</b>				
Is the physician or non-physician (NPP) privileged and credentialed to provide the services in this new service line?				
Has the scope of practice for all non-physician practitioners (NPP) been reviewed to ensure they are licensed to provide this service(s)?				
Have the anticipated ordering/referring physicians been verified in PECOS?				
Have state physician supervision requirements been met?				
<b>Joint Ventures</b>				
Is the program/service a Joint Venture?				
Have you reviewed the HIPAA Considerations in structuring the joint venture?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
<b>HIPAA</b>				
Has the new business service been added to the HIPAA organization chart? Contact your FPO.				
If access, use or disclosure of Dignity Health data is involved has a privacy impact assessment been completed by the FPO?				
<b>Legal / Contracting</b>				
Has Dignity Health Legal been notified of new service line development?				
Does the Medical Director contract meet all requirements as stated in Dignity Health Physician Transaction policy?				
Has Managed Care reviewed all contracts as needed?				
Has Legal reviewed all contracts for services including physicians, vendors, third party billing companies, and any other contracted services?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
If leasing office space to a physician have real estate leases been reviewed by Legal and /or Corporate Real Estate to ensure compliance with Dignity Health Physician Transaction policy and to ensure that current Fair Market Value has been assessed and documented?				
Is the service/program/business owned in part or in whole by a physician?				
Does the system for storage and retrieval of medical records ensure records are available for audit and medical record requests by payers?				
Does the electronic billing system allow for adequate back-up and data retrieval to ensure compliance with Dignity Health Record Retention policy? 70.2.020				
If using an EMR for professional services, have the documentation templates been reviewed to ensure E&M documentation guidelines will be met?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
<b>Professional Claim Billing/Coding</b>				
Will this service be performed by a physician?				
Have individual physician NPI's been validated?				
If one or more of the performing providers is non-physician practitioner (NPP), what name and NPI will appear on the CMS1500 claim form for each payer type?				
If the Non Physician Practitioner is employed by the hospital, please contact the Dignity Health System Compliance Director for Clinics				
Have CPT/HCPCS codes and documentation requirements been identified and reviewed by a Dignity Health or DHMF Coding Compliance Manager?				
Have encounter forms been created/updated and reviewed by a Dignity Health or DHMF Coding Compliance Manager?				
Do non-Medicare payers have specific coding/reimbursement requirements? If so, have these requirements been documented as outlined in the Dignity Health policy 70.4.016 "Payer Specific Coding Instructions"?				
Has the practice management system been updated to include the new CPT codes and fees?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
If a contract billing service is to be utilized, has this been reviewed by Dignity Health Compliance to ensure all CMS (Medicare/Medicaid) requirements have been met?				
Does the new service/business meet the Medicare/Medicaid program requirements for billing including review of applicable LCD's/NCD's and/or CMS transmittals?				
Has a New Provider/Program audit be arranged with Dignity Health or DHMF Compliance Manager?				
<b>Facility Charging / Coding / Billing</b>				
Have you reviewed the charging, coding and billing forms, policies and practices with a Dignity Health Coding Compliance Manager?				
Who will be responsible for the assignment of ICD-9 diagnosis codes? Is this person properly educated, qualified and competency tested?				



## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
Has a 60-90 day (post program start up) compliance audit of coding, charging and documentation been scheduled to ensure errors/problems are identified and corrected early in the start up phase of the service?				
Who will validate CPT/HCSPCS codes against the clinical documentation?				
Have all items on CDM been reviewed and audited for accuracy of codes, descriptions, and to ensure that any unique CMS (Medicare/Medicaid) requirements have been met in conjunction with System CDM team?				
Has CDM's been tested to ensure the appropriate charge description and associated charges appear correctly on the claim/patient's bill?				
Has a charge reconciliation process been implemented?				
Is there a process in place for the billing staff to return claims that were incorrect on initial submission to the hospital for correction?				
If a contract billing service is to be utilized, has this been reviewed by Dignity Health Compliance to ensure all CMS (Medicare/Medicaid) requirements have been met?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
Have the system and documents utilized to input charges been reviewed for accuracy and to ensure all CMS (Medicare/Medicaid) requirements have been met?				
Has the denial management plan been reviewed to ensure any charging/billing errors are identified and corrected?				
Has the cancel/credit tracking system been reviewed to ensure that all overpayments will be identified and promptly returned to the payer?				
Has a system been implemented to ensure that any outpatient charges related to the acute hospitalization are identified and meet the requirements of the 3-day rule?				
Has system been implemented to ensure that ABN's (Advanced Beneficiary Notice), MSP (Medicare Secondary Payer) and CMS Conditions of Admission/Participation are properly utilized?				
Are E&M leveling criteria established and associated policies and procedures completed?				
Are encounter form/charge form policies and procedures completed?				

## New Business/Service Compliance Checklist

Element	Resources	Action Required	Comments	Date Complete
Does the new service/business meet the Medicare/Medicaid program requirements for billing including review of applicable LCD's/NCD's and/or CMS transmittals?				
<b>Leadership</b>				
Have Service Line / Business leaders attended (or enrolled in) the Dignity Health Physician Transaction Training?				

January 24, 2003

Dear HCCA Colleagues:

On behalf of the HCCA Board of Directors and the many volunteers from across the country who served on the HCCA Compliance Performance Measurement Initiative Task Force and its Steering and Drafting Committees, we are pleased to announce the release of the following document, "**Evaluating and Improving a Compliance Program, A Resource for Health care Board Members, Health care Executives and Compliance Officers.**" This resource is now available to all HCCA members and other interested parties on the public section of the HCCA website at **[www.hcca-info.org](http://www.hcca-info.org)**.

This document is the product of an extensive collaborative process and reflects hundreds of volunteer hours of research, meetings, drafting, collaborative discussions, decades of collective professional experience, as well as the important feedback received from the HCCA membership through surveys, interactions at meetings and finally, through comments received during a 45-day review and comment period.

We trust that this document will provide added value by identifying and sharing information and best practices regarding the operation and evaluation of compliance programs. While principally developed for the benefit of HCCA members, this reference is intended to be a useful guide to all health care compliance professionals. Nevertheless, it is important to note that this document is not intended nor should it be used as a "cookbook" or "list of standards." One size certainly does not fit all. As a reference, you should use and tailor this information to meet the specific needs of your organization and to better inform your board members, senior management and executives.

This document will also serve as the foundation for the next steps in HCCA's continued efforts to provide practical tools to you, our members, to assess the performance of compliance programs within health care organizations. Recognizing the complexity and variety of compliance issues within different health care industry sectors, the HCCA Board has assigned the task of developing specific performance measurement tools for different health care industry sectors to the HCCA Compliance Focus Groups (CFG's), e.g., Health Systems CFG, Home Health CFG, Pharmaceutical CFG, etc. The CFG's will provide an appropriate and useful forum to attract volunteers and their ideas to tailor and customize these tools to fit specific industry sector needs.

We encourage you to volunteer your time and ideas and join the CFG that represents your sector of health care. *Become part of the solution – join a CFG today!* For more information on HCCA's CFG's, please contact Tracy Hlavacek at (888) 580-8373, via email at [tracy.hlavacek@hcca-info.org](mailto:tracy.hlavacek@hcca-info.org), or visit the HCCA website at [hcca-info.org](http://hcca-info.org).

With best regards,

L. Stephan Vincze, J.D., LL.M., CHC  
Chairman, Compliance Performance Measurement  
Initiative Task Force  
Chairman, HCCA Pharmaceutical Compliance Focus Group  
HCCA Board Member

Sheryl Vacca  
Immediate Past President, HCCA  
Chair, Drafting Committee  
HCCA Board Member



*Health Care Compliance Association*

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# **Evaluating and Improving A Compliance Program**

A Resource  
For Health Care Board Members, Health Care Executives  
and Compliance Officers

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## PREAMBLE

The goal of the HCCA Compliance Performance Measurement Initiative is to improve the quality and effectiveness of compliance programs by identifying and sharing information regarding the operation and evaluation of compliance programs.

Due to the complexity and volume of health care regulations and the relative infancy of compliance programs in health care organizations, management and governing bodies frequently have questions about compliance programs. Are we focused on the right issues? Is the program addressing our principal risks? How much should we spend? Are we deriving maximum value from our efforts? How do we evaluate the quality and effectiveness of our program? While this document does not provide definitive answers to these questions, it is intended to assist governing bodies, management teams, and compliance officers in health care organizations in evaluating and improving compliance activities. In short, this document is provided by the HCCA as a tool to help an organization determine whether the resources it devotes to compliance are effectively, efficiently and appropriately utilized.

Simply stated, the objective of a compliance program is to create a process for identifying and reducing risk and improving internal controls. Stated another way, from a legal enforcement standpoint, an effective compliance program reduces the likelihood that an organization will be found to have recklessly disregarded or deliberately violated the law. The aim of this document is to be a fluid guide to common indicators and recommended best practices for compliance programs, not a collection of rigid standards. In rare instances we have taken the position that a particular action or practice is an essential component of an effective compliance program. In most instances however, what the organization is advised to do depends on its size, resources, business activities, and past behaviors. We recognize and emphasize that “one size does NOT fit all.” Compliance activities are best tailored to the unique needs and risks of the organization. The common indicators identified in this document will not be applicable or appropriate for every organization and even those common indicators that are relevant may need to be adjusted or modified by the organization to achieve the objective of compliance.

Nevertheless, investigative and enforcement entities have consistently stated that a compliance program should be judged, at least in part, by how it compares to programs of similarly situated organizations. The HCCA believes that this document will help governing bodies, management teams, and compliance officers effectively evaluate compliance programs and serve as a useful tool in the effort to improve the quality and efficiency of compliance activities.

While the HCCA initiative is conducted principally as a benefit and service to HCCA members, the work of this initiative will be shared with other interested public and private parties in a sincere effort to promote greater understanding and progress in the field of health care compliance.

The HCCA Compliance Performance Measurement Initiative Task Force and Committee Members are:

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William Heffron  
Lewis Morris

Lori Richardson Pelliccioni  
Roy Snell  
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## Introduction

We live and operate in an era of risk. Nowhere is this truer than in the health care industry. While we have decades of experience in the development of programs to address risks associated with patient care, infectious diseases, workplace injuries, and natural disasters, most health care organizations have only recently recognized the seriousness of the risk posed by non-compliance with the complex laws that govern business practices in health care, like the False Claims Act, fraud and abuse, tax and antitrust laws. Many organizations have begun implementing compliance programs to address these risks and to answer new challenges like those posed by the Health Insurance Portability and Accountability Act, "HIPAA." Recent, highly publicized failures of corporate governance have raised questions regarding the role of governing bodies and increased the emphasis on promoting and enhancing board oversight.

Compliance programs play an important role in helping health care organizations fulfill their obligations to public and private payers, shareholders or bondholders, and the community at large. Health care organizations have recognized that such programs are important because the regulatory environment in which we operate is exceedingly complex, and we have a fundamental obligation to our patients and the public to ensure that our participation in government and private reimbursement systems and the operation of our health care organization is consistent with applicable laws and regulations.

### What Is A Compliance Program?

In its simplest terms, a compliance program is a systematic process aimed at ensuring that the organization and its employees (and perhaps business partners) comply with applicable laws, regulations, and standards. In the context of health care, it usually includes a comprehensive strategy to ensure the submission of consistently accurate claims to federal, state, and commercial payers. It frequently includes an effort to adhere to other applicable laws and regulations relating to the delivery of health care products and services. Some programs go beyond these areas and address antitrust, environmental, tax and other laws as well. However, the principal focus of most compliance programs is on health care specific laws.

In a general sense, a compliance program has two basic components - structural and substantive.

- The structural component includes the basic framework necessary to build and operate an effective compliance program. The structural component includes those elements articulated by the Office of the Inspector General as necessary elements of a compliance program. These elements would typically be included in any compliance program, regardless of the substantive legal or regulatory issues the organization is trying to address. Generally, a program would include standards (policies and procedures), high-level oversight, reporting, employee screening, education, auditing/monitoring, enforcement and prevention.
- The substantive component relates to the specific body of substantive law (Medicare, Medicaid, anti-kickback, Stark, insurance, ERISA, tax, antitrust, environmental, privacy, etc.) with which the organization is attempting to comply. Organizations frequently develop policies and education programs that explain to affected employees the obligations that the law imposes upon them in the performance of their particular job function. For example, if the Medicare program requires patient care providers to document patient care and treatment, an organization would seek to ensure that its patient care staff understands the documentation requirements. Similarly, where services must be provided by properly licensed and approved providers, care would be taken to ensure that providers

are properly qualified and enrolled. Also, health plans comply with laws governing mandated benefits, appeals and grievance procedures and timely claims payment.

A compliance program is much more than a policy communicating the organization's intent to comply with the applicable laws. In order to be effective, the compliance program must be designed in a manner which:

- Addresses the organization's business activities and consequent risks;
- Educates those persons whose jobs could have a material impact on those risks;
- Includes auditing and reporting functions designed to measure the organization's actual compliance and the effectiveness of the program, and to identify problems as quickly and as efficiently as possible;
- Provides for the prompt remediation of problems which are identified; and
- Contains enforcement and discipline components that ensure that employees take seriously their compliance responsibilities.

Creating an effective compliance program requires the commitment of the organization to comply with applicable laws. It also requires a systematic effort (scaled to the size, resources, and complexity of the organization) to understand its principal legal obligations and risks and to make employees aware of how the relevant laws and risks impact the performance of their job functions. In addition, employees will be made aware of their obligation to be an active participant in the organization's compliance effort.

## **Compliance Program Foundation**

In its various guidance documents, the Office of the Inspector General, "OIG," has spoken authoritatively on the basic elements of an effective compliance program. The Federal Sentencing Guidelines have defined an effective compliance program as "a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct."<sup>1</sup> Clearly, this requires more than just policy statements reminding employees of their obligation to obey the law. In fact, the Sentencing Guidelines discuss seven elements of a compliance program.

1. **Compliance Standards** "The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct." Comment 3.(k)(1).
2. **High Level Responsibility** "Specific individual(s) within high level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures." Comment 3.(k)(2).
3. **Trustworthy Individuals** "The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities." Comment 3.(k)(3).

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<sup>1</sup> Federal Sentencing Guidelines, §8.A.2.Comment 3.

4. Education "The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required." Comment 3.(k)(4).
5. Monitoring and Auditing "The organization must have taken reasonable steps to achieve compliance with the standards, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution." Comment 3.(k)(5).
6. Enforcement and Discipline "The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific." Comment 3.(k)(6).
7. Response and Prevention "After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law." Comment 3.(k)(7).

## **Evaluation and Measurement**

In recent years compliance professionals Boards and executive leadership of organizations that have implemented compliance programs, and enforcement officials who have an interest in compliance effectiveness have all wrestled with how to evaluate an organization's compliance efforts. Due to the relative infancy of such programs there is scant data of measurable and objective criteria on which to build an evaluation process.

As a practical matter, and in order to create a starting point for efforts to improve the quality and efficiency of compliance programs, we believe that a compliance program can be evaluated by analyzing two dimensions: effort and outcomes.

Effort is the time, money, resources and commitment that an organization puts into building and improving a compliance program. While effort by itself will not guarantee compliance, it is unlikely that outcomes will improve if the organization devotes inadequate time and resources to the task. Particularly in the first several years of a program, effort is one measure of effectiveness that an organization can use to assess its compliance program. How do the resources devoted to the program compare to similarly situated organizations (size and complexity)? Are we addressing the issues that create the greatest risk for similar organizations engaged in similar activities? Are we promptly refunding overpayments? Have we addressed the issues that the OIG has identified in its guidance documents?

Outcomes are the impact that our efforts have on our level of compliance. As the compliance program matures, the principle measure of effectiveness moves from effort to outcomes. If our processes are appropriate, patients receiving non-covered services in an outpatient setting will have first received an Advanced Beneficiary Notice or "ABN". If our education efforts are adequate, coding will improve over time. If our screening is consistent, the frequency with which we discover that we have employed or

contracted with an excluded individual decreases. If our processes are adequate we will have fewer instances where employees fail to receive required training. Our claim denial rates will decline, the number of payments to physicians without an appropriate contract will fall, and we will consistently have documentation that supports the claims we have submitted.

Obviously, progress will not always be linear. Staff turnover or personnel shortages will occur, something will fall through the cracks, the rules will change, new reimbursement methodologies will be adopted (APCs, RUGs, Home Health PPS, Medicare + Choice), new rules will be adopted (Stark), and new laws will be enacted (HIPAA). Each of these events may temporarily slow our improvement. Similarly, efforts will not always be perfect. An issue may be overlooked, an employee may ignore the rules, or systems may temporarily fail us. In these instances we must show that we have moved promptly to address an issue we missed in the past, appropriately disciplined the individual who disregarded the rules, and corrected the mistakes caused by human error or system failure.

However, a compliance program that cannot demonstrate improvement in mitigating risk areas cannot be deemed effective. Many providers are beginning to develop measurement tools to objectively evaluate compliance programs. This document reflects some of the benchmarks or indicators that are in use and the HCCA will continue to gather and share these tools with the health care industry. In doing so, it is our goal to improve the quality and efficiency of compliance programs in the organizations we are honored to serve.

## **Scalability**

Provider groups and representatives are understandably concerned about the time and effort required to implement, maintain and improve a compliance program. In many segments of health care, margins are razor thin if they exist at all. Providers are struggling with new government mandates, declining reimbursement, increasing numbers of uninsured, professional shortages, and technology challenges. The resources that an organization can devote to a compliance program are directly linked to both its size and its margins.

While many of the specific activities discussed in this document – and even in the federal guidance documents noted above – are relevant to most organizations, we recognize some activities will not work in all organizations. For example, comment 3(k)(5) suggests that organizations must have reporting systems, which employees and other agents may utilize “...without fear of retribution.” The OIG suggests, and many organizations utilize, hotlines (staffed either internally or externally) designed to preserve the anonymity of callers. As a practical matter, anonymity is difficult if not impossible in the context of a small physician practice, which employs only a handful of people. Even if the caller did not identify himself or herself, it is unlikely that the members of the clinic would not be able to identify the source of the call. However, while anonymity may be a good idea in many contexts, the important element is that the clinic has a process in place, which encourages employees to articulate their concerns (e.g., through a suggestion/question box). The clinic should also have a mechanism to reasonably evaluate and address the concern, and a culture that assures employees do not suffer retaliation as a result of participating in the process.

In short, with rare exceptions, the components of an effective compliance program described in this document can be altered if they are not relevant to the organization or if they are impractical given the organization’s size and structure. This document frequently suggests multiple alternatives for achieving a specific objective. Finally, this is the HCCA’s initial effort in this regard, but certainly not the last.

Accordingly, this reference should be used as a “living document”—one that will evolve over time with advances made and lessons learned in the compliance profession. This document has been formally issued by the HCCA only after the HCCA Board, HCCA members, other interested persons and organizations, and government had a meaningful opportunity to review the document, provide comments and feedback and participate in collaborative discussions about how to make the document more useful. We fully expect that the quality and utility of this document will improve as we continue to gather information and comments from our members and other interested persons, review our practices, measure our programs and improve our understanding of the laws, our organizations and our profession.

Questions are frequently raised regarding the respective roles of the Compliance Officer, management, and the Board of Directors (or relevant Board committee) in the compliance process. The HCCA believes that it is the Compliance Officer’s job to oversee the development and/or implementation of the compliance program, to monitor adherence to the program, and to assess the impact of the program on the organization’s compliance (outcome). These duties would include the program structure, content, education programs, monitoring processes and other pieces of the program working with those in operations in the organization and appropriate resources (e.g., legal, human resources, procurement, billing, coding, reimbursement, and accounts payable) within and/or outside the organization. In an era of resource constraints, it is also the Compliance Officer’s job to ensure that the program developed is as efficient as possible.

The role of management is to ensure that the Compliance Officer is provided adequate resources (taking into consideration the organizations size, risk, and resources) and to ensure that the program, once developed, is effectively implemented. Fundamentally, it is management’s job to ensure that the program developed by the compliance function is properly implemented.

The role of the Board is to ensure that the organization has implemented a compliance program that is reasonably calculated to be effective. One purpose of this document is to help the Board (and management) understand the components of an effective compliance program and enable the Board to more intelligently and efficiently fulfill its responsibility.

**We hope that the document is useful. If you have questions, suggestions or concerns, you can provide your comments to the HCCA at the following address: Attention Tracy Hlavacek, HCCA, 5780 Lincoln Drive, Suite 120, Minneapolis, Minnesota 55436.**

## **Indicator #1 – Policies and Procedures**

### **A. Rationale**

In order to effectively operate a compliance program, an organization must generally develop written standards, policies and procedures designed to address its principal risks. These written standards communicate organizational values and expectations regarding employee behavior, explain the operation of the compliance program, clarify and establish internal standards for compliance with laws and regulations, and help employees understand the consequences of non-compliance to both the organization and the individual.

Health care law and regulations are very complex. Providers and other health care organizations must comply with thousands of pages of laws, rules, manual provisions and other requirements that are specific to health care alone. Most health care organizations must also comply with the same tax, antitrust, employment, environmental and other laws that apply to business organizations generally. Meeting this obligation is most effectively accomplished in organizations that have developed policies designed to guide employee conduct. These policies will distill relevant laws and regulations into clear, understandable direction for employees. They will help focus the employee's attention on the principal compliance pitfalls or risks the organization faces.

### **B. Relevant Issues**

Building an effective compliance program does not require the development of hundreds or even dozens of policies and procedures. However, most compliance programs include policies and procedures that fall into three broad categories: (i) a Code of Conduct; (ii) policies relating to the operation of the compliance program; and (iii) policies addressing the organization's principal legal (substantive) risks.

The Code of Conduct is typically a document that sets forth in general terms the organization's commitment to comply with the law. It varies from one or two to more than 30 pages in length. It frequently includes statements or guidelines addressing the organization's principal legal risks, expectations relating to employee conduct, information regarding the organization's compliance program and instructions on how an employee can access the organization's reporting mechanisms (see Indicator # 3). It may outline fundamental expectations regarding employee behavior applicable to all employees. It is typically distributed to all employees upon commencement of employment.

Operational policies and procedures address the operation of the compliance program itself. Policies may address issues such as the compliance reporting structure in the organization, compliance education requirements, the operation of the hotline or other complaint mechanisms, how the organization will investigate complaints or problems, and how the organization will institute remediation efforts when issues are identified.

Substantive policies address the principal legal risks of the organization. As noted above, the volume of laws applicable to health care organizations is immense, and precludes policies on every issue. Consequently, most health care organization policies are focused on addressing applicable risk areas that have already been identified in the context of OIG guidance, fraud alerts, OIG workplans, or frequent enforcement actions. Organizations may also develop policies in response to specific issues identified in the course of the organization's own audits, investigations or other reviews and assessments.

## **C. Implementation**

### **Policies and Procedures**

1. The organization develops policies and procedures designed to address its principal business risks.
  - The organization has evaluated its principal risks.
  - The organization's policies address issues identified in guidance documents (e.g., OIG guidance, fraud alerts) or enforcement actions by the OIG and other government agencies whose legal requirements are applicable to the organization.
  - The organization's policies address previously identified serious weaknesses in its practices.
2. The organization develops policies that describe how the organization's compliance program operates and the consequences of non-compliance.
  - The organization has developed and distributed a Code of Conduct or similar document to all employees.
  - The organization has communicated alternative complaint mechanisms to employees.
  - The organization has a process in place to promptly address and rectify employee non-compliance.
3. The organization ensures that relevant employees and agents are promptly oriented to applicable new and revised policies and procedures.
  - The organization ensures prompt orientation to applicable policies for new employees.
  - The organization ensures prompt distribution of revised policies to existing employees.
4. The organization's policies and procedures are periodically reviewed and are updated to reflect changes in laws, regulations or processes.
5. The organization monitors adherence to its policies and procedures (See Indicator #4).
  - The organization reviews policies and procedures at regular intervals.
  - The organization has a process to monitor significant changes in law and modify policies as appropriate.
6. The organization appropriately disciplines employees who do not adhere to the organization's policies or procedures (See Indicator #5).

## **D. Role of Compliance Officer, Management and Board**

1. Compliance Officer: advises organization on policies that may be required; oversees development, distribution and implementation of policies; assures that policies accurately and effectively communicate legal and regulatory requirements; periodically reviews policies and initiates needed updates.
2. Management: provides adequate resources (taking into account the organization's size, risk, resources and scope of the compliance program); participates in policy development to assure that policies will be consistent with operations and capable of being implemented and followed; implements policies by conforming operations to policy requirements.
3. Board: may serve as originator or final adopter of some written standards, such as the Code of Conduct (Compliance Officer will generally develop for the Board's approval and adoption); may monitor to assure that legal risks are addressed.

## **E. Evaluation and Measurement**

### 1. Effort

- Do policies and procedures exist for relevant topics and areas?
- Has a risk assessment been completed to identify the relevant risk areas?
- Are the policies comprehensive?
- Are policies understandable and capable of being fully applied?
- Have the requirements of the policies and procedures been communicated to employees?
- Have any audits been conducted to monitor compliance with the policies and procedures?

### 2. Outcome

- Have audits revealed fewer errors in areas where policies have been implemented?
- Upon testing, are the internal controls established by policies working?
- When interviewing employees during an audit or review, do they understand what the policies require?



## **Indicator #2 – Ongoing Education and Training**

### **A. Rationale**

Internal standards in the form of a Code of Conduct and compliance policies are useful in initiating the process of explaining health care laws and regulations, and establishing processes for compliance within an organization. However, to promote understanding of these internal standards and of the requirements of external laws and regulations, an organization's compliance program should include an active education and training program. An effective compliance training program will generally provide ongoing education and training specifically designed for management employees, non-management employees, and non-employed business associates. Training will generally be designed to provide an overview of compliance program activities and requirements that is appropriate to the audience (e.g., information needed by management is generally distinct from that needed by non-management employees). Specific training is generally also provided to address legal and regulatory requirements that impact the performance of each significant category of job function within the organization (e.g., physicians, billing staff, admission staff), and provides information on how to raise questions.

The existence of an education and training program is an important component of compliance programs for a number of reasons, including the following:

- To promote understanding of and compliance with relevant federal, state and local laws and regulations.
- To enable implementation of the compliance program's policies and procedures and ensure that employees understand their role in the compliance process.
- To demonstrate the organization's commitment to compliance and ensure that commitment is carried out throughout the organization.
- To communicate the effect that industry standards and governmental requirements have on an organization's business activities and to improve skills for identifying potential compliance issues.

The overall benefit to an organization from an ongoing compliance education and training program is constant reinforcement of an organization's commitment to compliance and the expectation that everyone working for or affiliated with the organization is an integral part of the compliance effort. In addition, employees develop an understanding of the legal and regulatory requirements that most directly impact their specific job function.

### **B. Relevant Issues**

Education and training programs typically include information regarding how the organization's compliance program operates (structure) and as well as information on specific laws and regulations (e.g., reimbursement, coding, prompt payment requirements, etc.) that impact the organization (substantive). Education also frequently includes a discussion of the consequences of non-compliance, (e.g. recoupment, fines, penalties, exclusion) for both the organization and the individual.

## C. Implementation

### 1. Common Structural Education Topics

- Why the organization is implementing the compliance program
- The organization's commitment to compliance
- The necessity of adhering to the organization's policies and procedures as well as applicable laws and regulations
- The duty of employees to report concerns or misconduct
- A description of the organization's compliance program including reporting/complaint mechanisms and the organization's commitment to non-retaliation

### 2. Substantive Education Components

In the health care delivery, context education should include, a description of key substantive laws and regulations that affect the employee's job function. This education obviously varies for different employee groups but frequently includes information on such topics (as applicable and by way of example only) as:

- admitting/registration requirements
- documentation requirements
- privacy/confidentiality issues
- coverage and billing rules
- cost report preparation
- medical necessity
- charge entry risks
- coding requirements
- EMTALA
- licensure/qualification requirements

In addition, employees are typically provided with information regarding the consequences of violations of the various laws (e.g., false claims act(s), Stark, anti-kickback) that may be imposed on individuals or organizations. This typically includes discussion of fines, penalties, exclusion and other remedies that may be imposed on an offending entity or individual.

Those individuals in the management/administrative roles or those involved in negotiating, drafting or administering arrangements with other providers or business partners are also frequently provided education regarding laws which may impact provider relationships with referral and payment sources as well. These may include (as applicable and by way of example), anti-kickback laws, Stark laws, tax laws, and other laws.

Compliance training strategies include the entire range of traditional and emerging education programs. Lectures, videos, interactive CDs or Internet training, and other self and group study methods are utilized. These training sessions typically are part of an ongoing process and repeated on a regular cycle. Training sessions typically occur for both new and existing employees with appropriate revisions to the training content as the rules change or at regular intervals. The frequency of the training or length of the training interval depends on the directness of the link between the employees' job and principal risks of the organization, the

frequency of rule changes in the context of the employee's job functions, and the level of non-compliance in the particular area to which the education applies.

Education can be one of the most expensive components of a compliance program. In addition, development of education and training programs can be difficult as some organizations lack the expertise to develop those training programs internally. However, for the small organization there are a number of resources where education can be obtained free of charge or at relatively nominal prices. In addition, hospitals and other larger providers are frequently willing to assist the small physician practices in a community in compliance education efforts, a practice encouraged by the OIG in its compliance guidance for hospitals.

## **D. Role of Compliance Officer, Management and Board**

1. Compliance Officer: develops training programs that suit the unique needs of the organization, assuring that training accurately reflects and communicates legal and regulatory requirements; develops and implements tracking mechanisms to document attendance at and/or completion of required training.
2. Management: provides necessary funding to support compliance training program; enforces training requirements among the organization's staff; provides necessary accountability measures to support the mandatory nature of compliance training requirements.
3. Board: reviews periodic (e.g., annual) reports on status of completion of compliance training requirements throughout the organization; periodically reviews compliance training plan to confirm that necessary training is being provided.

## **E. Evaluation and Measurement**

### **1. Effort**

- Organizational policies require employees to receive periodic training and education regarding the organization's compliance program.
  - Percentage of employees who receive training regarding the organization's compliance program promptly following commencement of employment.
  - Percentage of employees in higher risk roles who receive specific, job related education designed to reduce the incidence of non-compliance in the department or function at intervals established by the provider.
- The organization evaluates the roles of its agents and provides education (or requires the agent's organization to provide education) if such agents directly impact the organization's compliance.
- The organization can demonstrate it has evaluated the role of non-employee agents and contractors and assessed the need to ensure they are adequately trained.

- The organization has a plan to train those non-employee agents or contractors who are determined to need training.
- The content of the education and training addresses the operation of the compliance program and the substantive legal issues that most directly impact the organization's risk and the employee's duties.
  - The organization has engaged in an assessment of its most significant risks by reviewing applicable OIG guidance, fraud alerts and work plans, through consultation with health care counsel or other experts, or by some other mechanism (consistent with the organization's size and resources) reasonably calculated to identify its principal risks.
  - The organization has a process to monitor changes in laws and regulations relating to its greatest risk areas and modifies education content as appropriate.
- The organization assesses the effectiveness of its education efforts by utilizing tests, which evaluate employee comprehension and measure impact on job processes, or some other mechanism designed to ensure the training is effective.
  - Failure to fulfill compliance education requirements is grounds for an employee's discipline up to and including termination.
- The organization consistently ensures that employees complete required education and takes appropriate steps where employees do not.

## 2. Outcome

- The organization has documentation that training and education of employees has occurred.
- The organization and its Compliance Officer have documentation that proves that policies and procedures and the Code of Conduct have been distributed to all applicable employees. Frequently, organizations will have a tear out sheet in the back of the Code of Conduct and will request that individuals simply sign the form and send it to the Compliance Officer upon receipt of the Code of Conduct.
- There is documentation in employee files showing discipline for employees who do not complete training or who do not return the receipt of the Code of Conduct.

## **Indicator #3 – Open Lines of Communication**

### **A. Rationale**

Compliance programs operate most effectively in organizations that encourage employees and business partners to report suspected wrongdoing so that it can be investigated and properly addressed. An organization's compliance efforts will be less effective if only a small number of individuals are willing to confront impropriety, than if the majority of employees are empowered to report their concerns. As an organization increases its numbers of employee-watchdogs, it will be better able to identify possible violations early and more immediately initiate investigation, determine the materiality of violations and, if necessary, implement the appropriate corrective action. An organization that encourages open communication will be more effective at identifying risk areas on which to concentrate its performance improvement efforts.

To achieve an open environment, employees at every level of the organization must believe that their good faith report of possible non-compliance will be taken seriously. They must be assured that the organization will not tolerate retaliation. They must be confident that if an investigation confirms impropriety, it will be appropriately addressed. Creating an environment where open communication about suspected misconduct is encouraged often requires ongoing affirmative efforts by those with leadership responsibility for the compliance program.

### **B. Relevant Issues**

The creation and maintenance of mechanisms to encourage and facilitate candid communication are frequently components of an effective compliance program. The following issues are generally considered and addressed in an organization's compliance program strategy:

- Creation of an environment in every segment of the organization within which employees feel free to report concerns, questions, and instances of improper conduct without fear of retribution or retaliation.
- Provision of a mechanism for confidential or anonymous reporting for employees who are uncomfortable reporting concerns to a supervisor or to the compliance officer.
- Tracking, documentation and oversight mechanisms to ensure that reports of suspected non-compliance are fully and timely investigated and addressed.
- Mechanisms to assure that management and the board are properly and regularly apprised of, and can take appropriate action on, issues identified in investigations that resulted from reports of non-compliance.

The clearly articulated expectation of open communication needs to permeate all levels of the organization. Board members, executive leadership, and the Compliance Officer need to promote the message that they expect everyone to adhere to a "culture of compliance" and give the assurance that reported issues and concerns will be acted upon.

## C. Implementation

1. Creating a Culture of Open Communication. To create a culture of open communication, organizations typically address some or all of the following issues in compliance program literature, organizational policies, training programs or otherwise:
  - Organizations often require employees and other associates at all levels of the organization to report compliance concerns, significant legal risk questions, and suspected or actual misconduct, and to allow this reporting requirement to be satisfied by a report to a supervisor, a compliance officer, or to the organization's confidential reporting mechanism.
  - Organizations with compliance programs communicate and publicize the existence, intent, process, and mechanisms available for raising compliance concerns.
  - Communication mechanisms used for clarification (both external and internal), questions or education can be the same mechanisms as those used for reporting potential concerns and issues.
  - Compliance programs typically explain how employees and those affiliated with the organization can expect reported concerns to be handled.
  - The Compliance Officer and compliance department staff often publicize their availability to receive reports of non-compliance from employees and others affiliated with the organization.
  - Managers and supervisors receive formal communication on their responsibility to respond appropriately and honestly when possible wrongdoing is brought to their attention. They are often trained on how to respond to questions and concerns and their responsibility to relay reports of non-compliance to the Compliance Officer.
  - Generally organizations adopt, publicize and enforce a no-tolerance policy for retaliation or retribution against an employee or associate who reports suspected compliance violations or misconduct.
2. Establishing Confidential/Anonymous Reporting Mechanisms.

Establishing a variety of reporting mechanisms can be an effective way to demonstrate the organization's desire that potential compliance issues be reported. Independent, confidential mechanisms outside of more traditional reporting methods (i.e., directly to supervisor, human resources, etc.) may give reluctant employees greater assurance when making reports.

  - Independent mechanisms may include hotlines, suggestion boxes, employee exit interviews, e-mails, and other forums that promote information exchange.
  - Reporting mechanisms need to be convenient to employees and those associated with the organization. This may mean having at least one mechanism that is available at all times.
  - Assurance of confidentiality, except where disclosure of identity is required by a legal obligation to resolved discovered non-compliance may also be important.

- Those reporting should be provided with clear information about what they may expect after reporting a suspected compliance issue (i.e., timely response, striving to preserve confidentiality, progress reports if appropriate).
3. Documentation of Compliance Related Reports. Compliance Officers will be able to more efficiently and accurately manage the compliance program if they have developed a formalized means to document and track reported questions and concerns.
- Establishing a process to document and track reported concerns, including the status of related investigations and corrective action, may improve an organization's efficiency in resolving reports and preventing or correcting ongoing non-compliance.
  - Confidential intake forms can be used to record an initial report of a potential compliance issue.
  - Thorough documentation of corrective actions implemented, disciplinary measures imposed, and any overpayments returned should generally be maintained in conjunction with the organization's tracking mechanisms.
  - The tracking process may be housed and maintained manually or may be automated to facilitate referral, trending and reporting.
4. Reporting to Board and Executive Leadership. Regularly informing an organization's Board and executive leadership of reported concerns will foster the culture of open communication, and will allow organizational leaders to respond appropriately to risks or improprieties that are identified through the organization's reporting mechanisms.
- An organization's executive leadership, compliance committee, and Board of Directors often receive statistical and trending information on reports or inquiries received through compliance reporting mechanisms. Reports and inquiries may be categorized by area of concern, seriousness of allegation, and otherwise, to allow organizational leaders to assess whether trends in use of the reporting mechanisms or in organizational operation or behavior suggest that improvements may be required.
  - Reports to executive leadership and/or to the Board often include specific reports on areas of material legal risk or significant breaches of policy or misconduct that have been identified, and the status of necessary corrective action steps.
  - An aging of reports and inquiries, from date of receipt by the compliance office, to date of resolution, may be maintained and reported periodically to organizational leaders to assure that inquiries and reports are investigated and addressed in a timely manner.

## **D. Role of Compliance Officer, Management and Board**

1. Compliance Officer: establishes and maintains reporting mechanisms; manages response to reports, including determining when investigation may be required; reports regularly to the

Board and executive leadership on reports and inquiries received; assists in setting a tone and creating a culture of open communication.

2. Management: primarily responsible for creating a culture of open communication by responding appropriately when reports are received; works with the compliance officer as needed to investigate reported concerns; executive leadership and/or compliance committee provides oversight and receives regular reports on trends or issues identified.
3. Board: provides oversight and receives regular reports on trends or issues identified; assists in setting a tone by mandating a culture that promotes open communication and assures effective response.

## **E. Evaluation and Measurement**

### 1. Effort

- Do the necessary communication policies exist and have they been implemented and maintained?
- Are reporting mechanisms appropriate to the size of the organization (i.e., suggestion boxes in smaller facilities vs. continuously available hotlines in larger, more geographically diverse, organizations)?
- Is the reporting mechanism available to all levels of the organization and to those affiliated with the organization?
- Are reporting mechanisms publicized throughout the organization?

### 2. Outcome

- Is analysis being conducted on reports to determine whether response is timely and thorough?
- Is there a trending of questions, issues raised or potential misconduct to direct where the organization should be focusing its efforts?
- Have employees been surveyed to evaluate their knowledge of the reporting mechanism?
- Does evidence show that there is a confidence in the reporting mechanism?



## Indicator #4 – Ongoing Monitoring and Auditing

### A. Rationale

Effective compliance programs include proactive monitoring and auditing functions that are designed to test and confirm compliance with legal requirements and with the organization's written compliance standards. These functions serve to test compliance with internal policies and procedures and with federal, state and local laws, regulations and rules. As such they may assist an organization's compliance activities by identifying possible misconduct or criminal activity.

Self-evaluation that occurs as a result of a compliance auditing and monitoring program is often critical in identifying areas where compliance standards have not been fully understood or fully implemented. An effective monitoring and auditing program may allow an organization to correct any oversight or resulting non-compliance before it creates significant risk to the organization.

The auditing and monitoring function of the compliance program can also be used to test the completion and effectiveness of functions at the heart of the compliance program, such as compliance training programs, employee and vendor screening, or whether disciplinary action is occurring and is appropriate. This function also provides a unique opportunity for a compliance program to measure and benchmark its own effectiveness.

Compliance audits are typically structured to test compliance in a finite cross section or functional area of the organization. It is, therefore, generally possible to repeat the same audit periodically, and thereby to measure not only the organization's current level of compliance, but also its progress in attaining higher levels of compliance as the compliance program matures.

### B. Relevant Issues

Compliance guidance documents often use a variety of terms when referring to the auditing and monitoring components of a compliance program. An *audit* is typically a more formal review of compliance with a particular set of internal (e.g., compliance policies) or external (e.g., laws and regulations) standards. Audits are typically conducted by individuals who are independent from the area being audited—usually compliance department staff or outside auditors. *Monitoring* refers to reviews that are repeated on a regular basis during the normal course of operations. An organization may monitor its activities as part of a corrective action plan, to assure that corrections implemented continue to be effective. Monitoring may also be initiated when no specific problems have been identified to confirm and document ongoing compliance.

*Prospective audits* occur before billing, allowing an organization to correct discovered errors before submitting the bill. *Retrospective audits* occur after billing and may require an organization to correct discovered errors by re-billing or self-disclosing to a payer or to the government. A *baseline audit* is typically the initial audit in a series of identical audits, and as such establishes the baseline against which progress measured by future audits is compared. A *risk assessment* is typically a broad based audit that may be used to identify opportunities for improvement either before development of the compliance program or workplan or periodically thereafter.

Critical issues to consider in developing an auditing and monitoring program include:

- Comprehensive programs typically include a variety of both auditing and monitoring functions.
- Properly trained and independent audit resources are key to a successful compliance audit program. Will the organization use internal or external resources? Does the organization have existing internal resources with necessary expertise and independence from the areas to be audited? At what level will the organization support budget allocation for a compliance audit program?
- Compliance auditors must be given authority to conduct audits and access to documents and other information needed to complete the audit process.
- The most effective compliance audit programs review operations in areas where the organization is at risk. The results of past internal reviews may help identify what risk areas an organization should focus on, or which areas may no longer require the same amount of attention. Patient/member satisfaction surveys can quickly point to risk areas, as can patient/member complaint logs, payment denial logs and other indicators. An organization should also review its compliance plan within the context of recent government issuances such as the OIG's annual Work Plan, Fraud Alerts, Bulletins and other guidance documents.

## **C. Implementation**

### **1. Developing an auditing and monitoring plan.**

Organizations typically develop an auditing and monitoring plan, setting out the areas that will be the focus of auditing or monitoring activity for a given period of time, such as a calendar or fiscal year.

- An Organizations' monitoring and auditing plans are often constructed based upon a review of risk areas that are generic to all health care organizations, in addition to those risk areas specific to the organization itself.
- Past organizational performance, patient complaints or satisfaction surveys, and guidance from the Office of Inspector General (e.g., OIG Work Plans and Fraud Alerts) are examples of resources that an organization uses to identify issues for audit.
- Consideration of the organization's audit budget and audit staff resources are critical to developing a workable auditing and monitoring plan.
- Issues that have previously been discovered and corrected by the compliance program should generally be included in the organization's monitoring and/or auditing plan, especially in periods immediately after they were discovered and corrected.
- The auditing and monitoring plan may include review of compliance with substantive internal (e.g., compliance policies) and external (e.g., an intermediary's local medical review policies) standards; and of operational components of the compliance program (e.g., the OIG database screening process).

- The methods used for each monitoring and auditing activity should be documented so that auditing and monitoring functions can be repeated in the future if that becomes necessary.
2. Conducting auditing and monitoring activities.
- To the extent practicable, an organization's compliance audit activities should be conducted by audit personnel who have expertise in the areas being audited, and who are independent from the activities being reviewed.
  - Monitoring activities may be conducted by independent audit staff or by operational staff responsible for compliance in the area that is being audited.
  - Findings from auditing and monitoring activities should be reported as appropriate to the compliance officer, to the organization's management, and to the board.
3. The method of review.  
Organizations may collect information using a variety of methods to increase their ability to identify improper procedures or activities. Methods of review that organizations might use include:
- Site visits
  - Interviews of personnel in areas such as management, operations, coding, claim development and submission, patient care and other activities
  - Questionnaires given to a cross-section of employees
  - Reviews of records and source documents, such as medical and financial records that support claims for reimbursement and Medicare cost reports
  - Reviews of written materials and documentation prepared by departments not included in the current review or audit.
  - Trend analyses or longitudinal studies that identify deviations, positive or negative, in specific areas over a given period of time
4. Addressing adverse findings.
- When auditing or monitoring activities identify opportunities for improvement or compliance failures, it is often appropriate and/or necessary to take corrective action to address the findings. When corrective action is taken, follow-up auditing and/or monitoring should be conducted to confirm the effectiveness of the corrective action.
  - Findings of significant noncompliance are generally promptly reported to the organization's internal management and the Board of Directors.

- Organizations promptly evaluate (usually in consultation with legal counsel) whether there is an obligation to report the existence of misconduct that may violate criminal, civil or administrative law to the appropriate governmental authority within a reasonable time after discovery. (In some instances, violations may be so serious, as to warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation.)
- Not all instances of errors necessitate the initiation of a formal disclosure process. For example, clerical or inadvertent billing errors with no apparent pattern are different from intentional “upcoding” or deliberate overbilling.

## **D. Role of Compliance Officer, Management and the Board**

1. Compliance Officer: establishes auditing and monitoring plan; oversees compliance audit functions; continuously reviews organizational risk areas to identify necessary auditing and monitoring activities; assists management with formulation of corrective action plans and oversees and/or verifies implementation of corrective action.
2. Management: works cooperatively with compliance officer to facilitate compliance audit activity; conducts or oversees monitoring activities of operations in manager areas; works with compliance officer to implement corrective action as required by adverse audit findings.
3. Board: is accessible to receive reports of severe adverse audit findings from the compliance officer; periodically reviews summary reports of audit findings; assures that compliance officer has adequate resources to conduct an adequate auditing and monitoring program.

## **E. Evaluation and Measurement**

### 1. Effort

- Is the organization conducting a regular auditing and monitoring program consistent with the size, complexity and scope of its business operations?
- To the extent possible, are audit staff responsible for conducting compliance audits independent from the areas of the organization that they are auditing?
- Does the organization have a written compliance auditing and monitoring plan that includes subject, method, and frequency of audits?
- If any major findings were made, was senior management and/or the Board notified as appropriate in a timely manner?
- When appropriate, have government agencies been notified of adverse finding in a timely manner?
- Have written corrective action plans been produced and followed when adverse findings were made?

- Are overpayments promptly refunded?
- Are audit plans built on organizational history?
- Have audit results been disseminated to the appropriate groups for corrective actions?

## 2. Outcome

- Do the results of audits indicate that the organization understands and is complying with internal and external laws, regulations, rules and policies?
- Does analysis of the results of repeat audits indicate an upward trend of improvement in the organization's understanding of and compliance with internal and external standards?

## Indicator #5 - Enforcement and Discipline

### A. Rationale

There are significant risks when health care organizations fail to meet the requirements and legitimate expectations of their stakeholders. Compliance programs play a key role in helping organizations to fulfill this obligation in the legal, regulatory and policy arenas. In so doing, an effective compliance program can assist an organization in earning and maintaining public trust.

The effectiveness of an organization's compliance effort is generally tied directly to its ability to affect the conduct of each individual in or associated with the organization. In many instances the compliance program's success will be achieved one individual at a time. Building and maintaining meaningful structures of accountability is critical to this effort. When compliance failures occur, there must be a process for enforcing compliance standards and for disciplining responsible individuals when discipline is appropriate. Enforcing standards and disciplining the individuals who violate them underscores the organization's commitment to compliance.

### B. Relevant Issues

- There are a number of relevant issues to consider when building enforcement mechanisms and disciplinary procedures. To assist in enforcement of standards, effective compliance programs generally include a process for identifying individuals and organizations whose background indicates a tendency toward improper conduct. Effective organizations generally avoid employing or contracting with such individuals or entities.
- A communication strategy that results in clear communication of enforcement and disciplinary standards throughout the organization will bolster the effectiveness of a compliance program.
- Communicating a commitment to compliance is most credible when this commitment clearly states that *all* individuals involved in the work of the organization—regardless of position or status—are accountable for compliance, are subject to the same disciplinary standards, and are expected to fully participate in the compliance effort. One important element of full participation that should be emphasized is that reporting potential compliance failures is a duty of all employees and business partners.
- Enforcement of standards generally requires establishing an effective working relationship between the compliance program and the functional areas of the organization that have primary responsibility for administering discipline.
- Effective enforcement and discipline requires an investigative process capable of substantiating alleged compliance failures (see Indicator #6).
- Oversight by an organization's compliance committee or another appropriate body may bolster effectiveness by enhancing the organization's ability to demonstrate that discipline is proportionate, and is administered fairly and consistently.

## C. Implementation

1. Screening employees and business partners. Effective compliance programs include a process for avoiding relationships with individuals or entities that have a tendency toward inappropriate conduct. This process generally includes some or all of the following:
  - Review of Office of Inspector General's (OIG) list of individuals and entities that are excluded from participation in government health care programs, and of the General Service Administration's (GSA) list of individuals and entities that are excluded from participating in government contracts.
  - Criminal record checks when appropriate or as required by state law.
  - Standard reference checks.
  - Review of the National Practitioner Databank.
2. Tying compliance standards to existing disciplinary processes. Because discipline is generally carried out by, or in accordance with, standards developed by other functional areas within the organization, compliance standards are typically tied to existing disciplinary processes.
  - Compliance program documents and an organization's disciplinary policy for employees generally cross-reference each other to facilitate progressive discipline of employees pursuant to existing human resources policy and procedure.
  - Medical staff bylaws, credentialing/privileging programs and vendor contracts are often written or amended to require compliance with an organization's compliance standards, and to facilitate temporary or permanent removal from an organization's medical staff upon violation of compliance standards.
  - Medical staff bylaws, credentialing/privileging programs vendor contracts, and the organization's policies allow an organization to immediately terminate any medical staff member, vendor or employee who is excluded by either the OIG or GSA. Generally these same documents require any individual or organization that is excluded on the OIG or GSA lists to immediately notify the organization of the exclusion.
3. Communication of enforcement and disciplinary standards. The compliance program includes processes for communicating enforcement and disciplinary standards to employees and business partners.
  - An expectation that all employees and business partners will report suspected unlawful activities or compliance violations is generally communicated throughout the organization.
  - Employees and business partners are informed that violation of compliance standards may result in appropriate discipline, up to and including termination, of employment, medical staff or contract relationship with the organization.

#### 4. Oversight of compliance discipline.

- Records of discipline for compliance violations are generally maintained and reviewed periodically by the organization's compliance committee or other appropriate oversight body to promote consistency and fairness.

#### **D. Role of the Compliance Officer, Management and the Board**

1. Compliance Officer: assists organization in developing appropriate standards for discipline and enforcement, and in tying compliance standards to functional areas within the organization that are responsible for administering discipline; establishes and implements a communication strategy to assure that enforcement and discipline standards are understood throughout the organization; maintains records of discipline resulting from compliance violations and reports periodically to the compliance committee and/or other oversight body.
2. Management: assists compliance officer in communicating standards for enforcement and discipline throughout the organization; works with compliance officer to assure that contracts, policies and procedures, and other controlling documents include appropriate ties to compliance standards so that the organization will be able to take appropriate disciplinary action when needed; generally responsible for carrying out discipline of employees and others within their area of responsibility.
3. Board: may periodically review aggregate data on enforcement and discipline to verify that compliance standards are being followed within the organization.

#### **E. Evaluation and Measurement**

##### 1. Effort

- Does the organization have policies and procedures addressing enforcement of compliance standards and discipline of individuals who violate them?
- Does the organization screen employees and business partners before initiating a relationship and periodically thereafter to assure that they have not been excluded by the OIG or GSA?
- Are enforcement and disciplinary standards communicated throughout the organization?
- Is compliance an element of performance reviews and incentive compensation decisions?

##### 2. Outcome

- Percentage of success in meeting the reporting requirements of Corporate Integrity Agreements (CIA's)
- Percentage of success in meeting audit recommendations



- Does a review of disciplinary actions taken as a result of compliance failures indicate that discipline is consistently and fairly administered
- Percentage of employees who satisfy the compliance elements of their performance reviews and incentive compensation decisions

## Indicator #6 – Investigation, Response and Prevention

### A. Rationale

While compliance programs are intended to promote adherence to applicable substantive laws and regulations, situations may still arise where conduct inconsistent with legal requirements is reported, suspected or even confirmed. An effective compliance program will include a process by which the organization can respond to these actual or potential violations.

### B. Relevant Issues

When an instance of potential non-compliance is reported or suspected, an effective compliance program will generally take some or all of the following steps:

- Promptly halt the non-compliance and halt or mitigate to the extent possible any ongoing harm caused by the suspected non-compliance.
- Fairly and expediently investigate to determine the existence, scope and seriousness of the non-compliance, and to identify the underlying conduct or process that caused the non-compliance.
- Respond with appropriate corrective action to confirmed non-compliance.
- Implement preventative measures to avoid similar instances of misconduct in the future.

This document outlines a number of proactive measures that an organization can take to promote and facilitate compliance with laws and regulations. However, an organization's timely and thorough response to discovered impropriety may be the most accurate barometer of the organization's compliance culture.

### C. Implementation

The following practices related to response and prevention of non-compliance are often found in effective compliance programs:

1. An investigation protocol outlining how the organization will respond to reported, suspected, or confirmed non-compliance. The term "investigation" is often used as shorthand to describe the various responses an organization might take to address known or suspected misconduct. Depending on the circumstances involved in the suspected misconduct, an investigation may be merely an informal inquiry, or it may involve more formal steps like a detailed audit of claims. As part of its compliance efforts, an organization should consider establishing and operating according to written protocols or policies for conducting investigations. Such protocols or policies may address some or all of the following:
  - Who in the organization is responsible for and authorized to determine (1) whether the suspected non-compliance and related circumstances warrant an investigation, and (2) what form the investigation will take.

- A system of checks and balances to ensure that decisions to abstain from initiating a formal investigation are reviewed by other objective individuals.
  - The role and/or qualifications of those who may be involved in conducting an investigation, including:
    - Requirements for requisite experience and/or substantive knowledge level, and
    - Requirements for assuring the objectivity of investigators and avoiding conflicts.
  - Guidelines or policies for determining when legal counsel or external experts should be involved in an investigation.
  - A requirement that investigations be conducted in a timely fashion and a process for accountability and oversight to assure that this requirement is met.
  - A process for tracking progress on and the status of an investigation.
  - Proper safeguards for preventing the inappropriate or inadvertent disclosure of confidential information that is obtained in or is part of the investigation.
  - Processes for securely maintaining evidence obtained in an investigation.
  - Requirements for documentation that internal investigators must maintain, which generally should include a description of the issue(s) investigated, the source of the allegation(s), a summary of evidence considered, and the final disposition of the investigation.
  - Record retention requirements for investigative reports and files. (Reports summarizing the investigation's findings along with the underlying evidence relied upon to reach investigative conclusions should be governed by the organization's document retention policies.)
  - Clear delineation of who has the authority to close an internal investigation.
  - The organization's processes for reporting findings of investigations to appropriate oversight or governing bodies.
2. Responding to discovered non-compliance with appropriate corrective actions. Appropriate response to discovered non-compliance might require an organization to take affirmative steps to address the non-compliance and to correct any harm that may have been caused by the non-compliance. Corrective actions steps that are frequently used in health care organizations include any or all of the following:
- Discipline or termination of employees or agents who intentionally or recklessly caused the non-compliance (see Indicator #5);
  - Repayment of identified overpayments; and
  - Self-reporting of the non-compliance to law enforcement or regulatory officials.

In developing a compliance program, an organization may want to develop written protocols that set out specific steps to be followed in each of these broad categories of corrective action. These protocols may include a process to enable independent verification that necessary corrective actions have been completed, and a requirement that all corrective action taken must be appropriately documented.

3. Responding to discovered non-compliance with preventative measures and monitoring. After determining the causes of discovered non-compliance, measures should be developed and implemented to prevent future recurrences, and appropriate monitoring is instituted to assure that preventative measures are operating effectively. Preventative measures may include some or all of the following:
  - Identification and repair of any internal control or management deficiencies that may have caused or contributed to the non-compliance;
  - Additional education in those departments that contributed to the deficiency.
  - Identification of and appropriate response to any deficiencies in competency or qualifications that may have contributed to the non-compliance;
  - Development and/or modification of policies, procedures or systems to address the deficiencies involved in the non-compliance; and
  - Identification and repair of similar deficiencies that may be causing risk of similar non-compliance in other areas of the organization.

In addition to any other preventative measures, an effective response to identified non-compliance will include appropriate monitoring of ongoing activities to assure that preventative measures have effectively eliminated recurrence of the non-compliance. This monitoring may be incorporated into the organization's auditing and monitoring program (see Indicator #4 above) or may be addressed separately. Generally, the Compliance Officer or his designee will be directly involved in monitoring for compliance during the months immediately following implementation of preventative measures.

4. Reporting investigation findings and outcomes to appropriate oversight bodies. Findings of investigations and outcomes of corrective action and prevention plans should be regularly reported to appropriate managerial and governing bodies. Compliance programs generally include one or more of the following reporting protocols:
  - Regular reports to a compliance committee composed of individuals from upper management on the status and progress of ongoing investigations;
  - Regular reporting to key members of upper management (e.g., CEO, CFO) who are not members of the compliance committee on the status and progress of ongoing investigations;

- Tracking and reporting to appropriate managerial and/or governing bodies on the amount of time that elapses between the opening and closing of an investigation;
- Periodic reporting to the Board of Directors or to a designated committee of the Board (e.g., the Audit Committee) of the status and progress of ongoing investigations that involve serious violations of law or significant risk to the organization.

The minutes of all governing or managerial bodies receiving reports on the findings, status and outcomes of compliance investigations should appropriately reflect oversight of the compliance program's investigative activity.

5. Involving legal counsel in response and prevention.

The purpose of a compliance program is to prevent violations of law and to ensure that if inadvertent violations occur the organization responds appropriately. Competent legal counsel can assist an organization in achieving these ends by providing legal advice, and by assisting in the development of the investigative plan and the organization's subsequent response to an investigation's findings. Organizations should consider involving legal counsel any time that suspected non-compliance may involve criminal misconduct, civil law violations, or significant overpayment liability.

One benefit of involving legal counsel in response and prevention is that communications between the attorney and the organization may be subject to the attorney-client privilege, and investigative work conducted at the direction of counsel may be protected by the attorney work product privilege. These privileges should not be used by the organization to avoid taking necessary corrective action steps. However, they may prove valuable in assuring that resolution of discovered problems is equitable and just.

6. Appropriate response to government inquiries and investigations.

Effective compliance requires that an organization respond in a lawful and appropriate manner upon learning of a government investigation of the organization's activities. Appropriate response to government investigations requires:

- Preserving (i.e., preventing alteration or destruction of) any written or electronic materials that are or could reasonably be known to be the subject of a government investigation;
- Notification of organizational leaders when a government inquiry is initiated;
- Appropriate response by employees who are contacted directly by government investigators. (Employees should be advised that they may speak with investigators but are generally not obligated by law to do so; that they may be entitled to have an attorney present if they do speak with investigators; and that the organization is willing to work with investigators and the employee to schedule an interview at an appropriate time. The organization should never direct employees not to speak with government investigators.)

An organization may wish to develop written policies or protocols that address each of these areas of response to government investigation or inquiry.

## **D. Role of Compliance Officer, Management and Board**

1. Compliance Officer: primarily responsible for overseeing or performing independent investigations and for documenting investigative efforts; reports findings of investigations to management and the Board as required by organizational policy; recommends corrective action and prevention strategies for adoption and implementation by management and/or the board as appropriate.
2. Management: responsible for cooperating in investigations of reported non-compliance; commits appropriate resources to conduct of investigations and to corrective action and prevention measures.
3. Board: oversees compliance efforts by receiving and assessing reports of findings and progress of internal investigations, and of corrective action and prevention measures; assures that it benefits both from the recommendations of the Compliance Officer and from the advice of counsel when corrective action may require report of the non-compliance to outside parties including the government.

## **E. Evaluation and Measurement**

### 1. Effort

- Has the organization developed a process for investigating reports of suspected non-compliance?
- Has the organization developed a process for responding appropriately to discovered non-compliance?
- Are the findings, status and outcomes of internal investigations reported regularly to appropriate oversight and management bodies? Do these bodies record their oversight of the organization's investigation, response and prevention activities in their respective minutes?
- Has the organization developed written policies or protocols for responding to government investigations?

### 2. Outcome

- Can the organization demonstrate that ongoing harm is halted promptly upon discovery of confirmed non-compliance?
- Does an aging of closed and ongoing investigations demonstrate that the organization is promptly resolving reports of suspected non-compliance?
- Are the organization's corrective action responses to investigations consistent with legal requirements and with the recommendations of relevant regulatory agencies?

- Do the organization's monitoring efforts indicate that preventative measures taken in response to non-compliance are effective in eliminating future instances of similar non-compliance?

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# DRUG DIVERSION: ENFORCEMENT TRENDS, INVESTIGATION, & PREVENTION

Regina F. Gurvich, MBA, CHC, CHPC



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- Definitions, causes, and sources
- Regulations and enforcement trends
- Role of the Compliance Officer
- Investigating and preventing drug diversion
- Case study

## AGENDA



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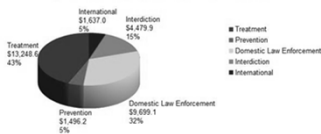
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US Drug Control Spending, FY2016 Enacted  
Budget Authority in Millions of Dollars. Source: ONDCP, February 2016



The estimated cost of controlled prescription drug diversion and abuse to Federal, State, and private medical insurers is approximately \$72.65 billion a year.

National Drug Control Budget FY 2017 Funding Highlights (Washington, DC: Executive Office of the President, Office of National Drug Control Policy, February 2017, Table 1, p.16, and Table 3, p. 19)

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### IN "CRAIN'S HEALTHCARE PULSE" (SEPTEMBER 2016)




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### DEFINITION, CAUSES, AND SOURCES

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### DEFINITION

Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended or illicit purposes

- Often due to addiction or for financial gain
- Proliferation of pain clinics has led to an increase in the illegal distribution of expired or counterfeit medications
- High-value and Schedule II – V Controlled Substances frequently diverted:
  - Opioids
  - Performance enhancing drugs (e.g. erythropoietin, anabolic steroids)
  - Psychotropic drugs
  - Antiretroviral drugs

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# THE CONTROLLED SUBSTANCES ACT OF 1970

- **Schedule I** - drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
  - Example: heroin, lysergic acid diethylamide (LSD), **marijuana (cannabis)**, 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote
- **Schedule II** - drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.
  - Examples: Combination products with less than 10 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Droxidine, Adderall, and Ritalin
- **Schedule III** - drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.
  - Example: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone
- **Schedule IV** - drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.
  - Example: Xanax, Sonata, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol
- **Schedule V** - drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.
  - Example: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule



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# CAUSES AND SOURCES

- Theft of sample medications
- Substituting or changing medications provided to patients
- Re-directing expired medications for use or distribution elsewhere
- Altering or falsifying medical record documentation
- 'Wasting' of medications
- Forged or counterfeit prescriptions
- Diverting large drug quantities when they are purchased or during delivery and receipt
- From automated storage and dispensing systems\* (ASDU or ADU)



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# DRUG DIVERSION @ HEALTHCARE FACILITIES

- New and complex drug diversion schemes are fueling this epidemic of prescription drug abuse
- Until recently, it was believed that most diverted controlled substances came from doctor shoppers, prescription forgery rings, pharmacy thefts, pill mills, and rogue Internet pharmacies
- Drug diversion has been associated with virtually every category of healthcare worker – from professional clinical staff to EMTs, nurses, to facility staff
  - Theft of drugs by employees with access to bulk pharmacy supplies or computerized medication delivery cabinets
  - Addicted employees stealing controlled substances intended for patients for personal use by substituting non-controlled substances for the ordered medication
- Even if the quantity of drugs that are diverted is relatively small, the hospital's liability is significant

OIG Spotlight on Drug Diversion - <https://oig.hhs.gov/newroom/spotlight/2013/diversion.asp>  
DEA Diversion Control Website - <https://www.deadiversion.usdoj.gov>



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### REGULATORY ENFORCEMENT TRENDS

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### ENFORCEMENT TRENDS

- Drug diversion contributed to a 4-fold increase in substance abuse treatment admission from 1998 to 2008 for individuals ages 12 and over
  - Since 2009 more people in the US have died annually from drug poisoning than from car crashes
- Healthcare providers are one of the leading sources of diverted drugs
  - Variety, types, and quantities of controlled substances purchased
  - Number of personnel involved in purchase, distribution, administration

CMS Medicare Learning Network - "Medicaid Program Integrity - What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?", ICN 909010 rev. 2014  
<http://olip.hhs.gov/newsecon/spotlight/2013/diversion.asp>



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### ENFORCEMENT TRENDS

- Involvement of criminal networks
  - include patient recruiters
  - money launderers, and
  - street dealers and gangs
- Some of these culprits have violent criminal histories, increasing the challenges and risks to law enforcement agents investigating these cases
- Top law enforcement priority
  - 9% increase in the 2016 DEA budget dedicated to diversion control



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# REGULATIONS & IMPACT

## Legal Framework

- **Controlled Substances Act**  
*This law regulates the manufacture and distribution of many drugs, including controlled substances*
- **Conditions of Participation**  
To qualify for Medicare certification and reimbursement, providers, and suppliers of health services must comply with minimum health and safety standards called "Conditions of Participation" ("CoPs"), including proper securing and distribution of drugs.
- **ICAHQ Requirements (or those related to Certifications of ACS, procedural suits, etc.)**  
*ICAHQ standards are the basis of an objective evaluation process that can help health care organisations measure, assess, and improve performance.*
- **Pharmacist licensure requirements**  
*Each state board of pharmacy has a set of requirements that a pharmacist must meet.*

## Impact

- Civil, criminal, and regulatory liability (FCA, certification status, CoPs)
- Impact on corporate liability rating and insurability (MedMal, D&O, etc.)
- Reputational harm (PR & Media attention)
- Impact on non-for-profit/ charitable status




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# FCA

- Providing medically unnecessary service
- Billing for
  - Services not rendered
  - Medically worthless
- Violating statutory, regulatory or contractual provision with a nexus to payment




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United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE  
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FOR IMMEDIATE RELEASE Monday, September 28, 2015

**MGH to Pay \$2.3 Million to Resolve Drug Diversion Allegations**

BOSTON – In the largest settlement of its kind involving allegations of drug diversion at a hospital, Massachusetts General Hospital (MGH) has agreed to pay the United States \$2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. In conjunction with this record monetary settlement, MGH has agreed to implement a comprehensive corrective action plan to prevent, identify, and address future diversions.

"Under the law, hospitals like MGH have a special responsibility to ensure that controlled substances are used for patient care and are not diverted for non-medical uses," said U.S. Attorney Carmen M. Ortiz. "Diversion of these drugs feeds addiction, contributes to potential illegal drug sales, and fuels the opioid epidemic that has had a devastating effect on the Commonwealth. We commend MGH for disclosing and addressing its diversion problems and for taking steps to ameliorate future diversion by hospital personnel."

"The DEA is committed to investigating hospitals that are not in compliance with the Controlled Substances Act (CSA)," said Special Agent in Charge Michael J. Ferguson. "Failure to do so increases the potential for diversion and jeopardizes the public health and safety. The diversion of prescription pain killers, in this case oxycodone, contributes to the widespread abuse of opiates, is the gateway to heroin addiction, and is devastating our communities. DEA pledges to work with our law enforcement and

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**Human Cost**

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**IS IT A BIG DEAL?**

About 100 people die from drug overdoses daily, with opioids accounting for 75%

- Reliable statistics on the prevalence of drug diversion by nurses are not available
- By its nature, diversion is a clandestine activity, and methods in place in many institutions leave cases undiscovered or unreported
- Drug diversion by healthcare providers is universal among institutions in the US

If your institution is not finding and reporting drug diversion, review your program with the goal of identifying its weak points

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### WHY DON'T WE HEAR ABOUT IT MORE?

- Under-reporting
  - to appropriate oversight agencies
  - To licensing authorities
- Fear of negative publicity
- Concern of State and Federal agency involvement
- Uncertainty about reporting requirements
- Justification that terminating the offender is enough




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### WHAT IS THE CCO'S ROLE?

- Drug diversion prevention, training, and controls must be incorporated in the elements of Compliance Program
- Efforts expanded, findings, and reports should be incorporated into overall Compliance Program dashboards
  - Management level compliance committee
  - Board level compliance committee
- Licensed professionals (PharmD, MD, DO, et al) expected to take an active part in prevention and reporting of diversions, and 'red flags'




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### INVESTIGATIONS

- Notifying GC if diversion is suspected (privileging investigation, as appropriate)
- Put together an investigation Work Plan / steps
- Conducting staff interviews
- Review of medical records
- Reconciling discrepancies
- Identifying and quantifying the issue (scope)
- Analyzing potential repayment and self-disclosure (FCA) obligations
- Reviewing DEA reporting requirements
- *Developing and retaining documentation trail*




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## CORRECTIVE ACTIONS

- Implementing written policies, procedures, and standards
  - Reviewing communication flow to ensure transparency
  - Initiating internal monitoring and auditing
  - Training and education
    - Re-train staff in affected areas
- For significant findings:
- Develop and implement organizational communication plan
  - Report the event through appropriate Board level committee
  - Consider HR policy on mandatory drug testing




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## INVESTIGATION

- A FEW THOUGHTS

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## DECISION POINTS

- Who leads investigation –
  - Generally – CCO, with support of GC, HR, Clinical leads
- In-house or outsource; fully or partially
  - Organizational sensitivities
  - Scope of the discovered issue and potential for risk exposure
  - Availability of impartial and confidential in-house clinical review by 'like' licensure
- Expert witness use
  - Retained through attorney-client privilege
  - Available to testify, if needed
  - Have experience testifying as an expert
  - Carefully selected in same specialty, same experience
  - Facilitating expert witness review, and report




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## MONITORING - RECONCILIATION

- What should be reconciled:
  - Drug inventory at the start of the day/ shift
  - Drug disbursements
  - Supply on hand at the end of the day/ shift
- Proper and ongoing monitoring detect issues in real time
- Publicizing the processes deters potential offenders



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## AD HOC AND PERIODIC AUDITING

- Identify vulnerabilities/ prescription spikes/ by provider
- Review sample of medical records/ administration records/ orders
- Review ASDU activity logs
- Reconcile variances
- Discuss findings with appropriate clinical/ administrative staff



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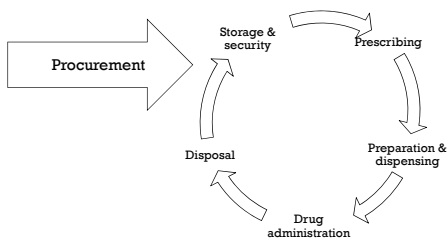
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## PREVENTION ALONG THE CHAIN



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## INTEGRATING PREVENTION PRACTICES

- Establishing oversight authority with clear reporting lines and ongoing monitoring activities
- Immediate communication of 'red flags' through the proper chain of command
  - Individual MD request for controlled substance (or family members)
- Implementation of e-prescribing (i-Stop in New York)
- Review of personnel involved in procurement, job rotations, and mandatory vacations for purchasing staff & management
- Segregation of duties
- Monitoring for COI / potential collusion

Centers for Medicare & Medicaid Services: "Partners in Integrity: What is the Prescriber's Role in Preventing the Diversion of Prescription Drugs?" January 2014. Available at <http://go.cms.gov/128447>

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## ESTABLISHING RELEVANT CONTROLS

- Daily reconciliation
- Properly securing and reconciling DEA-222 forms (if applicable)
- Orders vs receipts vs stocking
- Reviewing and securing delivery process
  - PharmD sign-off of receipt
  - Controlled and secure delivery to floors (if applicable)
- Access to pharmacy vault
  - Limited (periodic review of access)
  - Secure
  - Monitored
- Ad hoc inventory review

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## SYSTEM CONTROLS

- Access controls to ASDU
  - Limiting number of staff with access
  - Limiting number of "Super Users"/ "Administrators"
- Ongoing review of ASDU reports
  - By frequency of discrepancies (individual & area)
  - Higher wasting
  - Higher utilization

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## POLICIES AND PROCEDURES

- Risk assessment and process revisions documented through policies and procedures for
  - Ordering
  - Receiving
  - Stocking
  - Wasting
  - Destruction
  - Reporting
- Staff education
  - On processes
  - Reporting obligations and timelines
  - Proper use of ASDU system
    - Physical access
    - Software




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## ENGAGING CLINICIANS

- In March of 2016 the Centers for Disease Control and Prevention (CDC), developed the first-ever guidelines for dispensing addictive painkillers
  - The guidelines urge doctors to avoid prescribing opioids for patients with chronic pain, noting that the risks of such drugs outweigh the benefits for some people.
- In light of the new guidelines, some physicians are now
  - Requiring patients to sign "pain management contracts"
  - Agreement to random drug tests before receiving an opioid prescription
  - Some are implementing opioid prescribing guidelines.
- Access to tools ≠ utilization of tools:
  - Screening
  - Pain scale
  - Alternative protocols
- State-specific best practice guidelines

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. 2016;315(15):1624-1645




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## DEVELOPING ALTERNATIVE TREATMENT PROTOCOLS

- Creating and promulgating awareness of the issue
  - Mayo Clinic study indicates that up to 1 in 5 Pt with opioid Rx are at risk
- Alternative:
  - Nerve blocks,
  - Periarthicular injections
  - Neuraxial anesthesia
  - Anti-inflammatory drugs
  - Multi-modal therapies with post-op pain pumps
- Avoiding Rx for minor ailments (toothache, sprained ankle, etc.)
- Ongoing education
  - Clinicians
  - Patients




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# INTEGRATING PREVENTION PROTOCOLS INTO PRACTICE & ENGAGING NPP

- **Preventing Prescription Drug Misuse:** *Screening, Evaluation, and Prevention*
- **Treating Patients At-Risk for Substance Use Disorders:** *Engage Patients in Safe, Informed, and Patient-Centered Treatment Planning*
- **Managing Substance Use Disorders as a Chronic Disease:** *Eliminate Stigma and Build Awareness of Social Determinants*

August 22, 2016. Massachusetts Executive Office of Health & Human Services. Initiative to expand on Core Competencies to Combat Opioid Epidemic (<http://www.mass.gov/eohhsr/gov/newsroom/press-releases/eohhsr/core-competencies-to-combat-opioid-epidemic-expanded-31m>)




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- Increase in DEA budget signals increase in enforcement
- Heightened public concerns diversion and impact on communities
- Organizational and individual liability
- Imperative of proactive rather than reactive approach to mitigation

## WHY NOW?

## Critical Time




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# FROM THE TRENCHES — CASE STUDY




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## THE ISSUE

- Housekeeper opens a locker in the ER staff room
- A vial with a syringe and needle stuck in the top falls on her head
- Chaos ensues...



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## THE PLAYERS

- Nursing (including nursing administration)
- Doctors (ER Dept, Chair, Staff and PAs)
- Executive Administration
- Human Resources
- Pharmacy
- Compliance
- Security (physical, not IT)
- Consultants
- Outside Counsel
- Nurses Union



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## KEY STEPS

- Consultants were hired to conduct forensic interviews, review ER documentation and analyze use of the automated distribution cabinets (Omnipro) used to dispense drugs.
- Definition of the "relevant period" for the investigation was agreed upon by all players.
- The entire process from the ordering of drugs, to posting of orders in the electronic health record, to removing drugs from Omnipro, to administering the medication, documenting the administration and procedures for waste of excess narcotics were discussed with each interviewee to determine consistency and understanding of hospital policy and best practice.



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### CHAOS ENSUES

- Everyone is on the defensive as facts are gathered

What do we know?

- Verbal orders are issued, not followed up by written orders, against hospital policy.
- Nurses are not obtaining medications correctly from the Omnipro cabinets. Wrong patients are getting charged.
- Nurses are not consistently documenting the administration of medication.
- The ER Chair wants to blame Nursing.
- Nursing wants to blame the ER docs and Pas.




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### WHAT ELSE DO WE KNOW?

- Standard change of shift processes regarding counting of narcotics are not being followed.
- Pharmacy does not appropriately reconcile narcotics that are dispensed through the Omnipro cabinets.
- Nursing administration is conducting interviews in a biased manner, shutting out the consultants.
- For instance, the Director of Nursing hugs(!) an interviewee who is a prime suspect for drug diversion after her interview is over.




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### THE SIDE SHOW

- The Union took the position that nurses were being singled out as being at fault for the alleged diversion.
- Union representative mandated their presence at all member's interviews.
- The ER nursing staff threatened a walkout and/or work slowdown as well as notified Administration that they were going to leaflet on the perimeter of the hospital.
- In a show of solidarity, all of the ER day staff marched into Administration to protest the investigations.
- Administration, understandably, wanted quick resolution and end to the disruption.




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### THE FEDS AND THE STATE

- DEA notification is required for all material theft of narcotics in the hospital setting. The reports are made by the head of Pharmacy.
- As well, in New York City, the Bureau of Narcotics Enforcement is also notified and can re-interview people at will.
- It was decided in this case to make the report to the DEA under privilege and guidance by outside legal counsel.



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### RESOLUTION

About nine months later -

- One nurse terminated.
- Final written warnings issued to other nurses and PAs.
- One nurse put on probation and reassigned to a floor.
  - She wound up failing probation and being terminated from employment.
- Overhaul of processes in the ER and Pharmacy.



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**AND THEY ALL LIVED  
HAPPILY EVER AFTER**

**The End**

*(of that story)*



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**IN IDEAL WORLD**

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## INVESTIGATION OF SUSPICIONS

- Diversion team put on alert
- Verification of data and analysis of situation
- Nurse(s) immediately removed from patient contact or intercepted; drug cabinet access discontinued
- Urine drug screen (12 panel)
- Suspension pending conclusion of investigation
- Initial interview of nurse including review of underlying medical record and drug cabinet records (if available/ identified)
- If interviews involve multiple staff:
  - Consistency of interview questions (standard for union staff)
  - Documentation consistency retention
- Periodic communications with diversion/ investigative team

**“To privilege or not to privilege?”**

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## IF DIVERSION IS CONFIRMED

- Determine employment disposition(s) and implications
  - Part time, Locum
  - Union implications
- Review clinical documentation
  - Consider billing implications and rebill if necessary (self-disclosure potential)
  - Coordinate medical record amendment, if necessary, with HIM
- Was patient safety affected
  - Notify patients if applicable




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## RESOLVING THE ISSUES

- If repayment obligation is identified
  - Define scope
  - Self-disclosure requirement
- Re-billing for patients with missing medication/ services
- Address patient safety/ care issues




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## REPORTING

- Drug Enforcement Agency
  - Prompt reporting is expected (Form 106) ([www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov))
- Pharmacy Board/ American Society of Health-System Pharmacists ([www.ashp.org](http://www.ashp.org))
- State Licensure Board(s)
- Department of Health (patient harm issues)
- DEA position that obtaining certain information
- FDA/ OCI (tampering cases)
- Law Enforcement (crimes, issues of abuse/ neglect/ reckless endangerment, fraud)
- OIG
- Accreditation agencies (Joint Commission, AAAASF, etc.) ([www.jointcommission.org](http://www.jointcommission.org))
- Professional Liability Carrier(s)




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# ○ GOING FORWARD

A few thoughts

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# PROFILING THE DIVERTER

- Can be exemplary employees
- Someone you least expect
- Often first to volunteer to pick up extra shifts

*Things to watch for:*

- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc...)
- Personality changes
- Progressive deterioration in personal appearance/hygiene
- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc...)



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# MONITORING: USUAL SUSPECTS

- Correlation of Dx, Rx, and documentation
- Appropriateness of wasting – consistency of utilization vs. waste; timeliness
- Utilization of all Rx prescribed to Pt
- Documenting pain scores inconsistent with colleagues
- Giving implausible excuses for not administering narcotics (“may be discharged today”)
- Documenting administration of narcotics at the time of and after the discharge
- Administering narcotics to patients for whom it is not appropriate



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# BEST PRACTICES

Appendix Controlled Substance Diversion, Detection and Prevention Program  
Elements of Best Practice  
(Including Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
1	Original CS Controlled Substances, DEA Drug Enforcement Administration, ADM Automated Distribution Machine	
1a	1. Monitor serial and should be in place	
1b	2. Recommended element - Progress toward implementation should be made over time	
<b>CORE PRINCIPLES</b>		
1	The chain of custody and individual accountability of Controlled Substances (CS) are maintained at all times.	1
2	Organizational policies exist that address all aspects of CS medication use processes. Policies are regularly reviewed and are compliant with federal and state regulations.	1
3	Organizational policies are adhered to by all staff.	1
<b>STORAGE &amp; SECURITY</b>		
4	CS are securely stored in a locked location (i.e., ADM, safe, locked cabinet/drawer) at all times unless in the direct physical control of an authorized individual.	1
5	CS that are under the control of an authorized individual are not placed where their view may be obscured or where a distraction may prevent direct observation at all times.	1
6	Access to CS storage areas is monitored and limited to authorized staff.	1
7	CS brought into a patient that cannot be returned home are transferred to two purpose-coded healthcare staff and stored in a locked secure location area.	1
<b>PREPARATION</b>		
8	All CS are obtained from pharmacy.	1
9	Only authorized pharmacy staff can dispense CS.	1
10	The number of individuals authorized to order CS is minimized.	1
11	Registration of ADMS user names to the system and receipt of CS.	1
12	Registration of ADMS user names to the system and receipt of CS.	1
13	ADMS inventory counts are based upon usage in order to minimize excess stock.	1
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100	ADMS inventory counts are based upon usage in order to minimize excess stock.	1

<http://www.mayoclinicproceedings.org>


Appendix Controlled Substance Diversion, Detection and Prevention Program  
Elements of Best Practice  
(Including Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
<b>ORDERING / PRESCRIBING</b>		
18	CS are ordered only by licensed authorized prescribers with DEA authorization.	1
19	CS orders are generated by electronic systems with controlled access except in emergency situations or when not practical.	1
20	CS are not prescribed by an authorized prescriber for themselves or an immediate family member.	1
21	Change orders for CS are eliminated.	2
<b>PREPARATION &amp; DISPENSING</b>		
22	CS are dispensed in unit dose packaging whenever possible.	1
23	CS waste from compounded sterile product (CSP) preparation area in the pharmacy is collected and randomly assayed.	2
24	ADM technology is utilized in high volume CS pharmacy areas.	2
25	Secure, lockable, non-transparent medication delivery carts / containers are used to deliver CS.	1
26	ADM technology is utilized in patient care areas for the distribution and accountability of CS.	1
27	ADM managed CS are stored in a location with single pocket access.	1
28	Blind code scanning is utilized within registered ADM Medication.	2
29	A "blind count" process is used for all ADM managed CS. (A, see below)	1
30	The number of CS on ADM override status is minimized. (B, see below)	1
31	Blind ADM technology prevents tampering entry is used instead of passwords.	1
32	CS delivery to non-ADM areas requires co-signature for delivery and return.	1
33	Non-ADM CS cabinets are secured with an electronic lock that requires a user specific code or badge swipe.	2
34	ADM down time procedures are defined to maintain the control, documentation and accountability of CS.	1
<b>ADMINISTRATION</b>		
35	A valid order from an authorized prescriber exists for all CS administered.	1
36	CS are only administered by licensed independent practitioners or other licensed or registered health care providers within their scope of practice.	1
37	CS are retrieved from storage areas as close to the time of administration as possible.	1
38	The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.	1
39	CS for one patient at a time are obtained from the ADM / locked storage area.	1
40	The individual retrieves the CS from ADM / locked storage area is also the person that administers the medication.	1
41	All CS drawn up into syringes, if not immediately administered, are labeled per institutional policy and the initials of the individual that drew up the drug are written on the label.	1

Appendix Controlled Substance Diversion, Detection and Prevention Program  
Elements of Best Practice  
(Including Outpatient Pharmacies)


No	Best Practice Element	PRIORITY TIER
42	Initials on prepared syringes are verified immediately prior to administration to ensure that the syringe has not been switched.	1
43	CS waste from high risk areas (e.g. surgical, anesthesia, procedure, high volume and/or specific high-risk CS medications (e.g. fentanyl)) are returned to and reentered by the pharmacy. Universal precautions are used when handling waste.	1
44	Approved methods for washing a CS are defined in policy (e.g. squirted into sink, flushed down toilet).	1
45	The washing of all CS requires an independent witness and documentation, except in situations where waste is being returned to pharmacy for assay and assaying.	1
46	An individual witnessing CS washing verifies that the volume / amount being washed matches the documentation and physically watches the medication being washed per policy (e.g. squirted into sink, flushed down toilet).	1
47	Patient-specific CS residues are contained in a locked box (locking to prevent access) under constant surveillance.	2
48	Unused ADM managed CS are returned to a return bin and not to the original ADM pocket.	1
49	All CS returns to the pharmacy require co-signature in the patient care area and in the pharmacy.	1
50	Limited access lock boxes are available in all procedural areas where CS may be left unattended.	1
51	Empty containers of CS (e.g. vials) are discarded in limited-access waste containers (e.g. sharps boxes).	1
52	All CS administered are documented in the medical record.	1
<b>INVENTORY &amp; RECORD KEEPING</b>		
53	A perpetual inventory of all CS is maintained.	1
54	ADM managed CS counts are verified each time a CS drawer is accessed.	1
55	ADM managed CS are manually inventoried by two authorized health care providers if a blind count has not been performed within one week.	1
56	ADM CS Safe managed CS are manually inventoried by two licensed or authorized pharmacy providers on a regular basis.	1
57	Non-ADM managed CS are manually inventoried by two authorized health care providers every shift.	1
58	A biennial physical inventory of all CS is completed and documented per DEA requirements.	1
<b>SURVEILLANCE</b>		
59	CS waste is randomly tested for content.	1
60	ADM CS discrepancies reported by a blind count are resolved by two authorized health care providers within the shift / business day in which these are discovered. A process is in place for investigating discrepancies that are not satisfactorily resolved.	1
61	ADM CS surveillance reports are regularly created and assessed.	1
62	All paper CS Disposition and Inventory sheets are reviewed and audited.	1
63	Ordering vs Dispensing vs Administration documentation is audited (electronic preferred).	1





## Pharmaceutical Diversion in Medicare

Office of Inspector General  
Office of Investigations  
U.S. Department of Health and  
Human Services



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## HHS Office of Inspector General: Background

- **Mission:** Protect the integrity HHS programs as well as the health and welfare of program beneficiaries
- Fight fraud, waste, abuse in over 100 HHS programs
- Largest Inspector General's office in Federal Government
- Office of Investigations performs criminal, civil and administrative enforcement



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## Example HHS Programs

- Medicare (CMS)
- Medicaid (CMS)
- Center for Disease Control (CDC)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Substance Abuse & Mental Health Services Admin (SAMHSA)
- Agency for Healthcare Research and Quality (AHRQ)
- Food and Drug Administration (FDA)

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 **HHS/OIG: Components**

- **Office of Evaluations & Inspections:**
  - Conducts and publishes studies on various vulnerabilities in Medicare/Medicaid. Reports on OIG website with recommendations. Several drug related reports.
- **Office of Audit:**
  - Conducts independent audits of HHS programs/grantees. Also create reports and make recommendations.
- **Office of Council to IG:**
  - Provides legal counsel to IG and other components. Performs civil monetary penalties, provider self disclosures, collaborates with DOJ on national cases, provide advisory opinions to industry.
- **Office of Management and Policy:**
  - Provides mission and administrative support to the OIG. Data analytic unit.
- **Office of Investigations:**
  - Law enforcement arm of OIG. Traditional law enforcement techniques with contemporary data analytic tools to identify trends and targets for investigations and prosecution



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 **OIG Collaborative Effort**

- Tactical Diversion Squads (with DEA)
- Strike Force Units (FBI on HEAT initiative)
- With state, local LE
- Use/encourage Prescription Drug Monitoring Programs (PDMP)
- Support education of industry, patients, providers, pharmacists - Can't prosecute our way out of this problem





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 **HHS/OIG: Results**

- Over the last 5 years:
  - 4,478 Criminal Actions
  - 2,762 Civil Actions
  - 18,109 Exclusions
  - \$21.9 Billion in Monetary results
- Since 1997 - **\$31 Billion** returned to the Medicare Trust Fund
- Over last 3 years: **\$5 to \$1** return on Investment



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## Exclusion Authorities

- **Social Security Act (Sections 1128 and 1156)**
- **Approximately 3000 actions per year**
- **Duration from 3 years to Permanent**
- **47% Based on License Revocation/Suspension/Surrender**
- **48% Based on Convictions**
  - Health Care Fraud or other Program Related Offense,
  - Patient Abuse/Neglect,
  - Controlled Substance
- **Covers Medicare, Medicaid, Tricare, federal w/c, SCHIP, VA, and IHS (home mortgages, student loans)**

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## Recent OIG Drug Reports

- **Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills**
  - \$25M
- **Prescribers with Questionable Patterns in Medicare Part D**
  - 736 general care physicians
- **Retail Pharmacies with Questionable Part D Billing**
  - Over 2600 pharmacies identified
- **Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority**
  - Massage Therapists, Athletic Trainers, Home Repair Contractors, etc.

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## 2015 OEI Report



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**

HHS OIG Data Brief • June 2015 • OEI-02-15-00190

### Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D

**Key Takeaways:**

- ✓ Since 2006, Medicare spending for commonly abused opioids

Prescription drug abuse is a growing problem in this country. In 2011, the Centers for Disease Control and Prevention (CDC) declared prescription drug abuse an epidemic.<sup>1</sup> That year alone, over 1.4 million emergency department visits were caused

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 **Part D Breakdown**

- \$8.4 B spent on controlled drugs (6%)
- \$129 B spent on non-controlled drugs
- Predicted to double by 2023

3/24/2017 LIMITED OFFICIAL USE ONLY 2017/03/24

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 **Different Drug Jurisdictions**

- **DEA:** Controlled substance laws and regulations of the United States
- **HHS/OIG:** Pharmaceuticals billed to federal healthcare programs
  - Those paid by Medicare, Medicaid
  - Includes Controlled Substances paid by federal programs
  - But also includes Non-Controlled Substances

3/24/2017 LIMITED OFFICIAL USE ONLY 2017/03/24

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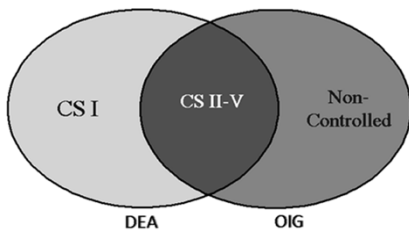
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**DEA & HHS/OIG Authority**



3/24/2017 LIMITED OFFICIAL USE ONLY 2017/03/24

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## Why Divert Non-Controlled?

- **Controlled Drugs:**
  - Diverted for recreational use
  - \$100+B in societal costs
- **Non-Controlled:**
  1. High reimbursement—financial crime. Not dispensed, just billed. Not “government” money
  2. Some diverted to other countries
  3. Others mixed into street cocktails with controlled substances; are “POTENTIATORS”



3/24/2017 LIMITED OFFICIAL USE ONLY 18

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## Potentiators

- Drug recipes that aggregate drugs that in combination enhance the euphoria
- May be another controlled drug but often are non-controlled drugs (OIG purview)
- Pushes patients over edge to respiratory arrest/death
- Hundreds of potentiators in thousands of combinations
- Large financial exposure to Medicare program



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## New Paradigms for Death

- Extraction methods for pure product
- Heavy use with potentiators (Mixed Drug Ingestions)
- New portals of entry (anywhere there is a good vascular bed) to avoid first-pass effect



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**Drug Blogs**

- Erowid.org
- Bluelight.org
- Drugs-Forum.com
- Opiophile.org

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**Erowid Recipe Blog**

Help Erowid win a 2013 Health Award

Knocked Out!!!  
Percocet, Fentanyl, Erowid & Lyrica

"Well, after that last entry I just kind of passed out. I remember seeing something out of the corner of my eyes and trying to grab for it but never actually catching it. Once I passed out I was GONE, people tried to wake me and I was completely unresponsive, they almost called 911 but decided against when they could see I was still breathing. So...yea...I am going to do it again pretty soon probably...."

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**How to Prepare IV Opana**

Extra Supplies for Injection (IVIM) or Rectal (R):

- 1) Spoon
- 2) Lighter (preferably butane torch)
- 3) Needle
- 4) Syringe (1cc or 2cc with 29 gauge needle if injecting)
- 5) Needle (27 G, Cotton Ball, Caplepin Filter, Gauze)

Optional Supplies for Injection (IVIM) or Rectal (R):

- 1) Second Spoon
- 2) Needle Filter
- 3) Citric Acid/Vinegar/Lemon Juice/Vitamin C

Process:

Optional: Crush Opana ER in table clamp.  
 Step One: Using Pedigree and/or designed 'skin catcher', grate the Opana ER TWP into small chunks. Tweezers will allow you to handle the pill once most of it has been grated. Grate the pill over a piece of aluminum foil (folded in half to create a single piece two layers thick) to catch any shards the Pedigree's 'skin catcher' misses.  
 Step Two: Preheat oven to 400 degrees Fahrenheit while grating the Opana ER with the Pedigree.  
 Step Three: Once the entire Opana ER has been grated as small as possible, dump the Pedigree's 'skin catcher' onto the layered aluminum foil. Use your credit card/Driver's license/plastic card to scrape pill chunks into a quarter (1/4) cent piece sized pile. The pile should not have much height to it, but there should be a few spots of aluminum foil visible through it as possible.  
 Step Four: Place the aluminum foil with the grated Opana ER on an oven preheated oven.  
 Step Five: Watch the pile of Opana ER as it heats in the oven. The pill chunks should turn brown in color and appear to melt/become 'gooey'. Do not let any of the pill turn black, but as soon as all but a lined area shade of brown, remove the aluminum foil from the oven and place it directly in the freezer. Due to variations in oven heating patterns, altitude, etc. the amount of time the pill will take to cook varies. DO NOT LET IT TURN BLACK. Better to remove the pill with one or two white spots than burn it. Make sure to place the aluminum foil and cooked pill directly into the freezer.  
 Step Six: Let the pill sit in the freezer for 2-7 minutes. Any 'gooey' spots should be hardened when the pill is removed from the freezer.  
 Step Seven: Remove aluminum foil and now 'freeze' pill from freezer. Using credit card/Driver's license/plastic card, scrape pill off of aluminum foil. Be careful not to tear aluminum foil while scraping pill off of it. The pill should come off the aluminum foil easily, but if it is 'gooey', then it needs more time in the freezer.

Based on the planned RDA, proceed to the specific instructions...

Inhalation (IN) Specific Process:

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**DJAGS**



## Prescription Drug Fraud

- A physician wrote illegal prescriptions for co-conspirator patients – more than 700,000 pills passed along to 6 different drug trafficking organizations.
- Norman Werther along with 61 associates received a combined 253 years in prison. Dr. Werther received 20 years and ordered to forfeit \$10 million.



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## Inside Pharmacy



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**DJAGS**



## Prescription Drug Fraud

- January 2016, Jaime Guerrero admitted to distributing and dispensing Schedule II and III controlled substances to patients without a legitimate medical purpose beyond the bounds of professional medical practice – resulting in patient death.



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## Slide 25

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**TJA(5)** Double check this photo. This, as well as several other slides, came from presentations I have created in the past and I believe there was a problem with the Werther photo. Unfortunately the link is archived so I can't double check it.

Trussell, Jennifer A (OIG/OI), 1/18/2017


## Slide 27

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**TJA(5)** Double check this photo. This, as well as several other slides, came from presentations I have created in the past and I believe there was a problem with the Werther photo. Unfortunately the link is archived so I can't double check it.

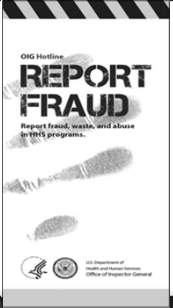
Trussell, Jennifer A (OIG/OI), 1/18/2017





### What To Do if you Suspect Fraud or Diversion Activity?

- Use available databases to scrutinize scripts; including your state PDMP database
- If receive a clearly fraudulent script, forged script, ID theft; engage law enforcement immediately
- If you suspect a Medicare provider or beneficiary is diverting, contact
  - 800-HHS-TIPS or at
  - [oig.hhs.gov/report-fraud](http://oig.hhs.gov/report-fraud)



REPORT FRAUD  
Report fraud, waste, and abuse in HHS programs.

OIG Hotline  
800-HHS-TIPS

U.S. Department of Health and Human Services  
Office of Inspector General

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## Thank You

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# Minimizing Stark Law Execution Risk

HCCA's 21st Annual Compliance Institute  
March 26, 2017

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### Program Purpose: Equip In-House Counsel to Meet Professional Obligation to Provide Competent Stark Law Advice

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- The overriding purpose of this program is to enable attendees to fulfill their ethical and professional obligations to provide competent representation under the Illinois Rules of Professional Conduct when providing Stark Law advice.
  - Rule 1.1 stipulates that "A lawyer shall provide competent representation to a client. Competent representation requires the legal knowledge, skill, thoroughness and preparation reasonably necessary for the representation."
  - Accordingly, attorneys who provide Stark Law advice must be knowledgeable regarding the intricacies of the highly complex Stark Law regulations and spot issues requiring expert advice.
  - This program will highlight Stark Law pitfalls and recent changes to enable attendees to meet this requirement.
  - We also will discuss some of the ethical quandaries that arise in the provision of Stark Law advice and implementation of physician arrangements.




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### Ethical Dilemmas in Stark Law Counseling: Relevant Rules of Professional Conduct

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- Several Rules are potentially implicated by the rendition of complex Stark Law advice, including:
  - Client Compliance with Law (Rule 1.2(d))
  - Organization as Client (Rule 1.13)
  - Conflict of Interest (Rule 1.7)
  - Terminating Representation (Rule 1.16)
  - Alteration and Concealment of Evidence (Rule 3.4)
  - Advocate in Non-Adjudicated Proceedings (Rule 3.9)
  - Misconduct (Rule 8.4)




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### Client Compliance With Law (Rule 1.2(d))

- A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is **criminal** or **fraudulent**, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of law.

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### Rule 1.7 – Conflict of Interest

- A lawyer shall not represent a client if the representation involves a concurrent conflict of interest.
- A concurrent conflict of interest exists if:
  - the representation of one client will be directly adverse to another client; or
  - there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to another client, a former client or a third person or by a personal interest of the lawyer.

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### Rule 1.7

- Commentary:
  - For example, a lawyer asked to represent several individuals seeking to form a joint venture is likely to be materially limited in the lawyer's ability to recommend or advocate all possible positions that each might take because of the lawyer's duty of loyalty to the others.
  - The critical questions are the likelihood that a difference in interests will eventuate and, if it does, whether it will materially interfere with the lawyer's independent professional judgment in considering alternatives or foreclose courses of action that reasonably should be pursued on behalf of the client.

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## Rule 1.7 – Exceptions

- The only exceptions are:
  - the lawyer reasonably believes that the lawyer will be able to provide competent and diligent representation to each affected client;
  - the representation is not prohibited by law;
  - the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal; and
  - each affected client gives informed consent.

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## Organization as Client (Rule 1.13)

- A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.
- If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or **a crime, fraud or other violation of law** that reasonably might be imputed to the organization, and that is likely to result in **substantial injury to the organization**, then the lawyer **shall** proceed as is **reasonably necessary in the best interest of the organization**.
  - Normally, this involves referral to a higher authority within the organization.
  - However, referral may not be necessary if a constituent had an innocent misunderstanding of law and reconsiders action on advice of counsel.
  - If highest authority within organization refuses to address action that is clearly a **crime or fraud**, lawyer **may** reveal information reasonably necessary to prevent substantial injury to the organization but **not** if information arose from lawyer's involvement in an investigation or defense of client.
- In dealing with an organization's directors, officers, employees or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization's interests are adverse to those of the constituents with whom the lawyer is dealing.
- A lawyer representing an organization may also represent any of its directors, officers, employees, or other constituents, subject to Rule 1.7 on joint representation.

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## Terminating Representation (Rule 1.16)

- Withdrawal is appropriate when:
  - Representation would violate the Rules of Professional Conduct or law.
  - The client persists in a course of action involving the lawyer's services that the lawyer reasonably believes is criminal or fraudulent.
  - The client has used the lawyer's services to perpetrate a crime or fraud.
  - The client insists upon taking action that the lawyer considers repugnant or with which the lawyer has a fundamental disagreement.

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### Alteration and Concealment of Evidence (Rule 3.4)

- A lawyer shall not unlawfully obstruct another party's access to evidence or unlawfully alter, destroy or conceal a document or other material having potential evidentiary value.
- A lawyer shall not counsel or assist another person to do any such act.

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### Advocate in Non-Adjudicated Proceedings (Rule 3.9)

- A lawyer representing a client before a legislative body or administrative agency (e.g., as a lobbyist) in a non-adjudicative proceeding shall disclose that the appearance is in a representative capacity and shall conform to the provisions of Rules 3.3(a) through (c), 3.4(a) through (c), and 3.5.
- Rule 3.3 requires "candor toward the tribunal."
- Rule 3.4 precludes falsification of evidence and assisting a witness in giving false testimony.
- Rule 3.5 bars *ex parte* communications unless authorized by law or court order, as well as seeking to influence an official by unlawful means.

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### Misconduct (Rule 8.4)

- Among other things, it is professional misconduct for a lawyer to:
  - Violate or attempt to violate the Rules of Professional Conduct, knowingly assist or induce another to do so, or do so through the acts of another.
  - Commit a criminal act that reflects adversely on the lawyer's honesty, trustworthiness, or fitness as a lawyer in other respects.
  - **Engage in conduct involving dishonesty, fraud, deceit, or misrepresentation.**
  - State or imply an ability to influence improperly a government agency or official or to achieve results by means that violate the Rules or other law.
  - Present, participate in presenting, or threaten to present criminal or professional disciplinary charges to obtain an advantage in a civil matter.
  - Violate an anti-discrimination law.

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## The Yates Memo: DOJ's Increased Focus on Individual Accountability

The 6-pronged memorandum regarding "Individual Accountability for Corporate Wrongdoing" issued by Deputy Attorney General Sally Quillian Yates to federal prosecutors on September 9, 2015 changes DOJ's policy on the resolution of criminal **and civil** cases.

1. To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct.
  - Failure to conduct a robust investigation may disqualify the company for credit.
2. Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.
3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.
4. Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
5. Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.
6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.

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## Ethical Implications of Yates Memo

- Under Rule 1.1 (competence), it is important for in-house counsel to take the Yates Memo into account when advising on the conduct of investigations.
  - The memo's emphases on diligent and thorough investigations of individual culpability makes a robust, timely, independent investigation essential.
  - It also means that individuals are more likely to insist on having their own counsel present for investigational interviews.
  - Robust "Upjohn" warnings must be given at the start of investigational interviews and in-house counsel should not downplay the potentially divergent interests of the company and the individual if questions arise.
- Not only is it an ethics violation to counsel a client or assist a client in criminal or fraudulent conduct under Rule 1.2(d), in-house counsel faces a pronounced risk of individual liability for doing so in light of the Yates Memo.

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## Ethical Implications of Yates Memo

- The Yates memo exacerbates potential conflicts of interest between the organization and any officer, director or other constituent potentially involved in wrongdoing, making joint representation more problematic under Rules 1.7 and 1.13.
- However, the Yates memo gives in-house counsel a lever to urge individual constituents to reconsider action involving potential violations of law before they take it.
  - Such reconsideration would obviate in-house counsel's ethical obligation to refer matter to a higher authority under Rule 1.13.
  - But if a constituent refuses to reconsider, referral up the chain becomes all the more essential in light of the heightened potential consequences for the organization.

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## Ethical Quandary #1

- Your hospital client receives a Government subpoena in connection with an sealed *qui tam* case. In reviewing potentially responsive documents, you find an email from the health system CFO to the CEO indicating that the hospital's group practice mistakenly took into account DHS collections in productivity bonus distributions for the past 5 years.
- The CEO responded that the past is water under the bridge but instructed the CFO to correct the issue going forward.
- The CEO calls your office, acknowledges the email trail and directs you not to produce it. He also asks for your advice on how to minimize his exposure.

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## What Do You Do?

- A. Suppress document and advise CEO on personal exposure
- B. Produce document
- C. Counsel CEO on consequences of suppression for the Hospital/ hope he changes his mind
- D. Go to Chairman of the Board
- E. Terminate representation

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## Stark Exceptions - What is Needed?

Terms of exception	In-office ancillary services [1877(h)(4); §411.352]	Bona fide employment [1877(e)(2); §411.357(e)]	Personal services arrangements [1877(a)(3); §411.357(d)]	Fair Market Value [§411.357(f)]
Must compensation be "fair market value"?	No	Yes - 1877(e)(2)(B)(i).	Yes - 1877(e)(3)(A)(v).	Yes - §411.357(f)(3).
Must be "commercially reasonable"?	No.	Yes (remuneration) - 1877(e)(2)(C).	Yes (aggregate services reasonable and necessary) - 1877(e)(3)(A)(ii).	Yes (arrangement) - §411.357(f)(4).
Must compensation be "set in advance"?	No	No.	Yes - 1877(e)(3)(A)(v).	Yes - §411.357(f)(3).
Scope of "volume or value" restriction.	DHS referrals - 1877(h)(4)(A)(v).	DHS referrals - 1877(e)(2)(B)(ii).	DHS referrals or other business - 1877(e)(3)(A)(v).	DHS referrals or other business - §411.357(f)(3).
Scope of productivity bonuses allowed.	Personally performed services and "incident to" plus indirect - 1877(h)(4)(B)(i).	Personally performed services - 1877(e)(2).	Personally performed services - §411.351 ("referral") and §411.354(d)(3).	Personally performed services - §411.351 ("referral") and §411.354(d)(3).
Are overall profit shares allowed?	Yes - 1877(h)(4)(B)(i).	No.	No.	No.
Written agreement required?	No.	No.	Yes, minimum 1-year term.	Yes (except for employment), no minimum term.
Physician incentive plan (PIP) exception for services to plan enrollees?	No, but risk-sharing arrangement exception at §411.357(n) may apply.	No, but risk-sharing arrangement exception at §411.357(n) may apply.	Yes, and risk-sharing arrangement exception at §411.357 may also apply.	No, but risk-sharing arrangement exception at §411.357(n) may apply.

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## FMV

...the value in arms length transactions, consistent with the general market value.  
"General market value" means the price that an asset would bring, as the **result of bona fide bargaining** between well-informed buyers and sellers who are **not otherwise in a position to generate business for the other party**; or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to the agreement who are **not otherwise in a position to generate business for the other party at the time of the service agreement**. Usually, the fair market price is...the compensation that has been **included in bona fide services agreements with comparable terms** at the time of the agreement ...where the...compensation has **not been determined in any manner that takes into account the volume or value of anticipated or actual referrals**.

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## FMV/GMV

- Included in definition:
  - Result of bona fide bargaining
  - Not in a position to generate business
  - Bona fide arrangements with comparable terms
  - Does not take into account the volume or value of referrals
- Because part of definition, will ask valuers to address
- How do you demonstrate?

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## Commercial Reasonableness

- No express definition in regulations, but commentary states:
  - **Phase I**: Sensible, prudent business agreement from the perspective of the parties
  - **Phase II**: Would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential for DHS referrals

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## Commercial Reasonableness

- Examples of Commercially Unreasonable Conduct/Arrangements:
  - Too many medical directors
  - Purchase of an asset, with no intention to ever use it
  - Complex arrangements with illogical components
  - No chance to earn a profit/foreseeable operating losses
  - Paying for early termination rights
  - Overbroad non-compete
  - Leasing an item for more than the cost to acquire

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## Safeguards for FMV Compliance

- Robust contract approval policies.
  - Require legal review for compensation arrangement outside of predefined parameters
- Document FMV rationale for all contractual arrangements.
  - Don't blindly rely on third-party valuations – conduct "critical eye" review to ensure that projected DHS revenue streams from physician do not figure into valuation and that reasonable benchmarks are used.
  - Specifically request experts to stipulate that compensation is commercially reasonable and does not take into account referrals.
- Build in automatic escalators or periodic FMV reevaluations under contractual arrangements at commercially reasonable intervals.
  - While auto renewal clauses are advisable, they make periodic FMV resets particularly important.

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## FMV Compensation Challenges

- Losses and "subsidiaries" – do they always result in an FMV problem?
- Limited duration of FMV opinions.
- At what time is fair market value determined?
- Comparables for value-based payments and non-productivity.
- The "opportunity cost" problem.
- MGMA and surveys – contain data not comp systems.
- Definition of FMV – doesn't take into account the volume or value of referrals.

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## Isolated Transaction Definition

- An isolated financial transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that:
  - Total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and
  - The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

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## Isolated Transaction Exception

- The amount of remuneration under the isolated transaction is:
  - Consistent with the fair market value of the transaction; and
  - Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties
- The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity

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## Isolated Transaction Exception

- There are no additional transactions between the parties for 6 months after the isolated transaction, except for:
  - Transactions that are specifically excepted under the other provisions; and
  - Commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician

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## Valuation of Physician Practices

- Three Basic Approaches to Value:
  - Cost Approach
  - Income Approach
  - Market Approach
- Source of Basic Valuation Approaches:
  - IRS Revenue Ruling 59-60
  - Finance community – academic and practical
- FMV vs. Investment Value or “Strategic” Value

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## Valuation of Physician Practices

- Problems with the Cost Approach
  - Substitution of equivalent service transactions may not be practical
  - Book Value (or Cost to Replace) may understate value
  - Aggregate cost exceeds income approach
- Problems with Market Approach:
  - Comparable data limited or non-existent
  - May include transactions between parties in a position to refer to one another
  - May include transactions involving strategic value

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## Valuation of Physician Practices

- Problems with Income Approach:
  - Income/Revenue may consider the income from referrals
  - Medical practices “zero out” every year – no earnings for owners without adjustments
  - Impact of future compensation

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## Determining FMV for Intangible Assets Absent Positive Cash Flow

- The primary issue lies within the concept of total enterprise value versus the value of individual assets
  - Sum of the parts or greater than value of whole
  - Economic benefit equivalent to costs avoided
  - Cost to assemble assets
- Workforce in-place considerations
  - Time and effort to recruit workforce
  - Ramp-up to full productivity
  - Include or exclude clinicians?

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## Determining FMV for Intangible Assets Absent Positive Cash Flow

- Patient charts
  - Cost to reproduce
  - HIPAA guidance
    - Labor for copying the PHI, whether in paper or electronic form
    - Supplies for creating the paper copy or electronic media (e.g., CD-ROM or flash drive)
    - Postage

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## Considerations in Time Shares and Real Property Leases

- “Local market” impact to value versus value for proximity to referral sources
  - Information regarding market comparable, industry/specialty specific leases may be limited
- Rates must be consistent with the specific terms of the agreement and condition of the space being leased
  - Class A, B, C space
  - NNN versus gross, common area maintenance, leasehold improvements, duration of the lease, etc.
  - Time share arrangements must factor any furniture, fixtures, equipment, staff, supplies, or other services provided into determination of fair market value

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## Personal Property (Equipment) Leases

- Market comparable data for most types of equipment, furniture, etc. is available through industry-specific sources
- Renewal of existing leases of equipment, furniture, etc. can be problematic
  - The one-time cost to purchase each leased asset versus the total historical lease payments for each specific asset should be factored into the decision to renew the lease.
  - The cumulative term of the lease versus the estimated useful lives for each specific asset should be factored into the decision to renew the lease.
  - Fair market value should have some basis in the current appraised value of the assets

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## Value-Based Clinician Compensation

- Allows for an objective method for moving some risk to employed clinicians
  - Shift from fee-for-service to episodic care
- Medicare adjustments under MACRA provide a means to measure applicable physician compensation adjustments
- Physician compensation impact
  - Incentives for improving quality, practice operations, and use of technology (or penalties for failing to do so)
  - Resource use (cost) will become the largest contributing factor for Medicare adjustments, and will provide challenges to traditional productivity-based compensation and traditional methods of evaluating fair market value

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## Ethical Quandary #2

Your VP of Business Development has negotiated a deal with a key orthopedic group to joint venture a new ambulatory care facility and provide various management and medical director services to the new facility.

- He gives you a term sheet and tells you to draft up the documents.
- When you raise concerns regarding the FMV of the “contributed assets” and compensation rate, as well as the high number of hours of service projected, he acknowledges the above FMV rates and that the physicians aren’t really going to provide the number of hours of service called for by the term sheet.
- Nonetheless, he says “Just get the document done – we need to do this deal to avoid losing this group’s admissions to our competitor. I’ll take responsibility if we are ever challenged.”

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## What Should You Do?

- A. Just get the documents done – if the deal blows up, you can produce a memo to file indicating you raised concerns and the VP assumed the risk.
- B. Refuse to paper deal terms that violate the AKS and will expose the organization to FCA risk.
- C. Counsel the VP on the risks to the organization and to him personally in light of Yates memo.
- D. Inform the CEO of your concerns.

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## Government and the Courts

- Key cases:
  - Bradford
  - Tuomey
  - Halifax
- What are the takeaways?

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## Bradford: Fixed Payment Can Take into Account Volume or Value

"A fixed payment compensation arrangement such as the one in this case may be considered as taking into account the volume or value of referrals — if that fixed payment is in excess of fair market value."

"We conclude that the compensation arrangement between BRMC and the doctors is inflated to compensate for the [doctors] ability to generate other revenues. Specifically, we find that the amount of the compensation arrangement was arrived at by taking into account the anticipated referrals from the doctors. We therefore conclude that the compensation arrangement between BRMC and the doctors is not — fair market value under the Stark Act."

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## Tuomey: Anticipating Volume or Value Can Run Afoul of FMV

"Our analysis of these sources, set forth below, yields the conclusion that compensation arrangements that take into account anticipated referrals do implicate the volume or value standard."

"It stands to reason that if a hospital provides fixed compensation to a physician that is not based solely on the value of the services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that such compensation by necessity takes into account the volume or value of such referrals."

"Thus, it is for the jury to determine whether the contracts violated the fair market value standard by taking into account anticipated referrals in computing the physicians' compensation."

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## Halifax: Source of Funds – Varies Based on Volume or Value

"The Incentive Bonus was not a 'bonus **based on** services personally performed' by the Medical Oncologists, as the exception requires. Rather, as described by the Defendants themselves, this was a bonus that was **divided up** based on services personally performed by the Medical Oncologists. The bonus itself was based on factors in addition to personally performed services -- including revenue from referrals made by the Medical Oncologists for DHS. The fact that each oncologist could increase his or her share of the bonus pool by personally performing more services cannot alter the fact that the size of the pool (and thus the size of each oncologist's bonus) could be increased by making more referrals." (emphasis original)

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## Safeguards for FMV Compliance

- Consider adoption of a physician compensation plan for employed physicians with a process for validating FMV compensation, including committee and/or outside review of all compensation prior to payment that would push physicians over predetermined thresholds and documentation of the rationale for such payment.
  - Include a mechanism for validating that the compensation methodology does not take into account the volume or value of DHS referrals.
- Contract management databases
- Time sheet requirements to ensure services actually rendered.
- Auto adjustments based on productivity reductions beyond pre-defined productivity corridor.

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### Ethical Quandary #3

- You are working with physician group representatives to develop a medical director and call coverage arrangement. The group is very frugal and has declined to have its own legal counsel. They request your advice on structuring certain specific aspects of the arrangement to comply with the Stark Law and AKS, including the compensation formula, length of term and hours expectation. How should you handle?

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### Employment v. In-Office: Differences

- Scope of productivity bonuses
- Profit-sharing bonuses
- Fair market value
- Commercial reasonableness

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### In-Office Ancillary Services Exception

Applies to DHS provided by a **physician group practice** if the following three tests are satisfied:

- | <u>Location</u>  | <u>Provider</u>  | <u>Billing</u>   |
|--|--|--|
| <ul style="list-style-type: none"><li>▪ Same building as a physician office (part-time occupancy permissible only if minimum office hour standards satisfied); or</li><li>▪ Centralized location occupied by group on full-time basis.</li></ul> | <ul style="list-style-type: none"><li>▪ By referring physician;</li><li>▪ By another physician in the group (including independent contractors); or</li><li>▪ By a non-physician supervised by physician in group.</li></ul> | <ul style="list-style-type: none"><li>▪ By group, wholly owned subsidiary or agent</li><li>▪ Under billing number assigned to group or subsidiary.</li></ul> |

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## Minimum Office Hour Standards

If DHS are offered in an office that is occupied on less than a full-time basis, there must be a physician office in the same building in accordance with one of the following three tests:

- The physician office is normally open at least 35 hours per week and one or more members of the group provide physician services at the office at least 30 hours per week;
- The office is open at least 8 hours per week; the individual referring physician practices at such office at least 6 hours per week; and the patient receiving the DHS ordinarily receives physician services at that location; or
- The office is occupied by the group at least 8 hours per week; one or more members of the group provides physician services there 6 hours per week; and the referring physician is present and orders the DHS during a visit on the premises or the referring physician or another member of the group is present while DHS are performed.

In each case, the services provided by the group at the office must include some physician services that are unrelated to the furnishing of DHS (although such services may lead to the ordering of DHS).

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## Group Practice Prerequisites

- Single legal entity with at least two physician members.
- Primary purpose = physician practice.
- All members furnish substantially the full range of services they routinely furnish through joint use of office space, facilities, equipment and personnel.
- Members furnish an average of 75% of their patient care services through group.
- Overhead expenses and income distributed based on prospectively determined methodology.
- Unified business with centralized decision making by a body representative of the group with effective control over groups assets/liabilities (including budgets, compensation and salaries)
- Consolidated billing, accounting and financial reporting.
- Members personally conduct at least 75% of patient encounters.
- Compensation is not based on volume or value of DHS referrals *except* in accordance with "Special Rules."

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## "Special Rules" For Group Practice Profit Distributions and Productivity Bonuses

- Physicians may be paid:
    - A share of the "overall profits" of the group
    - A productivity bonus based on personally performed services and/or "incident to" services
- as long as such profit share or bonus is not determined in a manner directly related to the volume or value of the physician's DHS referrals.
- Overall profits means:
    - Group's entire profits derived from DHS payable by Medicare/Medicaid
    - DHS profits of any component of the group consisting of 5 or more physicians
  - The following profit distribution and bonus methodologies are expressly permitted:
    - Per capita distribution of overall profits
    - DHS profit distribution or bonus based on allocation of non-DHS revenues.
    - DHS profit distribution or productivity bonus if DHS revenue  $\leq$  5% of total group revenue and no physician receives  $>$  5% of total compensation from DHS distribution.
    - Bonus based on total patient encounters or RVUs.
    - Any bonus or overall profit distribution methodology that is not directly related to volume or value of DHS referrals.

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## What Are Incident To Requirements?

- To be covered incident to the services of a physician or other practitioner, services and supplies must be:
  - An integral, although incidental, part of the physician's professional service
  - Commonly rendered without charge or included in the physician's bill
  - Of a type that are commonly furnished in physician's offices or clinics
  - Furnished by the physician or by auxiliary personnel under the physician's **direct supervision**
- Direct supervision requires that the supervising physician be in the **same office suite** and immediately available to provide assistance and direction throughout the time the "incident to" service is performed.

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## Profit Sharing and Bonuses Under Special Rules Based on Personally Performed and Incident To Services

	Bonus Based on Personally Performed Services	Bonus Based on Incident To Services	Profit Share
Professional Services and Other Non-DHS	Yes – Does not implicate Stark	Yes – Does not implicate Stark <sup>1</sup>	Yes – Does not implicate Stark
PT/OT	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules
Outpatient Drugs/Supplies	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules	Yes – In accordance with Special Rules
DME	No – Cannot be personally performed unless physician has own DMEPOS number	No – Same issue as for personally performed DME	Yes – In accordance with Special Rules
Lab	No	No – Never considered "incident to"	Yes – In accordance with Special Rules
Imaging	No	No – Never considered "incident to"	Yes – In accordance with Special Rules

<sup>1</sup> This is true for all DHS except professional component of imaging services.

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## Legal Quandary #1

A health system client wants to form a new entity to acquire physician practices and replicate the autonomy, flexibility and compensation model that the physicians currently have in their independent practices to the greatest extent possible.

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### Which of the Following Features are Potentially Problematic?

- A. Forming a "Pod" for each legacy practice and splitting Pod profits equally among Pod physicians.
- B. Same as above, but allowing Pod physicians to determine how to split the profit pool at the end of each year as long as the methodology is not directly related to the volume or value of DHS referrals.
- C. Paying physicians productivity bonuses based on the "permissible DME" (canes, crutches, etc.) and outpatient prescription drugs dispensed to each physician's patients and the imaging procedures supervised by each physician.
- D. Giving Pod physicians the right to approve the addition of new physicians to their Pod.
- E. Calculating Pod profits available for distribution without allocating centralized practice overhead.



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### Physician Supervision of Midlevel Clinicians

- Exception for assistance to compensate midlevels
- Billing considerations
  - "Incident to" billing, shared/split services, place of service
  - Consider the billing NPI and how it may impact productivity-based compensation
- How many midlevels can one physician supervise?
- Compensation amounts typically similar to that of collaborative agreements
- Overall physician compensation should be consistent with fair market value



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### Pooled Productivity/Equal Share

- Example:
  - 3 physicians of the same specialty
  - All wRVUs personally performed by the physicians are pooled and multiplied by a conversion factor
  - Each physician receives an equal share of the resulting pool (i.e., one-third)
- Does this comply with a Stark Law exception?



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### Pooled Productivity/Equal Share

- Three potentials:
  - MD #1 – paid more than the average
  - MD #2 – paid at the average
  - MD #3 – paid less than the average
- MDs #1 and #2 paid on 100% or less of their productivity, but what about MD #3?

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### Pooled Productivity/Equal Share

- “The amount of the remuneration . . . [e]xcept as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician . . . .”
- Do professional services personally performed by MDs #1 and #2 take into account the volume or value of MD #3’s referrals?
- What about fair market value?

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### Productivity v. Profit Share

- Using a pool of funds to then pay a bonus based on productivity
- When the source of funds is DHS revenues or profits, is it a productivity bonus or is it a profit share?
- Source or funding of the pool v. allocation of the pool

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## Source of Funds

- Typically, arises:
  - In diversified systems/multi-corporation structures
  - Payments to physician group from entity other than employer
  - Trying to characterize as productivity bonus
- Translates to “takes into account volume or value of referrals” – thus, you should be attuned
- This is Halifax
- DOJ now thinks any funds **originating** at hospital takes into account volume or value

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## Group Practices: Potential Pitfalls

- Too much autonomy for PODs – insufficient centralization over decision making, particularly where budgets, physician compensation and staff salaries are concerned.
- Too many part-time employed physicians with other jobs – members don't provide 75% of their patient care services through the group.
- Too many independent contractors – members of the group do not conduct 75% of encounters.
- Failure to prospectively determine compensation methodology.
- Post hoc variations from compensation formula – actual distributions do not match predetermined methodology.
- Bonus/profit share formula that takes into account the volume/value of DHS.

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## Group Practices: Potential Pitfalls

- Failure to include expenses allocable to DHS in bonus/profit pool calculations, resulting in exaggerated profits.
  - Insufficient allocation of overhead for services performed by hospital affiliates can also exaggerate profits.
  - Application of practice-wide contractual allowances, bad debt ratios or other assumptions can distort POD profits.
- Subsidization of group practice by hospital affiliate based on downstream DHS revenues.
- Profit pools for pods of less than five physicians (e.g., when a physician leaves a POD).
- Different postal addresses/suite numbers for offices where physician services and DHS are delivered.
- Inadequate physician supervision to satisfy IOAS exception or to base productivity bonus on incident to services.
- Insufficient physician office hours to satisfy minimum office hour rules.

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## Consultation Exception to Referral Definition

- The Stark Law applies to referrals, but “referral” does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy,” if:
  - The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and
  - The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

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## Consultation Exception to Referral Definition *cont'd*

- “Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:
  - (1) The physician’s opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.
  - (2) The request and need for the consultation are documented in the patient’s medical record.
  - (3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.
  - (4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient’s course of treatment and progress.”

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## Consultation Exception to Referral Definition *cont'd*

- Exception only applies to certain type of services ordered by certain types of physician specialists.
- Must result from a consultation initiated by another physician.
- Consultation definition requires a lot of things to occur:
  - Documentation.
  - Written report to physician who requested the consultation.

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### Ethical Quandary #4

- You advise the executive team that the current structure of the physician group/practice subsidiary does not comport with the Stark Law "group practice" definition and that your investigation indicates that the profit distribution methodology does not comply with the Special Rules. You recommend self-disclosure under the SRDP. You request information from the executive team to complete the SRDP forms, but the executive team drags its feet. After 6 months and repeated requests, you still do not have the requested information. What do you do?

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### What Do You Do?

- A. Continue to wait patiently until the data is produced (how long do you wait?)
- B. Counsel the client on the consequences of failure to refund known overpayments on a timely basis
- C. Go over management to the CEO/board of directors to force timely production
- D. Terminate representation

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### 60-Day Rule: Implications for Stark Law Violations

- The ACA 60 Day Rule requires any person who has received an overpayment to report and return the overpayment to the appropriate Medicare or Medicaid agency, intermediary or contractor with written notice of the reason for the overpayment by the later of:
  - 60 days after the date the overpayment was **identified**, or
  - The date on which any corresponding cost report is due (if applicable).
- "Overpayment" is defined by the ACA as any funds a person receives or retains under Medicare or Medicaid to which the person, "after applicable reconciliation," is not entitled.
  - This includes payments made by Medicare for DHS rendered pursuant to an unlawful referral under the Stark Law.
- Any overpayment retained past the deadline is an "obligation" under the reverse false claims provision of the False Claims Act ("FCA").

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## When is a Payment “Identified”?

- An overpayment is identified when a person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received and quantified the overpayment amount.
  - The “reasonable diligence” standard gives providers an opportunity to investigate reports of potential overpayments.
  - “Reasonable diligence” is demonstrated by timely, good faith investigation, which the preamble indicated is at most 6 months from the receipt of credible information absent extraordinary circumstances.
  - An overpayment is not “identified” until it is quantified (unless a provider fails to exercise reasonable diligence).
  - Overpayments identified by a probe sample need not be returned until the full overpayment is identified.
  - The overpayment may be identified using a valid extrapolation methodology described in the disclosure.

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## When is a Payment “Identified”?

- Failure to exercise reasonable diligence to investigate credible information regarding a potential overpayment will result in a violation of the 60 Day Rule under the “should have known” standard if an overpayment was received.
- Thus, a provider has 6 months after receiving credible information regarding a potential Stark violation to investigate and quantify any overpayments (absent extraordinary circumstances) and 60 days thereafter to report the overpayment.
- Given the complexity of Stark Law investigations and data analyses, a provider who makes timely, good faith efforts to investigate and quantify may be able to demonstrate “extraordinary circumstances” justifying more than 6 months to identify the overpayment amount.
- Disclosures under the Self Referral Disclosure Protocol (SRDP) satisfy the 60 Day Rule reporting requirement and no refund need be issued until the case settles.
- Because the 60 Day Rule lookback period is 6 years, most SRDP disclosures voluntarily report 6 years of data even though the SRDP only requires 4 years.

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Laura Keidan Martin is the national head of the firm’s Health Care practice and a member of the firm’s Board of Directors and Executive Committee. She counsels health care industry participants including, health systems, national ancillary service providers and life sciences companies, helping them structure their contracts and transactions, sales/marketing practices and physician compensation arrangements to meet state and federal regulatory requirements. Laura regularly assists clients with government and internal investigations and advises on corporate integrity and deferred prosecution agreements. She also helps clients develop and update their compliance programs and policies, provides compliance education and conducts compliance program effectiveness reviews.

Laura serves as lead counsel on complex transactions, often involving multiple parties and creative deal structures. Her broad-based antitrust practice includes antitrust compliance advice and representation through pre-merger reviews and investigations conducted by the Federal Trade Commission and Department of Justice.

Laura earned her BA in economics from the University of Michigan and her J.D. from Harvard Law School. Laura is past president of the Illinois Association of Health Attorneys. Her recognitions include *Chambers USA: America’s Leading Lawyers for Business* for both health care and antitrust, *Best Lawyers Lawyer of the Year 2012* for Chicago Health Care Law, and *Leading Lawyers Network’s “Top 10 Leading Women Lawyers in Illinois.”*

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Lou counsels clients on general corporate, transactional, and federal and state regulatory matters. He has represented hospitals and hospital systems in more than 50 acquisitions throughout his career. He also focuses part of his practice on physician group acquisitions. Clients recognize Lou for his "well-rounded" regulatory and transactional practice in physician acquisitions and contracts," with clients particularly commending "his thorough understanding of health organization operations" (*Chambers USA*).

In addition to hospital and physician group acquisitions, Lou also devotes a significant portion of his practice to regulatory matters related to federal taxation, Medicare and Medicaid fraud and abuse including anti-kickback and physician self-referral, certificates of need, the Affordable Care Act and other general regulatory matters.

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**Speakers**

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**HYPOTHETICAL FACT PATTERN**

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### Hypothetical Fact Pattern



- Scientific Drug Company of Columbus, Ohio, is excited to announce today it has received FDA approval for a breakthrough lung cancer drug called Freedom.
- Dr. Frank Johnson, Medical Director and PhD, has worked on the development of Freedom for 15 years.
- Dr. Johnson intended Freedom to be used for dementia and not lung cancer. Despite Dr. Johnson's work for the past 15 years, the FDA would not approve dementia as a permitted use for Freedom.




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### Hypothetical Fact Pattern

Once the FDA approved Freedom for lung cancer, the Scientific Drug Company's Compliance Department began training the Marketing Teams throughout the United States on the appropriate uses of the drug, Freedom.

Compliance Trainer, Jack Paul, put together extensive training materials for the Marketing Department for the appropriate use of Freedom.

Jack conducted training for all marketing employees. Jack specifically trained all marketing employees not to sell the drug, Freedom, for dementia despite Dr. Johnson's clear dissatisfaction with Jack's training materials.




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### Hypothetical Fact Pattern



In January Jack took a training trip to the Chicago office to train the Marketing staff on the appropriate uses of the new drug, Freedom. While in Chicago, Jack took his two nephews, ages eight and nine, to the Bulls game and expensed three Bulls' tickets as a Scientific Drug Company Marketing Compliance Teambuilding Activity. Jack also posted pictures of the Bulls game on Facebook.




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### Hypothetical Fact Pattern

- In April, Jack went to visit his primary care physician for his routine physical.
- Jack's primary care physician commented that Freedom was having a dramatic effect on two of his patients who are suffering from dementia.
- At Jack's primary care physician's comment as to the remarkable results that he was seeing, Jack inquired as to how it came about that the primary care physician was using Freedom for dementia.
- Jack's doctor explained that the Marketing Team from Scientific Drug Company had been in the office in February to explain the dementia use of the drug, Freedom.



CareSource 7

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### Hypothetical Fact Pattern

Jack immediately reported this to the Chief Compliance Officer of Scientific Drug Company, Brett Bender.

Jack reviewed with Brett that he had instructed all Marketing Departments to sell Freedom only for lung cancer and never for dementia.

Brett decided to hire outside counsel in order to conduct an Internal Investigation.



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### Hypothetical Fact Pattern

- ❖ Outside counsel, Joe Jackson, began interviews and interviewed the Vice President of Marketing, Tom Smith, regarding the Marketing Department's sales activity regarding the drug, Freedom.
- ❖ Mr. Jackson gave Mr. Smith an Upjohn Warning.
- ❖ Mr. Smith indicated he was willing to cooperate with Scientific's investigation of this matter; however, he wanted personal counsel paid for by the company and wanted an Indemnification Agreement for discussing any matters.



CareSource 9

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### Hypothetical Fact Pattern

A Finance Department employee, who was a friend of Jack, was processing the expenses for Jack's Chicago trip and had seen on Facebook that Jack had taken his two nephews to the Bulls game.



The date of the post on Facebook corresponded with the same expense for a Marketing Compliance Teambuilding Activity. The Finance Department employee reported this to the Chief Compliance Officer.



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### Hypothetical Fact Pattern

Jack became disillusioned as the Internal Investigation dragged on and no direct order was issued to stop the Marketing Department from marketing Freedom as a dementia drug.

Jack sought outside counsel and filed a False Claims Act complaint under seal regarding the off-label marketing and sales of Freedom.



Office of the Inspector General  
U.S. Department of Justice



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### Hypothetical Fact Pattern



- The Chief Compliance Officer confronted Jack regarding his expense account of the Bulls game.
- Jack refused to answer any questions until Jack received answers as to the progress of the Internal Investigation.
- Jack indicated he would answer all questions if Scientific Drug Company paid for counsel to represent him regarding this matter and provided him an Indemnification Agreement.
- Scientific terminated Jack for falsification of the expense report and failing to cooperate with an Internal Investigation.



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### Hypothetical Fact Pattern

Jack immediately files an Amended Complaint alleging retaliation in his False Claims Act filing under seal

The Department of Justice subpoenaed scientific drug company and requested the internal investigation report from outside counsel.

The Department of Justice demands the names of all employees responsible for the off-label marketing of Freedom.



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### WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

#### Directors

Committee Representation	Individual Representation
<ul style="list-style-type: none"> <li>• Special Litigation Committee</li> <li>• Compliance Committee</li> </ul>	<ul style="list-style-type: none"> <li>• Potential Caremark Issues</li> <li>• Potential Breaches of Other Fiduciary Duties                             <ul style="list-style-type: none"> <li>▪ Duty of Care</li> <li>▪ Duty of Loyalty</li> </ul> </li> </ul>

CareSource

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### WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?

#### RESPONSIBLE CORPORATE OFFICER DOCTRINE

- AKA the "Park Doctrine" – *United States v. Park*, 421 U.S. 658 (1975)
- Concept – officer stood in "responsible relation" to the underlying violative act or omission
- Origins
- Statutory Bases
  - Food Drug & Cosmetic Act
  - Has since expanded
- Bottom Line: Essentially Strict Liability Based Solely on Being in a Position of Control

CareSource

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**WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL ?**

**THE "YATES MEMO"**

Issued in September 2015 by the now famous (or infamous) former Acting Attorney General, Sally Yates, when she served as Deputy AG under Eric Holder.

DOJ Response to political and public outcry out of lack of individual accountability for the 2008-2009 "Great Recession"

**GIST**

Any corporate entity hoping to obtain cooperation credit from DOJ had better be prepared to throw one or more individual wrong-doers under the bus.

**RESULT**

Along with RCO, heightened emphasis by DOJ on holding individuals accountable for corporate wrongs.



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**WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL ?**

**Who Pays Legal Fees and Costs?**



See Johnston, McFadden, et al. *Indemnification and Insurance for Directors and Officers*, BNA Bloomberg Corporate Practice Portfolio Series, No. 54

- State general corporation law
- Company Articles of Incorporation and By-Laws
- Contracts (e.g., Indemnification Agreements)



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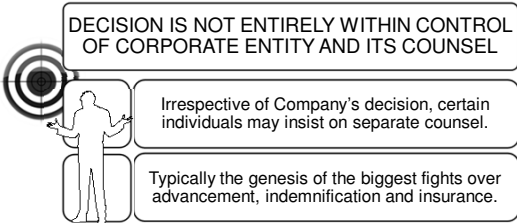
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**WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL ?**



DECISION IS NOT ENTIRELY WITHIN CONTROL OF CORPORATE ENTITY AND ITS COUNSEL

Irrespective of Company's decision, certain individuals may insist on separate counsel.

Typically the genesis of the biggest fights over advancement, indemnification and insurance.



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**WILL DIRECTORS, OFFICERS, OR EMPLOYEES NEED SEPARATE COUNSEL?**

**FORGING ALLIANCES – JOINT DEFENSE AND COMMON INTEREST AGREEMENTS**

- CONCEPT: US v. Them => Privileged Communications
- The Bane of Every Prosecutor or Plaintiff's Attorney
- Written or Unwritten?
- What happens when one member decides to that the best course is to save his/her own skin?
- Navigating Conflicts

CareSource 19

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**PLANNING THE INVESTIGATION**

**STEP 1: ISSUE IDENTIFICATION AND POTENTIAL EXPOSURE ASSESSMENT**

- What is at stake here? What is the worst-case scenario?
  - Administrative exposure – Exclusion
  - Civil exposure
    - False Claims Act
    - Shareholder's Derivative Suit
  - Criminal exposure
    - Kickbacks
    - Fraud
    - Statutory violations
    - RCO

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**PLANNING THE INVESTIGATION**

**Step 2: Collecting Documents**

- Legal Hold Notice
- Identification of Custodians
- Development of Keyword Search Protocols
  - E-mails are the nail that seals the coffin
- E-discovery Plan and Process
  - Creation of a searchable database
  - What are the inputs?
    - ✓ Backup tapes?
    - ✓ Other media?

CareSource 21

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### PLANNING THE INVESTIGATION

**Identification of Key Witnesses**

- ❖ Document Review
- ❖ High-Level Discussion with Control Group


Preparation of Witness Binders

**Resolution of Representation Issues**

Resolution of Privilege Issues

- ❖ Former Employees

**STEP 3:  
WITNESS  
INTERVIEWS**



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### PLANNING THE INVESTIGATION

**FORM OF REPORT**

Oral v. Written

Level of Detail

**KEY CONSIDERATION:  
DISCOVERABILITY**



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### PLANNING THE INVESTIGATION

ASSESSING THE PROS AND CONS OF SELF-DISCLOSURE AND "COOPERATION CREDIT"

- Regulatory Self-Disclosure Requirements
- Yates Memo revisited
- Sentencing Guidelines



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**CONDUCT OF THE INVESTIGATION**

**DETERMINATION OF THE CONTROL GROUP, POINTS OF CONTACT, AND LIMITATIONS ON COMMUNICATION**

Maintaining independence as the internal investigator, and the importance of being able to demonstrate it later.

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**CONDUCT OF THE INVESTIGATION**

**Communication Plan & Outline for Interviews**

- Upjohn Warning
- Introduction/case overview
- Investigator's role
- Overview of non-retaliation policy
- List of general and specific questions
- Concluding Messages: Reiterate confidentiality, non-retaliation policy, preserve all documents and abide by litigation holds, call investigator with further information

- List of legal issues to be researched
- List of applicable company policy and/or legal authorities

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**CONDUCT OF THE INVESTIGATION**

**WITNESS INTERVIEWS**

*Upjohn Warnings - Upjohn Company v. United States, 449 U.S. 383 (1981)*

**THE GIST**

This conversation is covered by attorney-client privilege. That privilege belongs to one entity and one entity only: the Company.

**WE DO NOT REPRESENT YOU.**

The Company, and only the Company, can decide whether to waive or maintain the privilege. 27

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**CONDUCT OF THE INVESTIGATION**

**A REPRESENTATIVE UPJOHN Warning**

Identify yourself as an attorney; identify your client

- Make clear that you represent NO ONE OTHER THAN THE CLIENT: "I do not represent you."

State the purpose of the interview

- Obtain facts, in confidence, in furtherance of providing legal advice to the client = the Company. Classic elements of the attorney/client privilege

Make clear to whom the privilege belongs and who can waive it.

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**CONDUCT OF THE INVESTIGATION**

**1**

A CLASSIC QUESTION FROM THE WITNESS: "Do I need my own lawyer?"

**2**

THE NECESSARY AND ONLY RESPONSE.

**3**

ORDER OF INTERVIEWS (typically bottom to top)

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**The Yates Memo: Background**

"In the most basic ways, though, corporate misconduct isn't all that different from everything else DOJ investigates and prosecutes.

**[Crime is crime.]**

And it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom. In the white-collar context, that means pursuing not just corporate entities, but also the individuals through which these corporations act."

Sally Quillian Yates, Deputy Attorney General, September 10, 2015

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## The Yates Memo: Background

**Issued:**  
September 9, 2015

**Recipients:**  
All DOJ Attorneys

### Goal:

Consistency across all DOJ departments in holding individuals accountable for illegal corporate conduct.



**Author:**  
Sally Quillian Yates,  
Deputy AG

**Subject:**  
"Individual Accountability for Corporate Wrongdoing"

**Content:**  
Six "key steps" to "strengthen our pursuit of individual corporate wrongdoing"



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## The Yates Memo: Significance



Continuing Evolution of Principles of Federal Prosecution of Business Organizations (U.S. Attorney's Manual 9-28.000)



Principles revised to reflect Yates Memo expanded focus on individuals



Prosecutors rely on Principles in determining whether and what charges to bring



Principles provide important guidance to corporations regarding compliance programs and cooperation during investigations



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## The Yates Memo: 6 Key Steps

1

• Eligibility for any cooperation credit requires corporations to **provide DOJ with all relevant facts** about the individuals involved in the misconduct.



2

• Both criminal and civil corporate investigations should focus on **individuals from the investigation's inception.**



3

• Criminal and civil DOJ attorneys handling investigations should be in **routine communication** with one another.



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### The Yates Memo: 6 Key Steps

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• **No corporate resolution will provide protection** from criminal or civil liability for individuals, except in "extraordinary circumstances."

• Corporate cases should not be resolved without a "clear plan" to **resolve related individual cases** before the statute of limitations expires, and declinations as to individuals in such cases must be memorialized.

• Civil attorneys should consistently focus on individuals and evaluate whether to **bring suit against an individual based on considerations** beyond the ability to pay.

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### The Yates Memo: Implications

Increased pressure on prosecutors to pursue individuals

Possible increases in civil actions due to the increased communication requirement

More cooperation deals with lower level executives in order to reach highest level leaders

Chilling effect on corporate cooperation with federal prosecutors due to "all or nothing" approach

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### The Yates Memo: Implications

- Chilling effect on self-reporting by corporations
- Chilling effect on personal cooperation with internal compliance investigations
- Conflicts of interest:
  - Legal representation (personal/corporate)
  - Involvement of personal stakeholders in internal corporate investigation
- Waivers of attorney-client privilege?

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### The Yates Memo: Action Items

#### Proactive

- Review and enhance compliance program
- Make leadership aware of Yates Memo
- Document efforts to remain compliant

#### Reactive

- Retain counsel experienced in criminal investigations (particularly in dealing with DOJ)
- Promptly deal with conflicts of interest



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### DRAFTING THE REPORT



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### DRAFTING THE REPORT

#### CASE INFORMATION

- Investigative Team Details (names, position/roles, contact information)
- Name of Legal Counsel (if involved)
- Complainant/Referral Source Details (names, position/roles, contact information, date report or complaint was submitted, manner in which report was made (hotline, in-person meeting with CCO, exit interview, etc.))
  - Summary of Allegations (description, seriousness, type, dates of alleged violation(s), names of parties involved)



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### DRAFTING THE REPORT

SCOPE OF INVESTIGATION

**1** Succinctly state the scope of the investigation

**2** Summarize the objective of the investigation



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### DRAFTING THE REPORT

#### INVESTIGATION PLAN

- Categories of documents collected ✓
- Litigation holds ✓
- List of referral source(s) and witnesses interviewed ✓
- Order of interviews ✓



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### DRAFTING THE REPORT

#### Documentation of Interviews

- Promptly and accurately memorialize interview
- Be complete.
- Document all parties who were present during interview.
- Document provision of Upjohn Warnings and Witness's acknowledgment of them.
- Be consistent in format and organization of interview notes.
- Summarize how key concepts were explained (see previous slide).
- Include language that satisfies the elements of the attorney/client privilege and the attorney work product doctrine.



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### DRAFTING THE REPORT

**Document Investigator Impression of Interviews**  
(separate from summaries of interviews)



Credibility Assessments

Interview's Notes/ Impressions Section



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### DRAFTING THE REPORT



**DOCUMENT EVIDENCE**



Attach key documents



Attach key companies policies, code of ethics provisions, or legal authorities



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### DRAFTING THE REPORT


**Factual Findings**



- Summarize the facts that decision makers need to know
- Business units and functions, individuals involved
- Dismiss facts that are irrelevant
- If two or more positions are at issue, discuss both sides
- Weigh the facts
- Finance related findings



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### DRAFTING THE REPORT




"Mr. X logged onto a government web portal with another employee's log-in credentials."

"Mr. X's supervisor was aware that Mr. X logged onto a government web portal with another employee's log-in credentials."

"There is no company policy or procedure for the use of log-on credentials on government web portals."

**Example of Factual Findings**



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### DRAFTING THE REPORT

**Examples of Conclusions**  
(note how conclusions and recommendations track factual findings)



- "Mr. X violated \_\_\_ CFR Section \_\_\_ and may have violated 18 U.S.C. § 1001
- "Mr. X's supervisor failed to supervise Mr. X's adherence to the company's log-in policies"
- "The company's internal controls regarding use of log-on credentials is in adequate."



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### DRAFTING THE REPORT


**EXAMPLES OF RECOMMENDATIONS**



"Mr. X should be disciplined or terminated."

"Mr. X's supervisor should be disciplined or moved to a non-supervisory position."

"The company should develop internal IT controls and retain an outside IT security consultant to assist it in doing so."



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## DRAFTING THE REPORT

- Summarize follow-up steps
  - Corrective Action/Process Improvement
  - Determine if voluntary disclosure should be made
    - Determine if overpayments were made and must be repaid
  - Determine if fines are to be paid
    - Determine if licensing bodies or regulators must be notified
  - Notify complainant that appropriate action is being taken

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## PRESENTING THE REPORT

- Status reports (how frequent and audience)
- Reports to management
- Reports to Audit and Compliance Committees
- Reports to governing boards



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**UPJOHN WARNING**

We are conducting an investigation for the \_\_\_\_\_ ("Company") into certain events related to \_\_\_\_\_. We believe that you may have facts and/or documents that may be relevant to our investigation and we appreciate you meeting with us.

To be clear, we serve as counsel to the Company. We are not your personal counsel and cannot give you legal advice.

In addition, your communications with us, as part of this investigation, are confidential and protected by, among other things, the attorney-client privilege. As the Company is our client, the attorney-client privilege belongs solely to the Company. Accordingly, the Company, in its sole discretion, may elect to waive the privilege and reveal your communications with us to third parties, including the government.

As part of this investigation, we are interviewing a number of employees to gain a better understanding of the relevant issues. The fact that we are conducting this investigation does not mean the Company believes that any current or former employee has engaged in improper or illegal conduct. It simply is the process through which the Company ensures that it maintains the highest standards of corporate integrity. Your candor and honesty are critical to our ability to conduct effectively our investigation. To maintain the integrity of this investigation, we request that you keep our conversations today confidential. We appreciate your cooperation.

Employee \_\_\_\_\_  
 Print Employee Name \_\_\_\_\_  
 Date: \_\_\_\_\_  
 I acknowledge receipt of a copy of this Upjohn Warning.  
 Employee \_\_\_\_\_  
 Date: \_\_\_\_\_

**UPJOHN WARNING**

I am a lawyer for \_\_\_\_\_ and I do not represent you personally. I represent only \_\_\_\_\_.

I am conducting this interview to gather facts in order to provide legal advice for \_\_\_\_\_.

This interview is part of an investigation to determine the facts and circumstances in order to advise \_\_\_\_\_ how best to proceed.

Your communications with me are protected by the attorney-client privilege. But the attorney-client privilege belongs solely to \_\_\_\_\_ not you. That means \_\_\_\_\_ alone may decide to waive the attorney-client privilege and reveal our discussion to third parties. \_\_\_\_\_ alone may decide to waive the privilege and disclose this discussion to such third parties as federal or state agencies, at its sole discretion and without notifying you.

In order for this discussion to be subject to the privilege, it must be kept in confidence. In other words, with the exception of your own attorney, you may not disclose the substance of this interview to any third party, including other employees or anyone outside of the company.

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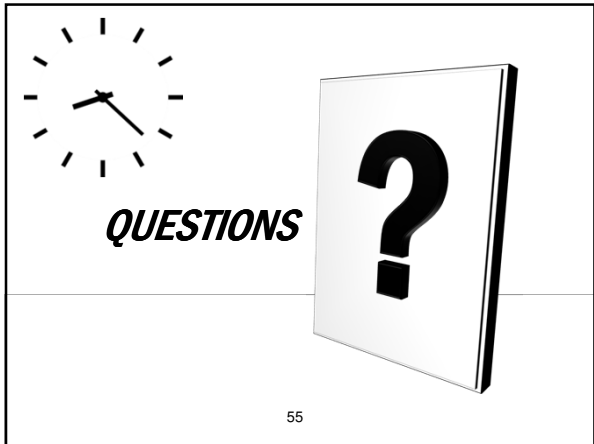
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 **21<sup>st</sup> Annual Compliance Institute**  
**March 26-29, 2017**

Tim Murray MS,MT(ASCP) CHC  
National Director of Laboratory Compliance  
[timothymurray@catholichealth.net](mailto:timothymurray@catholichealth.net)  
610-594-5102

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 **Maintaining Laboratory Compliance**  
**in an Ever Changing Healthcare**  
**Regulatory Environment**

**OR**

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 **Labland, it is NEVER a**  
**dull moment!**

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**Catholic Health Initiatives**  
Imagine better health.™

Do you ever feel like this as a compliance professional?



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**Compliance Plan Benefits**

Laboratories have their own guidance from the Office of the Inspector General for developing a compliance plan published in the FR 8/24/1998. Described seven fundamental elements that were to be contained in each plan. This was to replace the previously issued plan published March 3, 1997 and was more consistent with the compliance program guidance issued with respect to the hospital and homecare industries.

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**Catholic Health Initiatives**  
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**Compliance – Overall Purpose of Compliance Programs**

- Effective internal controls that promote adherence to legal requirements
- Culture that promotes prevention, detection, and resolution of unlawful conduct
- Demonstrate commitment to compliance process

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**Catholic Health Initiatives**  
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### Compliance – Overall Purpose of Compliance Programs

- Written policies, procedures and standards of conduct
- Compliance officer and compliance committee
- Effective training and education
- Effective lines of communication
- Enforcement of standards through well-publicized disciplinary guidelines
- Internal monitoring and auditing
- Responding promptly to detected offenses and developing corrective action

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### Compliance Plans - Operationalization Written Policies, Procedures and Standards of Conduct

Appendix A Clinical Laboratory Overview  
 Appendix B Final Compliance Program Guidance for Clinical Laboratories – 08/1998  
 Appendix C Areas of Concern Identified by the OIG  
 Appendix D Sample Monitoring Tool  
 Appendix E Special Fraud Alerts, Advisory Bulletins and Other Communications by the OIG  
 Appendix F Designation of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee  
 Appendix G Names of a Clinical Laboratory Compliance Officer and Clinical Laboratory Compliance Committee Members  
 Appendix H Education and Training  
 Appendix I CRP Reporting System  
 Appendix J Clinical Laboratory Orders/Ordering Procedure

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**Catholic Health Initiatives**  
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### Compliance Plans - Operationalization Written Policies, Procedures and Standards of Conduct

Appendix K Clinical Laboratory Medical Necessity Procedure  
 Appendix L Clinical Laboratory Coding and Validating ICD Coding Procedure  
 Appendix M Clinical Laboratory Billing Procedure  
 Appendix N Marketing, Sales and Business Development of Laboratory Services Procedure, Improper Inducements, Kickback and Self-Referrals  
 Appendix O Clinical Laboratory Research Procedure  
 Appendix P Application for Laboratory Licensure (CLIA) License  
 Appendix Q Non Routine Information Requests or Communications from Governmental or Regulatory Agencies  
 Appendix R Clinical Laboratory Specific Procedures  
 Appendix S Proficiency Testing (PT) Policy Requirements

Printed documents are for reference only. For the most current version refer to Inside CHI, Corporate Responsibility Community, Public Folders, Laboratory, Addendum  
 Laboratory Compliance CRP Plan Addendum Effective Date: 02/01/14 Addendum Revised 02/01/17  
 Annual Review 02/01/17

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### Compliance Plans- Operationalization Staff Education and Competency

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### Compliance Plans – Operationalization Annual Tasks

Laboratory Name:  Laboratory Address:  Completed By:

**OH Clinical Laboratory Addendum Annual Responsibilities Checklist FY 2017**

As an aid to assist laboratory leaders in completing laboratory addendum review and monitoring expectations, the following has been compiled to provide general guidance on tasks listed in the addendum which must be completed annually to assure a functioning laboratory compliance program. The results of these reviews and monitor tasks should be documented.

	Date of Completion	Comments
1. Review any laboratory addendum updates after 02/28/17 with laboratory compliance committee and laboratory staff.	<input type="text"/>	
2. If required by entity policy or your specific accrediting agency, have appropriate laboratory personnel sign off on the annual reviewed/updated document, Laboratory Administrative Director, Laboratory Medical Director.	<input type="text"/>	
3. Perform an annual laboratory compliance review activity as described in The Clinical Laboratory Addendum, Appendix A, paragraph three. This requirement may be superseded by a national Compliance Committee assigned yearly monitor. Released in December each year.	<input type="text"/>	
4. Review the Office of the Inspector General (OIG) annual work plan at: <a href="http://oig.dhs.gov/reports-and-publications/reports-and-index.asp">http://oig.dhs.gov/reports-and-publications/reports-and-index.asp</a> . You can sign up for a subscription for the year's publication at: <a href="http://oig.dhs.gov/plan-notifications">oig.dhs.gov/plan-notifications</a>	<input type="text"/>	

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### Compliance Plans – Operationalization Annual Tasks

Laboratory Name:  Laboratory Address:  Completed By:

5. The Clinical Laboratory Compliance Officer or designee reports to the entity Corporate Responsibility Officer (CRO) on a regular basis or at a minimum annually the compliance activities of the laboratory as directed in the Clinical Laboratory Addendum. This task can be accomplished in the form of compliance meeting minutes or as a separate report to the entity compliance committee or CRO. Appendix D, due pointwise.	<input type="text"/>	
6. This report should also include the status of accomplishing the responsibilities listed in the addendum for the Laboratory Compliance Officer and the Laboratory Compliance Committee as listed in Appendix E.	<input type="text"/>	
7. Review and update as needed the names of the Clinical Laboratory Compliance Officer and the members of the Laboratory Compliance committee. Appendix D.	<input type="text"/>	
8. Ensure all required compliance education requirements are met. Appendix H.	<input type="text"/>	
9. If laboratory tests are billed any other way than cashless completion, i.e. On receipt or order. The results of the device used monitoring program to ensure no incomplete or test not performed is billed in error are reported annually to the local OIG. Appendix M.	<input type="text"/>	
10. Laboratory supplies furnished to referral sources are tracked to ensure that all supplies are provided in quantities that are appropriate. Appendix N.	<input type="text"/>	

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### Compliance Plans- Operationalization Monitoring

Evidence of Compliance	Red= extra emphasis and review						
Question Number							
2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that it is most current.							
3. Choose a representative test ask the interviewee to walk through the procedure with you and point out the items listed in lines 3a-3c.							
3a. Look at Test Kit and individual components and check to see that all are within expiration date.							
3b. Look at control results and confirm that they are within the manufacturer's expectations.							
3c. Look at temperature records and compare to manufacturer's storage requirements (room temp, refrigerated and frozen where appropriate) Recommend that acceptable temp ranges be included on documentation chart.							
3d. If any of the above are not within expected parameters investigate what the corrective action was and review with interviewee the follow-up actions. (See below)							
3d.i. Patients not reported, called manufacturer to troubleshoot, told supervisor/lab director, If temperatures were off, moved specimens/reagents to an acceptable temperature controlled area.							
3e. Separate documentation of this information is not required but ask how the lab would handle identifying patients tested using a recalled defective test kit?							
3f.c.i. Ask interviewee to demonstrate how results are entered/documented in patient chart, How they would troubleshoot bad controls or instrument readings?							
7. Testing staff should verbalize that they review each new kit instructions for changes or that their supervisor informs and educates them of new changes. Someone MUST review each new insert for changes. (Best practice documents that fact)							
8b. Ask staff to show you in the manufacturer's insert where the manufacturer describes the correct specimen to collect for analysis.							
8c. Ask testing staff to show you evidence of a typical test order.							
8d. Log is not required (Best Practice) but interviewee needs to be able to verbalize how to confirm to an inspector or the laboratory medical director that controls were acceptable after the fact (days, weeks later)							

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### OIG Work Plan for 2017

- OIG will review payments to independent labs to determine compliance with selected billing requirements
- Billing of Lab Services in 2016
- Histocompatibility Lab Billing
- Protecting Access to Medicare Act (PAMA) & Medicare Access and CHIP Reauthorization Act (MACRA) Implementation

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### Internal Monitoring and Auditing

Annually the National Laboratory Compliance Committee reviews the OIG Work Plan and develops system wide monitoring for each moderate and above CLIA Laboratory.

- Each laboratory leader will be asked to review three months (July 1, 2016 - September 30, 2016) outpatient lab account data as the initial data set. Ten (10) accounts will be randomly selected from each month (total of 30 accounts). Each laboratory leader will be asked to review each of the thirty (30) randomly chosen laboratory accounts looking at the actual provider order versus the result report versus the bill versus coding for accuracy. If any systematic errors are discovered, a corrective action statement/plan will need to be submitted to the local CRO and the CHI National Laboratory Compliance Committee. This activity will meet the needs of self-monitoring requirement as described in the Laboratory Compliance Addendum.

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**Proficiency Testing – Electronic Training**

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A spirit of innovation, a legacy of care.

Laboratory Proficiency Testing




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**Proficiency Testing – Electronic Training**

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Remember:

PT specimens may **NEVER**, under any circumstances, be sent out of your laboratory.

- **NEVER** enter into discussion with another laboratory about PT results before the due date set by the testing agency for reporting results.
- **NEVER** analyze a PT specimen sent to you from another laboratory - even if the laboratory is located in or owned by your hospital or CHI.

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**Proficiency Testing (PT) Referrals**



**PROFICIENCY TESTING**

**DOs and DON'Ts**

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient care tests regardless of where the test is performed. The final CLIA regulations were published in the Federal Register on February 26, 1992. The requirements are based on the complexity of the test and the type of laboratory where the testing is performed. On January 24, 2003, the Center for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality System Laboratory regulations that became effective April 24, 2003.

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**Appendix S  
 Proficiency Testing (PT) Policy Requirements**

Besides describing the actual process for handling the PT specimens and how the specimens are to be rotated to different representative testing personnel during all shifts on which those tests are being performed, the PT policy/plan must also include, at a minimum, the following statements:

- The laboratory must not send proficiency testing samples or portions of such samples to another laboratory for analysis.
- The laboratory staff must handle all PT specimens in the same manner as a patient sample.
- There may be no inter laboratory communication concerning a PT challenge until after the challenge cutoff date.

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**Appendix S (Continued)  
 Proficiency Testing (PT) Policy Requirements**

- PT samples may only be analyzed on primary equipment and may not be analyzed on secondary equipment until after the challenge cutoff date.
- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify Laboratory leadership who will notify CMS of the receipt of those samples.

The plan must also explicitly emphasize that PT challenges are only to be analyzed and reported on behalf of the CLIA licensed laboratory for which they were obtained. Laboratories may not share PT specimens with other licensed CLIA laboratories. Purchased PT samples are tied directly to the CLIA number of the purchasing laboratory and to share that specimen with another laboratory and to report the result of the second laboratory will be interpreted as specimen referral which carries steep penalties.

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**Proficiency Testing Pitfalls!**

- PT Sharing
  - Proficiency testing is assigned by CLIA number and may only be ordered for and reported by that specific number.
    - Owned physician practice laboratories in same or contiguous building
      - Under main laboratory CLIA number
        - » Primary instrument- different PT vendor?
      - Separate CLIA number
    - Owned physician practice laboratories off campus
      - Separate CLIA number
    - Central Monitoring of Owned Physician Practice Laboratories by Hospital Laboratory Staff.
      - Different PT vendors!
      - “Never the twain shall meet”
      - Be leery of networks with multiple laboratory access

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### Reflex Testing - Common Errors

- 2010 Noridian Administrative Services- Error Rate Testing (CERT) analysis indicates providers are performing additional laboratory services based on a standard written or implied protocol, rather than a patient-specific physician order.
- Complete Blood Count (CBC), CBC with automated Differential, CBC with Automated Differential Reflex
  - Which one?
    - Complete Blood Count, automated- 85027
    - Complete Blood Count, with differential WBC, automated -85025
- Urinalysis (UA), UA Dipstick, UA with microscopic, UA with Microscopic Reflex, UA with Microscopic Reflex with Culture Reflex - Which one?

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### Common Errors- Reflex Testing

**Decision Document:**

Decision Document: Review of ordering of a potential reflex test

**Background:**  
The Hospital and Ambulatory Care departments are reviewing the existing order sets to ensure what tests could be reflexed for any given test order. Below are some examples of how we will implement this in Lab.



**Notes:**

1. Reflexes to UA with culture based on the order of the orderable procedure(s).  
Example: Urinalysis with culture. If indicated, reflexes UA with culture to culture.
2. Reflexes to UA with Microscopic Reflex based on the order of the orderable procedure(s).  
Example: Urinalysis with Microscopic Reflex. If indicated, reflexes UA with Microscopic Reflex to UA with Microscopic Reflex.
3. Reflexes to UA with Microscopic Reflex with Culture based on the order of the orderable procedure(s).  
Example: Urinalysis with Microscopic Reflex with Culture. If indicated, reflexes UA with Microscopic Reflex with Culture to UA with Microscopic Reflex with Culture.

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### Common Errors- Incomplete Panels

- Incomplete Panels- Due to lipemia, hemolysis
  - If all components of an approved panel cannot be performed for whatever reason i.e. due to the condition of the specimen, the full panel may not be billed. Only those components actually analyzed and reported may be billed.

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### Common Errors- Environmental Monitoring

- Environmental conditions of storage and testing areas for supplies and equipment must be monitored to ensure that manufacturer required storage conditions are met.
  - Environmental conditions be monitored each day and results documented. Corrective action must be documented if results are not within acceptable limits. This includes weekends and holidays.
    - Humidity
    - Temperature
      - Room
      - Refrigerator
      - Freezer

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### Common Errors- Personnel Records

- Personnel Policies for Individuals Directing or Performing Non-waived Tests
  - Educational Credentials 42 CFR, Part 493, Subpart M for
    - What is required?
      - Transcripts
      - Diplomas
    - PSV primary source verification
      - » Ref: S&C: 16-18- CLIA, April 1, 2016
        - » Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.
        - » Professional certification, such as medical technology certification or nursing licenses IS NOT considered sufficient evidence of meeting the personnel qualifications.

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### Common Errors- Competency Assessment Who Can Perform?

- Competency documentation of testing personnel
  - Moderate Complex Laboratories
    - Technical Consultant (TC) BS in a chemical, physical or biological science or medical technology -2 years of laboratory training or experience, or both
    - Assignment of responsibilities by Laboratory Medical Director
    - Annual assessment by director
  - High Complex Laboratories
    - Technical Supervisor (TS) Micro, Chem ,bachelor's degree in a chemical, physical or biological science or medical technology- 4 years of laboratory training or experience, or both, in high complexity testing
    - General Supervisor (GS) Associate degree in a laboratory science, or medical laboratory technology-2 years of laboratory training or experience, or both, in high complexity testing
    - Assignment of responsibilities by Laboratory Medical Director
    - Annual assessment by director

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### Medical Necessity

- Educate physicians and other reasonable steps to avoid claims for unnecessary services
  - Requisition – conscious ordering of each test by physicians
  - Notices
    - General
    - Custom profile
  - Educate re ABNs
  - Monitor to make sure not contributing to unnecessary tests

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### Payment for Hospital Outpatient Tests

Packaged into Hospital Outpatient Prospective System unless:

- “Non-patient” test
- No other hospital outpatient services from same “encounter” or
- Removed 1/1/17 :Tests “clinically unrelated” from other hospital services from same “encounter” and ordered by different physician

Applies to tests performed by hospital directly or “under arrangements”

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### Medicare Reimbursement APC/OPPS Bundled Payments

- **One-two punch!**
  - **Effective January 1, 2017**
    - Expansion of Molecular Pathology Laboratory Test Exception to Include Certain Advanced Diagnostic Laboratory Tests (ADLTs): In CY 2014, we adopted a policy to exclude molecular pathology tests from our laboratory packaging policy.
    - Discontinuation of the 'L1' Modifier: In CY 2014, we created modifier L1 to allow for separate payment of laboratory tests for use when (1) laboratory tests were the only services on the claim, or (2) when the laboratory test or tests were “unrelated” to the other services on the claim, meaning that the laboratory test was ordered by a different physician for a different diagnosis than the other services on the claim.
    - Packaging Based on Claim instead of Based on Date of Service: A hospital stay that may span more than one day are packaged according to OPPS packaging policies.

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### Protecting Access to Medicare Act 2014 (PAMA)

**Second Punch!**

Goal of PAMA is to overhaul the Clinical Laboratory Fee Schedule (CLFS). To set new reimbursement rates to match the weighted median of the reported commercial rates paid to large commercial laboratories. CMS estimates that laboratory Medicare revenues will decrease 5.2 Billion over the next 10 years.

After a year delay, CMS published the final rule for implementation of PAMA in the June 23, 2016 Federal Register. The final rule clarifies and changes several key requirements that were in the proposed rule that was released for public comment last fall. There still are a few unanswered questions, but in this briefing, I will give answers according to the information that CMS has released in the final rule and two MLN Matters articles.

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### It is applicable WHAT?

**Applicable Laboratories**

- ❖ Have a CLIA Certification
- ❖ Bill under their own NPI
- ❖ Have a majority of their Medicare revenue come from the CLFS or the PFS.
- ❖ Has received over \$12,500 in Medicare reimbursement during the 6-month data collection period.

**Applicable Data**

- ❖ The specific HCPCS code associated with the test
- ❖ The private payer rate for each test for which final payment has been made during the data collection period.
- ❖ The associated volume for each test at each payment rate

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### PAMA Critical Dates For Applicable Laboratories

Data collection period  
➤ **Jan. 1 through June 30, 2016**

Reporting period  
➤ **Jan. 1 through March 31, 2017**

CMS will publish preliminary CLFS for public comment  
➤ **Early September 2017**

Final CLFS rates published in November 2017  
➤ **Effective Jan. 1, 2018**

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**Thank You .....**



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Laboratory Name:	Laboratory Address:	Completed By:
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**CHI Clinical Laboratory Addendum Annual Responsibilities Checklist CY 2017**

As an aid to assist laboratory leadership in completing laboratory addendum review and monitoring expectations, the list below has been compiled to provide general guidance on tasks listed in the addendum which must be completed annually to assure a functioning laboratory compliance program. The results of these reviews and monitor tasks should be documented in the entity laboratory compliance

	Date of Completion	Comments
1. Review any Laboratory Addendum updates after 02/01/YY with laboratory compliance committee and laboratory staff.		
2. If required by entity policy or your specific accrediting agency, have appropriate laboratory personnel sign off on the annual reviewed/updated document. Laboratory Administrative Director, Laboratory Medical Director Etc.		
3. Perform an annual laboratory compliance review activity as described in The Clinical Laboratory Addendum, <b>Appendix A, paragraph three</b> . This requirement may be superseded by a National Compliance Committee assigned yearly monitor. Released in December each year.		
4. Review the Office of the Inspector General (OIG) annual work plan at: <a href="http://oig.hhs.gov/reports-and-publications/workplan/index.asp">http://oig.hhs.gov/reports-and-publications/workplan/index.asp</a> You can sign up for automatic notification of the yearly publication at: <a href="#">OIG Work Plan notification</a>		
5. The Clinical Laboratory Compliance Officer or designee reports to the entity Corporate Responsibility Officer (CRO) on a regular basis or at a minimum annually the compliance activities of the laboratory as directed in the Clinical Laboratory Addendum. This task can be accomplished in the form of compliance meeting minutes or as a separate report to the entity compliance committee or CRO. <b>Appendix F, dot point two.</b> a. This report should also include the status of accomplishing the responsibilities listed in the addendum for the Laboratory Compliance Officer and the Laboratory Compliance Committee as listed in <b>Appendix F</b> .		
6. Review and update as needed the names of the Clinical Laboratory Compliance Officer and the members of the Laboratory Compliance committee. <b>Appendix G</b>		
7. Ensure all required compliance education requirements are met. <b>Appendix H</b>		
8. If laboratory tests are billed any other way than upon test completion. I.e. On receipt or order. The results of the developed monitoring program to ensure no incomplete or test not performed is billed in error are reported annually to the local CRO. <b>Appendix M</b>		
9. Laboratory supplies furnished to referral sources are tracked to ensure that said supplies are provided in quantities that are appropriate. <b>Appendix N</b>		
10. If appropriate, the results of the periodic monitoring of computers and interface contracts as required by the entity policy. <b>Appendix N</b>		
11. Review any local CRO approved referral source gifts as they apply to <a href="#">CHI CRP Policy</a> View Items 1-2e in the CHI CRP Policy. The results of this monitor will be reported to the entity CRO. <b>Appendix N</b>		
12. Review <b>Appendix S</b> Proficiency Testing Procedure Requirement and ensure that current policy meets the expectations within that Appendix.		

**Click the link below to view the current CHI Clinical Laboratory Compliance Addendum:**

[Laboratory Compliance Addendum](#)

Waived Testing Assessment

<b>Please complete all demographic info and answer questions 1 - 14a.</b>				
<b>If the information on the license is not accurate, confirm and document (use box to the right) that appropriate agencies have been notified of change. I.e. new director, moved (Document Correct Information) Note: Licenses are generally not updated immediately, normally updates are made on a two year payment renewal cycle.</b>		Name of Agency notified and date of the notification. List any other comments if necessary:		
<b>CLIA/state license # as it appears on license :</b>		<b>Questions/Clarifications/Follow-up as needed, please contact:</b>		
<b>Name of lab as it appears on the CLIA/state license and any correction:</b>		Yellow Highlight Each Test Done At This Lab		<b>Tim Murray</b>
<b>Lab Address as it appeared on the license and any correction:</b>		Cholesterol	Prothrombin Time	<b>Director, Laboratory Compliance</b>
		Fecal Occult Blood	Rapid Strep	<b>Catholic Health Initiatives</b>
		Glucose	Sedimentation Rate	<b>Ph 610-594-5102</b>
		Hemoglobin	Urinalysis Dipstick	<a href="mailto:timothymurray@catholichealth.net">timothymurray@catholichealth.net</a>
<b>Consultant Name (If Any) :</b>		Hemoglobin A1C	Urine Pregnancy	
<b>Testing personnel interviewed:</b>		Hematocrit	Others List to Right	
<b>Name of Laboratory Contact:</b>		Influenza		
<b>Laboratory Contact Number:</b>		Lyme Disease		Rev 9-16
<b>Date Assessment Completed:</b>		Ovulation		
		Place "X" in Box for Answer		
<b>FY 2017 - Waived Testing Assessment</b>		<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. Are all tests performed classified as waived? §§493.15(c), and 493.1775(b)(3) See below for abbreviated list of waived tests				
Cholesterol, Fecal Occult Blood, Glucose , Hemoglobin, Hemoglobin A1C, Hematocrit, Influenza, Lyme Disease, Ovulation, Prothrombin Time, Rapid Strep, Sedimentation Rate, Urinalysis Dipstick, Urine Pregnancy				
2. Does the laboratory have the current manufacturer's instructions for all tests performed?				Evidence of Compliance (Click on tab for interpretation.)
3. Does the laboratory follow the current manufacturer's instructions for all tests performed by:				Evidence of Compliance (Click on tab for interpretation.)
a) Using the appropriate specimen?				
b) Adding the required reagents in the prescribed order?				

Waived Testing Assessment

c) Adhering to the manufacturer's storage and handling instructions?				
d) Using the proper expiration date for the storage method?				
e) Performing the quality control as required by manufacturer?				
f) Performing function checks or calibration?				
g) Performing confirmatory tests as required?				
h)Temp Checks and documents results each day of supply/reagent storage?				
h1)Are there hi/ low acceptable temperature ranges established and documented for each device monitored? Including Room temp if storage requires it?				Evidence of Compliance (Click on tab for interpretation.)
h2)Corrective action if out of range?				
i) Reporting the patients' test results with the terminology or in the units described in the package insert?				
j) Performing and documenting instrument maintenance as described by the manufacturer?				
4. Does the testing personnel understand the manufacturer's instructions for all tests performed?				Use information from 3 above for subjective assessment
5. Does the testing personnel:				
a) Document the name of the test, reagent/control lot number, and expiration date for all tests performed?				Recommended (Evidence of Compliance)
b) Are laboratory personnel given training when they are newly hired?				Please describe i.e. OJT/vendor training
<b>b1)IF answered YES to 5 b, how is the training documented?</b>				
6. Are testing staff:				
a) Observed or evaluated to assure they can provide accurate and reliable testing?				
<b>a1)If answered YES to 6 a, how is the observation/evaluation documented?</b>				
b)Shown how to document the patient's test results?				Evidence of Compliance (Click on tab for interpretation.)
c) Shown how to identify inaccurate results and/or test system or device problems?				
d) Shown how to handle inaccurate results or device problems?				Staff should verbalize that patient results would not be reported until all quality checks are within manufacturers specifications.

Waived Testing Assessment

7. Are the testing personnel informed when there's a change in the test procedure or if there's a new test kit?				Evidence of Compliance (Click on tab for interpretation.)
<b>a)If answered YES to 7, how is that process documented?</b>				
b) Does the laboratory routinely check incoming package inserts to ensure there have been no changes in the product or procedure?				
c) Are all the products clearly labeled to advise of a revision?				Evidence of Compliance (Click on tab for interpretation.)
8. Have the testing personnel ever been asked to repeat a waived test?				
a) If yes, was the second result different than the original result?				
b) If the second result was different from the first result, what result did the physician use?				
9. Does the laboratory phlebotomy/testing staff:				
a) Check patient identification?				Conversation confirms that two patient identifiers must be used
a1) Is there a written procedure?				Best practice
b) Collect the proper specimen for the test requested?				Evidence of Compliance (Click on tab for interpretation.)
b1) Is there a written procedure?				Best practice not required
c) Require a Lab order (On patient's chart or hard copy) before performing a test?				Evidence of Compliance (Click on tab for interpretation.)
c1) Is the order kept 7 years?				
d) Maintain a log or record of laboratory tests performed?				Not required but should be able to verbalize how they would investigate a manufacturers' recall of a product
e) Maintain a log or record of quality control results for each waived test instrument?				Evidence of Compliance (Click on tab for interpretation.)
e1) Does testing staff look at numeric Quality Control results for shifts and trends daily and on an ongoing basis?				
f) Keep the patient's test report in the patient's chart?				
10. Does the laboratory use any waived test kits that require additional confirmatory procedures? (Need to Send out or perform another test in house)				Give example if yes
11. Does the laboratory send the specimen out to another laboratory to meet the additional requirement?				
a) If the specimen is sent out to meet the additional requirements, does the laboratory report results prior to receiving the confirmation report?				Explain situation

Waived Testing Assessment

b) Are the results of the confirmatory test documented in the patient's chart?				
12. Does the laboratory staff identify:				
a) Instrument or device error codes?				
b) Internal or electronic (procedural) quality control failure?				
c) External (liquid) quality control failure?				
d) Proficiency testing failure? If appropriate.				
e) Test results not correlating with patient's symptoms or history?				
13. Are the laboratory's results timely? Timely= ordering physician satisfied with turn around time				
14. Is the laboratory voluntarily enrolled in proficiency testing?				Not required unless accredited by CAP (College of American Pathologists)
<b>14a) If 14 is yes, please list the name of the proficiency testing company(ies).</b>				

## Waived Testing Assessment

### Evidence of Compliance

Red= extra emphasis and review

Question Number

2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that is most current.

3. Choose a representative test ask the interviewee to walk through the procedure with you and point out the items listed in lines 3a-j

Look at Test Kit and individual components and check to see that all are within expiration date

Look at control results and confirm that they are within the manufacturer's expectations

Look at temperature records and compare to manufacturer's storage requirements (room temp, refrigerated and frozen where appropriate) Recommend that acceptable temp ranges be included on documentation chart

If any of the above are not within expected parameters investigate what the corrective action was and review with interviewee the follow-up actions. (See below)

I.e. Patients not reported, called manufacturer to troubleshoot, told supervisor/lab director, If temperatures were off, moved specimens/reagents to an acceptable temperature controlled area

5a. Separate documentation of this information is not required but ask how the lab would handle identifying patients tested using a recalled defective test kit?

6b,c,d. Ask interviewee to demonstrate how results are entered/documented in patient chart, How they would troubleshoot bad controls or instrument readings?

7. Testing staff should verbalize that they review each new kit instructions for changes or that their supervisor informs and educates them of new changes. Someone MUST review each new insert for changes. (Best practice documents that fact)

9b. Ask staff to show you in the manufacturer's insert where the manufacturer describes the correct specimen to collect for analysis.

9c. Ask testing staff to show you evidence of a typical test order.

9e. Log is not required (Best Practice ) but interviewee needs to be able to verbalize how to confirm to an inspector or the laboratory medical director that controls were acceptable after the fact (days, weeks later)



**Laboratory Repayment Project Information Form**  
**All information is to be Completed by Project Owner**

<b>Entity Location Details</b>	
Initiation date	34T
Entity Name	Enter MBO Name
Hospital/Location(s) and City, State	Enter Hospital Name and Locations (as applicable) and City, State
Entity Project Owner	Enter Name here
Entity Laboratory Director Name	Enter Name here
Entity Laboratory Department Administrative Executive (VP)	Enter Name here
Entity CRO Name	Enter Name here

<b>Project Details</b>	
What billing discrepancy was identified at the entity? Include details test name, billing identification number, HCPCS code.	
Describe the issue that was identified here.	
How was the Issue Identified?	
Explain how the issue was identified here	
What caused the Issue?	
Explain what caused the billing discrepancy here	
Was the Issue corrected?	
If Yes, When was the Issue corrected?	34T
How was the issue corrected?	
Explain how the issue was corrected here	
If known, when did the issue start?	Explain the length of time

<b>Project Logistics Determined During Legal Consult</b>	
What is the lookback period (i.e., Time Period) for the repayment analyses?	
Provide the lookback start and end dates	
What payers will be Included in repayment analyses? Normaly Medicare, Medicaid and their managed care plans.	
Provide the payers to be included in the analyses	
Name of attorney directing repayment	Enter Name here
Will the project be performed under the Attorney Client Privilege (ACP)?	
Will CHAN be requested to perform the project	

<b>Laboratory Repayment Project Finalization Information</b>	
Date data analysis accepted by directing attorney	34T
Date directing attorney provided templates and direction for entity repayment.	34T
Date reimbursement was made to payer/s. Must be less than 60 days from attorney acceptance date.	34T
Date CRO entered incident into EthicsPoint	34T
Return copy of this completed form to attorney director, entity CRO and Director of Laboratory Compliance .	

Dear Lab Administrative Director:

A potential laboratory miscoding error has been identified in your laboratory charge description master (CDM) that may potentially end in governmental plan repayment. In order to be able to assure that we performed a thorough analysis, there are some steps to be followed to ensure good communication, data analysis accuracy/integrity and timely reporting. You need to make certain that your entity Corporate Responsibility Officer (CRO) XXXXXXXX is aware of the situation. I also advise letting your entity VP and other senior leaders as required know of the situation and keep them updated as we progress. Please see attached typical data request for repayment analysis when appropriate.

The normal chain of events that occurs when a billing/coding error is discovered:

1. Notify Vice President or senior executive responsible for the laboratory department
2. Notify entity (CRO)
3. Notify national laboratory compliance director
4. Complete Laboratory Repayment Project Request Form (included)
5. A meeting with CHI legal, you and the Director of Laboratory Compliance will be set up by the Entity CRO after items 1 and 2 below are accomplished. The purpose of this meeting will be direct analysis, develop an action plan and assign responsibilities on a go forward basis.

Simultaneously you should:

1. Identify the date that the correction of the error was completed, implemented and confirmed.
2. Determine when the error first occurred if possible for example there was a software change, new test initiated and assigned an incorrect code or old code discovered to be incorrect.
3. Legal will hear the presented information and determine a repayment corrective action if necessary.
4. If repayment is determined, legal will direct that the identification of all non-bundled (Post 1/2014) and all (Pre 1/2014) out and non-patients from PPS or sole community hospitals having the following payer types: Medicare, Medicaid and their managed care plans in addition to any other federal payers are to be identified and repayment amounts will be determined. Providing the data in the format as required by the legal department's repayment template. This can be accomplished at the entity level or assigned by the entity to the Catholic Health Auditing Network (CHAN) to complete. [Recommended]
5. Once legal accepts the repayment data, repayment will be made by the entity as directed by the assigned attorney within 60-days of their acceptance date.
6. At the entity level, the repayment process will be directed and completed by the local (CRO).
7. All analytic work, identifying and quantifying identified repayments must be completed within six (6) months of discovery.

Please feel free to refer to me any questions you or your leadership may have.

**Tim Murray, MS, MT (ASCP), CHC**

Director Laboratory Compliance  
Corporate Responsibility  
367 Eagleview Boulevard, Exton, PA 19341  
P 610-594-5102 | F 610-363-1790  
[timothymurray@catholichealth.net](mailto:timothymurray@catholichealth.net)  
[www.catholichealthinitiatives.org](http://www.catholichealthinitiatives.org)

## Compliance Issues Affecting Clinical Laboratories

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## Content of Presentation

Clinical Laboratory Services  
Compliance Formula  
Selected Licensure/Certification/Enrollment Issues  
False Claims Applicable to Labs  
• The Match Game  
• *Medical Necessity and Related Documentation Issues*

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## Content of Presentation

• Regulatory Violations  
• Return of Overpayments  
• Payment for Hospital Outpatient Tests  
Federal Anti-Kickback Statute  
Stark Self-Referral Prohibition  
Pricing Issues for Laboratories

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**Clinical Laboratory Services**

- Fungible
- High Volume
- Reliance on Referring Physicians
- Lack of Medical Necessity Documentation
- Potential Revenue from Reference Tests

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**Compliance Formula**

Intent  
+ Knowledge of Rules  
+ Process  
Compliance

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**Compliance Formula**

**Intent**

“If you’re going to talk the talk, you’ve got to walk the walk.”

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### Compliance Formula

#### Rules - Compliance is a many-headed beast

- Federal and state laws and regulations and private payer requirements
  - Licensure, certification and enrollment requirements
  - Claims for payment including medical necessity issues
  - Relationships with referral sources
  - Miscellaneous

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### Compliance Formula

#### Process

- Ongoing Process
- Coordination of Activities
- Those who should know, do know

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### Compliance Formula

- Continuous monitoring of referral patterns and related receipts
- “Small” or uncomplicated issues can result in big problems, e.g., failure to update enrollment application, failure to maintain and produce Medicare with requested records or information

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**Licensure/Certification/Enrollment**

**Proficiency Testing Referrals - Regulatory Principles**

- Lab prohibited from intentionally referring PT samples to another lab for analysis. CMS: Referral is "intentional" if lab employee requests another lab to test PT sample
- CMS cannot revoke CLIA certificate of lab that provided PT samples to another lab, when it did not direct that lab to test PT samples or seek its test results. *J.B. and Greeta B. Arthur Comp. Cancer Ctr. Lab.*, Dept. Appeals Board, CR 2436 (Sept. 21, 2011)

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**Licensure/Certification/Enrollment**

**CMS Application of PT Referral Prohibition**

- Reflex, distributive or confirmatory testing may not be "intentional" referral. 42 C.F.R. § 493.801(b)(4)
- Prohibition applied broadly, to cover virtually any handling of PT samples or test results by another lab
- Includes lab in same hospital building with separate CLIA certificate
- Applies to waived tests, at least those performed by labs with waiver certificates

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**Licensure/Certification/Enrollment**

**Best Practices To Avoid Prohibited PT Referrals May Include**

- Detailed Policies
- Employee Education
- Internal Audits
- Use of Different PT Organizations for Related Labs

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**Licensure/Certification/Enrollment**

**Medicare Billing Privileges**

- Lab's Medicare enrollment and billing privileges revoked when on-site review indicated that it was not yet "operational." *TC Foundation, Inc. v. CMS, Dept. Appeals Board*, CR 2834, CCH ¶ 122,766 (June 18, 2013)
- Similar theory applied against lab closed at time of inspection. *Community Medical Lab., LLC v. CMS, Dept. Appeals Board*, CR 2635, CCH ¶ 122,650 (Oct. 2, 2012)

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**Licensure/Certification/Enrollment**

**Medicare Billing Privileges**

- Provider or supplier's Medicare billing privileges may be revoked based on "a pattern or practice of submitting claims that fail to meet Medicare requirements." 42 C.F.R. §424.535(a)(8)(ii)
- CMS indicates that such claims include those for services that are not reasonable and necessary
- CMS declined to impose intent standard

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**Licensure/Certification/Enrollment**

**Enrollment Form**

- Effective January 6, 2017, civil monetary penalties of up to \$50,000 for any false statement, omission or representation on any enrollment application. 81 Fed. Reg. 88334, 88341, 88358 (Dec. 7, 2016)

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**False Claims Applicable to Laboratories**

- Billing for tests not ordered or performed
- Miscoding of CPT codes
- Misrepresentation of diagnosis codes
- Lack of medical necessity
- Overpayments
- Regulatory violations
- Stark/Kickback violations

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**False Claims Applicable to Laboratories**

- False Claims Act prohibits
  - filing, or causing to be filed “false or fraudulent” claims
  - Using false statement to “conceal, avoid or decrease” a government obligation
  - Failure to return overpayments

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**False Claims Applicable to Laboratories**

- Intent under FCA
  - “Intent to defraud” not required
  - “Reckless disregard” of claim’s truth or falsity sufficient
- Other Federal and State statutes may prohibit similar conduct related to governmental and *non-governmental* payment claims

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### The Match Game

- First Generation
  - Test ordered
  - Test performed
  - Test billed (CPT or HCPCS code)

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### The Match Game

#### Test Orders

- CMS does not require a physician's signature on a laboratory requisition, but such a signature may prove that a test was ordered.
- In the absence of a signed requisition, labs may be dependent on content of physician's medical record to prove test was ordered.

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### The Match Game

#### Test Orders

- Court upholds *denial* of claims for audiological testing when medical records did not reflect physician's intent or knowledge that tests were to be performed. *Doctors Testing Ctr. v. HHS*, 2014 WL 112119 (E.D. Ark., Jan. 10, 2014), *aff'd*, 588 Fed. Appx. 517 (8th Cir. 2015)

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### The Match Game

#### Test Orders

Laboratory could not be *paid* for biopsies because no documentation of physician order. *Nephropathology Assocs., PLC v. Sebelius*, 2013 WL 3285685 (E.D. Ark. 2013)

Relator stated claim *under FCA* in alleging that laboratory performed unordered FISH tests. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)

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### The Match Game

#### Tests Performed and Billed

- *U.S. ex rel. Ketrosier et al v. Mayo Foundation*, 729 F.3d 825 (8th Cir. 2013)
  - Relator alleged that Mayo filed false claims because it did not prepare a per-slide separate written report for each special stain
  - Court dismissed because no rule clearly required such separate per-slide report as a condition of payment

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### The Match Game

- Second Generation Additions
  - Test *knowingly* ordered
  - Lab did not contribute to unnecessary tests

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### The Match Game

#### Medical Necessity – OIG Advice

Lab's responsibility (per OIG compliance guidance)

- Not contribute to unnecessary testing
- Honest, straightforward, fully informative and non-deceptive marketing (including tests offered, tests resulting from order, financial consequences to payers)
- Provide freedom of choice (e.g., reflex or not)

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### The Match Game

#### Medical Necessity – OIG Advice

- Educate physicians and other reasonable steps to avoid claims for unnecessary services
  - Requisition – conscious ordering of each test by physicians
  - Notices – General and Custom profiles
- Educate re ABNs
- Monitor tests utilization

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### The Match Game

#### Medical Necessity – OIG Advice – Custom Profiles

Annual Notices

- Medicare reimbursement for each component of profile
- Custom profiles may result in tests which are not covered, reasonable and necessary and will not be billed
- Individual who knowingly causes submission of false claim may be subject to sanctions

*Annual notices do not guarantee payment of particular claim(s)!*

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## The Match Game

### Medical Necessity – Custom Profiles

U.S. pled FCA action against medical group and related physicians based on:

- Use of custom panels that included unnecessary tests
- Use of "lab standing orders" ("house orders") not ordered by treating physician

*U.S. v. Family Med. Ctrs.*, 2016 WL 6601017 (D. S.C. Nov. 8, 2016)

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## The Match Game

### Third Generation Additions

- Lab's responsibility to demonstrate that tests were *actually* medically necessary
  - Compliance issue
  - Financial issue

See Mazer, Robert E., Medicare Medical Necessity Requirements Continue to Vex Clinical Laboratories, G2 Compliance Advisor (Sept. 2014)  
<http://www.g2intelligence.com/wp-content/newsletters/gca/2014-09-GCA.pdf>

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## The Match Game

### Sanctions vs. Lost Revenue

- Various statutes can result in imposition of penalties for submission of claims that the person knows or should know were not medically necessary. See, e.g., 42 U.S.C. § 1320a-7a(a) (civil monetary penalties)
- May not apply, however, if laboratory did not contribute to unnecessary testing. According to OIG, regulatory exception "would normally protect a laboratory from being subject to exclusion for providing unnecessary tests ordered by a physician...." 57 Fed. Reg. 3298, 3307 (Jan. 29, 1992)
- *Protections have little, if any, impact on loss of revenues from tests deemed unnecessary!*

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### Medical Necessity

#### General

“[N]o payment may be made . . . for items or services . . . [that] are not reasonable and necessary for the diagnosis and treatment of illness or injury.”

42 U.S.C. § 1395y(a)(1)(A).

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### Medical Necessity

#### Burden of Proof

“No payment shall be made . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider . . .” 42 U.S.C. § 1395l(e)

Payments to providers are precluded unless provider furnishes information to determine amounts due upon request. OIG Work Plan – FY 2017

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### Medical Necessity Documentation

#### CMS Regulations Related to Use of Diagnostic Tests

“All . . . diagnostic laboratory tests . . . must be ordered by the physician who is treating the beneficiary, that is, the physician who . . . treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem. Tests not ordered by [suc]h physician . . . are not reasonable and necessary . . .” 42 C.F.R. § 410.32(a).

Lack of documentation related to *physician’s use of lab results* has resulted in determination that tests were not medically necessary.

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### Medical Necessity Documentation

#### Intent - CMS Regulations Related to Use of Diagnostic Tests

"This policy is designed to assure that beneficiaries receive medically necessary services and to prevent patterns of abuse, such as the furnishing of diagnostic tests that are screening (non-covered) services . . . For example, we have heard of situations in which a physician is employed for the sole purpose of ordering diagnostic tests (in nursing homes or mobile centers).

\* \* \*

"The intent of the policy is to assure that the physician who orders the test is responsible for the management of some aspect of the patient's care."

61 Fed. Reg. 59490, 59497 (Nov. 22, 1996).

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### Medical Necessity Documentation

#### CMS Regulations

Physician ordering diagnostic service required to maintain documentation of medical necessity in patient's medical records. 42 C.F.R. § 410.32(d)(2).

Lab submitting claim must maintain (1) documentation received from ordering physician and (2) documentation that its payment claim accurately reflects such information. *Id.*

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### Medical Necessity Documentation

#### CMS Regulations

CMS may find information required to be maintained by lab inadequate to demonstrate medical necessity, and may request medical records from physician. If information not provided, CMS may deny claim. 42 C.F.R. § 410.32(d)(2).

Lab may request additional information from ordering physician to document that services are reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

*Regulations do not require physician's cooperation!*

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## Medical Necessity Documentation

### Administrative Case Law

Clinical laboratory has burden of producing documentation of medical necessity. *See Meridan Laboratory Corp. v. Advance Med. Corp.*, Dept. Appeals Board, Decision of Medicare Appeals Council, Doc. No. M-11-568 (June 24, 2011), remanded, *Meridan Laboratory Corp. v. Sebelius*, 2012 WL 3112066 (W.D. N.C., July 31, 2012) (remanded for consideration of limitation of liability principles).

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## Medical Necessity

### Limitation of Liability

Where a determination is made that payment may not be made based on lack of medical necessity and the patient and provider "did not know, and could not reasonable have been expected to know, that payment would not be made . . . then . . . payment shall . . . be made for such items or services . . ." 42 U.S.C. § 1395pp(a)(2).

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## Medical Necessity

### Without Fault

There shall be no recovery where incorrect payment made to individual who is without fault or if such recovery would defeat the purposes of Medicare or be against equity and good conscience. 42 U.S.C. § 1395gg(c).

"Without fault" requires laboratory to have exercised reasonable care in billing for and accepting payment

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### Medical Necessity Documentation

#### Proactive Steps

Educate physicians related to medical necessity criteria, supporting documentation and ABNs  
Physician's agreement to hold lab harmless for tests denied based on lack of documentation of medical necessity (if possible)

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### Medical Necessity Documentation

#### Proactive Steps

Securing Physician's Cooperation – Physician's agreement to provide documentation (*which may or may not be helpful*)

- Existing contract, such as for client-billing
- Acknowledgement of annual notices
- Laboratory requisition

Physician – Lab Relations

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### Regulatory Violations as Basis for FCA Claim

- *U.S., ex. rel. Escobar v. Universal Health Servs., Inc.*, 136 S. Ct. 1989 (2016). FCA not “vehicle for punishing garden variety . . . regulatory violations.” False claim must be material to government’s decision to pay claim.
- *U.S. ex. rel. Hansen v. Deming Hosp. Corp.*, 992 F. Supp.2d 1137 (D. N.M. 2013) – no claim for liability under FCA for CLIA violations (pre-*Escobar*)

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**Regulatory Violations as Basis for FCA Claim**

Execution of supplier agreement requiring claims to comply with laws, regulations, and program instructions could cause claims related to Stark or FAS violation to violate FCA. *Daugherty v. Bostwick Labs*, No. 1:08-CV-00354, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012)

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**Return of Overpayments**

**Medicare Program; Reporting and Returning Overpayments; Final Rule 81 Fed. Reg. 7654 (Feb. 12, 2016)**

Overpayment recipient must "report and return" overpayment within 60 days of date on which overpayment is "identified."

Overpayment is considered "identified" when person:

1. Has determined that it has received an overpayment and quantified overpayment; or
2. Should have determined that it has received an overpayment and quantified overpayment through use of reasonable diligence.

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**Return of Overpayments**

**General Principles**

- Regulation applies to any overpayment identified within 6 years of its receipt.
- Obligation to report and return applies irrespective of reason for overpayment.
- Payment properly received will not become an overpayment as a result of a subsequent change in law or regulation (but watch out for "clarifications").

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### Return of Overpayments

- “Reasonable diligence” includes:
  1. “Proactive compliance activities” conducted in good faith by qualified individuals to monitor claims for receipt of overpayments, and
  2. “Reactive investigative activities” conducted in good faith in timely manner by qualified individuals in response to “credible information” about potential overpayment.
- “Credible information” includes information that supports a reasonable belief that an overpayment may have been received.”

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### Return of Overpayments

#### Overpayments Based on Medical Necessity

- Requirements apply to “medical necessity” determinations.
- CMS: “There may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence.”
- Limitation of liability principles do not impact obligation to report and return overpayment.

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### Return of Overpayments

#### Return of Overpayments (to whom)

- To OIG – “potential fraud against the Federal health care programs”
- To CMS – Stark only violation
- To Contractor – “merely an overpayment”
- To U.S. Attorney’s Office – (does not satisfy 60-day rule)
- To State

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### Return of Overpayments

#### Enforcement

- Civil False Claims Act (on which regulations are based)
- Effective January 6, 2017, Civil Monetary Penalties of up to \$10,000 for each item on service for which an overpayment was not timely returned. 81 Fed. Reg. 88334, 88341, 88358 (Dec. 7, 2016)

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### Return of Overpayments

#### Impact of Compliance

- Does not eliminate CMP liability (or other liability) if it exists. 81 Fed. Reg. 88339.
- Medicare regulations permit suspension of Medicare payments when there is reliable information that an overpayment exists or when payments to be made may not be correct (as well as when there is a credible allegation of fraud). 42 C.F.R. § 405.371

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### Return of Overpayments

#### Self-Audits Can Result in FCA Liability

- FCA potentially violated when medical group failed to follow up on self-audit that reflected incorrect claims for payment
- Potential liability for both refusal to investigate possibility of overpayments received during audit period and for subsequent submission of claims
- *U.S. and Wisconsin, ex. rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, 2013 WL 1307013 (E.D. Wisc. 2013)

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**Payment for Hospital Outpatient Tests**

- Packaged into Hospital Outpatient Prospective System unless:
  - “Non-patient” test
  - No other hospital outpatient services from same “encounter” or
  - Tests “clinically unrelated” from other hospital services from same “encounter” and ordered by different physician
- Applies to tests performed by hospital directly or “under arrangements”
- CMS assigned codes designate packaging status of particular lab test

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**Payment for Hospital Outpatient Tests**

**Submission of Claims – Outpatients vs. Non-Patient Tests**

- Provision of services in hospital-based clinic may cause individual to be outpatient
- Can such an outpatient become a non-patient by obtaining lab tests from unrelated entity?

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**Federal Anti-Kickback Statute ("FAS")**

- Prohibited Conduct
  - Knowing & willful
    - Solicitation or receipt of
    - Offer or payment of
  - Remuneration
    - In return for referring a Program patient, or
    - To induce the purchasing, leasing , or arranging for or recommending, purchasing or leasing items or services paid by Program

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### Federal Anti-Kickback Statute

- Statutory Exceptions
- Regulatory Safe Harbors
- Advisory Opinions
- ACO waivers

*Contract arrangements that purport to be limited to private pay business may raise issues under FAS (and related state laws)*

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### Federal Anti-Kickback Statute – ACO Waivers

Clinical laboratories may enter into arrangements with ACOs participating in Medicare Shared Savings Program ("MSSP") that would otherwise violate the FAS (and Stark Law) if the arrangements:

- Reasonably related to purposes of MSSP and properly documented, including governing board's meaningful determination of such
- Purposes of MSSP include:
  - Promoting accountability for the quality, cost, and overall care for Medicare patient population as described in the MSSP, managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO, or encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.

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### Federal Anti-Kickback Statute

#### Special Fraud Alert: Laboratory Payments to Referring Physicians (2014)

General Principles:

- *Previously* emphasized that providing free or below-market goods to physician referral source, or paying more than FMV for services, could constitute illegal remuneration
- Payments intended to induce or reward referrals are unlawful, even if payments are FMV for services; payments exceeding FMV increase probability of unlawful payment
- Payments for services paid for by others, such as Medicare, provides evidence of unlawful intent

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**Federal Anti-Kickback Statute**

Specific Principles:

- Physicians and labs which participate in Special Processing Arrangements may be at risk under FAS
- Physicians and labs which participate in Registry Arrangements in which payments are related to test referrals, and do not reflect physician's efforts, may be at risk under FAS

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**Federal Anti-Kickback Statute**

**Advisory Opinion 16-12**

- Labeling test tubes and specimen collection containers for dialysis facilities, at no cost, by lab personnel in lab's facility
- Offered as necessary to obtain or retain dialysis center business
- OIG: Potentially violates FAS
  - Services would otherwise be performed by dialysis center's employees
  - Inference, supported by lab's representation, that free services intended to influence laboratory selection

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**Federal Anti-Kickback Statute**

**Advisory Opinion 15-4**

- Provide clinical lab testing without charge for patients in commercial plans in which the lab was out of network
- Referring physicians not at financial risk for the lab services
- OIG determined "remuneration" to the physician
  - Physician's convenience in working with a single lab
  - "relieve physician practices of the expense for any interface that the physician practice no longer would maintain."

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**Federal Anti-Kickback Statute**

**In-Office Phlebotomists (IOPs)**

- Labs may provide IOPs at no cost, provided
  - IOPs provide only specimen collection and processing services for the lab
  - No services for physician’s practice or in-office lab
- May labs pay rent to physician practices for space used by the IOP?
- State law issues

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**Federal Anti-Kickback Statute**

**Marketing Arrangements**

- Statutory and regulatory exception for payments related to *bona fide* employment relationship
- Independent contractor arrangements may violate the FAS and may be legally unenforceable. *Joint Technology, Inc. v. Weaver*, Case No. CIV-11-846-M (CCH) ¶ 304,295 (W.D. Okla. Jan. 23, 2013)
- *Management* arrangements that include marketing services may raise issues under FAS (and/or state laws)

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**Federal Anti-Kickback Statute**

**Competitor Lawsuits**

“Conduct violating the [FAS] and the Stark Law may provide the basis for liability under recognized common law causes of action and other state statutory laws,” such as prohibitions against unfair or deceptive conduct. *Millennium Labs, Inc. v. Universal Oral Fluid Labs, LLC* (M.D. Fla., Aug 16, 2013).

Whether or not FAS and the Stark Law are relevant to state unfair competition law is a novel and complex issue of state law. *Ameritox, Ltd. V. Millennium Labs*, 803 F.3d 518 (11th Cir. 2015).

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**Stark Self-Referral Prohibition**

- Physician may not refer:
  - Medicare or Medicaid patients
  - for “designated health services”
  - to an entity with which the physician or an immediate family member has
  - a “financial relationship”
- Subject to exceptions in statute and regulations

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**Stark Self-Referral Prohibition**

**Compensation Arrangements Exceptions (generally)**

- In writing
- Not exceed what is reasonable and necessary
- Term at least one year
- Payments set in advance and unrelated to referrals or other business generated
- Commercially reasonable without regard to volume or value of referrals

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**Stark Self-Referral Prohibition**

**Discounts**

- Exception for payments by physicians
  - Fair market value *not* required for clinical laboratory services
  - Fair market value required for other services

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**Stark Self-Referral Prohibition**

**Client Entertainment**

- Stark non-monetary compensation exception
  - Items or Services
  - Annual aggregate limit (\$398 for CY 2017)
  - Not take into account volume or value of referrals or other business generated
  - Not solicited by physician

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**Stark Self-Referral Prohibition**

- Stark remuneration excludes
  - Forgiveness of amounts owed for inaccurate or mistaken tests or billing errors
  - Items, devices or supplies used solely to
    - Collect, transport, process, or store specimens
    - Order testing or communicate test results

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**Pricing Issues for Laboratories**

- “Swapping” - Advisory Opinion 99-13, discount arrangement between Pathology Group and Hospitals or Physicians
- OIG Indicia of “Suspect” Discounts
  - Discounted prices below fully loaded (not marginal) costs
  - Discounted prices below those given to buyers with comparable “account” volume, but without potential Program referrals

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**Pricing Issues for Laboratories**

- Subsequent Retreat
  - Discounts below fully loaded costs not per se unlawful
  - Must be a “linkage” between the discount and referrals of Program business

Letter of Kevin G. McAnaney, OIG Industry Guidance Branch (April 26, 2000) <http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm>

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**Pricing Issues for Laboratories**

**Fair Market Value vs. Cost**

- Compliance Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076 (August 24, 1998), uses “fair market value” benchmark
- Advisory Opinion 11-11 reiterates “below cost” theory of “swapping”

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**Pricing Issues for Laboratories**

**“Substantially in Excess”**

- May not bill Medicare “substantially in excess” of “usual” charge
- No enforcement activity since law passed in 1972
- Overall volume of test charges made to payers other than Medicare or Medicaid that are below Medicare/Medicaid fee schedule should be substantially less than one-half of non-Medicare/non-Medicaid test volume. Letter of Kevin G. McAnaney, OIG Industry Guidance Branch (April 26, 2000)

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**Pricing Issues for Laboratories**

**State Law Issues**

- Medicaid pricing limitations-various state laws
  - Many states require providers to bill at “usual and customary” rates
  - “Usual and customary” may be defined as lowest fee charged by lab.

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**Pricing Issues for Laboratories**

**Recommended Policies**

- Never tie client pricing to Medicare/Medicaid referrals
- Ensure that client bill pricing is profitable on a stand-alone basis
- Be cognizant of pricing patterns across clients
- Carefully review state law regarding Medicaid pricing

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**QUESTIONS?**



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## Tools to be a Successful Laboratory Compliance Officer

Barb Senters, CCEP, PHR  
Chief Compliance & Ethics Officer  
Ameritox




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### Agenda

- I. Lab Scam Overview
  - Tale as Old as Time
  - Consequences and Resources
- II. Just what the doctor ordered...or is it?
  - EMR challenges
  - In Office Phlebotomists/Processor challenges
- III. Risk at Each Step of the Lab Process
  - Risk Based Audit Protocols
- IV. Toxicology Risks
  - Authorized Provider
  - Testing Method
  - Medical Necessity

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## Tale as Old As Time...



*The  
LabScam  
Story...*

*... "Those who do not  
learn from the past  
are condemned to  
repeat it."  
-George Santayana*

...The first systematic nation-wide law enforcement project in the medical field. -Grob, George (2,000, Jan). Medicare Payments for Clinical Laboratory Services, Vulnerabilities and Controls. [www.oig.hhs.gov](http://www.oig.hhs.gov)

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 **The Labscam Story** 

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National Health Laboratories (NHL)-the government alleged the laboratory had induced physicians into ordering tests that were not medically necessary.

- Alleged that NHL added HDL and serum ferritin to its standard chemistry profile. These tests were then billed separately to the Medicare Program in addition to the charge for the standard chemistry.
- The government alleged that it was significant that the price charged to physicians for their non-Medicare patients only increased nominally. (Client Billing)
- NHL paid \$111 million, and pled guilty to criminal violations.

The government then sued other clinical laboratories alleging violations of the Federal False Claims Act and collected over \$800million dollars.

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 **Labscam-Two Alleged Themes**


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**Requisition** 

- The "Tool of the crime". Panels were offered that didn't disclose the individual components, though billed individually, or give the option to order individual tests.
- Unbundling-running specimens through a single piece of automated multi-channel equipment, then billing separately for each component.
- Incomplete or missing orders from providers.

**Free Services** 

- Or discounted to be less than fair market value (FMV)
- Professional courtesy testing
- Client Pricing like value meals for profiles
- Free equipment, supplies, services
- Gifts

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 **"Labscam" Changed the Landscape**

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- The government brought suit against hospitals that provided clinical laboratory testing: Operation Bad Bundle
  - alleged hospitals were overpaid because they had billed separately for certain tests that were ordered as "panels".
  - DRG Window-Tests for beneficiary within 3 days of admission are considered "in patient" covered by the hospital's DRG payment, not the clinical lab fee schedule (Medicare Part B)



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 "Labscam" Changed the Landscape

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**1<sup>st</sup> Model Compliance Plan by the OIG**  
 August 1998, 63 Fed. Reg. 45079  
 Includes guidance on variety of topics:

- Medical Necessity
- Billing
- Use of Standing Orders
- Custom Profiles
- Disclosure
- Pricing to Physicians
- Billing & ABN's
- An Annual Notice to Providers



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 Just What the Doctor Ordered...

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- Medicare requires that the test be ordered by the physician or other authorized person who is involved in treating the patient. 42 C.F.R. § 410.32. CMS
- Non-physician practitioners (such as clinical nurse specialists, clinical psychologist, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) who provide services that would be covered as physician services, if furnished by a physician, may be considered physicians under the treating physician rule. They must be acting within their authority under state law and within the scope of their Medicare statutory benefit. 42 C.F.R. § 410.32(c).

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 Just What the Doctor Ordered...


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§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1))

Section 2. (ii) Submitting the claim- The entity submitting the claim must maintain the following documentation:

- A. The documentation that it receives from the ordering physician or nonphysician practitioner.
- B. The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or non-physician practitioner.

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## Just What the Doctor Ordered?

**Scenario:**  
Susie is a lab Phlebotomist at Dr. Pepper's office. She received a script written order for "testosterone". Your lab offers five different tests that contain the word "testosterone".

- Testosterone, Free Bioavailable, LC/MS/MS (\$54.15)
- Testosterone, Total Immunoassay (\$35.17)
- Testosterone, Free (Dialysis) and Total LC/MS/MS (\$69.86)
- Testosterone, Total and Free and Sex Hormone Binding Globulin (\$99.47)
- Testosterone, Free, LC/MS/MS (\$34.69)



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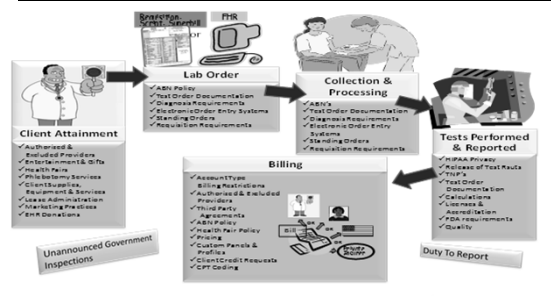
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## Risk areas in each step-Audit Protocols



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## Client Attainment

Risk	Reference	Mitigation
Marketing Practices	Millennium CIA, OIG Guidance for Clinical Labs	Ensure marketing materials & messaging are aligned with company clinical guidance. Document approval process, audit. Ensure clinical leaders are making clinical decisions. Compliance & CMD partnership.
Authorized & Excluded Providers	Medicare allows states to determine authorized providers. 42 C.F.R. § 410.32. CMS	Ensure a process to review non-MD provider types prior to set-up and verify OIG Exclusion Lists. Example: Optometrist, Psychologist, Nurse Practitioner, Mid-wife, etc.
Entertainment & Gifts	Stark Law, Special Advisory Bulletin Aug. 2002	Prohibit non-reimbursed expenditures, Stark Tracking, an Exception process, train on beneficiary hardship scenarios.
Focused Arrangements	Fraud Alert June 2015	Ensure process for Focused Arrangements contracts, FMV calculation process/documentation, services provided, etc.
Client Supplies	Can create compensation arrangements. Laboratories should only provide supplies directly related to the collection and processing of lab specimens.	Review the items being supplied. Single use needles, vials, specimen cups are permitted. Reusable items such as biopsy needles, syringes, injection needles are not. Dual-use supplies such as gloves and band aids are not permitted as they may be used by the physician's office. The rule states that labs or the physician should be able to demonstrate that the number of permitted items and supplies were appropriate for the level of referrals expected.

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## Lab Test Order

Risk	Rationale	Mitigation
Are all tests received or confirmed (within 30 days) in writing from an authorized provider?	Performing tests without a specific test order may violate CLIA and state law. Billing for tests that were not ordered may violate the False Claims Act. Failure to obtain or maintain documentation of test orders could violate CLIA and state law.	Train Phlebotomists & Lab Audit, Audit, Audit
Do the same controls apply to your electronic ordering system?	Same as above. Refer to Labscam lawsuits "requisition was the tool of the crime" because of how tests were marketed.	Audit to ensure proper controls of profiles, proper disclosures, and translations.
Custom Profiles		

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## Lab Test Order

Risk	Rationale	Mitigation
Attaining original order if Lab Phlebotomist enters into electronic ordering system.	Only an authorized person may choose laboratory tests.	Determine if the client or Lab Phleb is entering orders, audit for original provider orders to ensure they match.
Requisition Design -constructed for providers to make individual decision -Review the test options to ensure proper menu that doesn't steer providers to higher reimbursable tests.	OIG Guidance for Clinical Labs	Review the requisition and marketing material. Collaborate with Coders and CMO.
Ambiguous Orders	<i>Labs should not bill for testing until the tests the provider intended are clarified.</i> Id. At 45080-81	Phlebotomist & Lab Training, Audit!

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## Laboratory Audit Protocols

Audit Protocol	Rationale	Elements Monitored
Accounts Payable Ledger	Ensure compliant relationships with current, potential referral sources, & that proper agreements are in place.	FMV for Medical Director (consultants), Charitable Contributions, Specimen Collection Services, Test Send Outs, Payments to any provider
Anatomic Pathology		Direct Billing State Laws, CPT Coding, Technical & Professional Component Review
Facility Information	Ensure proper permits, licenses and accreditation.	Accurate performing site disclosure, CLIA #, Medicare/Medicaid Provider #, Medical Director (FMV if contracted).

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Audit Protocol	Rationale	Elements Monitored
Co-pays & Deductibles	Could implicate the Anti-Kickback statute Federal Register Dec. 19, 1994	Review Sales and Billing process. Audit. Implement financial hardship exception.



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 Toxicology Laboratory Issues

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- Testing Method
  - Presumptive vs. Definitive
  - Cutoffs
- Medical Necessity
  - Audits
    - Average Tests Per Requisition
    - Average # of times panels ordered on same patient in 12 months

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 **Presumptive vs. Definitive Methodology**


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Palmetto Local Coverage Determination (LCD) L35724, " Controlled Substance Monitoring and Drugs of Abuse Testing"

*Limitations of Presumptive UDT:*

*Primarily screens for drug classes rather than specific drugs, and therefore, the practitioner may not be able to determine if a different drug within the same class is causing the positive result; Presumptive IA is limited due to:*

- *Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class.*
- *Given that not all prescription medications or synthetic/analog drugs are detectable and/or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive.*
- *While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4 methylenedioxy—methylamphetamine (MDMA-ecstasy) and phenycyclidine (PCP), they may not be optimal tests for many prescription drugs, namely opiates, barbiturates, benzodiazepines and opioids.*

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 **Presumptive vs. Definitive methodology**

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Palmetto Local Coverage Determination (LCD) L35724, " Controlled Substance Monitoring and Drugs of Abuse Testing"

- *Definitive UDT is reasonable and necessary for the following circumstances: Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT.*
- *Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;*
- *Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances and*
- *Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.*

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 **Conflicting Policies**

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Anthem Clinical UM Guideline: Drug Testing or Screening in the Context of Substance Use Disorder and Chronic Pain.2/4/16

Definitive urine drug testing is considered medically necessary when all of the following criteria are met:

- The presumptive urine drug testing was done for a medically necessary reason; and
- The presumptive test was negative for prescribed medications, positive for a prescription drug with abuse potential which was not prescribed, or positive for an illegal drug and
- The specific definitive test(s)ordered are supported by documentation specifying the rationale for each quantitative test ordered and
- Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.

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 **Medical Necessity**

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- Medicare coverage is limited to items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” 42 USC 1395y(a)(1)(A)
- Medicare requires health care practitioners and providers to assure that health services ordered for government patients are “provided economically and only when, and to the extent, medically necessary.” 42 USC 1320c-5(a)(1)

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 **Toxicology Risk Reduction**

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- ✓ Educate providers on the proper use of tests.
  - Medical Necessity, Frequency, Chart Documentation
- ✓ Partner with Chief Medical Officer to conduct audits.
  - Average tests per requisition
  - Specific patient groups vs. drug risks
  - Review profile utilization
- ✓ Annual Disclosure Letter
- ✓ Specimen Processor & Lab Test Order Audits

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The best prize that life offers is the chance to work hard at work worth doing.

-Theodore Roosevelt

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# HCCA

P14 Discover How Managed Care Plans are Responding to their Obligations in Detecting, Investigating and Preventing Fraud and Abuse in the Health Care System

Sunday, March 26, 2017 9AM to 12AM

Mary Beach  
Caron Cullen  
Katherine Leff  
Bernadette Underwood

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# AGENDA

- ▶ SIU Mission
  - FWA Prevention
  - FWA Identification
  - FWA Investigation
  - Correction
  - Reporting
- ▶ Program Integrity/Compliance

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# SIU MISSION

Report

Prevent

Identify

Investigate

Correct

Fraud, Waste, and Abuse

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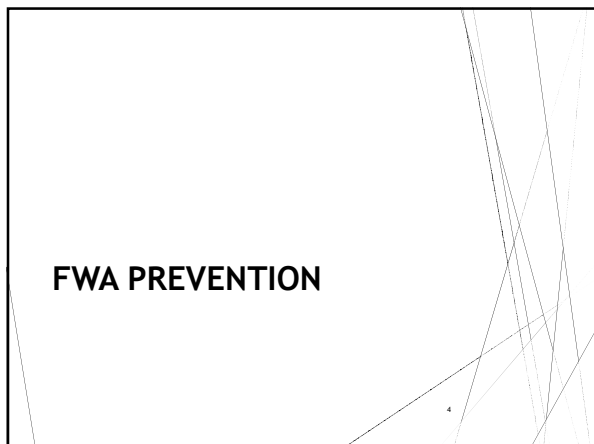
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**PREVENTION**  
*Education & Training*

- Members
- Providers
- Employees

FROM THE OFFICE OF THE INSPECTOR GENERAL:  
 The Office of the Inspector General (OIG) has awarded two additional contracts of Medicare programs and program beneficiaries from fraud, waste and abuse.

**OIG Issues:**  
 A Strategy to Avoid Increases and Increase Fraud and Abuse Issues

**OIG Issues Part 2:**  
 Medicare, Medicare Part B

- Training Programs
- Website
- Member/Provider Manuals
- Newsletters
- Anti-fraud Plan
- OIG Links

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**PREVENTION**  
*Reporting Mechanisms*

- FWA Hotlines
- Ethics & Compliance Hotlines

**Easy Compliance Reporting**  
**Ethics and Compliance Reporting**  
 Anonymous: 877-LINKCISM or 877-546-5276  
 Website: <http://caresource.safesay.info>

**Fraud, Waste, and Abuse Reporting**  
 Anonymous: 877-725-4523 (or internally dial ext. 2300)  
 Write to: (use this form) Special Investigations Unit, PO Box 1940, Dayton, OH 45401-1940  
 Nonanonymous: E-mail: [EWAB@caresource.com](mailto:EWAB@caresource.com), Fax: 800-418-0248

Posters  
 Intranet Site  
 Badges  
 Website

CareSource has a non-retaliation policy. This means no action of retaliation or reprisal will be taken against anyone for reporting a complaint or inquiry. Hotlines are available 24 hours/day.

- Anonymous
- Confidential
- Non-retaliation

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### PREVENTION

*Programs*

- Clearinghouse
- Instructions
- Coding Assist
- Clinical Edits
- Provider Education Letters
- Provider Pre-pay review
- Claim Line Pre-pay Review



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### Clinical Edits

- ▶ Clinical editing rules
  - ▶ Rebundle
  - ▶ Duplicates
  - ▶ Modifiers
  - ▶ Mutually Exclusive
  - ▶ Invalid Coding
- ▶ Edits customized per line of business

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### Clearinghouse

- ▶ Duplicates
- ▶ Patient sex and surgical procedure do not match
- ▶ Member mismatch

### Coding Assist

- ▷ Peer Comparison base line
- ▷ Send claim back to provider in clearinghouse with notification of aberrancy
- ▷ Follow with letter to provider
- ▷ Certified coder calls provider
- ▷ Monitor for billing behavior change

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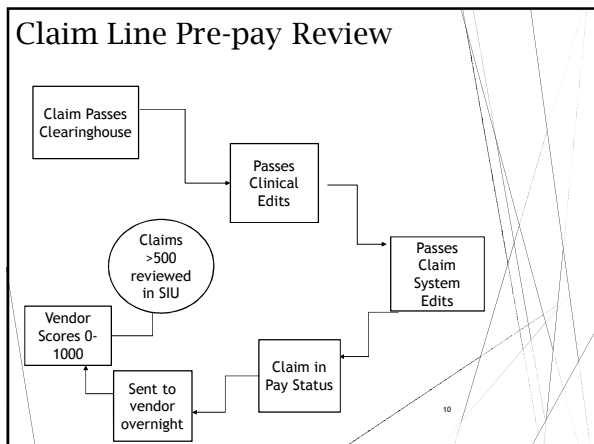
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### Provider Education Letter

To whom it may concern:

As part of our ongoing process to identify fraud, waste, and abuse in the healthcare system, CareSource may periodically conduct an audit of medical claims data.

During a recent review of medical claims data, a pattern of unbundling ophthalmic exams and refractive services was noted. CareSource policy, which follows CMS guidelines, states that when the refractive service (92015) is performed during a routine eye exam (e.g., CPT codes 92002, 92004, 92012, 92014); the refraction is considered part of the exam and is not separately reimbursable.

Please reference CareSource Network Notification dated October 28, 2011 regarding the CareSource refraction policy. For your convenience, the notification is included with this letter.

This letter is being sent for educational purposes in the hopes that the areas of concern highlighted will be addressed by your practice.

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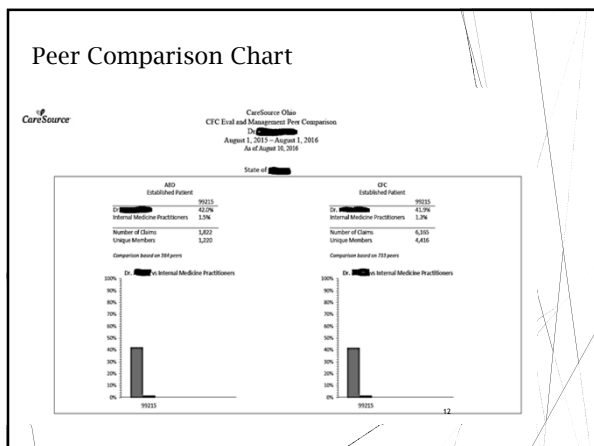
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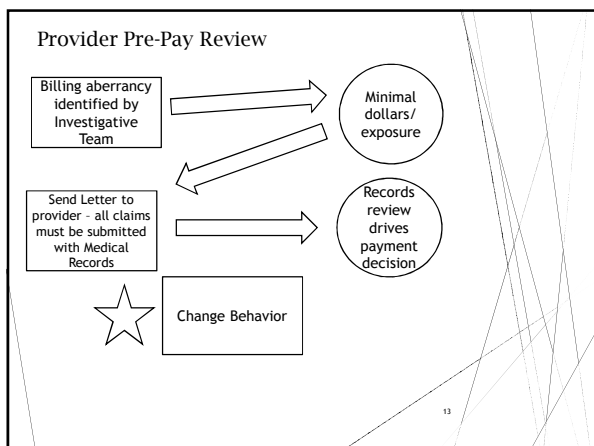
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**PROVIDER PREPAY NOTIFICATION LETTER**

[DATE]

[PROVIDER GROUP NAME]  
[PROVIDER NAME]  
[ADDRESS]  
[CITY, STATE, ZIP]

Dear Provider,

Please be advised that CareSource has implemented Prepayment Review of your Medicaid claims.

CareSource is mandated by the Centers for Medicare and Medicaid Services to have an effective surveillance and utilization program that safeguards against unnecessary and inappropriate use of Medicaid services and overpayment of services. In addition, in an effort to safeguard the Medicaid program, your state office for Program Integrity requires a continuum of activities to be carried out, including pre-payment review.

Our team will be evaluating various sources of information for risk related practices. Prepayment reviews look for overutilization of services or other practices that, directly or indirectly, result in unnecessary cost to the health care industry. Examples include but are not limited to: selection of the wrong CPT, HCPCS, ICD-10 code/s for services or supplies, lack of documentation in the medical record to support services billed, billing for items or services that should not or were not provided based upon documentation in the medical record. These audits can also confirm appropriate utilization of cost effective supplies and substantiating documentation to support services provided to the member. Based upon the finding of our evaluation, you have been selected for a comprehensive medical review.

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Prepayment Review of Medicaid claims is not a sanction and is not subject to appeal. Charges for services that do not meet guidelines for reimbursement will be subject to denial.

Prepayment review will be implemented beginning on [DATE] for those claims with date of service beginning [DATE] that have not yet been paid or submitted. All claims must now be submitted with appropriate supporting documentation (including but not limited to: office notes, individualized treatment plans, operative reports, office procedures and testing results).

During the time that you are on Prepayment Review please be advised that any claim submitted without the required documentation will be denied. Should additional records be required to support services billed, you will be notified via letter and will have 30 days to submit the additional requested documentation. If CareSource is not in receipt of the additional documentation within 30 days from date of notification letter, the entire claim will be denied.

Please ensure that all documentation sent to CareSource is in paper format and photocopied as single-sided copies to the following address:

CareSource  
Attention Prepayment Review Team  
PO Box XXXX  
Dayton, Ohio 45401-XXXX

Please do not submit appeal requests until claim has been processed and decisioned.

If you have any question about submission of claims, please contact ----- via email to -----@CareSource.com or via phone to (937) --- ----.

Sincerely,  
CareSource Provider Pre-Pay Team

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**FWA IDENTIFICATION**

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### Creating an Effective Program Integrity Program - Stakeholders

<b>Internal</b>		<b>External</b>	
<u>FWA Awareness and Collaboration</u>		<u>Monitoring and Intelligence Gathering</u>	
<b>Compliance Department</b> <ul style="list-style-type: none"> <li>Fraud Helpline (internal and external)</li> <li>Fraud Tips</li> <li>PCO and RMM collaboration</li> </ul>	<b>Health Plan</b> <ul style="list-style-type: none"> <li>HP Leadership</li> <li>Gov't Relations</li> <li>Provider Relations</li> <li>HCMS</li> </ul>	<b>NHCAA</b> <ul style="list-style-type: none"> <li>Latest schemes and trends</li> <li>Fraud Alerts</li> <li>SIRS database</li> </ul>	<b>State Regulatory Agency</b> <ul style="list-style-type: none"> <li>Program Integrity</li> </ul>
<b>Pharmacy</b> <ul style="list-style-type: none"> <li>PBM</li> <li>Audits/Investigations</li> </ul>	<b>Clinical Services</b> <ul style="list-style-type: none"> <li>Appeals and grievances</li> <li>Medical Directors</li> <li>Quality of care issues</li> <li>Coding and policy changes</li> </ul>	<b>HHS-OIG</b> <ul style="list-style-type: none"> <li>Referrals</li> <li>Sanctioned List</li> <li>Enforcement Database</li> <li>Fraud Alerts</li> <li>Task Force referrals</li> </ul>	<b>CMS</b> <ul style="list-style-type: none"> <li>Health Integrity Referrals</li> <li>Part C E &amp; Work Group meetings</li> <li>Fraud Alerts MEDIC</li> <li>HPPP</li> </ul>
<b>Provider Contracting</b> <ul style="list-style-type: none"> <li>Credentialing</li> <li>Sanctioned Providers</li> </ul>		<b>HEAT Strike Force</b> <ul style="list-style-type: none"> <li>Enforcement Activity</li> </ul>	<b>FBI</b> <ul style="list-style-type: none"> <li>Task Force</li> <li>Private Health Care Fraud</li> </ul>
<b>Health Care Analytics</b> <ul style="list-style-type: none"> <li>Anti-Fraud Tools</li> </ul>		<b>Attorney General (AG)</b> <ul style="list-style-type: none"> <li>Insurance Fraud Division</li> <li>Medicaid Fraud Control Unit</li> </ul>	

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### Internal Identification Sources

- ▶ Compliance
  - ▶ Fraud Hot Line - Internal and External
  - ▶ Associate FWA Training
- ▶ Provider Contracting
  - ▶ Credentialing
  - ▶ Sanctioned Providers
- ▶ Health Plan
  - ▶ Government Relations
  - ▶ Provider Relations
  - ▶ Health Care Management Services

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## Internal Identification Sources

- ▶ Pharmacy
  - ▶ PBM
- ▶ Clinical services
  - ▶ Appeals and Grievances
  - ▶ Medical Directors
  - ▶ Quality of Care Issues
  - ▶ Coding and Policy Changes
- ▶ Health Care Analytics
  - ▶ Costs Containment

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## Internal Identification Sources

- ▶ Special Investigations Unit
  - ▶ Anti-Fraud Tools
    - ▶ Post-payment Review
    - ▶ Pre-payment Review

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**FICO Insurance Fraud Manager**

Home Review Claims Review Providers Review Procedures Add Suspect Investigations

### Review medical claim

Expand all sections

Claim	Provider	Member
Claim ID: [REDACTED] Claim lines: 2 Overall score: 999 Total billed: \$34,590.00 Total paid: \$25,797.29 Total allowed: \$25,797.29	Provider ID: [REDACTED] Performing provider name: [REDACTED] Doing business as: [REDACTED] Performing provider score: 999 Performing provider NPI: [REDACTED]	Member ID: [REDACTED] Member name: [REDACTED] Gender: [REDACTED] Date of birth: [REDACTED] Age: [REDACTED]

**Analysis**

High-Risk

The analysis looks at all bills submitted by a member on a particular day, then the procedure performed on the member.

Score: 999	Provider: E217029
Member: [REDACTED]	Claim line code: 2
Procedure: J411209	Allowed standard deviation: \$25

Claim	Line	Procedure	Modifiers	Diagnosis	Type of service	Rate	Discount	Day standard deviation	Procedure average	Procedure ID	Days
[REDACTED]	2	0206		Yes	SD	\$2,749.6	\$700	\$785	\$925	[REDACTED]	28
[REDACTED]	1	9922	Tr	Yes	DRD	\$2,24	\$628	7470	24,024	[REDACTED]	1

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### CASE TRACKING SOFTWARE

The screenshot displays a web-based case tracking system. On the left is a navigation menu with categories like 'Case Entry', 'My Responsibility', 'Pending Cases', 'Open Cases', and 'All Cases'. The main area shows a 'Case Details' view for a specific case, including fields for Case #, Status, Business, and Priority. Below the screenshot, two callout boxes labeled 'Dashboard' and 'Case Details' have arrows pointing to their respective sections in the interface.

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### External Identification Resources

- ▶ NHCAA
  - ▶ Latest Schemes and Trends
  - ▶ SIRIS Database
  - ▶ Training Opportunities
- ▶ Health and Human Services - Office of Inspector General
  - ▶ Sanctioned List
  - ▶ Fraud Alerts
  - ▶ Task Force Referrals

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### External Identification Resources

- ▶ State Regulatory Agencies
  - ▶ Program Integrity Unit
  - ▶ Insurance Fraud Division
  - ▶ Medicaid Fraud Control Unit
- ▶ CMS
  - ▶ MEDIC Fraud Alerts
  - ▶ Part C & D Work Group Meetings
- ▶ FBI
  - ▶ Task Force Meetings

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### External Identification Resources

#### Medicare Fraud Strike Force Locations



Source: Medicare Fraud Strike Force, HHS Office of Inspector General, <https://oig.hhs.gov/fraud/strike-force/>

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### External Identification Resources

#### Healthcare Fraud Prevention Partnership

The HFPP began in 2012 and started with approximately 20 Partners.

Today the HFPP has grown to 75 Partners, including federal agencies; private payers; and anti-fraud, waste, and abuse associations.

- Exchange of Information
- Leverage Analytic Tools
- Forum to share successful practices and effective methodologies

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### Healthcare Fraud Prevention Partnership

- Studies & Algorithms
- In-person regional information sharing sessions
- Real-time provider alerts
- Fraud scheme notifications



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WHERE DO WE START?

- ▶ Gather information!
- ▶ What kind of information?
- ▶ How do we determine if there is a credible allegation or evidence of fraud?

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DEFINITION: CREDIBILITY  
*Merriam Webster Dictionary*

- 1: the quality or power of inspiring belief
- 2: capacity for belief
- 3: the quality of being believed or accepted as true, real, or honest

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## CREDIBLE EVIDENCE

### *The legal definition*

Credible evidence is not evidence which is necessarily true, but is evidence worthy of belief, that is, worthy to be considered by the jury. It is often natural, reasonable and probable as to make it easy to believe.

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## GATHER PRELIMINARY INFORMATION (1)

- ▶ What does that look like?
- ▶ Who is involved? Provider/member/vendor.
- ▶ What is the specific issue or allegation fraud or abuse?
- ▶ What is available that makes you think there is a concern?

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## GATHER PRELIMINARY INFORMATION (2)

- ▶ How much exposure does the Plan have?
- ▶ How urgent the situation is? Is there potential member harm?
- ▶ Based upon these answers, you may proceed in various ways.

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**DO YOU HAVE CREDIBLE EVIDENCE TO PROCEED?**

- ▶ NO. What actions do you take now?
- ▶ YES. Proceed with a Comprehensive Investigation.

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**GATHER COMPREHENSIVE INFORMATION**

- ▶ Review the provider / member/vendor files
- ▶ Pull 3 to 6 years of comprehensive paid and denied claims
- ▶ Research the medical necessity, CPT code and the regulation
- ▶ Determine if other providers / members are involved
- ▶ Interview the person submitting the allegation if possible

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**GATHER COMPREHENSIVE INFORMATION**

- ▶ Obtain medical records for analyzing
- ▶ Perform a service verification call
- ▶ Possible surveillance & onsite visit
- ▶ Prior internal complaints or external complaints documented from state of federal agencies,
- ▶ Online sources such as the internet, Facebook, LinkedIn, etc.,

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### Gather Information...

- ▶ This investigative stage may also include: interviewing relevant parties such as the provider or member, obtaining signed statements from witnesses or the subject of the investigation, and reviewing a sampling of claims data.
- ▶ Review internal systems to assure it has been configured correctly (really a preventative step).

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### Gather Information...

- ▶ Any action taken in the investigation stage, whether it is requesting medical records, conducting an interview, completing a telephone call, or requesting claims reports, must be documented in the case files.

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### Is There Credible Evidence to Proceed?

- ▶ NO. What actions do you take now? Let it go...
- ▶ YES. Proceed with an evaluation of the facts.

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## EVALUATING the INFORMATION

- ▶ What conclusions may you draw from the information and whether we have a potential FWA case or not?
- ▶ Some questions to consider: What does the information and data tell us?
  - Is there reasonable explanation for the situation or behavior that was suspected as fraudulent or abusive?
  - Would this medical treatment for this diagnosis be consistent with acceptable medical practices?
  - Do you have a statement from an independent clinician to state a contrary position?
  - What is the provider's explanation?

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## QUESTIONS TO CONSIDER...

- ▶ Do we have any admission of guilt by the member or provider?
- ▶ Do we have signed statements from relevant parties, i.e., from a member, to state that the member never received the service billed?
- ▶ Is this information reliable?
- ▶ Do other factors come into play, e.g., has the member ever been diagnosed with dementia?
- ▶ Does the claim data support the allegation of inappropriate billing?
- ▶ Do you have enough information to make a decision? If so, what is the decision and what are your next steps? If not, what other information would be helpful to make a decision? Is the information available?

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## REAL LIFE STORIES

### *Provider A*

Optical

- ▶ Exposure: \$ 250,000
- ▶ Scheme: unlawfully used various providers NPI / EIN to create contracts with various MCO's in NYC and they also used the provider's information to open bank accounts / furnish the office with the best equipment available. With the help of a billing agency they managed to obtain member information to falsify medical records / claims. In this case, we were unable to directly recovery the funds as the provider was indicted.
- ▶ Civil law suit.

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## REAL LIFE STORIES

### Provider B

**Pain Management**

- ▶ Exposure: Significant Member Harm
- ▶ Scheme: Provider refused to bill health plan, required members to pay \$150 or \$200 cash per "office visit." The only service was to write a RX for controlled substances (suboxone, methodone). An E/M visit for substance use is a Medicaid covered service; member billing is prohibited.
- ▶ Initial overpayment recovery is to make the members whole.
- ▶ This case is still open pending responses from NY Office of Medicaid Inspector General (OMIG) and NY Office of Professional Medical Conduct (OPMC), Drug Enforcement Agency (DEA).

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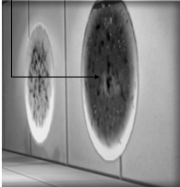
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## REAL LIFE STORIES

### Providers C and D

**Examples**

- ▶ Mama bought me a CT Scanner -
  - ▶ 6.5 Years in prison
- ▶ Tiptoeing through the portal

Member eligibility  
Guess at member names

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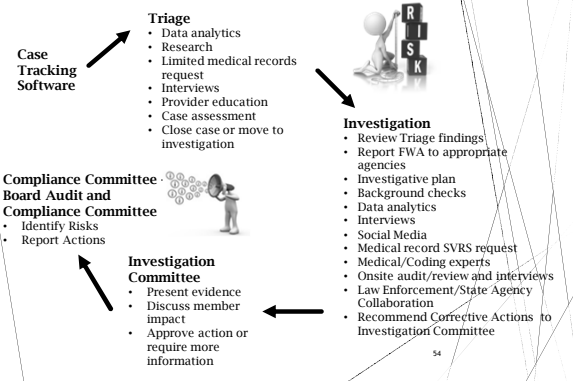
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## INVESTIGATE



**Case Tracking Software**

**Triage**

- Data analytics
- Research
- Limited medical records request
- Interviews
- Provider education
- Case assessment
- Close case or move to investigation

**Investigation**

- Review Triage findings
- Report FWA to appropriate agencies
- Investigative plan
- Background checks
- Data analytics
- Interviews
- Social Media
- Medical record SVRS request
- Medical/Coding experts
- Onsite audit/review and interviews
- Law Enforcement/State Agency Collaboration
- Recommend Corrective Actions to Investigation Committee

**Investigation Committee**

- Present evidence
- Discuss member impact
- Approve action or require more information

**Compliance Committee Board Audit and Compliance Committee**

- Identify Risks
- Report Actions

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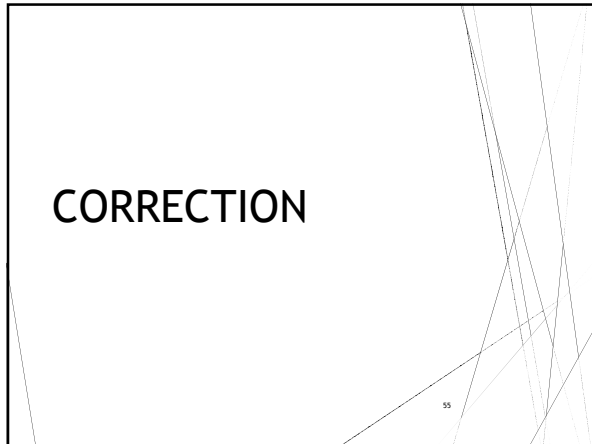
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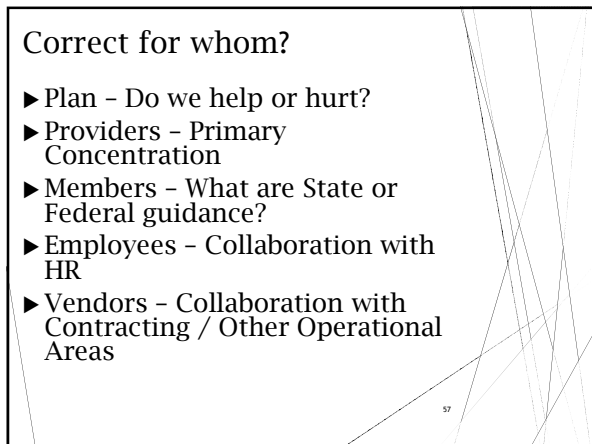
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### Plan Issues

- ▶ Is your claims processing system configuration appropriate?
- ▶ What has the Plan done to contribute to potential issues?

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### Provider Training & Education

- ▶ Arrange for specific training of the provider and office staff for the identified issue.
- ▶ If you are seeing trends, offer periodic coding classes, or newsletters, or faxblast to all offices

When:

- ▶ If it appears to be a lack of understanding
- ▶ If this has not been a recurring theme with this provider's claims

Provider



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### Provider on Review

For the claims in questions, consider:

- ▶ Require authorizations for all services in question, or
- ▶ Review claims prior to the release, or
- ▶ Request medical records for all cases.

When:

- ▶ The issue keeps appearing and perhaps training and education did not make a difference.



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### Provider Limitations

- ▶ Close Providers Panel to New Membership
  - ▶ Limit availability of Provider to members.
- When:
- ▶ You are working with provider to resolve issues.
  - ▶ You feel it is somewhere between errors and perhaps abusive practices.



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### Provider Overpayment Recovery

Consider: What claims will be processed, paid, and denied going forward? What action is needed to address past claims. Actions will vary.

- ▶ Request a refund on claims/issues in question
- ▶ Withhold the payment of future claims to recover overpayments
- ▶ Negotiate a settlement amount

When:

You reach a conclusion that the claims were paid incorrectly and/or should not be paid going forward.



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### Provider Auditing

"Auditing is a formal, systematic and disciplined approach designed to evaluate and improve the effectiveness of processes and related controls. Auditing is governed by professional standards, completed by individuals independent of the process being audited, and normally performed by individuals with one of several acknowledged certifications. Objectivity in governance reporting is the benefit of independence."



Source: Defining the Meaning of Auditing and Monitoring & Clarifying the Appropriate Use of the Terms, by Mark P. Ruppert, CPA, CIA, CISA, CHFP. Accessed at: <https://www.ahia.org/assets/Uploads/pdfupload/WhitePapers/DefiningAuditingAndMonitoring.pdf>

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## Provider Monitoring

"Monitoring is an on-going process usually directed by management to ensure processes are working as intended. Monitoring is an effective detective control within a process."



Source: Defining the Meaning of Auditing and Monitoring & Clarifying the Appropriate Use of the Terms, by Mark P. Ruppert, CPA, CIA, CISA, CHFP.  
Accessed at:  
<https://www.ahia.org/assets/Uploads/pdfUpload/WhitePapers/DefiningAuditingAndMonitoring.pdf>

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## Provider CAP

- ▶ Establish a formal Corrective Action Plan (CAP) (see template) for the Provider to include:
  - ▶ What the issue was
  - ▶ Who is the responsible party
  - ▶ What is going to be done to rectify it
  - ▶ By what date
  - ▶ Consequences if fail to implement
  - ▶ Validate

When:

- ▶ Multiple findings
- ▶ Dollar Threshold is "\$\$"



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## Provider CIA

- ▶ Establish a "Compliance" Integrity Agreement with the Provider (similar to a Corporate Integrity Agreement issued by the DOJ)

When:

- ▶ Significant, multiple findings
- ▶ Dollar threshold is "\$\$\$"
- ▶ Termination may not be an option
- ▶ The provider is willing to work with you



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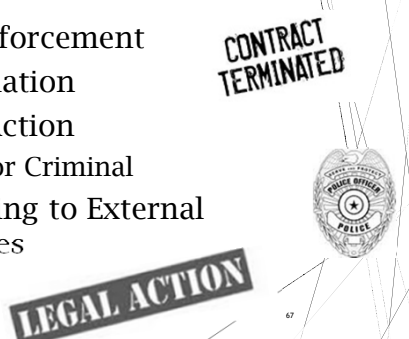
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### Other Provider Sanctions

- ▶ Law Enforcement
- ▶ Termination
- ▶ Legal Action
  - ▶ Civil or Criminal
- ▶ Reporting to External Agencies



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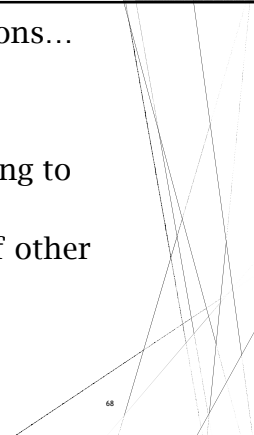
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### Other Provider Sanctions...

When:

- ▶ Provider is not willing to work with you.
- ▶ You have run out of other options.



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### Employee Considerations

Work with Human Resources but consider...



- ▶ Confidentiality
- ▶ Experience in Investigations
- ▶ Disciplinary Actions
- ▶ Terminations, if needed

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### Member Considerations

Is it the Health Plan's obligation to investigate and take corrective action against members?

- ▶ No!
- ▶ Prepare Documentation
- ▶ Distribute to State or Federal Regulatory Agencies
- ▶ Share with Commercial Insurance Policyholders



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### Vendor Considerations

Who is managing vendors / FDRs?

- ▶ Contractual obligations
- ▶ Validation Processes
- ▶ Variance Reports
- ▶ Oversight at an Enterprise Level



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# REPORTING

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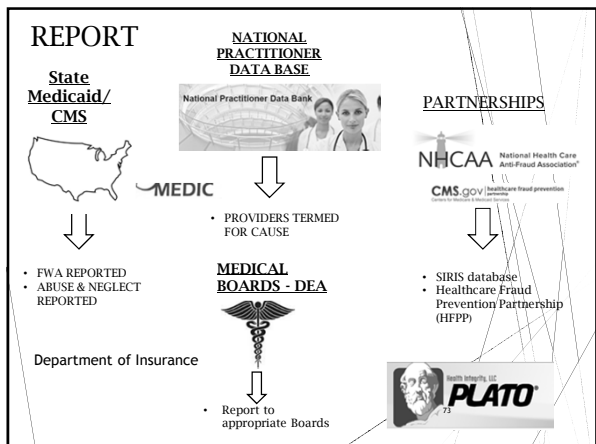
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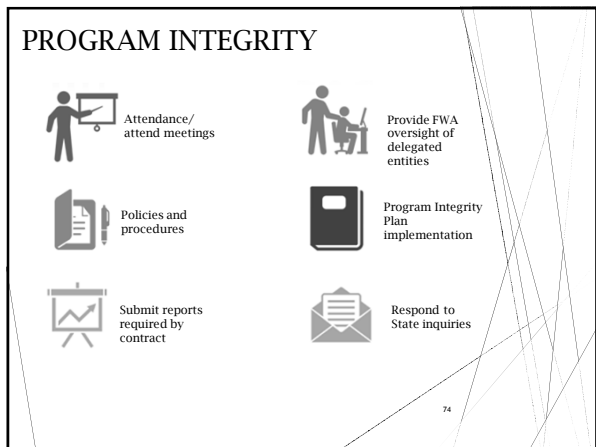
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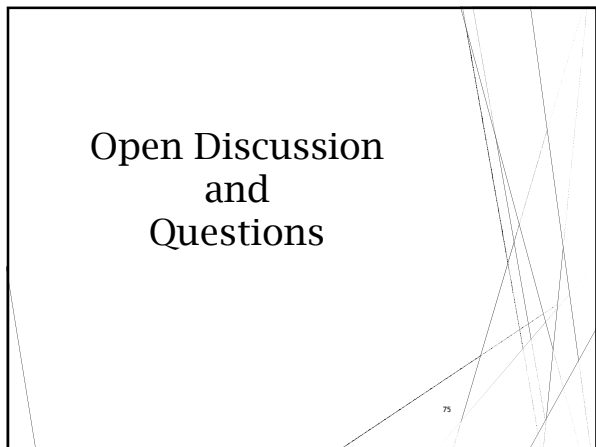
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## Contact Information

Mary Beach  
765-438-3557  
[mbeach@hmsfederal.com](mailto:mbeach@hmsfederal.com)

Bernadette Underwood  
[bunderwood43@gmail.com](mailto:bunderwood43@gmail.com)  
845 633-9144

Caron Cullen  
(212) 388-0990  
[caroncullen@msn.com](mailto:caroncullen@msn.com)

Katherine Leff  
937-531-3451  
[Katherine.leff@caresource.com](mailto:Katherine.leff@caresource.com)



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# Leveraging DMAIC & Active Management for Sustainable Quality Improvements:

Kristine Koontz, PhD, SSGB  
Amy Diane Short, MHSA, CSSBB

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## Kristine Koontz, Ph.D.

- Clinical Psychology—Science Practitioner
- Six Sigma Green Belt
- Vice President of Quality and Corporate Integrity
- Oversight of Behavioral Health Organization
  - Residential and Community Settings
  - Intellectual Disabilities, Mental Health, Autism Spectrum Disorders
  - Lifespan services
- USA: PA, DE & CT
- International: Moldova, India



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## Amy Short, MHSA

- BS Psychology
- MHSA (Master’s Health Services Administration)
- Certified Six Sigma Black Belt
- Operational Oversight of Hospital Functions
- QI Leadership of Implementation Research at Academic Health Center
- Patient Advisory Council Mentor
- University of Cincinnati IRB Member
- Administrative Director of Center of Improvement Science, Cincinnati CCTST



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## Presentation Overview

- A New Approach
- Getting to Know You
- DMAIC
- Stakeholder Engagement
- Control Revisited
- Managing the Game of Hot Potato
- Auditing and Active Management



## *Active Learning*

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## Changes from YOUR Feedback

- Broad, Proven Concepts with a Deeper Dive on 1-2 Ideas
- Trace a Successful Project
- Balance Between Didactics and Activities




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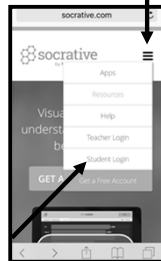
## Icebreaker: Who Are You?

- Answer Privately in Socrative.com,
- Type in Room Number:  
**AMYSHORT**
- Login as Student
- Enter at Least One Letter as a Name

Or Use the App



Click Here to Login



Click Here for Menu

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### How Experienced Are You in QI?

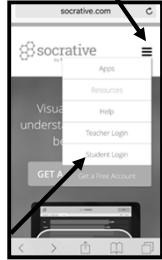
- Answer Privately in Socrative.com,
- Type in Room Number:  
**AMYSHORT**
- Login as Student
- Enter at Least One Letter as a Name

Or Use the App



Click Here to Login

Click Here for Menu




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### Successful Organizations

- Understand what their customers want
- **Understand how they are measuring up**
- **Can describe, monitor and adjust processes**
- Can examine and support employee performance and functions
- Can quickly identify and respond to internal and external demands

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### Successful Organizations Use DMAIC

Define  
Measure  
Analyze  
Improve  
Control

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DMAIC

**Define**

Measure

Analyze

Improve

Control

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What Compliance Issue  
Keeps You Up at Night?



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DMAIC

Define

**Measure**

Analyze

Improve

Control

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Find a way to make the important measurable instead of making the measurable important

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### Where the Journey Begins: Data



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### Why Data?

- You Cannot Manage what You Cannot Measure



- Data → Information → Knowledge → Wisdom

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“In God we trust.  
All others, bring  
data.”

-W.E. Deming

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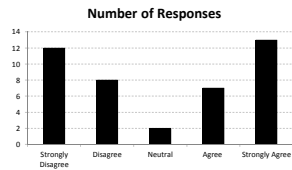
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Measurement 101: “Eyeball your data”

- The Importance of Visual Inspection
- First Step in Analyzing and Understanding Your Data



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Shhhhh....It's a Secret



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## Measure

### The Process Map

**Ambulatory Procedure for Direct Admits**

**Post-Flow**

1. It is important to grab a vital count and compare to vitals. If a percentage response is not met, the patient should be taken to the OR.
2. This section should be made in coordination with the patient management team. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
3. If a vital response is not met, the patient should be taken to the OR.
4. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
5. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
6. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
7. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
8. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.
9. The patient should be taken to the OR if the patient is not stable to allow a C-Call on the day of the procedure.

**Details: 4/1/2017**  
LAW 10/10/2017

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## Process Mapping in a Nutshell

“Every system is perfectly designed to get the results it gets.”

*The only way to get different results is to change the system*

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## Why Process Map?

- You Can't Fix a Problem Until You Understand the Present State
  - ... How It REALLY Works
  - .... Everyone Shares the Same Understanding
- Process Maps Reveal Where Improvement Is Needed Most
- Process Mapping Helps Keep a Project in Scope

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## Process Map Errors

- Only Working with Those Distal to the Process
- Mapping the Improved Process First
- Mapping the Way a Process is “Supposed to Work”
- Incorrect Level of Abstraction
- Not Verifying Accuracy



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## DMAIC

Define  
Measure  
**Analyze**  
Improve  
Control

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## Analyze

- Walk the Process Map and Refine It
  - Spend Time with the People Who Do the Work
- Re-scope if Needed
- Capture Cycle Times
- Brainstorm Ideas for Improvement
  - Fishbone Diagrams
  - Affinity Diagrams



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DMAIC

Define  
Measure  
Analyze  
**Improve**  
Control

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Piloting Improvement and Change

We must remember...

**All Improvements stem from change,  
but not all changes are improvements**  
&

Hope is not an improvement strategy

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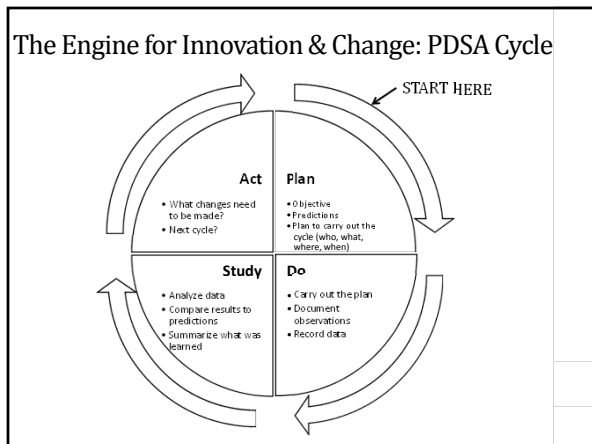
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### Hoorah for PDSA!

- Action-oriented Learning
- Scientific Process
  - Hypothesize
  - Experiment
  - Evaluate
  - Synthesize
- Avoid "Analysis Paralysis"
- Lessons in STUDY and ACT Become Public Knowledge and Speeds Generalization
- Minimal Expenditures \$\$
- Vertical Team Facilitates Buy-in

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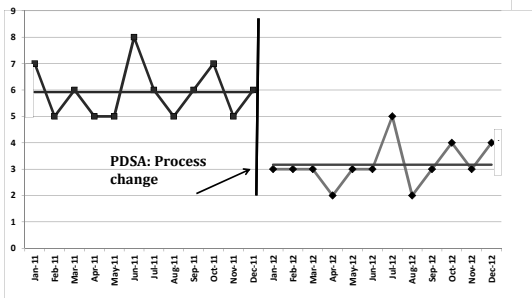
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### Test the Change




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### DMAIC

- Define
- Measure
- Analyze
- Improve
- Control**

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## Now What?

C  
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- “Surface” Key Process and Outcome Measures
- Timely Data Entry = “Knowable” Individual and Group Performance
- Embed Use of Data into Management Repertoire

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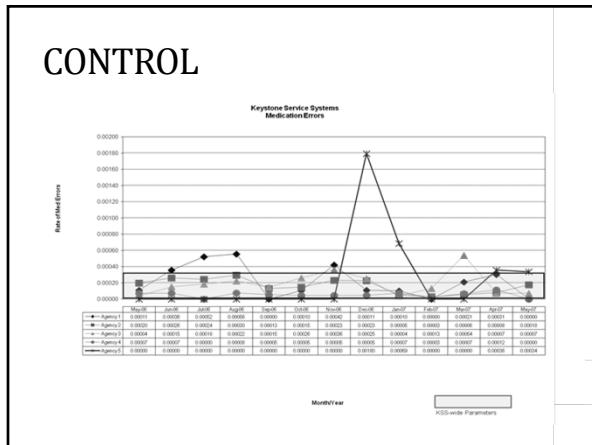
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## CONTROL

- This is the Most Difficult Phase in DMAIC
- Maintaining the Gains
- Safeguards: What Will Be Done to Keep this on Track?
- Responsibility Rests on the Process Owner (Role of KPI)

- What Happens in this Phase?
  - Pick the Right Control Method (Checklists, Monitoring, Reporting)
  - What is Acceptable Variance?
  - Document the Response Plan

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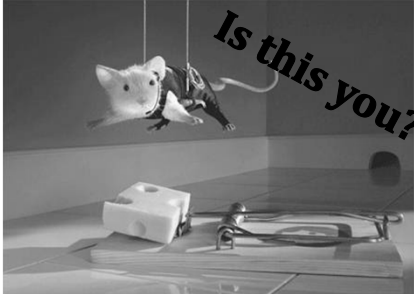
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### Mission Impossible



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### It Takes a Team!



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### But... I'm All Alone

**Sustainable, transformative, change requires an engaged, interdisciplinary, team**

- Let your leadership know what you need
- Work these principles as best you can in you own sphere
  - It takes time
  - It takes constant effort
  - It's worth it!



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## Successful Organizations

- **Understand what their customers want**
- Understand how they are measuring up
- Can describe, monitor and adjust processes
- **Can examine and support employee performance and functions**
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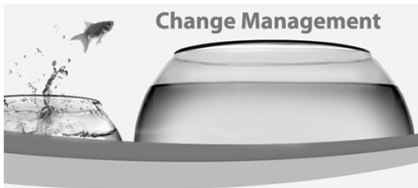
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... Is multifactorial and complicated!

- Today's focus is on:
  - Stakeholder engagement
    - Communication (bite sized!)

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## Stakeholder Engagement

Stakeholder: Anybody who can affect or is affected by an organization, strategy or project



From OGC Successful Delivery Toolkit 2005

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## Stakeholder Engagement

**What you get from stakeholder engagement:**

- Agreement on purpose and direction (i.e. buy-in) of a project or program
- Early identification of potential issues, conflicts and benefits
- Generation of new ideas
- Defusion of conflict situations before these impede progress
- Increased community cohesion and strengthened shared identity

REVIT Stakeholder Engagement: A Tool Kit  
[http://www.revit-nw.europa.org/selfguidingtrial/27\\_Stakeholder\\_engagement\\_a\\_toolkit-2.pdf](http://www.revit-nw.europa.org/selfguidingtrial/27_Stakeholder_engagement_a_toolkit-2.pdf)

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## Stakeholder Engagement

**Key elements for stakeholder identification:**

- Who is directly responsible for the decisions on the issues?
- Who is influential in the area, community and/or organization?
- Who will be affected by any decisions on the issue (individuals and organizations)?
- Who runs organizations with relevant interests?
- Who is influential on this issue?
- Who can obstruct a decision if not involved?
- Who has been involved in this issue in the past?
- Who has not been involved, but should have been?

REVIT Stakeholder Engagement: A Tool Kit  
[http://www.revit-nw.europa.org/selfguidingtrial/27\\_Stakeholder\\_engagement\\_a\\_toolkit-2.pdf](http://www.revit-nw.europa.org/selfguidingtrial/27_Stakeholder_engagement_a_toolkit-2.pdf)

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## Who Are Your Stakeholders?

Name and Role	Strategic Objective	Scope of Influence	Coherence with Objective		Key Alliances
			Yes	No/Indifferent	
Jane Doe, Clinical Manager	Care Delivery	Clinical site/Staff	Indifferent		Corporation, VP HR

Adapted from "Mainstreaming Participation"  
<http://www.fsnnetwork.org/sites/default/files/en-ovmp-instrumente-aktuelleranalyse.pdf>

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### Stakeholder Actions

**Someone's position on the grid shows you the actions you have to take with them:**

- **High power, interested people:** these are the people you must fully engage and make the greatest efforts to satisfy
- **High power, less interested people:** put enough work in with these people to keep them satisfied, but not so much that they become bored with your message

www.mindtools.com

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### Stakeholder Actions

**Someone's position on the grid shows you the actions you have to take with them:**

- **Low power, interested people:** keep these people adequately informed, and talk to them to ensure that no major issues are arising. These people can often be very helpful with the detail of your project
- **Low power, less interested people:** again, monitor these people, but do not bore them with excessive communication

www.mindtools.com

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## Understand Your Stakeholders

- What financial or emotional interest do they have in the outcome of your work? Is it positive or negative?
- What motivates them most of all?
- What information do they want from you?
- How do they want to receive information from you? What is the best way of communicating your message to them?
- What is their current opinion of your work? Is it based on good information?
- Who influences their opinions generally, and who influences their opinion of you?

www.mindtools.com

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## Understand Your Stakeholders

- Do some of these influencers therefore become important stakeholders in their own right?
- If they are not likely to be positive, what will win them around to support your project?
- If you don't think you will be able to win them around, how will you manage their opposition?
- Who else might be influenced by their opinions? Do these people become stakeholders in their own right?

www.mindtools.com

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## Strategic Tip: Be Compelling

**Don't "push it through" - it's much better to convince people that it's important and urgent - only that way can you get a clear commitment from others**

- What conditions create the need for change?
- What are the underlying causes?
- Have you identified and made a case for the change?
- Have you identified the one crucial reason for change?
- "WIIIFM"?

www.mindtools.com

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## Strategic Tip: Get the Word Out

One size does not **fit** all for communication

- Which stakeholders will need regular one on one chats?
- Do you need to do organization wide "town halls"?
- Do people at your organization read emails reliably?
- Can you put articles in the company newsletter?
- Which regular operational or staff meetings should you attend?
- Is a special activity required to gain attention?

[www.mindtools.com](http://www.mindtools.com)

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## But... I'm All Alone

**Sustainable, transformative, change requires an engaged, interdisciplinary, team**

- Let your leadership know what you need
- Work these principles as best you can in you own sphere
  - It takes time
  - It takes constant effort
  - It's worth it!



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## Successful Organizations

- Understand what their customers want
- **Understand how they are measuring up**
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- Can examine and support employee performance and functions
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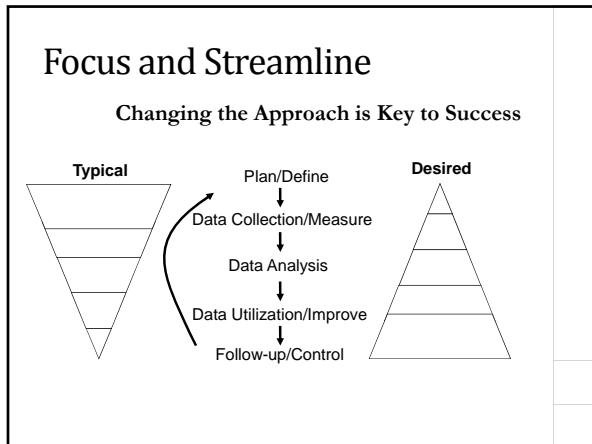
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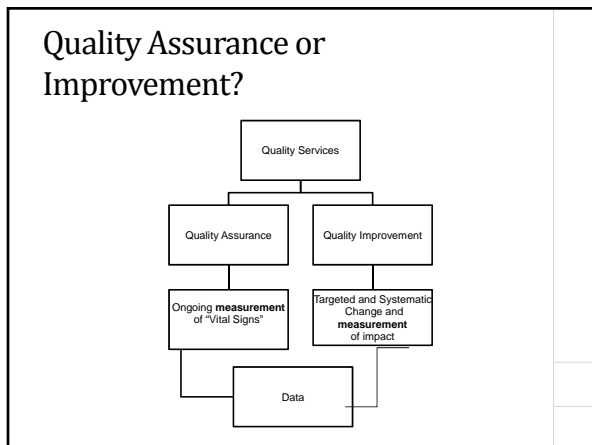
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### Key Performance Indicators (KPIs)

- How do you measure success
- Type of performance measurement
- Help an organization define and measure progress
- Linked to an organization's mission and vision
- Should include regular examinations of goals/expectations

**Are We Consistently Meeting Stakeholders Service Expectations And Goals?**

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## Active Management vs. Auditing

Component	Active Management with Data	Auditing
Scale	Population	Sample
Time	Close to real time	Retrospective
Opportunities to examine Performance Status	Frequent	Dependent on audit schedule
Focus	Current and Future	Retrospective and Future
Organizational Risk	Catch issues quickly	Depends on Audit timeframe

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Whoever Owns  
the Process,  
Shoulders the  
Responsibility

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Questions?



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## Compliance Investigations 101: CO Toolbox Essentials

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### Session Speakers



Walter E. Johnson  
Director of Compliance & Ethics  
Kforce Government Solutions

Dawn E. Lambert  
Chief Privacy/Information Security Officer  
IASIS Healthcare



Cindy W. Hart, CPA, CHC, CPC,  
Compliance Professional

Adam K. Weinstein  
Chief Operating Officer/ Compliance  
Best Companion Homecare Services



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### Agenda

- **Interviewing Basics** : Strategies to get the information you need from the employees; while covering privacy, security, HR and legal aspects are important during and after the interview
- **Partnerships**: Knowing when to engage Legal for establishing privilege and possibly IT to collect substantial evidence; HR is a powerful ally and often, management too!
- **Tools**: Using SBAR (and other tools) to document the investigation using clear, concise, and legible structure

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## The Interview Before The Interview



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## Stages of a Complete Compliance Interview

- Introduction / Rapport
- Free Narrative
- Drawing
- Follow-Up Questions
- Reverse Order Technique
- Challenge Questions

Source: Michael Johnson, CEO, Clear Law Institute  
<http://www.clearlawinstitute.com>

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## Introductory Question #1

To whom does the compliance officer report to at your organization:

- a. CEO
- b. CFO
- c. GC
- d. Board
- e. Other

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## Introductory Question #2

How does your organization determine compliance risks?

- a. Conducts a separate interview based compliance risk assessment
- b. Reviews the OIG Work Plan with compliance committee members
- c. Neither of the above
- d. Something other than the above

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## Available TOOLS

- Compliance Dashboard
- GAP Assessment
- HIPAA Investigation
- Sanction Score Card
- Phase 2 OCR Protocols

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**SESSION BREAK**



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### Compliance Program – 90 Day Review (continued)

		Month 1	Month 2	Month 3
<b>INCREASE PROGRAM LEVEL AND DEPARTMENT LEVEL ACCOUNTABILITIES FOR PROGRAM DEVELOPMENT</b>	Assign individuals to assist with the development of department level compliance programs	Compliance Officer	x	x
	Select pilot department to proceed through the development process	Compliance Committee		x
	Select department to develop and implement departmental compliance program	COO & committee		x
	Direct additional departments to develop and implement departmental programs	COO & committee		x
	Direct remainder of departments to develop and implement departmental programs	COO & committee		x

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### Compliance Program – 90 Day Review (continued)

		Month 1	Month 2	Month 3
<b>AUDITING AND MONITORING / RISK ASSESSMENT</b>	Review Each of the High Risk Areas identified for each program	COO & Program Leader	x	
	Develop Monitoring Guidance Sheet - description of risk, variables measured, periodicity	Program Leader	x	x
	For Highest (or High) Risk Areas - Develop Monitoring Protocol - Ensure Implementation	Program Leader	x	x
	For Less Than High Risk - Ensure Mechanism to periodically assess	Program Leader		x
	Require Periodic Reporting on high risk monitoring metrics - Compliance Committee	COO & committee		x
	Develop Overall Compliance Scorecard by Program for All Highest Risk Items	COO & Program Leader		x
	Develop and Implement Corrective Action Planning Process / Format	COO & Program Leader		x

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### Compliance Program – 90 Day Review (continued)

		Month 1	Month 2	Month 3
<b>POLICY REVIEW / TRAINING PLANS</b>	Review Existing Body of Compliance Policies to Ensure Comprehensive & Complete	COO		x
	Direct review of Program Level Compliance Policies to Ensure Adequate	COO & Program Leader		x
	Review Corporate Compliance Training Materials Approach	COO		x
	Review / Develop Program Level Compliance Training / Content & Delivery / Tracking	COO & Program Leader		x

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# SBAR

## Situation – Background – Analysis - Recommendation

### SITUATION

**Situation:** Clearly and *briefly* define the situation. For example, 'Mr. Jones has multiple prescriptions of Coumadin in his home and he is unclear as to which ones he is supposed to take.'

### BACKGROUND

**Background:** Provide clear, relevant background information that relates to the situation. In the example above, you should consider including the patient's diagnosis, the prescribing physicians, and the dates and dosages of the medications.

### ANALYSIS

**Assessment:** A statement of your professional conclusion

### RECOMMENDATION

**Recommendation:** What do you need from this individual? For example, 'Please clarify which is the correct dose of Coumadin for Mr. Jones to take and which physician will be responsible for managing his anticoagulant therapy?'

Source: Joint Commission

[https://www.jointcommission.org/home\\_with\\_the\\_joint\\_commission\\_sbar\\_%26%82%93\\_a\\_powerful\\_tool\\_to\\_help\\_improve\\_communication/](https://www.jointcommission.org/home_with_the_joint_commission_sbar_%26%82%93_a_powerful_tool_to_help_improve_communication/)

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# SBAR

## Situation – Background – Analysis - Recommendation

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## Situation Background Analysis Recommendation

**SBAR:** **Rescheduled Flight** **Completed by: Michael Johnson**  
Date: 3/29/2017

SITUATION	ANALYSIS
<p>United Airlines announced flight without any needed permits. It is possible flight was cancelled at the request of government officials.</p>	<ul style="list-style-type: none"><li>The AIRCRAFT's decision not to allow the flight from Newark, New Jersey to Cook, Colorado.</li><li>The decision was supported by financial analysis and approved by Board on AIRCRAFT.</li><li>The AIRCRAFT, the last regular flight from Newark, New Jersey to South.</li><li>United Airlines.</li><li>An Airline of the Past Authority, David Thomas had the approval authority over United Airlines flight project.</li><li>Investment concludes that David Thomas would not approve the longer permit before the flight to South Newark, New Jersey to South Carolina was cancelled.</li><li>That Authority's decision not to authorize over the longer project to get the flight cancelled.</li><li>The regular flight was cancelled when the David Thomas was approved as chairman of the Past Authority.</li><li>The flight was cancelled because of the "Government's flight".</li><li>It was cancelled two years after management which in the later than David Thomas resigned as chairman of the Past Authority.</li></ul>
BACKGROUND	RECOMMENDATION
<ul style="list-style-type: none"><li>Completed Airlines had a regular flight from Newark, New Jersey to Columbia, South Carolina.</li><li>The original performance, Completed Airlines cancelled the flight before it merged with United Airlines.</li><li>In 2013, the flight from Newark Liberty International Airport to Columbia, South Carolina was cancelled.</li><li>In 2013, David Thomas became chairman of the Past Authority.</li><li>In 2014, the flight from Newark Liberty International Airport to Columbia, South Carolina was cancelled.</li><li>In 2014, David Thomas resigned as chairman of the Past Authority. The AIRCRAFT, the airline decided to resume the regular flight.</li></ul>	<p>Assessment:</p> <p>1) My recommendation is: <b>Denial</b></p> <p>2) An alternative is: <b>Denial</b></p>

**SAMPLE**

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# SESSION BREAK




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## Placemat Report

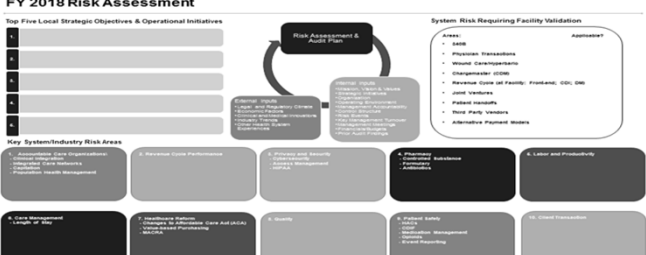
### FY 2018 Risk Assessment

Top Five Local Strategic Objectives & Operational Initiatives

Risk Assessment & Audit Plan

System Risk Requiring Facility Utilization

Key System/Industry Risk Areas




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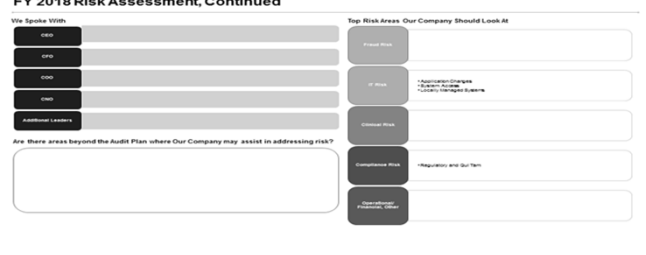
## Placemat Report

### FY 2018 Risk Assessment, Continued

We Spoke With:

Top Risk Areas Our Company Should Look At

Are there areas beyond the Audit Plan where Our Company may assist in addressing risk?




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## Section 1557 Checklist

OCR at [ocrmail@hhs.gov](mailto:ocrmail@hhs.gov) :

- An entity that applies to receive Federal financial assistance (FFA) must sign and date and submit an Assurance of Compliance form (HHS 690) that commits them to compliance with five civil rights statutes, as listed in the Assurance form. This form can be found on the Office for Civil Rights website.
- If an entity receives or is applying to receive ONLY Medicare Part B FFA, that entity is not required to sign and submit an Assurance of Compliance, because Medicare Part B is not considered FFA. If the entity receives other FFA, however, such as Medicaid, then it is obligated to sign and submit an Assurance of Compliance.

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## Section 1557 Checklist

– Section 1557 applies if you are a health program or perform health activities, which receive Federal financial assistance provided or made available by the Department, and every health program or activity administered by a Title I entity.

– Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

– § 92.8 Notice requirement – next 4 slides

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## Section 1557 Checklist

• Has the entity taken appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

– The entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities

– YES            NO            Partial

– Supporting documentation:

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**Section 1557 Checklist**

- The entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure equal opportunity to participate to individuals with disabilities

- YES      NO      Partial  
- Supporting documentation:

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**Section 1557 Checklist**

- The entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency (LEP)

- YES      NO      Partial  
- Supporting documentation:

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**Section 1557 Checklist**

- The entity informs how to obtain aids and language assistance services

- YES      NO      Partial  
- Supporting documentation:

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**Open Discussion (Q & A)**



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# Privacy and Information Security Violation Sanctions Guidelines

(August 8,, 2014)

**INFORMATION:** The sanctions listed below mainly pertain to a first offense unless otherwise stated. Other performance issues, multiple or repeat offenses, or circumstances that indicate malicious intent, may result in an increase of the severity of the assigned sanctions.

**Based on the severity and risk involving any confidential or protected patient information (PHI), employee or business information, Human Resources reserves the right to adjust the severity of the assigned sanctions with supporting documentation.**

## **DEFINITIONS:**

**Breach:** An “unauthorized acquisition, access, use or disclosure of PHI which compromises the security or privacy of the PHI, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.”

**PHI:** Protected Health Information

**Privacy:** Freedom from unauthorized intrusion.

**Significant Harm:** Having meaningful or a likely influence / threat of physical, mental, financial damage.

\*\* Each event may be different and will have a risk assessment completed by the System Privacy Officer or entity Privacy Site Coordinator (PSC). If it is determined that the patient could experience significant harm (reputation, financial, physical, or mental) as per the HIPAA regulation criteria, then the level of compromised PHI will be determined as “High”. A patient may also provide the assessment and consider an event significantly harmful requiring a higher level of action on ’s part.

**Unsecured PHI:** Information that is not encrypted while at rest or during transmission or the encryption standard used to secure PHI does not meet:

- National Institute of Standards and Technology (NIST) guidelines; and
- Federal Information Processing Standard (FIPS) Publication 140-2, (FIPS PUB 140-2), a federal standard used to accredit cryptographic tools or applications.

**Willful Neglect:** A conscious, intentional failure or reckless indifference to the obligation to comply.

## Standard Privacy/Information Security Sanctions Table - Employee

Category or Incident Type	Verbal Warning and possible Privacy/IS Retraining	Written Warning and Required Privacy/IS Retraining	Three-day Suspension or Final Written Warning and Required Privacy/IS Retraining	Involuntary Termination
<b>GENERAL OVERVIEW</b>  Column description →  Scenarios ↓	Use when incident appears unintentional, unknowing, and results in low or no harm to patient.	Use when breaches of Privacy or Security result in low or no harm to patient or Hospital.	Use when breaches of Privacy or Security result in significant harm to patient or Hospital. (may be unintentional)	Use when breaches of Privacy or Security results in personal gain, malicious intent, significant harm to patient, high liability to , required reporting and/or media notification
<b>PHYSICAL SECURITY</b> Improper disposal of PHI		Improper disposal of PHI, no possible harm to patient or Hospital	Willful neglect in disposal of PHI low or no harm to patient or Hospital	
Failure to secure ePHI (includes unauthorized removal of PHI from property)		Failure to secure either electronic or non-electronic PHI/Confidential information (low/no harm to patient/Hospital and/or no breach notification)	Willful neglect in failure to secure either electronic or non-electronic PHI/Confidential information (low or no harm to patient/Hospital and/or no breach notification)	Willful failure to secure non-electronic PHI/Confidential information (significant harm to patient/Hospital and/or breach notification)
<b>ELECTRONIC SECURITY</b>  Failure to sign off or lock computer	Failing to sign off or lock a given computer terminal when not in use		Willful neglect in failing to sign off or lock a given computer terminal when not in use (without access by another)	Allowing another user to utilize the system via his/her access code (password) resulting in wrongful access of PHI or other highly confidential employee / business information.  Deliberately attempting to wrongfully access another employee's email, files or any hospital system, including EHR.
Failure to secure electronic PHI (e.g. copied to mobile media, not enabling proper access restrictions, etc.)		Failure to secure electronic PHI/confidential information (no risk of harm to patient/Hospital and/or no breach notification)	Willful neglect in failing to secure electronic PHI/Confidential information (low or no harm to patient /hospital and/or no breach notification)	Failure to secure electronic PHI/Confidential information (significant harm to patient/Hospital and/or breach notification)

## Standard Privacy/Information Security Sanctions Table - Employee

Category or Incident Type	Verbal Warning and possible Privacy/IS Retraining	Written Warning and Required Privacy/IS Retraining	Three-day Suspension or Final Written Warning and Required Privacy/IS Retraining	Involuntary Termination
<b>Unsecured email</b>	Failure to encrypt email with PHI included or as an attachment, sent to a non- network address. (low or no harm to patient)	Failure to encrypt email with PHI included or as an attachment, sent to a non- network address. (significant harm to patient)	Willful neglect in failing to encrypt email with PHI included or as an attachment, sent to a non- network address.	
<b>ACCESS</b> Access own PHI		Willful neglect - Accessing own medical records/PHI		
Family records  High confidential, pt, empl/business info for personal gain/malicious intent			<u>Willful neglect in accessing</u> family members records (first offense, both PHI and specific protected information such as (Behavioral, STD, family planning, substance abuse, HIV/AIDS, etc.) and the potential for harm does exist as a result)	Accessing HIGHLY confidential PHI under false pretenses, without having a working need to do so. (Behavioral, STD, family planning, substance abuse, HIV/AIDS, etc. considered HIGHLY Confidential)  Accessing, <u>disclosing</u> and /or <u>amending</u> PHI of a patient without having a job duty - reason to do so, or confidential employee/hospital information for personal /professional gain or malicious intent to sell or harm others.
Access patient PHI with no working need to know (includes employee/patient PHI)			<u>Accessing</u> the record of a patient without having a job duty/working reason to do so (low or no harm to patient and/or no reporting required) "Snooping" (elect. Record, documents, etc.)	<u>Willful neglect in accessing, disclosing, and/or amending</u> PHI job duty/working reason to do so resulting in potential significant harm to patient. (Including but not limited to behavioral, STD, family planning, substance abuse, HIV/AIDS, etc.)
Request other user to obtain PHI		Request another user or employee to share (verbalize) PHI of any patient.	Requesting another user or employee to <u>access</u> patient information outside of his/her access ability or job duties (first offense) (elect. record, papers)	



## Standard Privacy/Information Security Sanctions Table - Employee

Category or Incident Type	and Verbal Warning possible Privacy/IS Retraining	Written Warning and Required Privacy/IS Retraining	Three-day Suspension or Final Written Warning and Required Privacy/IS Retraining	Involuntary Termination
Financial / billing info of pt.			Accessing the financial or billing information of a patient without a job duty reason to do so (no significant harm to patient /guarantor and/or no reporting required.). Known as "Snooping".	Accessing, amending, and/or using billing information of a patient without a job duty / working reason to do so and/or disclosing the information to a non covered entity (none or any potential significant harm to patient/guarantor). This would include SSN and credit card / financial information.
<b>DISCLOSURE OR USE</b> Release PHI to wrong person or pt - Lack of proper ID verification		Unintentional - not properly verifying the patient and <u>disclosing</u> PHI to another party where patient identity is disclosed. (low or no harm to patient or breach notification)	Willful neglect in not properly verifying the patient and <u>disclosing</u> PHI to another party where patient identity is disclosed. (low or no harm to patient or breach notification)	
Social Media posts			Posting information regarding patients (no names) publicly such as on social media sites which are inappropriate or the patient could be reasonably identified.	Posting information regarding patients (no names) publicly such as on social media sites which are inappropriate or the patient could be reasonably identified with significant harm to patient.
Pt. or employee pt. with significant harm				Accessing record of a patient (including employee pt.) without having a job duty reason to do so and/or <u>disclosing</u> the information to another party not involved in the patient's care (significant harm to patient and reporting required)
Access/amend PHI for personal gain / malicious intent				Accessing, <u>disclosing</u> and /or <u>amending</u> PHI or Hospital information for personal or professional gain or intent to sell or sale of the information.

## Standard Privacy/Information Security Sanctions Table - Employee

Category or Incident Type	and Verbal Warning possible Privacy/IS Retraining	Written Warning and Required Privacy/IS Retraining	Three-day Suspension or Final Written Warning and Required Privacy/IS Retraining	Involuntary Termination
Discussing pt. PHI (wrongfully discussing or when overhead in an unsecure area)		Discussion of pt. PHI with others for work purposes yet in an area where overheard by others. (low level of harm to pt and/or no breach notification required)	Willful neglect in discussing patient care/situations with health care or other individuals without a “need to know”. (low level of harm to patient and/or no breach notification required)	Accessing, <u>disclosing</u> and /or <u>amending</u> PHI or Hospital information for malicious purposes or personal gain.
Leaving message	Leaving a message for a patient/parent that exceeds the minimum necessary standards (no risk of harm to patient and no reporting requirement)	Leaving a message for a patient/parent that exceeds the minimum necessary standards (second offense and no risk of harm to patient and no reporting requirement)	Willful neglect in leaving a message for a patient/parent that exceeds the minimum necessary standards (first offense, low harm to patient, no reporting requirement). May include highly confidential PHI (Behavioral, STD, substance abuse, HIV/AIDS, etc.)	
Publication or presentation PHI		Publication or presentation of PHI without patient authorization (low or no harm to patient)	Publication or presentation of PHI without patient authorization (significant harm to patient and breach notification). NOTE: if Research – report to IRB.	
ID Theft/Fraud				Use of PHI for identity theft or obtaining and or using) financial information (credit card, etc.), (significant harm to patient)
Not properly verifying identification (e.g.: giving document with PHI to wrong person; leaving PHI message on wrong phone)	Not properly verifying individual’s identification before disclosing information, whether by phone, in person or in writing. (no harm to patient)		Willful neglect in not properly verifying individuals by phone, in person or in writing (low or no harm to patient and no breach notification) before disclosing information.	Willful neglect in not properly verifying individuals by phone, in person or in writing (significant harm to patient and breach notification) before disclosing information.

## Standard Privacy/Information Security Sanctions Table - Employee

Category or Incident Type	and Verbal Warning possible Privacy/IS Retraining	Written Warning and Required Privacy/IS Retraining	Three-day Suspension or Final Written Warning and Required Privacy/IS Retraining	Involuntary Termination
<b>DATA, INFO ACCURACY &amp; INTEGRITY</b> Registration – wrong pt.		Registration Errors – Negligence resulting in wrong patient being admitted/registered and a privacy breach (low/no harm to pt.).	Registration Errors – Negligence resulting in wrong patient being admitted/registered and a privacy breach (significant harm to pt.).	Intentional Registration Error – Wrong patient being admitted / registered resulting in a privacy breach and/or other legal issue.
Registration – wrong information		Registration Errors – Wrong pt. information documented resulting in a privacy breach (low/no harm to pt.) (PCP, contact, ins., etc.)	Registration Errors – Wrong pt. information documented resulting in a privacy breach (significant harm to pt.) (PCP, contact, ins., etc.)	Intentional Registration Error – Wrong/false pt. information documented resulting in a privacy breach and/or other legal issue
Misdirected fax	Misdirected Fax with PHI resulting in PHI <u>disclosure</u> (no harm to patient and/or no reporting required)	Misdirected Fax with PHI resulting in PHI <u>disclosure</u> (second offense and low or no harm to patient and/or no reporting required)	Willful neglect in misdirected Fax with PHI (significant harm to patient and/or reporting required of breach notification)	
Misdirected mail		Misdirected mailing with PHI to another patient, person or entity in error (low or no harm to pt.)	Misdirected mailing with PHI to another patient, person or entity in error (significant harm to patient and breach notification).	Willful or intentional mailing of PHI to a wrong patient, person, or entity, resulting in significant harm to the correct patient and breach notification.
Altering PHI - falsification				Altering PHI or medical record/falsification of records.
<b>RESTRICTION REQUESTS</b> Failure to respect approved pt. request		Failure to respect approved patient requested restrictions with low or no harm to the patient.		Failure to respect approved patient requested restrictions with significant harm to patient and/or breach notification.

**NOTE:** These guidelines support the System Privacy and Information Security Sanctions Policy.

**DEFINITION:** Workforce Members/Non-employees: persons whose conduct in the performance of work for is under the direct control of whether or not they are paid by . This includes, but is not limited to: Medical staff affiliates, Academic instructors, Students, Residents, Volunteers, Trainees, Agency personnel, Board members

<b>WORKFORCE MEMBERS / NON - Employee</b>	
	In the event of a violation by a workforce member / non- employee with access to PHI software, the Chief Privacy Officer and entity Privacy Site Coordinator will work with the entity Medical Staff President and/or Chief Physician Executive, medical office manager and/or Privacy Officer of an outside entity, or company manager to assist with investigation and the appropriate sanction for that individual. Should the incident have legal involvement, personal gain, malicious intent, or resulting in significant harm to a patient, network termination, loss or suspension of staff privileges, etc. could be immediately initiated.

**References:**

2011 – AHIMA Sanction Guidelines for Privacy and Security Violations / Breaches

**In Collaboration with:**

Privacy Committee  
Ethics & Compliance Department  
HR Leadership

Revised: Aug. 8, 2014

New/Revisions: 9/2013, 10/2013











Company LOGO/Header

Compliance Effectiveness - FY2016

Section	Scoring
1. Oversight of Compliance Program	95%
2. Risk Assessment	47%
3. Compliance Policies and Procedures	70%
4. Training and Education	80%
5. Open Lines of Communication	100%
6. Monitoring and Auditing	75%
7. Response to Detected Deficiencies	50%
8. Enforcement of Disciplinary Standards	57%
TOTAL	72%

<b>Oversight of Compliance Program</b>	SCORE	
	Max	Actual
The Hospital has appointed a Compliance Officer (CO) with responsibility for oversight and coordination of Compliance Program activities.	10	10
The Compliance Officer/ Director have job descriptions. If the Compliance Officer has multiple responsibilities in the organization, the job description addresses their compliance responsibilities. The Compliance Officer's performance review reflects compliance efforts.	10	10
The CO reports to the CEO for their compliance responsibilities. The CO and CEO have meetings to discuss the Compliance Program on at least a quarterly basis. (5 points per session)	20	20
The CO has established a Compliance Program Committee with authority and responsibility for ensuring the local Compliance Program functions as an effective program. The Compliance Program Committee meets at least quarterly. (5 points per session)	20	20
The CO provides an annual written report to the Board of Directors regarding the status of the Compliance Program, including ongoing investigations.	10	10
The CO or the person with day-to-day responsibility for the Compliance Program makes presentations to the Board of Trustees on the status of the Compliance Program, including ongoing investigations. The reports must include the following information: .	10	5
(1) Results of Compliance Program effectiveness assessment (annual basis);		
(2) Focus areas at the hospital level (every meeting);		
(3) Monitoring and auditing results (every meeting);		
(4) Significant compliance investigations (every meeting);		
(5) Associate Compliance Program training and education (annual basis);		
(6) Conflicts of interest (annual basis)		
Privacy and Security Officers have been appointed and oversight of compliance with HIPAA regulations is incorporated into the compliance program (e.g., policies and procedures, training, open lines of communication, reporting, monitoring and auditing , response to detected deficiencies and enforcement of disciplinary standards).	20	20
	100	95

<b>Risk Assessment</b>	Max	Actual
A risk assessment was performed to identify compliance risks. Examples include a review of OIG Work Plan, governmental audits, industry literature, results of monitoring and auditing, issues from any other source, input received from high risk departments, new programs or services.	25	15

Compliance work plan is updated at least annually to reflect the results of the risk assessment.	25	15
Both the objectives and progress made toward their achievement are routinely reported to the Compliance Committee and Board of Directors.	25	5
	75	35

## Policies and Procedures

	Max	Actual
General Compliance Program Policy is consistent with OIG Compliance Program (guidance), including provisions required by the Deficit Reduction Act. The Policy and Standards of Conduct are reviewed every two years or as necessary based on regulatory changes.	20	15
Standards of Conduct are distributed to: Associates, Medical Staff, Board Members, and Vendors. (5 points each)	20	15
A policy has been implemented on excluded provider sanction screening for : Associates, Medical Staff, Vendors, and Board Members. (5 points each)	20	15
Written contracts/agreements include standard language requiring contractors to disclose immediately any proposed or actual debarment, exclusion or other event that makes the contractor ineligible to participate in the Federal health care programs or Federal procurement or non-procurement programs. (Quality – review a sample of 20 contracts)	20	10
Conflicts of Interest Disclosure Statements are obtained annually from each trustee, principal officer, member of a committee with Board delegated powers and key Management, Employed Physicians, Contract Medical Directors, and Board members (as defined by the organization). Statements are reviewed by CO and Management for potential conflicts of interest and any conflicts are appropriately addressed and reported. (Calculate % obtained)	20	15
	100	70

## Training and Education

	Max	Actual
A process is in place to ensure new associates receive compliance introduction and orientation within 90 days of commencing employment. New hiring orientation materials will include a review of: <ul style="list-style-type: none"> <li>Standards of Conduct, Identity and role of the CO</li> <li>Identity and role of the Privacy Officer , etc.</li> </ul>	20	20

All associates completed annual Compliance Program training. It includes the Standards of Conduct; the identity and role of the CO; and the existence of the Alert Line (hotline).	20	20
Focused Education (IHEAL) has been completed in the following high-risk departments: Coders, Admission, Revenue Cycle/Billing, Management, etc.	20	10
General compliance education specific to the hospital or education in high risk compliance areas was offered to the Medical Staff at least once in the past 24 months.	20	10
General compliance education specific to the hospital or education in high risk compliance areas was provided to members of the Board of Trustees at least once in the past 12 months.	20	20
	100	80

## Ongoing Auditing and Monitoring

	Max	Actual
<u>Inpatient Audit</u> : inpatient order, comply with 2 midnight rule, ICD-10 diagnosis, DRG assignment, Present on Admission codes, discharge disposition, etc. completed on 30 accounts.	20	10
Calculate the improper payment error rate for the entire sample (overpayment plus underpayment [gross, not net] divided by total payment for the sample).	20	15
0% - 5% = 20		
5.1% - 7% = 15		
7.1% - 9% = 10		
9.1% - 10% = 5		
10.1% and over = 0		
<u>Outpatient Audit</u> objectives are to assess and verify that all ICD-10 diagnosis codes, CPT/HCPCS codes, modifiers and number of units reported on the UB-04 claim form for payment are supported by documentation in the medical record; to verify the presence of a valid physician order that supports medical necessity for ancillary tests performed, coded and billed; audit a sample of 30 records at a minimum.	10	10
Calculate the improper payment error rate for the entire sample (overpayment plus underpayment [gross, not net] divided by total payment for the sample).	20	15
0% - 5% = 20		
5.1% - 7% = 15		
7.1% - 9% = 10		
9.1% - 10% = 5		
10.1% and over = 0		

Physician Services Audit objectives are to assess and verify that all ICD-10 diagnosis codes, Evaluation and Management (E/M) Level and other CPT/HCPCS codes, modifiers, number of units and place of service codes reported are supported by documentation in the medical record; to verify documentation that supports medical necessity for ancillary tests performed, coded and billed; and to calculate, report and correct errors and improper payments. (Review 10 encounters per practitioner once per year.)	10	10
Calculate the improper payment error rate for the entire sample (overpayment plus underpayment [gross, not net] divided by total payment for the sample).	20	15
0% - 5% = 20		
5.1% - 7% = 15		
7.1% - 9% = 10		
9.1% - 10% = 5		
10.1% and over = 0		
	100	75

## Open Lines of Communication

	Max	Actual
An anonymous compliance hotline has been publicized throughout the Entity and associates have been notified that they can report compliance concerns without fear of retaliation.	10	10
Alert Line calls are logged and an issue-tracking mechanism is maintained.	20	20
Documentation of each investigation (including Alert Line calls on Human Resource issues) is maintained and is adequate to support that the issue was thoroughly investigated and action plans were implemented, if needed. Issues may be identified by various sources, including: Alert Line; internal monitoring and auditing; external sources ; and associates.	20	20
	50	50

## Response to Detected Deficiencies

	Max	Actual
<u>COMMUNICATION OF AUDIT RESULTS</u>		
Ensure that the results of audit(s) are communicated to the CO and Compliance Program Committee.	10	10
<u>ACTION PLAN DEVELOPMENT AND COMPLETION</u>		
Ensure that all corrective action plans that address causes of errors are developed, with agreed upon action plan owner(s) and completion dates and that the potential impact of the issue on other departments/entities is considered.	20	15
<u>REBILLING WITHIN 60 DAYS</u>		

Ensure that all incorrect claims are rebilled as soon as possible, but no later than 60 days after verification of the amount of overpayment and issuance of the final audit report.	20	10
<u>REPORTING AND RETURNING OF SELF IDENTIFIED MEDICARE OVERPAYMENTS WITHIN 60 DAYS</u>		
The Centers for Medicare & Medicaid Services (CMS) requires Medicare Parts A and B health care providers and suppliers to report and return overpayments by the later of the date that is 60 days after the date an overpayment was identified, or the due date of any corresponding cost report, if applicable.	20	10

70 35

	Max	Actual
<b>Enforcement of Disciplinary Standards</b>		
Consistent disciplinary or other appropriate actions are taken, and documented, in response to violations of compliance policies.	10	5
Performance evaluations for associates include participation in Compliance Program education.	20	10
The following are screened against the OIG's List of Excluded Individuals and Entities (LEIE) and the General Services Administration's (GSA/SAM) Excluded Parties List System (EPLS) prior to hiring, credentialing, contracting, and/or ordering tests. Evidence of screening is retained (screen prints). Where applicable, state Medicaid exclusion lists should be checked: Associates, Medical Staff, and Vendors	20	15
The following are screened monthly against the OIG's and GSA/SAM's excluded provider lists and follow-up is performed on any exceptions identified as a result of the screening: Associates, Medical Staff and Vendors.	20	10
	70	40
TOTAL	665	480

95%

47%

70%



80%

75%

100%

50%

57%

72%

Compliance Assignment	
<b>JAN</b>	2016 Compliance Evaluation
	Review of Medicare Observation Stays
	PG- Use of Mid Levels/Incident to Billing
<b>FEB</b>	Important Message from Medicare Re-Audit
	PG- Reasonableness of Prolonged Services
	2017 Risk Assessment Part 1
<b>MAR</b>	Medical Director Timesheets
	PG- Physician Home Visits Reasonableness of Services
	2017 Risk Assessment Part 2
<b>APR</b>	Signatures of Conditions of Admission Services Re-Audit
	Appropriate Use of Incentive Spirometry CPT 94640 Re-Audit
	PG and OP- Modifier JW- Drug Waste of Single Use Vial Drugs
<b>MAY</b>	Review of Medicare 0-1 Day IP Stays Re-Audit
	Claim Processing for Self Administered Drugs
	PG- Use of ABNs
<b>JUN</b>	Appropriateness of IRF/Correlation of Dispo Codes
	Review of Medicare Observation Stays Re-Audit
	PG- Use of Research Studies
<b>JUL</b>	Cardiac Cath/Endomyocardial Biopsy (Mod 59)
	Appropriateness of HBO Therapy

	PG- Review of Financial Interests Reported Under the Open Payments Program
<b>AUG</b>	EMTALA Transfer Logs w/Supporting Documents
	Appropriateness of Intensive OP Program (BHU)
	PG-Use of External Contracts/Vendor Agreements
<b>SEP</b>	Oversight of Provider- Based Facilities
	Free Standing ED and Diagnostic Imaging Centers
	Ambulatory Surgical Centers- Quality Oversight
<b>OCT</b>	High Use of Medicare Outpatient Physical TX
	IP Psychiatric Facility Outlier Payments
<b>NOV</b>	Review of ED Provider On-Call Logs
	High Use of Sleep Testing Procedures
<b>DEC</b>	Federal HC Payments After Bene's Date of Death
	Careview Audit

# 2017 COMPLIANCE WORK

## HIPAA Privacy Assignment

Privacy - Opt-out/Emergency

Communications with Law Enforcement

HIPAA Privacy Gap Assessment

Victims of Abuse & Neglect

Business Associate Review

OIG Compliance Guidance Review

OIG Compliance Guidance Review

Breach Reporting

Minimum Necessary Standard
HIPAA Privacy Gap Assessment
Notice of Privacy Practices
Breach Reporting
Minimum Necessary Standard
Minimum Necessary

# PLAN ADDENDUM

## HIPAA Security Assignment

BioMedical Device Review

HIPAA Security GAP Assessment

2017 Risk Analysis

Business Associate Review

2017 Risk Analysis

OIG Compliance Guidance Review

OIG Compliance Guidance Review

Workstation Review



HIPAA Security GAP Assessment

BioMedical Device Review

3rd Party Access Review







*HOW TO TELL*

# YOUR BOARD OF DIRECTORS

AN EFFECTIVE COMPLIANCE STORY  
IN EVERY BOARD MEETING



*From your trusted partner*



## **With insights from**



Katie Smith, EVP, Chief Compliance Officer, Convercent  
Erica Salmon Byrne, EVP and Executive Director of BELA, The Ethisphere Institute  
Panelists from the Converge '16 User Conference



# THIS GUIDE IS DESIGNED EXCLUSIVELY TO HELP YOU:

- Plan a board report roadmap: based on the meeting cadence of your organization, you can easily plan out when and what you need and where to get the right data, determine key milestones, when to bring in other key stakeholders like HR or legal, and when to start packaging it all together.
- When to get draft information out for appropriate internal review and editing processes.
- Know what topics of your compliance program to present to your board.
- See a checklist of things to start thinking about and when so you're not left at the 11th hour the night of your board meeting on the hunt for the right information.
- Prepare for the questions the board may ask you.
- Get your message across in a concise way that resonates with your board.
- Own the compliance function, get the respect you deserve and help drive meaningful and impactful conversation.
- Formulate your board deck with a sample board reporting template.

At the end of this short guide, you will be able to apply these foundational principles to every board meeting and report you prepare to present. However, it is worth noting that compliance professionals should produce a plan for the entire year with different themes and topics covered in each quarter. The board does not want to look at and review the same information in each meeting or have the same presentation in the fourth quarter than they had in the first. This approach will also set you up to shape your story better throughout the year.

CLICK HERE TO DOWNLOAD OUR  
PLANNING ROADMAP TEMPLATE

[DOWNLOAD](#)

# INTRODUCTION

*A calendar reminder comes up on your computer screen that the quarterly board meeting will begin in 15 minutes.*

Of course you know it's starting soon – it's all you and your team and your company have been preparing for in the last few weeks (some even longer). However, you don't feel incredibly confident in what you are about to say, you're nervous, you only have 20 minutes to present to the board and you have only two PowerPoint slides. How are you going to fit in all of what you want to say, with all the appropriate context, in the matter of 20 minutes?

Meanwhile, your helpline is bringing in reports of employee morale being low due to a major shift in a department's structure and you need to update a policy around social media after some male sales employees posted a picture on the company page while they were at a football game, had too much drink and captured the photo without their shirts on.

Needless to say, you have a lot of competing priorities and a lot resting on your mind; definitely not clear enough to stand in front of your board.

Right before you walk into the board room you have an epiphany: next time, next quarter, this is going to be different; this feeling of nerves and unease is going to be ones that transform into confidence, enablement and leadership.

But how?

Meeting with your board of directors can make or break the trust your company has in compliance and its dependence on the role, on you, and your team. Telling them a story that helps them get to the 'a-ha' moment is part art, part science, part skill and part luck. However, the most crucial ingredient is knowing your audience.

Results from the [January 2016 Compliance Strategy and Performance survey](#) we conducted in conjunction with The Ethisphere Institute, told us there is a clear trend of chief ethics and compliance

officers reporting directly to the CEO (36%), with a dotted line reporting to the full Board or Audit committee. Twenty-five percent report directly to the board, the survey found. The conversation you have in the formal meeting cadence must be world-class, to the point, effective, impactful and leave each board member informed.

Chief compliance officers struggle with finding time. Being on a constant back-to-back meeting schedule makes it difficult to find the bandwidth to prepare for the demands and expectations of a board meeting. But yet, despite your best intentions of being strategic, you often get stuck in the pendulum of making reactionary decisions. And when it comes to the tangible report you ultimately share with your board, it's hard to step away from the constant churn of, "what meeting do I have to go to next?" even though you have a well-developed long-range strategy. This guide will help you step outside of the daily grind so you can have the most successful and lasting meeting with your board of directors.

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# TELL THE RIGHT STORY

## CREATE YOUR COMPLIANCE STORY ARC

Every good story has a beginning, middle and end. Stories have a plot and setting, characters, heroes, villains and usually always end in a resolution. By framing your conversation with the board similarly, it will:

- Challenge traditional and often dull presentation slides
- Defy deficit attention spans
- Increase the likelihood of the board remembering the compliance message, (the moral of the story)

## SET THE SCENE - INTRODUCE THE CHARACTERS

- Defines the status quo

## CONFLICT

- Interrupts the status quo and creates a conflict with the protagonist

## CLIMAX

- Brings the audience to the peak of the tension, where the protagonist is taking action to resolve the conflict

## RESOLUTION

- The new status quo, where the audience sees the results of the protagonist's actions

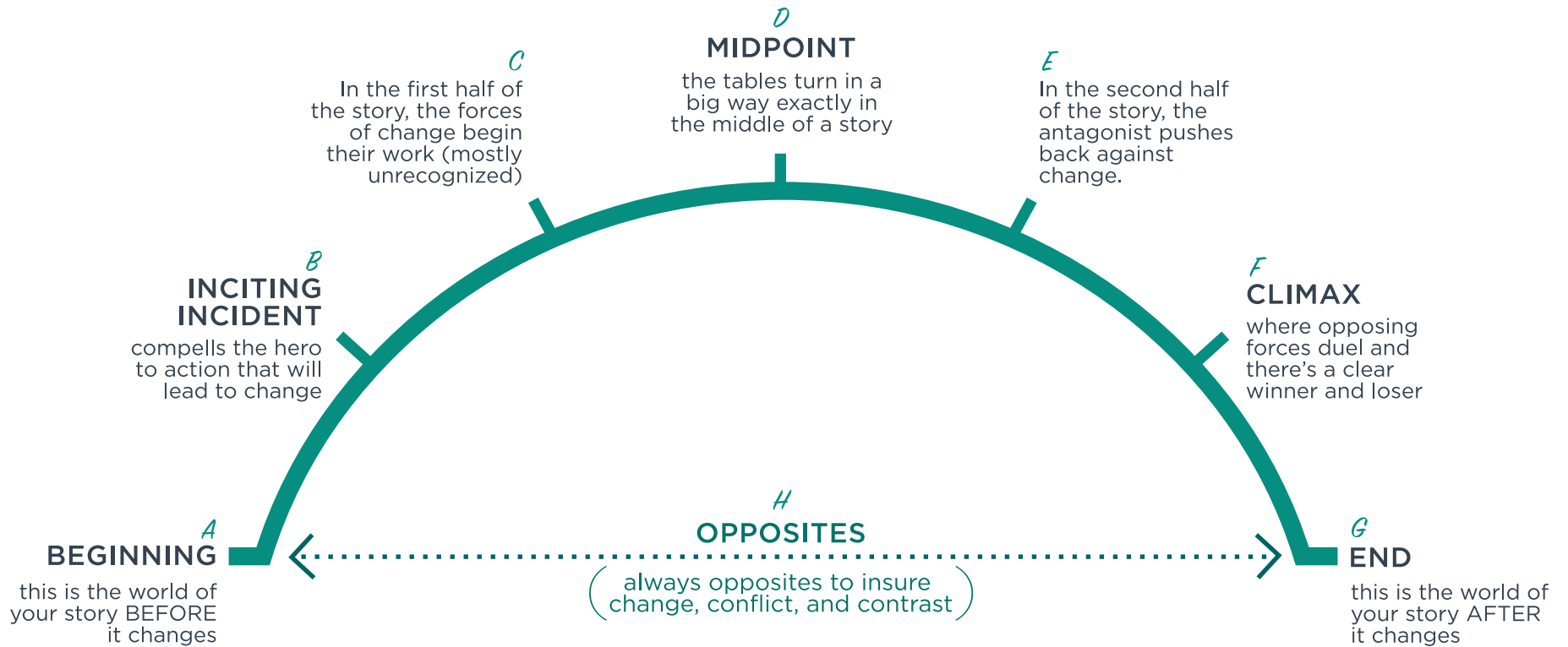


# STORY ARC

DOWNLOAD JUST THIS PAGE



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## CREATE YOUR COMPLIANCE STORY ARC:

A \_\_\_\_\_

E \_\_\_\_\_

B \_\_\_\_\_

F \_\_\_\_\_

C \_\_\_\_\_

G \_\_\_\_\_

D \_\_\_\_\_


H \_\_\_\_\_



# ALIGN YOUR STORY WITH AN EXISTING NARRATIVE IN THE INDUSTRY FOR VALIDATION

*As you tell your story and identify gaps in your program, consider the seven elements of an effective compliance and ethics program as outlined by the United States Sentencing Commission in the Federal Sentencing Guidelines Manual:*

1. Establish Policies, Procedures and Controls
2. Exercise Effective Compliance and Ethics Oversight
3. Exercise Due Diligence to Avoid Delegation of Authority to Unethical Individuals
4. Communicate and Educate Employees on Compliance and Ethics Programs
5. Monitor and Audit Compliance and Ethic Programs for Effectiveness
6. Ensure Consistent Promotion of the Program and Enforcement of Violations
7. Respond Appropriately to Incidents and Take Steps to Prevent Future Incidents



While these are the bolts of your program, know that the expectations of your program are evolving to a built in approach as well. Your board is going to be looking for compliance to constantly be proactively building and designing activities into the organization's existing operations. Why? Simply put, this helps "reduce drag and conflicting views on risk while increasing overall business impact," according to the CEB Compliance & Ethics Leadership Council. Make sure you add any of these ancillary activities into the narrative you share with your board. The DOJ is looking deeper at your program in a similar way with the addition of Compliance Counsel Hui Chen who stated that every single piece of your program absolutely needs to be tied to the actual operation and aligned with the day-to-day of the business.

Alignment of the compliance functions gives compliance more skin in the game. The business unit is now in the position to provide strategic direction, proactively identify possible risks and keep the company operationally ethical. This is a true advantage for you and your program and strategy.

Look at the operations of your compliance program to determine which topics in each area you can dig deeper. Which of these topical areas will help make your narrative stronger? What data can you pull

from these areas to help support your initiatives and your program overall?

1. Code of Conduct
2. Policies and procedures
3. Training and awareness
4. External current events
5. Monitoring and auditing
6. Remedial measures in response to deficiencies
7. Receiving reports of and responding to potential compliance violations

When presenting the categories of relevant issues as they relate to your program and organization, remember to consider each board member's other interests. Many, if not all board members sit on many other boards and have a passion in a variety of industry areas (that's what makes their perspective great to have). To cater the conversation to various areas of board member interest try using a heat map to show allegations, for example, in each risk profile and overall risk to the company, issues and types. You can then determine that some areas may or may not impact the company as it currently stands and show specific areas to the board where compliance has taken care of the situation.



## PRESENTING YOUR DATA AND LEVERAGING BENCHMARKING

In determining ethical companies, Ethisphere examines compliance programs using the following criteria, which is also used in evaluating company's for the Institute's coveted World's Most Ethical Company™ Award. These aspects are also closely aligned with industry best practices and federal expectations.

- Compliance and Ethics Program - 35%
- Corporate Social Responsibility and Sustainability - 20%
- Culture of Ethics - 20%
- Governance - 15%
- Leadership, Innovation and Reputation - 10%

This data set, provided to us with permission by Ethisphere, provides the industry's most meaningful and actionable analysis. Consider framing your story around these areas and using the same weighted approach in your narrative so you are not stuck on one topic for too long or forget to mention a key aspect of your program.

## LEVERAGING THE DATA: DRAWING THE STORY OUT OF THE ARITHMETIC

Provide your board with the big picture - the motivations as well as the best practices around robust compliance programs in general. Then, explain the specifics behind your company's ethics and compliance philosophy, strategy and systems - and their role in it all.

## PROVIDE A CLEAR BIG PICTURE

The board must understand that taking ownership of your company's compliance program is very much its job, that they set the tone at the top and that it's vital to the organization's success. They are the doctors overseeing the program's health so to speak, and because of this, should have more of a stake in your program.

## HOLISTICALLY LOOK AT YOUR ORGANIZATION

If you can step out beyond your helpline numbers - ideally, you want to show overall trends of your organization such as ethics and compliance, fraud, HR or whatever groups receive complaints and trigger investigations. Unless you are all in one system, this will require mining this data in multiple options such as:

- Allegations and inquires - the latter demonstrates proactivity on the employees' part to ask before they do something.
- Data that can tie to effectiveness of the program's communications and training.
- Show substantiation rates and show your board what you are doing about it.
- Case trends and root cause - what caused it and what you are doing about it.
- How are you meeting the needs of your stakeholders such as your board, employees, shareholders and local community?

*The following data sources should explain why a compliance program is important and what a good program looks like. The information that can help support those objectives is:*

## HELPLINE AND INTERNAL REPORTING:

- Number of calls to your helpline
- Helpline statistics
- Number of issues that come from each investigation
- Corrective actions taken as consequence of policy revisions, self-reporting, or disciplinary action
- Attrition rates
- Issues reported to your office through other reporting mechanisms
- Root cause analysis results
- Open door reports

## CULTURE SURVEYS AND RISK ASSESSMENTS:

- Do employees feel safe and free of retaliation to speak up?
- Do employees feel comfortable reporting something their manager may be doing?
- Do employees believe the company will do something with what they report?

## INFORMAL DATA COLLECTION ANECDOTAL KNOWLEDGE (OFTEN MORE VALUABLE THAN SURVEY DATA):

- Who are the people in the field pushing out culture?
- What ways do you work with these employees to adjust your policies and training?
- How often do you visit these teams in-person to gather this kind of information?

## OTHER INFORMATION:

- Compliance training statistics
- Policy attestation rates



# SHOW, DON'T TELL

***Being efficient with your time in the short range is a huge challenge, compliance practitioners tell us. And to be the most effective with your time in front of the board, consider an aspect of a good story: show, don't tell. Show results. Show your plans. Show your strategy.***

Details, details, details. Don't tell the board what you have been doing all quarter, show them by using well-placed details to bring each initiative or activity to life. Great storytellers do this by using expressive dialogue to show the emotion and attitude of their characters. You can use this same technique to be more effective with your time in front of the board. Think of your employees as your characters and give your board more insight into the daily grind of how they carry and sustain the company culture and values or how they do not and what you are doing to ensure that is not the status quo.

## REMIND YOUR BOARD WHY THEY SHOULD CARE

***Due to the U.S. Department of Justice's Yates Memo, your board's interest in hearing your story is a personal one. Under this memo, they are personally liable and accountable for any high-profile compliance failures. Expect and assume you will have a highly engaged audience the day of your board meeting, especially during your time slot.***

As stated earlier, board members are busy and have vested interests in a variety of different places. There is no harm in honestly reminding your board why companies and those governing them need to pay special attention to the company's compliance program.

Help to put compliance in context and provide a more illustrated look of the function and its impact on the company. Use some current examples in the headlines that are relevant to your industry. Show then how your compliance program has specifically impacted that topic for the company. Make the point that headline grabbing

scandals can happen to everyone and anyone if they are not equipped or prepared with a compliance foundation. Example scandals to present: Wells Fargo, Wal-Mart, HSBC, or Pzifer, and of course, the infamous cases of WorldCom and Enron.

Structure the conversation by starting off with any new regulation, laws or judicial guidance that came in that quarter or year that pertains to your industry and your company. Provide examples of how an excellent compliance program can be worth it.



## DON'T FORGET TO SHARE THE BRIGHT SIDE.

Provide a good example of a compliance program being effective. In 2012, for example, a Morgan Stanley employee was sentenced to nine months in prison for FCPA violations in China. Yet, the DOJ declined to prosecute the firm on account they were able to show the employee was trained on FCPA seven times and reminded him to comply at least 35 times.

## SHOW ETHICS AND COMPLIANCE WINS.

Share a story with your board of an issue that was reported which resulted in something positive for the company such as a near miss, process improvement, policy change or addition. This will show your program is working and demonstrate its effectiveness and procedural justice.

When sharing your story, give the board proof points of how your program is evolving and staying innovative. You may consider adding details in your story around activities that occur during the company's Ethics and Compliance Week or when you implemented a new technology solution to automate a compliance activity.



# THE NUTS AND BOLTS OF WHAT EXACTLY YOU SHOULD REPORT TO THE BOARD

## *Deliver a regular and thorough report to the board*

Compliance executives typically have a team of other professionals helping them collect the right data. Be sure the person that heads up the actual work is in the room with you. This allows the board to directly question the person who is closest to the issues and build a relationship with them.

It's important to highlight what risks you are seeing in the company and in the industry as a whole. You want to educate your board, put them at a peace of mind that you have your finger on the pulse and minding the shop. Provide a heat map visual. This allows you to risk rate your allegations to depict the severity of your issues and how you're addressing them. In other words, you may have a high number of reports but that does not necessarily mean the company is in jeopardy.

For example, if you consider high risk allegations such as discrimination and their percentage of case makeup compared to low risk such as: "my boss is a jerk," can keep the board from getting overly excited.

Give them a sense of health in the organization by sharing the most recent information you have available on:

- Helpline statistics
- Compliance training statistics
- Policy attestation rates
- Investigation reports
- Risk assessments and changes
- Quarter-over-quarter statistical comparison
- Culture assessment reports
- Compliance-related statistics from employee surveys
- Important changes or rulings in compliance law as applicable to your jurisdiction and industry
- Any other relevant data

## KEY PLAYERS

The key compliance actors within the company as well as the reporting chain. If the compliance lead has direct access to the CEO and board, say so (if not, you should arrange for such access and then say so).

## INCENTIVES

How compliance plays into executive and management compensation and incentives.

## RISK

How the program covers the company's high-risk areas at home and abroad. Make clear how these initiatives apply not only to employees, but also to business partners, vendors, subcontractors and third parties.

## CULTURE

How the company is fostering an ethical culture and how leadership supports those efforts.

## RESOURCES

What you spend on the compliance program, that number is rising or falling, and why. Is the compliance department appropriately staffed?

## LEADERSHIP

What top management is doing to foster a culture of compliance and how the company is leveraging middle management who, being near the front lines, are an invaluable resource.

## TRAINING AND AWARENESS

What training programs are available for different types of employees and what internal communication strategies and vehicles are being used to keep ethics and compliance top of mind across the organization.

## ASSESSMENT

The ongoing monitoring and auditing processes that assess the program's effectiveness, including how periodic program reviews are done and how the program has been validated by an independent third party.

## RESPONSE

The processes and communication lines the company has established to review compliance violations, how responses are calibrated and what measures have been put in place to stop it from happening again.

## OPEN DOOR

How you encourage employees to come forward with reports of misconduct and how you disseminate your non-retaliation policy. Tell the board how your managers are trained to field employee reports, document alleged misconduct and move reports up the reporting chain in a timely manner - as well as the steps in place to investigate them.

CLICK HERE TO DOWNLOAD A SAMPLE BOARD PRESENTATION



DOWNLOAD

## PLANNING

To wrap up, describe your plans for the compliance program during the next year and beyond.

## TELL BOARD MEMBERS HOW THEY CAN GET INVOLVED

Give each board member the opportunity to engage in the program. For example, some companies are posting director interviews about ethics and compliance on their company intranet. Some of the most effective examples involve sharing ethical challenges the board member faced in their own career. A director might also volunteer to take an employee ethics award winner to lunch, or lend their voice to employee compliance communications. They may have better ideas (you should ask them), but the bottom line is that involving your board will increase their awareness and support of the program --- and sends a powerful message to employees, regulators and other stakeholders that the board has made compliance priority.



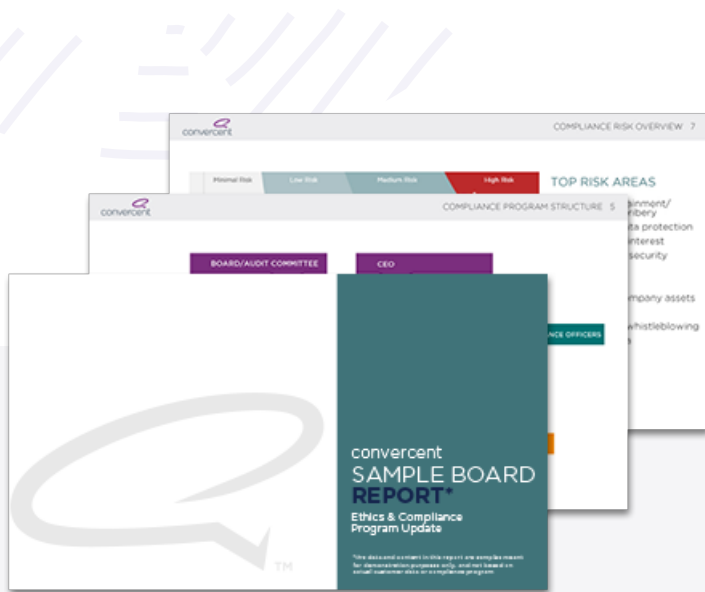
# CONCLUSION

Remember, effective boards ask questions. But rather than telling them what questions they should ask, your company and compliance program should focus on putting together a solid edifice of information using the planning roadmap and story arc provided here - including both hard data and a narrative perspective - about the nature and effectiveness of your compliance program.

Keep your board updated formally with quarterly meetings and informally through a designated champion to keep current board members up-to-date on what you and your compliance team are doing to maintain high compliance standards and minimize risk. The higher quality your board coaching and briefing are, the better the remaining questions from your board members will be. All in all, taking this foundational and repeatable approach to keeping the lines of communication open and honest between you and your board will strengthen your company's governance, controls and compliance program.

# RESOURCES FOR YOU

Take advantage of these free downloads:



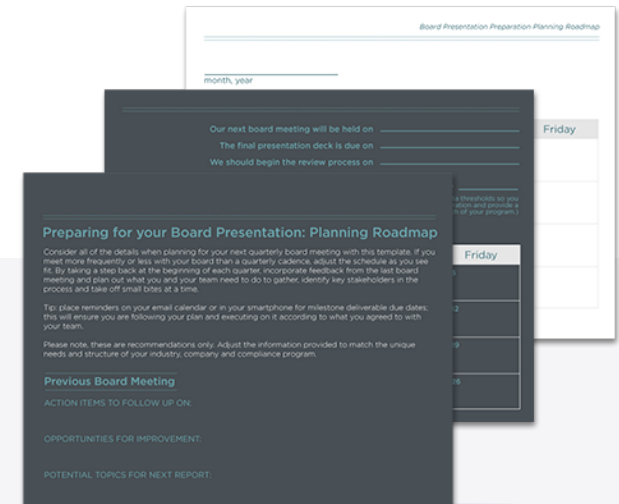
SAMPLE BOARD REPORT

DOWNLOAD



BoD FAQs: 45 QUESTIONS YOUR BOARD CAN (AND SHOULD) ASK ABOUT THE COMPLIANCE PROGRAM

DOWNLOAD



PLANNING ROADMAP TEMPLATE

DOWNLOAD

# CONTRIBUTORS



## KATIE SMITH

*EVP, Chief Compliance Officer, Convercent*

Katie Smith serves as EVP and Chief Compliance Officer for Convercent. Bringing nearly 20 years' experience from the high tech, energy, insurance and financial services industries, Katie has implemented ethics and compliance programs for multinational companies. Her professional passion flourishes in building compliance programs from the ground up and raising awareness throughout the company on the importance of proactive compliance and ethics management.



## ERICA SALMON BYRNE

*EVP, Executive Director of Business Ethics Leadership Alliance (BELA), Ethisphere Institute*

Erica Salmon Byrne is the Executive Vice President, Governance and Compliance for The Ethisphere Institute, where she has responsibility for the organization's data and services business and works with Ethisphere's community of clients to assess ethics and compliance programs and promote best practices across industries. Erica also serves as the Executive Director of the Business Ethics Leadership Alliance.



## ABOUT CONVERCENT

Convercent's risk-based global compliance solution enables the design, implementation and measurement of an effective compliance program. Delivering an intuitive user experience with actionable executive reporting, Convercent integrates the management of corporate compliance risks, cases, disclosures, training and policies. With hundreds of customers in more than 130 countries — including Philip Morris International, CH2M Hill and Under Armour — Convercent's award-winning GRC solution safeguards the financial and reputational health of your company. Convercent is backed by Sapphire Ventures, Tola Capital, Azure Capital, Mantucket Capital, and Rho Capital Partners. Convercent is based in Denver, Colorado.



TM

convercent  
SAMPLE BOARD  
**REPORT\***

Ethics & Compliance  
Program Update

\*the data and content in this report are samples meant for demonstration purposes only, and not based on actual customer data or compliance program



COMPLIANCE PROGRAM OVERVIEW

COMPLIANCE RISKS

PROGRAM INITIATIVES

PROGRAM PLAN



COMPLIANCE  
**OBJECTIVES**

TM

**AWARENESS:** We communicate our commitment to ethics and compliance broadly and frequently to our executives, employees and third parties

**COMPETITION:** We win business fairly, based on the merits of our products, services and people

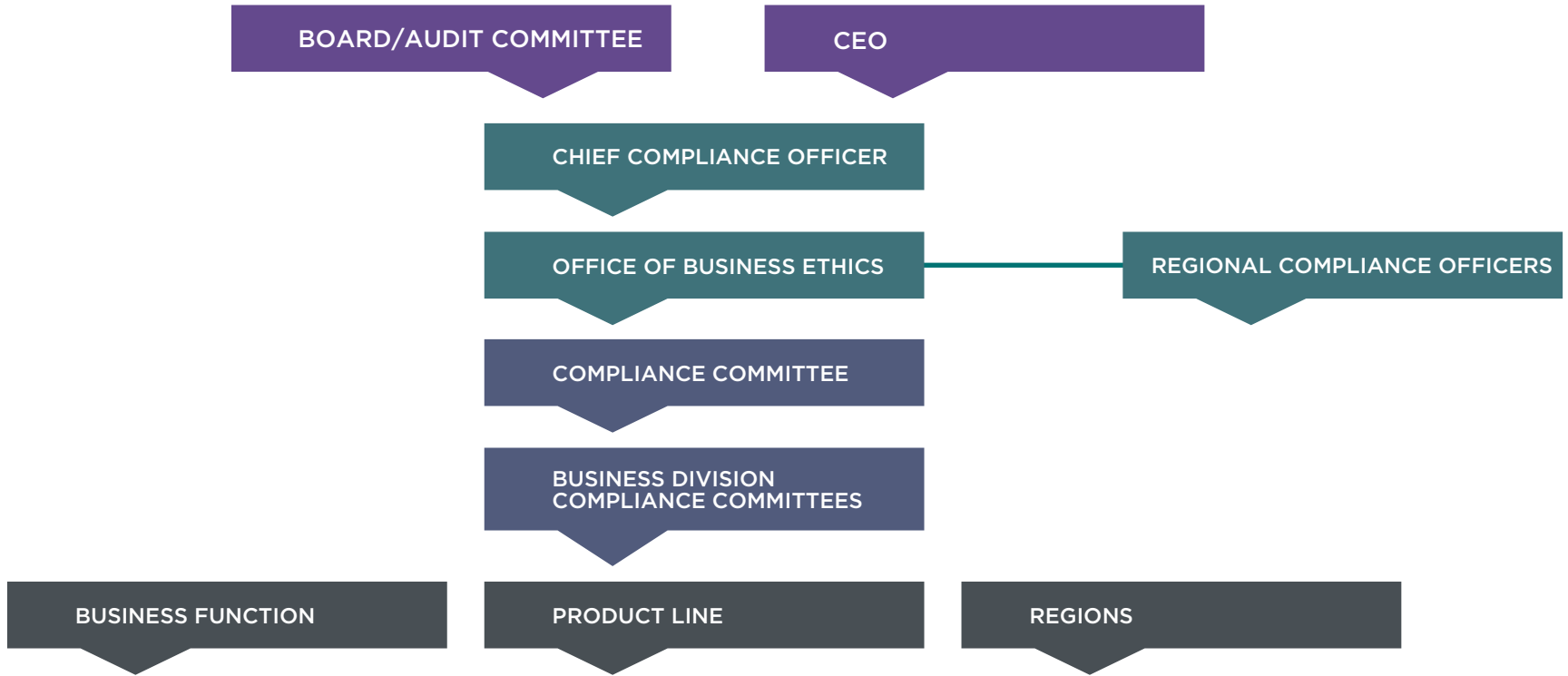
**ANTI-CORRUPTION:** We don't pay or promise anything of value to earn business or competitive advantage

**PRIVACY & DATA PROTECTION:** We protect personal information from unauthorized access, use, storage or disclosure

**COMMITMENT TO OPEN DOOR/NON-RETALIATION:** We want employees to raise concerns, questions or reports of misconduct without fear of retaliation

**SUPPLY CHAIN COMPLIANCE:** We ensure our third-party suppliers are conducting business responsibly and sustainably

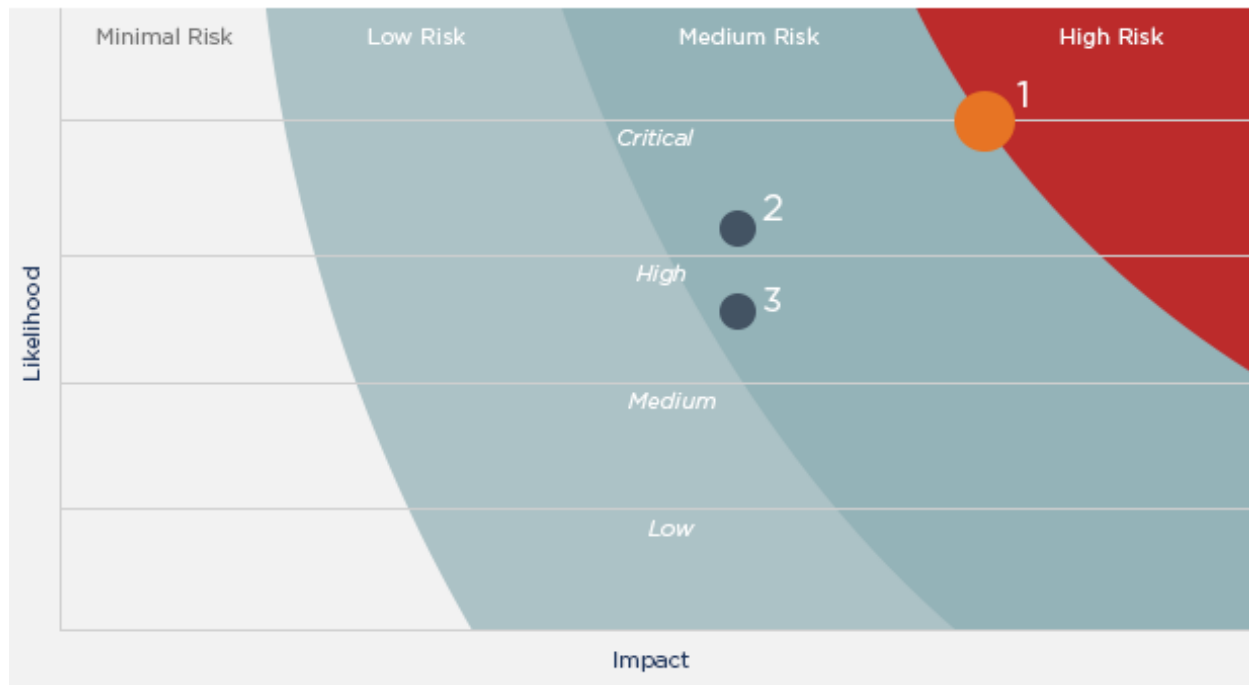
**ZERO TOLERANCE:** We have a zero tolerance policy for compliance violations; and we identify, investigate and address violations rapidly and appropriately





COMPLIANCE  
**RISKS**

TM



## TOP RISK AREAS

1. Gifts/entertainment/kickbacks/bribery
2. Privacy & data protection
3. Conflicts of interest
4. Information security
5. Fraud
6. Harassment
7. Misuse of company assets
8. Antitrust
9. Retaliation/whistleblowing
10. Social Media

## BUSINESS CHANGES THAT IMPACT RISK

Opened new offices in Mexico and London

Acquired call center in Sioux Falls

Expanded into new consumer market with product launch

## ENVIRONMENT CHANGES THAT IMPACT RISK

Supreme Court ruling on whistleblowers

Competitor settlement for antitrust

DOJ anti-corruption enforcement focus in China

Dodd-Frank conflict minerals disclosure mandate

Brazil's new "Law to Combat Corruption"

RISK	LIKELIHOOD	SEVERITY	VELOCITY	INITIATIVES
Bribery	Medium	Critical	Rapid	<ul style="list-style-type: none"> <li>• Gifts &amp; entertainment policy</li> <li>• New hire training and annual refresher courses</li> <li>• Dedicated session in annual manager training</li> <li>• Semi-annual communication to entire workforce</li> <li>• Quarterly communication to high-risk employee population</li> <li>• Third-party FCPA compliance program assessment and benchmarking</li> </ul>



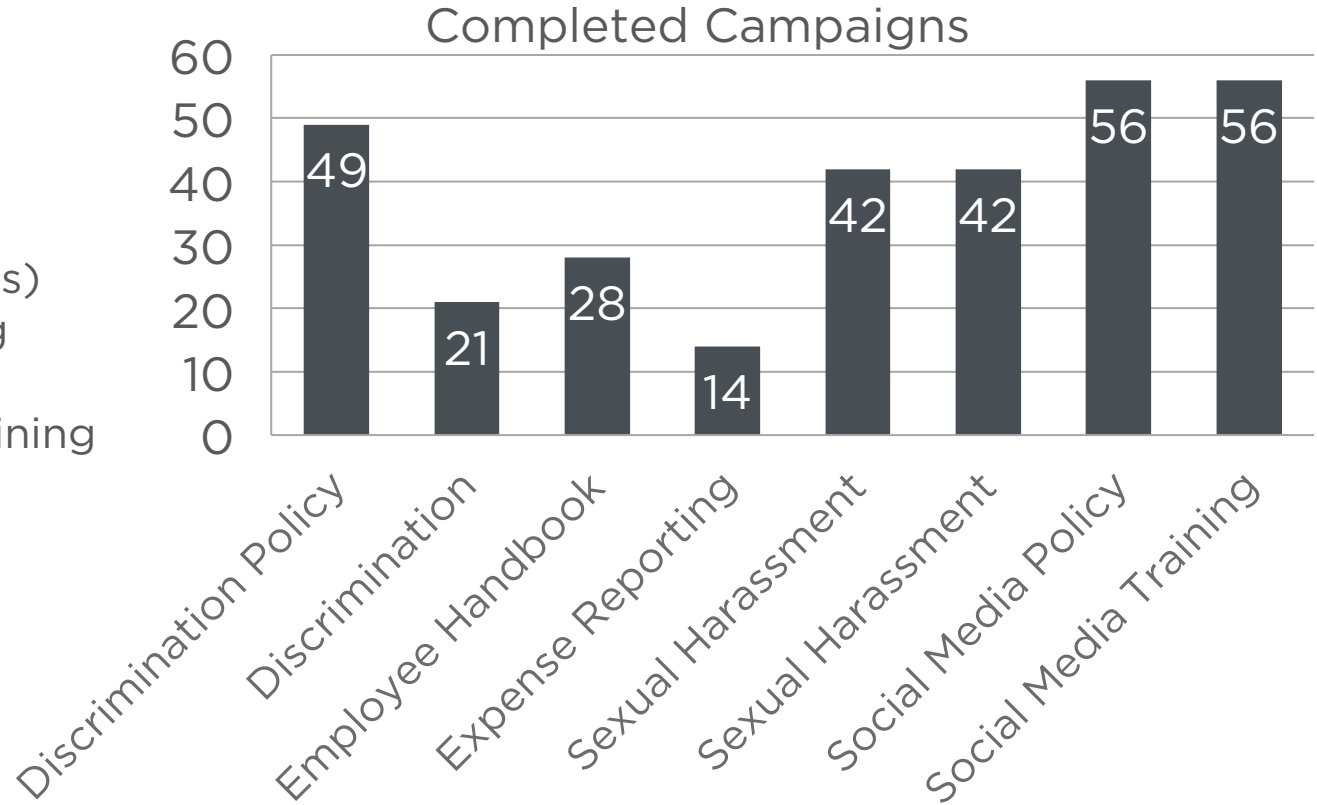


COMPLIANCE  
**INITIATIVES**

TM

### CRITICAL AREAS

- FCPA training (rollout in progress)
- Expense reporting training
- Discrimination training

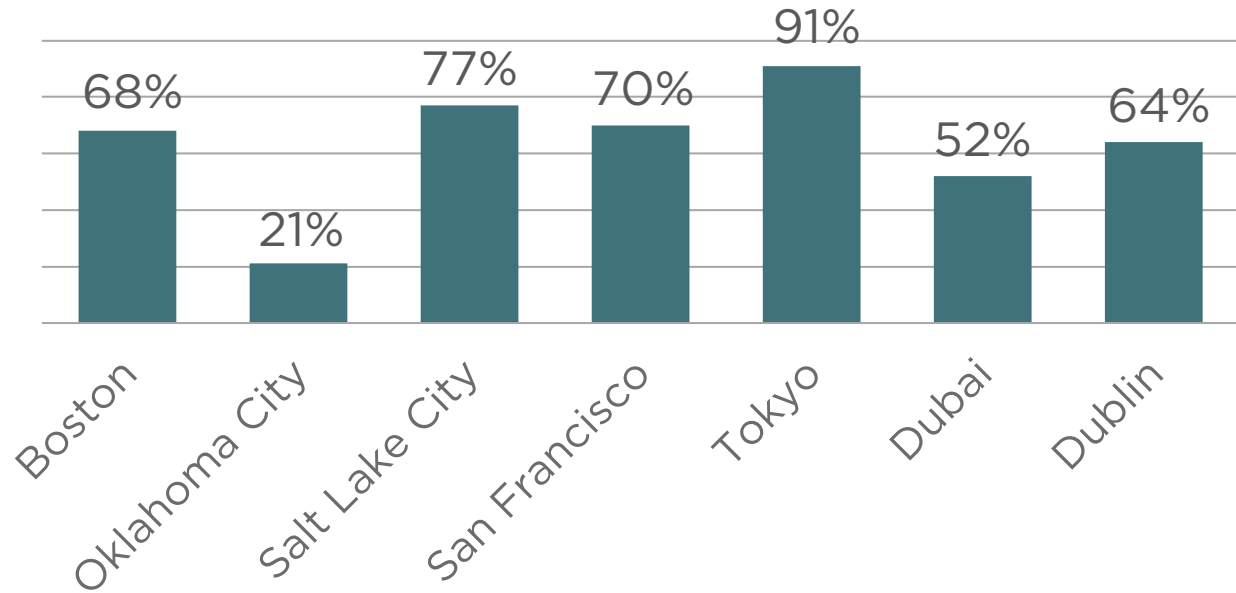


# COMPLETION BY LOCATION

## CRITICAL AREAS

- Oklahoma City - leading location of cases and incidents

## Policy Attestation Rate

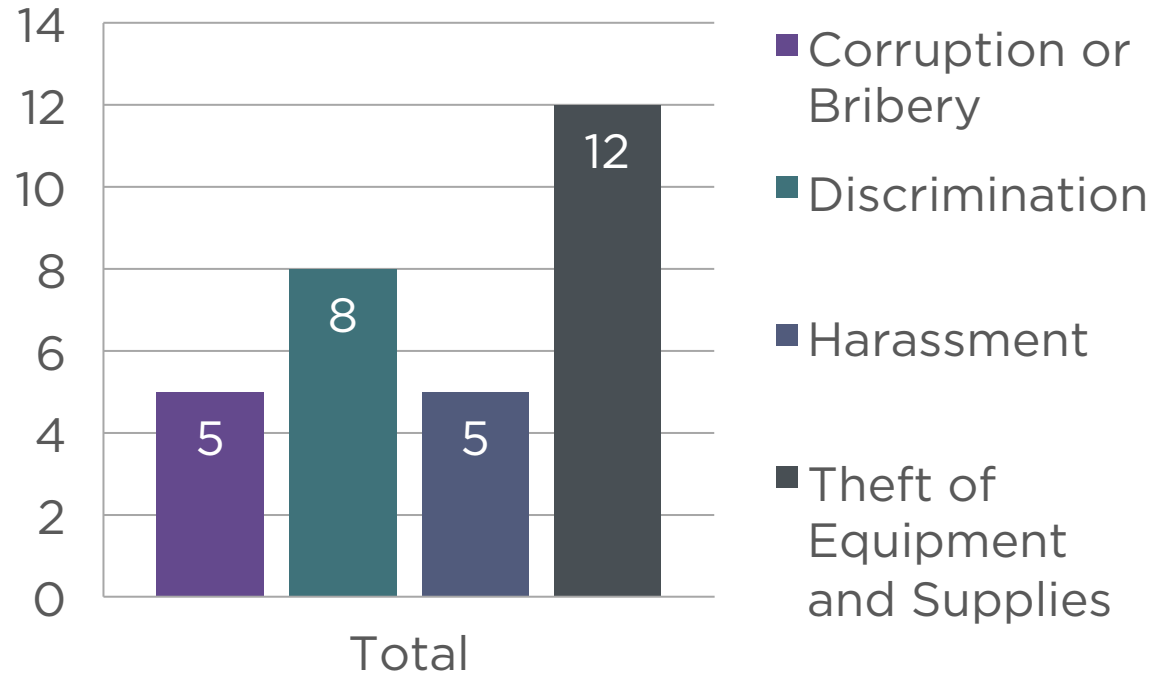


# INCIDENT REPORTS

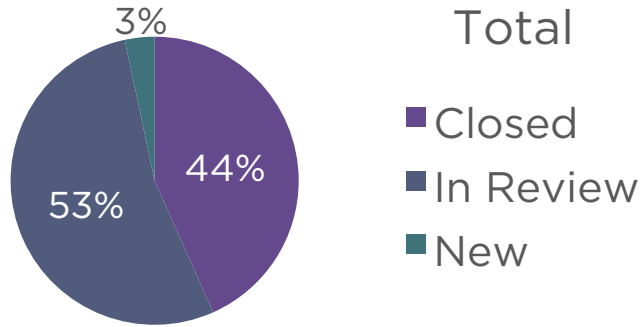
## HIGH RISK AREAS

- Theft
- Discrimination - also critical area in policy\*

\* Discrimination training needs to be a focus area in Q3



# INCIDENT REPORTS



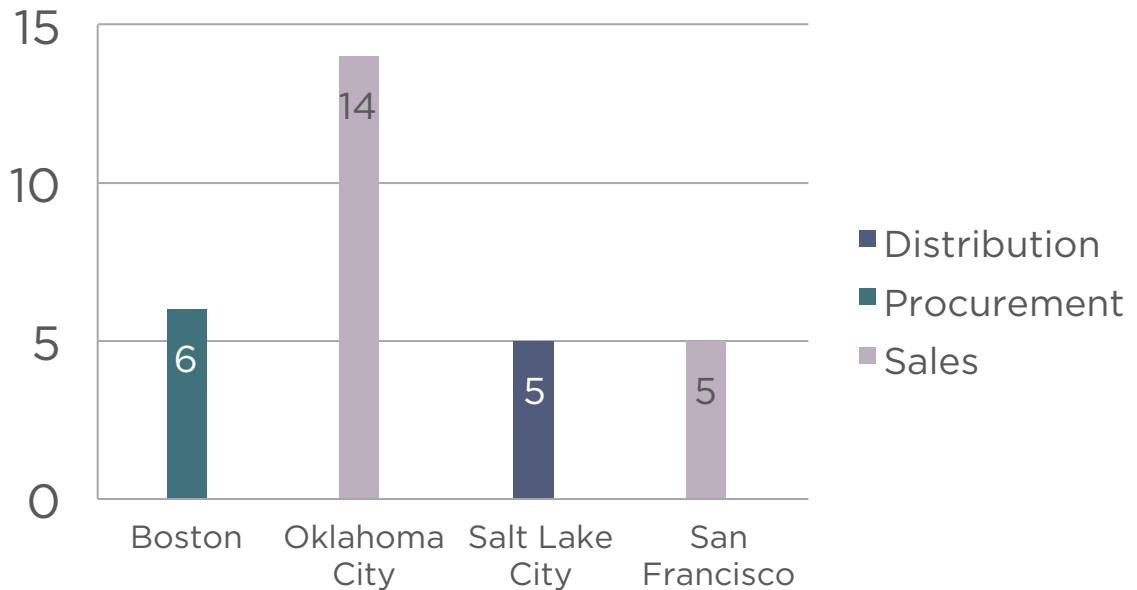
Total

- Closed
- In Review
- New

## CRITICAL AREAS

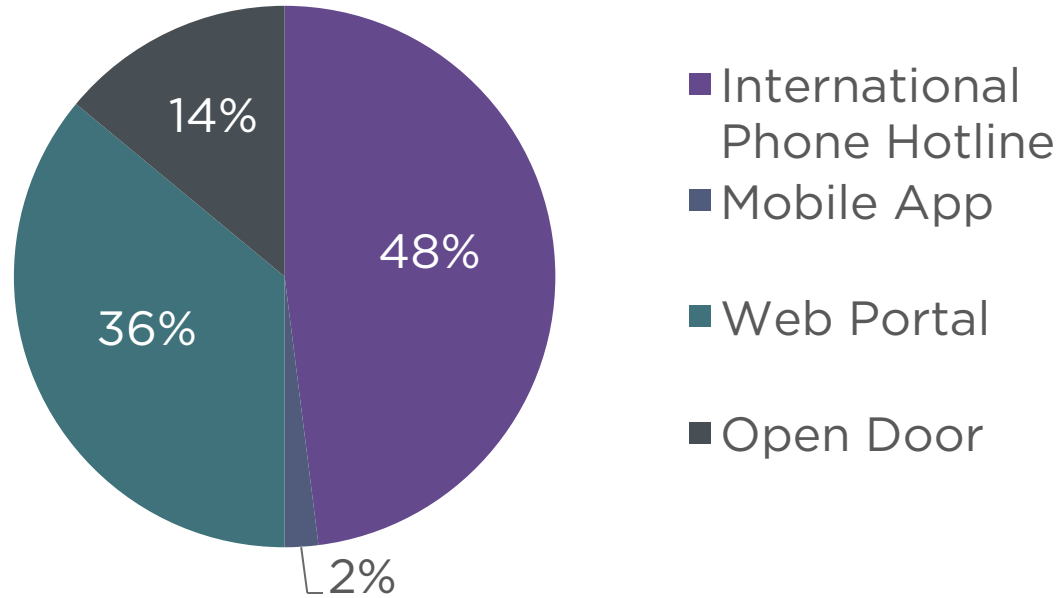
- Sales organization
- Oklahoma City

## Location Hotspots

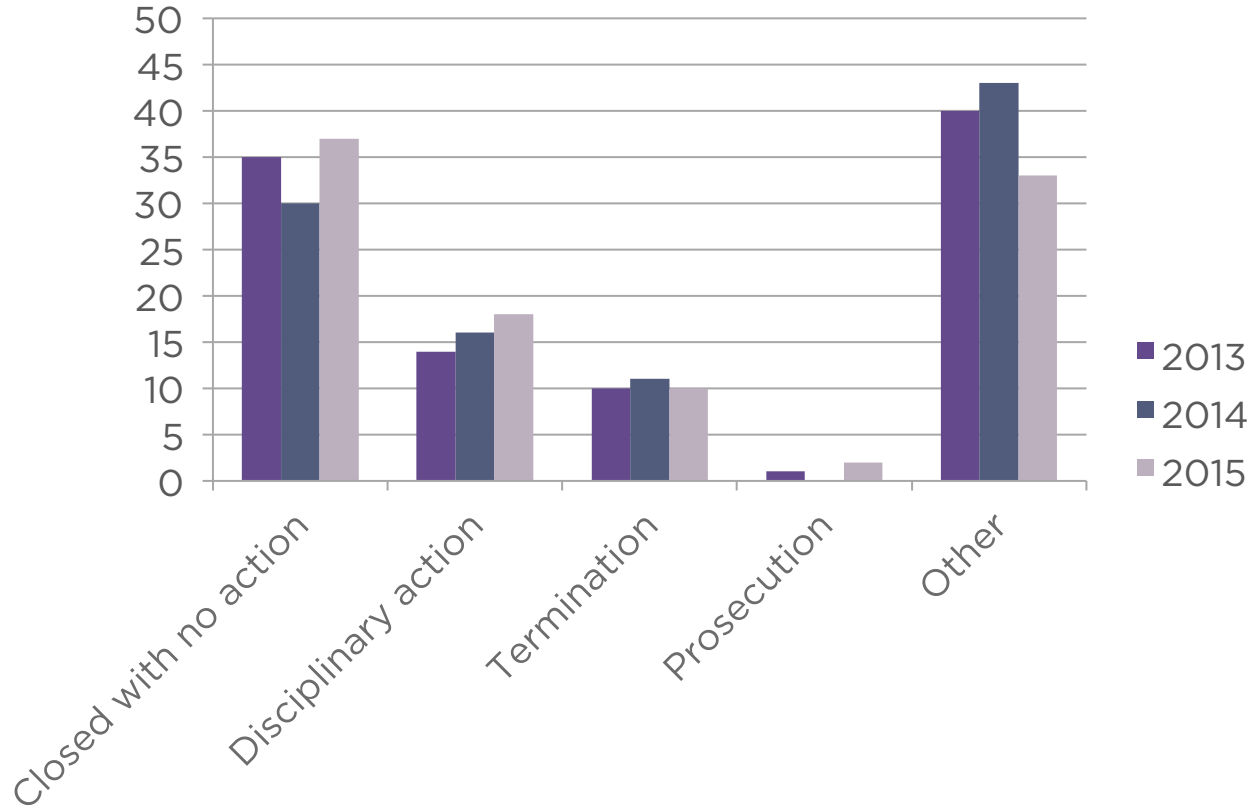


- Distribution
- Procurement
- Sales

## INCIDENT REPORTS BY SOURCE

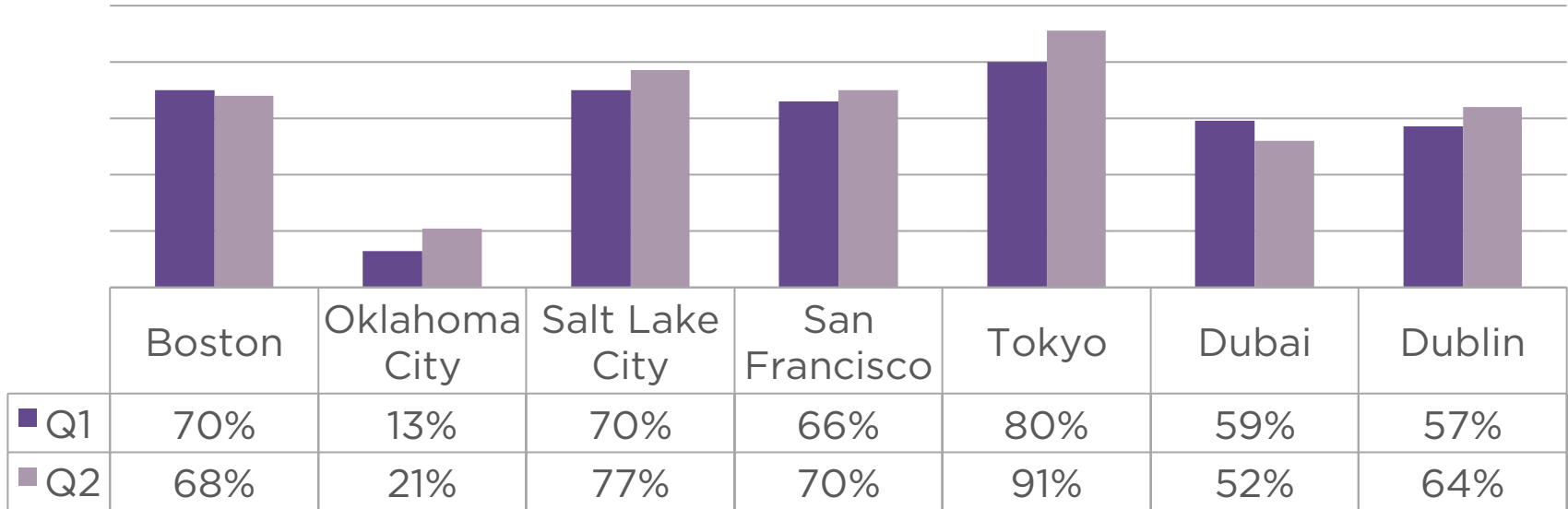


# INCIDENT DISPOSITION



# QUARTER OVER QUARTER: POLICY

## Policy Attestation Rate





## QUARTER OVER QUARTER: INCIDENTS





COMPLIANCE  
**PLAN**

TM

## PROGRAM:

- Finalize implementation of compliance program management solution
- Undergo third-party compliance program assessment and benchmarking
- Present full findings to audit committee and summary to board
- Review/refresh risk assessment framework

## POLICIES:

- Distribute “expired” policies to internal stakeholders for review/edits/approval
- Identify potential policy gaps and weaknesses based on incident reports

## TRAINING:

- Refresh anti-corruption training course
- Engage third party provider for refresher courses for top three risk areas

## THIRD PARTIES

- Initiate supplier surveys and screening protocol

QUARTER	KEY INITIATIVES*
Q1	<ul style="list-style-type: none"> <li>• Intranet home page: CEO 2014 kickoff, restatement of compliance commitment, link to critical policies/hotline</li> <li>• Regional ethical leadership training: front-line managers</li> <li>• Joint email from CCO and Chief Supply Chain Officer to suppliers on survey requirements</li> <li>• Internal code campaign kick-off: rotating space on signs, screensavers, intranet banner ads and employee newsletters</li> <li>• Intranet/newsletter spotlight topics: expense reports, conflicts of interest (quick hit training video)</li> </ul>
Q2	<ul style="list-style-type: none"> <li>• Internal code campaign: Middle managers make final push for 100% completion</li> <li>• Regional ethical leadership training: executives and board</li> <li>• Intranet/newsletter spotlight topics: fraud, harassment</li> </ul>
Q3	<ul style="list-style-type: none"> <li>• Regional ethical leadership training: non-manager employees</li> <li>• Intranet/newsletter spotlight: social media, information security</li> </ul>
Q4	<ul style="list-style-type: none"> <li>• Intranet/newsletter spotlight: gifts &amp; entertainment (with quick hit training video)</li> <li>• Issue supplier survey findings/reports</li> </ul>

\*these are in addition to policy and training campaigns auto-delivered by our compliance management solution (e.g., California Sexual Harassment training delivered on biennial hire anniversary dates)

# IMPLEMENTATION STATUS

## HOTLINE

- Now fully implemented and compliant
- Reporting options: Web portal, anonymous hotline accessible in 7 countries, email, open-door reports still encouraged
- Reports automatically create case for follow-up

## INVESTIGATIONS

- All investigation materials digitized and in central location accessible by appropriate parties
- Implemented escalation and security permissions system based on report type

## POLICIES

- All available in central online library
- Attestations now tracked digitally in one location
- 4 policies updated this quarter
- 5 policies due for review in Q3

## TRAINING

- Mobile training option being rolled out
- Working to link policies to training modules
- Acknowledgements tracked alongside policy attestations and incident reports

YEAR	KEY INITIATIVES
2016	<ul style="list-style-type: none"> <li>• Third-party compliance program assessment and benchmarking</li> <li>• Refresher courses</li> <li>• Supplier screening</li> <li>• Review/refresh risk assessment framework</li> </ul>
2017	<ul style="list-style-type: none"> <li>• Employee culture survey rollout</li> <li>• Refresh code of conduct and code training course</li> <li>• Risk assessment rollout</li> <li>• “Tone in the middle” management training and communications</li> </ul>
2018	<ul style="list-style-type: none"> <li>• Supplier code of conduct drafting and rollout</li> <li>• Expand auditing and monitoring of third parties</li> <li>• Tie compliance to performance measures and incentives</li> </ul>



THANK  
**YOU**

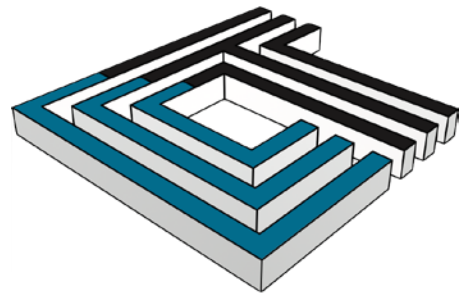
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# OCR Audit Readiness Toolkit

Revised April 2016

David Holtzman  
VP, Compliance Strategies  
CynergisTek, Inc.





CYNERGISTEK

# FACILITY

## HIPAA Incident/Breach Investigation

Name and Title of Individual Completing this RCPO

#	Questions	Answers	Instructions
1	Privacy Incident Number		Format: P(facility #)-yy-mmdd (B) (NB) (FW)
2	Date of Occurrence (date the incident actually occurred)		Format: mm/dd/yyyy
3	Date of Discovery (date incident was discovered by staff, Business Associate, etc.)		Format: mm/dd/yyyy
4	Date Incident Reported (to RCPO)		Format: mm/dd/yyyy
5	Privacy Incident Type		Use drop down menu to select response
6	Location of Incident		Use drop down menu to select response
7	Scope of Incident		Use drop down menu to select response
8	Number of Affected Individuals		Type in the exact number of affected individuals
9	Secured or Unsecured PHI involved		Use drop down menu to select response
10	Details of incident		Type in the details of this incident
11	Business Associate involved?		Use drop down menu to select response

12 ***If "Yes" to Question #11, complete Business Associate information tab***

14	Safeguards in place prior to incident	<input type="checkbox"/> Privacy Rule Safeguards (training, <input type="checkbox"/> Security Rule Administrative Safeguards (risk analysis, risk <input type="checkbox"/> Security Rule Physical Safeguards (facility access controls, workstation security, etc.) <input type="checkbox"/> Security Rule Technical Safeguards (access controls, transmission <input type="checkbox"/> NONE	Place a check mark in the applicable box(es)
----	---------------------------------------	--	--

15 Does the incident meet an exemption?

	A. Good faith, unintentional acquisition, access or use by a workforce member acting under the organization's authority and within his/her scope of authority, and did not result in further use or disclosure of the PHI.	<input type="checkbox"/> This exemption does not apply <input type="checkbox"/> Exemption applies (describe in #16)	
--	--	--	--

	B. Inadvertent disclosure by a person authorized to access PHI at the same Covered Entity, Business Associate, or OHCA in which the Covered Entity participates, and the information was not further used or disclosed.	<input type="checkbox"/> This exemption does not apply <input type="checkbox"/> Exemption applies (describe in #16)	Place a check mark in the applicable box(es)
	C. A disclosure of PHI where the Covered Entity or Business Associate has a good faith belief that the unauthorized individual to whom the disclosure was made would not reasonably have been able to retain such information.	<input type="checkbox"/> This exemption does not apply <input type="checkbox"/> Exemption applies (describe in #16)	
	D. Data is limited to a limited data set that does not include dates of birth or zip codes.	<input type="checkbox"/> This exemption does not apply <input type="checkbox"/> Exemption applies (describe in #16)	
16	If an exemption was acknowledged in #15, provide detailed information to support the exemption.		Document details to support the exemption
17	Comments / Additional Information		Document any additional comments or information concerning the incident
18	Was there a HIPAA Privacy or Security Rule violation?		Use drop down menu to select response
<b><i>If "Yes" to Question #18, proceed to Risk Assessment.</i></b>			
<b><i>If "No" to Question #18, incident documentation is complete.</i></b>			
19	If documentation is complete, list the date this incident is deemed closed.		Format: mm/dd/yyyy

# Business Associate

0

Name of BA

Address

City

State

Zip Code

Contact Name

Contact Phone

Contact E-Mail

# Risk Assessment

0

#	Questions	Answers	Instructions
<b>Nature and Extent of the PHI</b>			
1	What is the nature and extent of PHI involved?		Use drop down menu to select response
	Type(s) of data compromised?	<input type="checkbox"/> Demographic Information <input type="checkbox"/> Financial Information <input type="checkbox"/> Clinical Information <input type="checkbox"/> Other	Place a check mark in the applicable box(es)
2	Demographic data elements compromised?	<input type="checkbox"/> Name <input type="checkbox"/> SSN <input type="checkbox"/> Address/ZIP <input type="checkbox"/> Drivers License <input type="checkbox"/> Other Identifier	Place a check mark in the applicable box(es)
	Financial data elements compromised?	<input type="checkbox"/> Credit Card/Bank Acct # <input type="checkbox"/> Claims Information <input type="checkbox"/> Other Financial Information	
	Clinical data elements compromised?	<input type="checkbox"/> Diagnosis/Conditions <input type="checkbox"/> Lab Results <input type="checkbox"/> Medications <input type="checkbox"/> Other Treatment Information	
3	If "Other" was selected as the response in #1 or #2, above, describe the type of data or data elements involved.		Document details to support selecting "other" in question #1 or #2
<b>The unauthorized person who used the PHI or to whom the PHI was disclosed</b>			
4	Does the person have obligations to protect privacy and security?		Use drop down menu to select response
	Does the person have the ability to re-identify the PHI?		Use drop down menu to select response
5	Was PHI actually viewed or accessed?		Use drop down menu to select response
<b>The extent to which the risk to the PHI has been mitigated.</b>			
	What is the risk to the PHI after mitigation?		Use drop down menu to select response

6	Can the person who received the PHI provide satisfactory assurances that the PHI will not be further used or disclosed or that it will be destroyed?		Document details.
	What level of effort has been expended to prevent future related issues and or to lessen the harm of the actual breach?		Document details.
7	Comments or additional information concerning the Risk Assessment		Document any additional comments or information concerning the Risk Assessment
<b><i>If a breach has occurred, proceed to Breach Notification.</i></b>			
<b><i>If no breach has occurred, incident documentation is complete.</i></b>			
8	If documentation is complete, list the date this incident is deemed closed.		Format: mm/dd/yyyy

# LoProCo Assessment

0

Factor 1	0	Nature and extent of PHI involved
Factor 2	0	Who was the unauthorized person
Factor 3	0	Was PHI actually acquired/viewed
Factor 4	0	Risk to PHI after mitigation
1-2	0	0
1-3	0	0
1-4	0	0
2-3	0	0
2-4	0	0
3-4	0	0
Low	0	
Medium	0	
High	0	
<b>SCORE:</b>	<b>0</b>	

\*\* Score is based on:

Low - 1 point

Medium - 4 points

High - 8.3 points

# Breach Notification

0

#	Questions	Answers	Instructions
1	Date Individual Notice was Provided		Format: mm/dd/yyyy
2	Was substitute notice required?		Use drop down menu to select response
3	If "Yes" on #2, describe the manner in which substitute notice was achieved.		Document details to support completion of substitute notice -or- type "N/A" if substitute notice was not required
4	Was media notice required?		Use drop down menu to select response
5	If "Yes" on #4, describe the manner in which media was notified.		Document details to support media notification -or- type "N/A" if substitute notice was not required
6	Was State Notification required?		Use drop down menu to select response
7	If "Yes" on #6, describe the details of the State Notification.		Document details to support state notification -or- type "N/A" if state notification was not required
8	Were 500 or more individuals involved in this breach?		Use drop down menu to select response
9	If "Yes" on #8, list the date HHS/OCR was notified of breach.		Format: mm/dd/yyyy or leave blank if #10 applies
10	<b>If "No" on #8, HHS/OCR will be notified of breach at the time of annual notification, by Chief Privacy Officer.</b>		
11	Actions taken in response to breach.	<input type="checkbox"/> Adopted encryption technologies <input type="checkbox"/> Changed password/strengthened <input type="checkbox"/> Created a new/updated Security Rule <input type="checkbox"/> Implemented new technical safeguards <input type="checkbox"/> Implemented periodic (non)technical <input type="checkbox"/> Improved physical security <input type="checkbox"/> Performed a new/updated Security <input type="checkbox"/> Provided BA with additional training on <input type="checkbox"/> Provided individuals with free credit <input type="checkbox"/>	Risk  Place a check mark in the applicable box(es)



		<input type="checkbox"/> Revised business associate contract(s) <input type="checkbox"/> Revised policies and/or procedures <input type="checkbox"/> Sanctioned workforce member(s) <input type="checkbox"/> Took steps to mitigate harm <input type="checkbox"/> Trained or retrained workforce <input type="checkbox"/> Other	
12	If "Other" was selected in #11, describe actions taken.		Document details to support the actions which were taken in response to breach
13	Comments / Additional information		Document any additional comments or information concerning the breach
<b><i>Conclusion of Breach Documentation</i></b>			



**Standard Privacy/Information Security Sanctions  
Determination Table**

<b>Category</b>	<b>Level</b>	<b>Points</b>	<b>Score</b>
Occurrence	Employee's first information privacy and/or security violation within the last 12 months	<b>1</b>	
	Employee's second information privacy and/or security violation within the last 12 months	<b>2</b>	
	Employee's third information privacy and/or security violation within the last 12 months	<b>3</b>	
	Employee's fourth information privacy and/or security violation in the last 12 months	<b>4</b>	
Discovery Method	Employee self-reported his/her violation	<b>1</b>	
	Coworker reported employee's violation	<b>2</b>	
	Discovered during a standard or random system audit or reported by outsider (i.e. local pharmacy, business etc...)	<b>3</b>	
	Employee discovered to have violated rules, regulations, and/or policies after a patient reported the issue or incident	<b>4</b>	
Disclosure Medium	The employee disclosed sensitive information verbally	<b>1</b>	
	The employee disclosed sensitive information physically (i.e. discharge instructions, prescription, etc...)	<b>2</b>	
	The employee disclosed sensitive information electronically (i.e. fax, email)	<b>3</b>	
	The employee disclosed sensitive information by 2 or more of the above mediums <b>(If the disclosure was to the employee's personal email or was an image taken with the employee's personal digital device this violation will result in immediate termination.)</b>	<b>4</b>	
Reasoning	The employee accidentally disclosed sensitive information.	<b>1</b>	
	The employee believed (s)he was correctly handling sensitive information	<b>2</b>	
	The employee accessed or used sensitive information inconsistent with his/her job responsibilities and/or beyond minimum necessary to perform his/her duties. The employee chose to ignore policy/procedure/regulations related to proper handling of sensitive information.	<b>3</b>	
	The employee accessed or used sensitive information with the intention of generating personal gain and/or with the intention of causing harm to the patient or was snooping (prying into the private affairs of others). <b>This violation will result in immediate termination.</b>	<b>4</b>	
Patient Involved	1	<b>1</b>	
	2 to 99	<b>2</b>	
	100 to 499	<b>3</b>	
	500 or more	<b>4</b>	
Exposure	Internal – sensitive information was only exposed to employees within the facility	<b>1</b>	
	Local – sensitive information was exposed to local area only (i.e. city)	<b>2</b>	
	Regional – sensitive information was exposed throughout the regional area (i.e. state)	<b>3</b>	
	Widespread – sensitive information was exposed throughout the country and/or internet (i.e. Facebook, Twitter, blog). <b>This violation will result in immediate termination.</b>	<b>4</b>	
Education	The employee has not received formal compliance training.	<b>1</b>	
	The employee has completed information privacy and security training at orientation.	<b>2</b>	
	The employee has completed annual information privacy and security training.	<b>3</b>	
	The employee has completed department specific training, compliance training and orientation.	<b>4</b>	
Investigation and Employee Response	No investigation required.	<b>1</b>	
	The employee was cooperative, helpful and professional when contacted for information regarding the investigation.	<b>2</b>	
	The employee was uncooperative, slow to respond and did not provide requested information when contacting regarding the investigation.	<b>3</b>	
	The employee purposefully mislead the investigation, provided false information, or attempted to cover up the mistake. <b>This violation will result in immediate termination.</b>	<b>4</b>	
	<b>Verbal Warning and possible Privacy/Security re-education</b>	<b>0-7</b>	
	<b>Written Warning and required Privacy/Security re-education</b>	<b>8-19</b>	
	<b>Three (3) day suspension OR Final Written Warning and required Privacy/Security re-education</b>	<b>20-28</b>	
	<b>Termination</b>	<b>29-32</b>	

DRAFT

**UCLA Compliance and Privacy Program**

<b>Clinical Department or Area:</b>						
<b>HIPAA Walkthrough Assessment</b>						
	Always-yes	Usually	Sometimes	Seldom	Never - No	N/A
<b>Printing</b>						
Printer in non-public, secure location						
Print-outs retrieved promptly						
Unnecessary/excess print-outs containing PHI destroyed in timely manner						
<b>Fax / Copier</b>						
Fax/Copiers in non-public, secure location						
Faxes/copies retrieved promptly						
Fax number verified before sending patient information						
Regularly used fax numbers pre-programmed to decrease risk of misdialing						
Faxes sent display confidentiality statement						
Recipient informed what to do if fax received erroneously?						
Fax transmission confirmation is available						
<b>Storage / Disposal</b>						
File cabinets supervised, locked, or in locked rooms						
PHI in binders supervised, in locked cabinet or locked room						
PHI no longer needed is shredded and not placed in the rubbish bin						
Shredders sufficiently available						
Business Associate contracts for shredding services contain approved privacy language						
Documents are accessible on a need to know basis						
If document access is requested, requestor asked to, and able to provide identification and acceptable reason for accessing data						
Access for purpose of disclosure is documented						
<b>Duplication controls</b>						
Copies are stamped as COPY, dated and initialed						
<b>Computers</b>						
Screen protected from unauthorized onlooker viewing						
Computer access of PHI is controlled through the use of passwords						
Access levels correspond to each user's need to access that information						
Employees log out when they are finished accessing information						
Screen savers used and have reasonably short period until screen saver activated						
<b>Telephones</b>						
Voices lowered when discussing PHI. If the discussion is sensitive, a telephone is available where employee cannot be overheard						
Callers asked for identifying information to establish "need to know"?						

**UCLA Compliance and Privacy Program**

<b>HIPAA Walkthrough Assessment</b>						
	Always-yes	Usually	Sometimes	Seldom	Never - No	N/A
Messages left on voice recorders provide call-back information but do not state medical treatment/diagnosis						
<b>Exchange of PHI</b>						
If document access is requested, requestor asked to, and able to provide identification and acceptable reason for accessing data						
Employees understand privacy and confidentiality policies						
Employees attempt to maintain privacy when engaged in discussing private matters						
Minimum necessary information asked on sign-in sheets, i.e., no symptoms, diagnosis, etc.						
PHI sharing is limited to the minimum necessary?						
<b>E-mail</b>						
E-mail sent displays confidentiality statement						
When PHI is sent via e-mail, the subject line contains the word CONFIDENTIAL						
E-mailing sensitive material is avoided						
<b>Mail</b>						
Mail containing PHI is marked confidential						
Mail containing sensitive PHI is hand delivered						
Mail containing PHI is sent in a sealed envelope						
<b>Personnel issues</b>						
If staff are required to wear ID badges, they are worn						
There are notices reminding staff of patient privacy						
Passwords are not shared						
Passwords are secure and not in evidence						
When an employee changes positions but remains at UCLA Health System, PHI accessibility is assessed, and access to those areas no longer part of the employee's duties are removed						
When an employee leaves, the ability to access PHI is removed						
PHI remains within the covered entity, i.e., employees do not remove PHI without following applicable policies						
No PHI is posted, or otherwise in open view to the public						
Desks clear of patient information when unattended						
Employees communicate privacy concerns to manager; HIPAA compliance staff notified, if appropriate						

<b>HIPAA Walk Through Assessment</b>	
	<b>Comments</b>
<b>Printing</b>	
Printer in non-public, secure location	
Print-outs retrieved promptly	
Unnecessary/excess print-outs containing PHI destroyed in timely manner	
<b>Fax / Copier</b>	
Fax/Copiers in non-public, secure location	
Faxes/copies retrieved promptly	
Fax number verified before sending patient information	
Regularly used fax numbers pre-programmed to decrease risk of misdialing	
Faxes sent display confidentiality statement	
Recipient informed what to do if fax received erroneously?	
Fax transmission confirmation is available	
<b>Storage / Disposal</b>	
File cabinets supervised, locked, or in locked rooms	
PHI in binders supervised, in locked cabinet or locked room	
PHI no longer needed is shredded and not placed in the rubbish bin	
Shredders sufficiently available	
Business Associate contracts for shredding services contain approved privacy language	
Documents are accessible on a need to know basis	
If document access is requested, requestor asked to, and able to provide identification and acceptable reason for accessing data	
Access for purpose of disclosure is documented	
<b>Duplication controls</b>	
Copies are stamped as COPY, dated and initialed	
<b>Computers</b>	
Screen protected from unauthorized onlooker viewing	
Computer access of PHI is controlled through the use of passwords	
Access levels correspond to each user's need to access that information	
Employees log out when they are finished accessing information	
Screen savers used and have reasonably short period until screen saver activated	
<b>Telephones</b>	
Voices lowered when discussing PHI. If the discussion is sensitive, a telephone is available where employee cannot be overheard	
Callers asked for identifying information to establish "need to know"?	
Messages left on voice recorders provide call-back information but do not state medical treatment/diagnosis	
<b>Exchange of PHI</b>	

If document access is requested, requestor asked to, and able to provide identification and acceptable reason for accessing data	
Employees understand privacy and confidentiality policies	
Employees attempt to maintain privacy when engaged in discussing private matters	
Minimum necessary information asked on sign-in sheets, i.e., no symptoms, diagnosis, etc.	
PHI sharing is limited to the minimum necessary?	
<b>E-mail</b>	
E-mail sent displays confidentiality statement	
When PHI is sent via e-mail, the subject line contains the word CONFIDENTIAL	
E-mailing sensitive material is avoided	
<b>Mail</b>	
Mail containing PHI is marked confidential	
Mail containing sensitive PHI is hand delivered	
Mail containing PHI is sent in a sealed envelope	
<b>Personnel Issues</b>	
If staff are required to wear ID badges, they are worn	
There are notices reminding staff of patient privacy	
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When an employee changes positions but remains at UCLA Health System, PHI accessibility is assessed, and access to those areas no longer part of the employee's duties are removed	
When an employee leaves, the ability to access PHI is removed	
PHI remains within the covered entity, i.e., employees do not remove PHI without following applicable policies	
No PHI is posted, or otherwise in open view to the public	
Desks clear of patient information when unattended	
Employees communicate privacy concerns to manager; HIPAA compliance staff notified, if appropriate	





**SBAR:**

Reinstated Flight

[http://www.nj.com/news/index.ssf/2016/12/scandal\\_probe\\_on\\_samson\\_flight\\_to\\_cost\\_united\\_24m.html](http://www.nj.com/news/index.ssf/2016/12/scandal_probe_on_samson_flight_to_cost_united_24m.html)

**Completed by:** Walter Johnson

**Date:** 3/26/2017



### SITUATION

United Airlines reinstated flight without using standard process. It is possible flight was reinstated at the request of government official.

### BACKGROUND

- Continental Airlines had a regular flight from Newark, New Jersey to Columbia, South Carolina.
- Due to poor performance, Continental Airlines cancelled this flight before its merger with United Airlines
- In 2012, the flight from Newark Liberty International Airport to Columbia, South Carolina was reinstated.
- In 2012, David Samson became chairman of the Port Authority.
- In 2014, the flight from Newark Liberty International Airport to Columbia, South Caroling was cancelled.
- In 2014, David Samson resigned as chairman of the Port Authority. On MM/DD/YY, the airline decided to reinstate the regular flight.

**SAMPLE**

### ANALYSIS

- On MM/DD/YY, a decision was made to cancel the flight from Newark, New Jersey to South Carolina.
- This decision was supported by financial analysis and approved by Board on MM/DD/YY.
- On MM/DD/YY, the last regular flight from Newark, New Jersey to South Carolina occurred.
- As chairman of the Port Authority, David Samson had the approval authority over United Airlines hangar project.
- Interviews conclude that David Samson would not approve the hanger project unless the flight to from Newark, New Jersey to South Carolina was reinstated.
- Port Authority chairman used his authority over the hanger project to get the flight reinstated.
- The regular flight was reinstated when the David Samson was appointed as chairman of the Port Authority.
- The flight became commonly known as the “chairman’s flight.
- It was cancelled two years after reinstatement which is the same time David Samson resigned as chairman of the Port Authority.

### RECOMMENDATION

Alternatives:

- 1) My recommendation is... Rationale: \_\_\_\_\_.
- 2) An alternative is... Rationale: \_\_\_\_\_.

**Final ROP: Things You Need To Do And  
Suggestions On How To Get Them Done**

**Barbara J. Duffy, Shareholder and Litigation  
Department Chair  
Lane Powell, Seattle WA**

**Nan Impink, Executive Vice President of  
Compliance and Regulatory Affairs  
Sava Senior Care, Atlanta GA**

**Paula Sanders, Principal and  
Healthcare Co-Chair,  
Post & Schell, Harrisburg PA**

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**Overview of Presentation**

- Overview of Substantive Changes in the Final Rule
  - Person Centered Care;
  - Staffing & Competency;
  - Changing Patient Population And Care Needs;
  - Resident Rights;
  - New Grievances Requirements;
  - Discussion about Abuse, Neglect, and Incident Reporting, Timeframes, and Overlaps;

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**Overview of Presentation**

- Overview of Substantive Changes in the Final Rule
  - QAPI Requirements.
  - Compliance & Ethics;
  - Survey And Enforcement; and
- Policy Writing – Tips, Suggestions And Plan of Attack

*Note: The presenters thank the American Health Care Association and in particular, Dr. David Gifford for permission to use various materials and slides with this presentation.*

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## Overview of Changes in Final Rule

### Overview of Changes in Final Rule

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- ### Changes to ROP Sections Within Final Rule
- Basis & Scope( § 483.1)
  - Definitions ( § 483.5)
  - Resident Rights ( § 483.10)
  - Abuse & neglect, ( § 483.12)
  - Admission, transfer, and discharge rights ( § 483.15)
  - Resident assessment ( § 483.20)
  - Comprehensive person centered Care planning ( § 483.21)
  - Quality of life ( § 483.24)
  - Quality of care § 483.25)
  - Physician services ( § 483.30)
  - Nursing services ( § 483.35)
  - **Behavioral health services ( §483.40)**
  - Pharmacy services ( § 483.45)
  - Laboratory, radiology, and other diagnostic services ( § 483.50)
  - Dental services ( § 483.55)
  - Food & nutrition services ( § 483.60)
  - Specialized rehabilitative services ( § 483.65)
  - Administration ( § 483.70)
  - **Quality assurance and performance improvement ( §483.75)**
  - **Infection control ( §483.80)**
  - **Compliance and ethics ( §483.85)**
  - Physical environment ( § 483.90)
  - Training requirements ( § 483.95)
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- ### Phase 1: *Effective Date* of the Final Rule (11-28-16)
- Phase 1
- Phase 1 (\* this section is partially implemented in Phase 2 and/or 3)
- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>- Resident Rights and Facility Responsibilities*</li> <li>- Freedom from Abuse Neglect and Exploitation*</li> <li>- Admission, Transfer and Discharge*</li> <li>- Resident Assessment</li> <li>- Comprehensive, Person-Centered Care Planning*</li> <li>- Quality of Life</li> <li>- Quality of Care*</li> <li>- Physician Services</li> </ul> | <ul style="list-style-type: none"> <li>- Nursing Services*</li> <li>- Pharmacy Services*</li> <li>- Laboratory, radiology and other diagnostic services</li> <li>- Dental Services*</li> <li>- Food and Nutrition*</li> <li>- Specialized Rehabilitation</li> <li>- Administration (Facility Assessment – Phase 2)*</li> <li>- Quality Assurance and Performance Improvement* - QAA Committee</li> <li>- Infection Control – Program*</li> <li>- Physical Environment*</li> </ul> |
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**Phase 2: 1 Year Delayed Effective Date (Nov. 2017)**  
**Phase 3: 3 Year Delayed Effective Date (Nov. 2019)**

## Phases 2 and 3

Phase	Primary Implementation
Phase 2	<ul style="list-style-type: none"><li>• Behavioral Health Services*</li><li>• Quality Assurance and Performance Improvement* - QAPI Plan</li><li>• Infection Control – Facility Assessment and Antibiotic Stewardship **</li><li>• Physical Environment- smoking policies *</li></ul>
Phase 3	<ul style="list-style-type: none"><li>• Quality Assurance and Performance Improvement* - Implementation of QAPI</li><li>• Infection Control – Infection Control Preventionist *</li><li>• Compliance and Ethics</li><li>• Physical Environment- call lights at resident bedside *</li><li>• Training *</li></ul>

\*This section is partially implemented in other phases.

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## Significant Changes

- Person Centered Care;
- Staffing & Competency;
- Changing Patient Population And Care Needs;
- Resident Rights;
- New Grievances Requirement and Documentation Risks
- QAPI Requirement and Survey Issues
- Discussion about Abuse, Neglect, and Incident Reporting, Timeframes, and Overlaps;
- Compliance & Ethics.

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## Person Centered Care Person Centered Care

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**Person Centered Care**

- Resident Representative Changes;
- 48-Hour Baseline Care Plan;
- Comprehensive Care Plan;
- Discharge Planning Process.

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**Changes in Resident Representative  
( § 483.10(b)(1-4))**

- Representative has the right to exercise the resident's rights to the extent those rights are properly delegated to them;
- Resident retains those rights not delegated, including the right to revoke a delegation;
- Must treat Representative decisions as decisions of the Resident BUT not beyond what is required by court or delegated by Resident; and
- Must report concerns that Representative not acting in best interests of Resident.

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**48-Hour Baseline Care Plan**

- New requirement - Phase 2
- Initial set of instructions to facilitate smooth transition of care and to provide effective, person-centered care starting at admission

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### 48-Hour Baseline Care Plan

- Minimum of 6 key elements:
  - Initial goals based on admission orders;
  - All physician orders, including medications and administration schedule;
  - Dietary orders;
  - Therapy services;
  - Social services; and
  - PASARR recommendations, if PASARR completed.
- Could be replaced by the comprehensive care plan if done within 48 hours of admission.

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### Comprehensive Care Plan ( § 483.21)

- Phase 1 requirement
- Develop and implement a comprehensive, person-centered care plan for each resident, consistent with the resident rights set forth in the ROPs:
  - Include measurable objectives and timeframes to meet resident's needs (medical, nursing, mental and psychosocial) as identified in the comprehensive assessment;
  - Describe at a high level services to be provided as well as resident's goals and preferences;
- Include summary of resident's strengths, goals, desired outcomes, life history, personal and cultural preferences, PASARR findings and specialized services needed.

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### Comprehensive Care Plan

- Prepared and reviewed by IDT that now must include, in addition to attending physician and RN with responsibility for that resident, nurse aide and member of food and nutrition services:
  - Include resident and their representative(s) to the extent practicable; document an explanation if not practicable
- Reviewed or revised after comprehensive assessment and quarterly review assessment

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**Comprehensive Care Plan**

- Rooted in resident's rights (483.10(c))
  - Participate in developing the plan, be informed of the care to be provided, and participate in decision-making, in language he or she can understand;
  - Identify individuals and roles to participate, request meetings, request revisions to plan;
  - Participate in establishing goals and expected outcomes of care, including duration, frequency, type, and amount;
  - Be informed of care options, risks, benefits, alternatives.

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**Comprehensive Care Plan**

- Rooted in resident's rights (483.10(c)) (con't.)
  - Refuse or discontinue treatment;
  - Self-administer meds if IDT determines clinically appropriate;
  - Be informed in advance of changes to the plan;
  - Receive the services in the plan; and
  - Review and sign off on significant changes.

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**Discharge Planning Process ( § 483.15)**

Purpose & Intent

- Partner with the resident to maximize the likelihood that they may be able to return to the community, if they want to, without complications.

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### Discharge Planning Process #1

#### Required steps

- Create an IDT which includes the resident;
- Evaluate the resident's discharge potential, goals, and needs;
- Document results of discharge plan;
- Create a discharge plan (see below for required content);
- Update discharge plan;
- Share discharge plan with the resident

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### Discharge Planning Process #1 (con't.)

- Prepare resident & their representative for discharge;
- Notify Ombudsman of *all* discharges and transfers;
- Document reason for discharge or transfer
- Provide required information to receiving provider; and
- Complete a discharge summary.

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### Information Accompanying Resident at Discharge or Transfer

- Ensure specified information is copied and available to go with resident:
  - Contact information of practitioner responsible for care;
  - Resident representative information;
  - Advance Directive Information;
  - Special instructions or precautions;

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**Information Accompanying Resident at Discharge or Transfer**

- Ensure specified information is copied and available to go with resident: (con't.)
  - Most recent comprehensive care plan goals;
  - Resident's discharge summary;
  - Other documents as needed; and
  - Resident's consent to share information.
- Develop checklist to ensure all required information is sent

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**Discharge Summary Template: Phase 1 Requirement**

- Key elements:
  - Recapitulation of stay (diagnoses, pertinent lab tests and results, course of illness/treatments/therapy);
  - Final summary of resident's status (specified items from comprehensive resident assessment, including needs, strengths, goals, preferences);

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**Discharge Summary Template: Phase 1 Requirement**

- Key elements: (con't.)
  - Medication reconciliation;
  - Post-discharge plan of care (where individual will reside, arrangements for follow-up care, consent to share discharge summary); and
  - Other elements as determined by facility.

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**Staffing & Competency**

**Staffing & Competency**

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**Staffing and Staff  
Competency Requirements**

- Quality of Care ( § 483.25);
- Nursing Services ( § 483.35);
- Administration ( § 483.70); and
- Training Requirements ( § 483.95).

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**Rule Text:**

§ 483.25 Quality Of Care- "Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. **Based on the comprehensive assessment of a resident**, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following":\*

- Vision & Hearing;	- Prostheses;
- Skin Integrity;	- Pain Management;
- Mobility;	- Dialysis;
- Incontinence;	- Trauma Informed Care;
- Assisted Nutrition & Hydration;	- Bed Rails
- Respiratory Care;	

\* Emphasis supplied

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**Quality Of Care**

- Very specific requirements on addressing certain conditions;
- All implemented in Phase 1 except trauma informed care (Phase 3); and
- “Based on the comprehensive assessment of a resident”  
–Common phrase throughout the rule.

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**Rule Text on Resident/Facility Assessment**

- § 483.35 (Nursing Services) - The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at 483.70(e).

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**Rule Text on Resident/Facility Assessment**

- § 483.70(e) Facility assessment. The facility must conduct and document a facility wide assessment to determine what resources are necessary to care for its residents competently during both day to- day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include: [resident population, facility resources, and a facility and community based risk assessment, utilizing an all hazards approach.

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### Competencies of Staff and Assessments

- Adds a “competency” requirement for determining the “sufficiency” of nursing staff, based upon facility assessment:
  - which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of individual care plans.

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### Competencies of Staff and Assessments

- Facility must ensure staff competency in providing treatment and care in accordance with professional practice; and
- Must review the current processes around vision & hearing, skin integrity, mobility, incontinence, colostomy, urostomy & ileostomy, assisted nutrition & hydration, parenteral fluids, respiratory care, prostheses, pain management, dialysis, trauma informed care, and bed rails.

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### Training Requirements ( § 483.95)

- Largely Phase 3, except Phase 1 requires:
  - Abuse/Neglect/Exploitation (c)
  - Dementia Management expanded beyond nurse aides to other direct staff (g)(2)
  - Care of the cognitively impaired (g)(4)
  - Feeding Assistant requirement. (See p. 68870)

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**Changing Patient Population  
and Care Needs**

**Changing Patient Population  
And Care Needs**

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**Changing Patient Population  
and Care Needs**

- Physical environment must accommodate patient population and care delivery innovation;
- Physician services;
- Pharmacy needs addressed;
- Infection control; and
- Behavioral health.

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**Physical Environmental ( § 483.90)**

- Center must be equipped to allow residents to call for staff through a communication system which relays the call directly to a staff member or to a centralized staff work area from each resident's bedside;
- Establish policies regarding smoking, smoking areas and smoking safety that also considers non-smoking residents; and
- Conduct regular inspection of all bed frames, mattresses, and bed rails, to identify areas of possible entrapment.

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**Physical Environmental ( § 483.90)**

- Any facility newly certified or approved for construction (including remodeling) after November 28, 2016, must have bedrooms with no more than two residents AND must have a private bath including at least a toilet and sink for each resident room:
  - A bathroom that is located between two patient rooms and is accessible from each does not meet this requirement; and
  - For purposes of this requirement, a “renovated or remodeled area” means an area that requires residents to be moved out of the area to complete work:
    - For example, if a facility is conducting a major renovation on a wing and all patients must be relocated, included in that renovation must be eliminating any 4-bed rooms and ensuring that each patient room is equipped with its own bathroom including at least a sink and a toilet.

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**Physician Services ( § 483.30)  
Phase 1**

- CMS Summary: We are allowing attending physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals and therapy orders to therapists.
- Additional Highlights:
  - The attending physician can delegate the writing of order to Dietician and to therapists per their state’s scope of practice; NPs and PAs and covering physicians cannot delegate authority; only the attending physician.

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**Physician Services ( § 483.30)  
Phase 1**

- Additional Highlights:
  - Physician must approve an admission however an NP or PA can now write the admitting orders

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**Intent & Purpose ( § 483.45 )**

Reduce medication prescribing and administration that increases the risk of adverse events in elderly

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**Pharmacy Services ( § 483.45 )**

- The pharmacist must review a resident's medical chart during each monthly drug regimen review;
- Revision of existing requirements regarding "antipsychotic" drugs to refer to "psychotropic" drugs with requirements to reduce or eliminate their need;
- New MRR process where pharmacist must identify and documents "irregularities";

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**Pharmacy Services ( § 483.45 )**

- Must provide a written report regarding irregularities to the attending physician, medical director, and DON; and
- The attending physician must document: that he/she reviewed the identified irregularity, the action taken to address the irregularity, or the reason for not changing the medication related to the identified irregularity.

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**Drug Regime Review Process**

Phase I

- Need a Drug regime review P&P
  - **psychotropic drug** defined;
  - “**irregularity**” defined;
- Training to staff and physicians/prescribing practitioners on monthly drug regimen (review P&P and new regulatory requirements);

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**Drug Regime Review Process**

- Audit monthly DRR, medication error rates to be consistent with policies, procedures and regulatory requirements; and
- Must Incorporate identified areas for process improvement into QAPI.

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**“Irregularity” Defined**

What is considered an irregularity (e.g. including, but not limited to, unnecessary drug criteria):

- Excessive dose (including duplicate drug therapy);
- Excessive duration;
- Without adequate monitoring;
- Without adequate indications for its use; and
- Use in presence of adverse consequences which indicate dose should be reduced or discontinued.

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### **Change Psychotropic Medication**

A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) Anti-psychotic;
- (ii) Anti-depressant;
- (iii) Anti-anxiety; and
- (iv) Hypnotic.

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### **Infection Control ( § 483.80)**

▪ CMS Summary: We are requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist.

- Additional Highlights:
- Expanded required elements of facility IPCP.
  - Annual review of facility IPCP and update program as necessary.

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### **Infection Control**

- Additional Highlights: (con't.)
- Specific qualification requirements for Infection Preventionist.
  
  - Infection Preventionist must be member of QAA committee and report on IPCP on a regular basis.

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**Laboratory, Radiology, and Other Diagnostic Services ( § 483.50)**

- Facility must promptly notify the ordering physician, PA, NP, or clinical nurse specialist of lab results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders; and
- Physician extenders can order radiology and other diagnostic services and must be promptly notified of results falling outside of clinical reference ranges in accordance with facility policies and procedures.

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**Behavioral Health Services ( § 483.40)**

- Develop and implement process to meet requirements at § 483.40 (b)(1) and (b)(2) related to providing services to a resident to correct an assessed problem related to mental disorder or psychosocial adjustment difficulty and, if an assessment did not reveal a mental or psychosocial adjustment difficulty, prevent an occurrence of such in a resident if clinically unavoidable;
- Facility must provide medically-related social services for highest practicable well-being as necessary; and
- Also dementia training to all direct staff (see § 483.95).

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**Resident Rights**

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**§ 483.10 Resident Rights**

- Reasonable access to electronic communication
- Advance directives § 483.10(b)(8)
- Develop Grievance policy with “grievance official”
- Revise visitation rights;
- Accommodate needs of LGBT residents and same sex spouses;
- Pre-dispute Arbitration Prohibition???

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**Resident Rights – Facility Responsibilities**

- Planning and implementing care: Places much more emphasis on person-centered care and the inclusion of residents in the care planning process;
- Affirmative action to inform residents of a change of physician;
- Written policies and procedures regarding visitation and restrictions visitation rights, including any clinically necessary or reasonable restriction or limitation or safety restriction or limitation when consistent with the regulations;

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**Resident Rights – Facility Responsibilities**

- New rules regarding deposit of residents’ funds and notices;
- 3 years of survey and complaint documents available;
- Posting of a list of agencies and advocacy groups; and
- 60 days advance notice when there are changes in charges.

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**Grievances and Grievance Process**

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**Grievances and Grievance Policies  
( § 483.10(j))**

- Incorporates the facility responsibilities at existing § 483.10(f) and require that facilities ensure that residents know how to file grievances;
- Must establish a grievance policy to ensure the prompt resolution of grievances;
- Identify a Grievance Officer;
- Provide a copy of this policy upon request, as well as make information about filing grievances available to residents;

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**Grievances and Grievance Policies  
( § 483.10(j))**

- Written Grievance Decisions –
  - Date grievance received and summary of resident's grievance;
  - Steps taken to investigate the grievance;
  - Summary of the pertinent findings or conclusions regarding concerns;
  - Statement as to whether the grievance was confirmed or not confirmed;
  - Any corrective action taken or to be taken by the facility as a result of the grievance; and
  - Date of written decision.

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**Grievances and Grievance Policies  
( § 483.10(j))**

Facility *required to take a number of actions in response to a grievance*, including:

- Preventing further violations of resident rights during an investigation;
- *Immediately reporting allegations* of neglect, abuse (including injuries of unknown source), and/or misappropriation of resident property, by anyone furnishing services on behalf of the facility, to the administrator of the facility and as required by state law;

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**Grievances and Grievance Policies  
( § 483.10(j))**

- Ensuring that all *written grievance decisions* include the required information;
- Taking *appropriate corrective action* in accordance with state law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction confirms a violation of any of these residents' rights within its area of responsibility; and
- Maintain *3 years of decisions* (... "evidence demonstrating the resolution of complaints and grievances").

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**42 C.F.R. § 483.10(j) –  
Grievances and Grievance Policies**

- Develop Policy and Procedure related to Grievance policy; and
- Establish a process for responding to grievances by family and or residents.

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**Reporting on Allegations of Abuse / Neglect / Exploitation / Injuries of Unknown Origin (A/N/E/loUO)**

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**Knowledge Check**

- The new rule says reasonable suspicion of a crime and all allegations of A/N/E must be reported in how long:
  - A) All A/N/E immediately, and crimes within 24 hours;
  - B) Abuse within 2 hours and crimes within 5 days;
  - C) It depends on how serious the crime or A/N/A allegations are;
  - D) None of the above.

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**Freedom From Abuse, Neglect, and Exploitation (A/N/E) ( § 483.12)**

- Facilities Obligations:
  - Have a process for ensuring that residents are free or at the least restrictive level of chemical restraints;
  - Have a process for ensuring that staff are qualified and in good standing;
  - Develop P&P related to the prohibition of abuse, neglect and exploitation; and
  - Train staff on abuse, neglect and exploitation.

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### New Definitions Around Abuse, Neglect, and Exploitation (A/N/E)

- “abuse”
- “adverse event”
- “exploitation”
- “misappropriation of resident property”
- “mistreatment”
- “neglect”
- “person-centered care”
- “resident representative”
- “sexual abuse”

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### Freedom From Abuse, Neglect, and Exploitation (A/N/E/loUO) ( § 483.12 )

Note change in reporting timing:

(c)(1) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must ... Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are *reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury*, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

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### Reporting Requirements – Keeping Them Straight

- The final rule has included Elder Justice Act reporting obligations, as well as reporting obligations in situations of abuse, neglect, exploitation, mistreatment, injuries of unknown origin and misappropriation; and
- Time frames to report to State Agency abuse and serious bodily injury is much shorter than was previously the case.

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## Elder Justice vs State Reporting Obligations

ELDER JUSTICE ACT REPORTING TO THE STATE AGENCY AND LAW ENFORCEMENT	TIMEFRAME FOR REPORTING ABUSE, NEGLIGENCE, ETC to the STATE AGENCY ENFORCEMENT
Must report to Law Enforcement and The State Agency events which cause reasonable suspicion that a crime has been committed <b>which results in serious bodily injury</b> within <b>two 2 hours</b> .	Alleged violations of abuse or events <b>which result in serious bodily injury</b> must be reported immediately to the State Agency, but not later than <b>two (2) hours</b> after the allegation is made.
Must report to Law Enforcement and the State Agency events which cause reasonable suspicion that a crime has been committed <b>which does not result in serious bodily injury</b> within twenty-four (24) hours.	Alleged violations of neglect, exploitation, mistreat, including injuries of unknown origin or allegations that do not involve abuse or result in serious bodily injury must be reported to the State Agency not later than <b>twenty-four (24) hours</b> after the allegation is made

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## Examples

EXAMPLES	ELDER JUSTICE ACT	STATE AGENCY REPORTING
Theft of money	Yes, within 24 hours	Yes, within 24 hours
Assault with serious injury	Yes, within 2 hours	Yes, within 2 hours
Unwitnessed Fall without serious injury	No, unless suspicion of a crime	Yes, within 24 hours
Small bruise	Yes, if suspicion of a crime. No, if no suspicion of a crime	Yes, within 24 hours
Damage to wheelchair	Yes, if suspicion of a crime (intentional damage to property), No, if damage does not create reasonable suspicion of a crime	No

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## Examples

EXAMPLES	ELDER JUSTICE ACT	STATE AGENCY REPORTING
Resident left on bed pan for three hours	No, unless suspicion of a crime (criminal neglect?)	Within 2 hours if serious bodily injury. Within 24 hours if no injury
Alleged verbal abuse	Yes, within 24 hours	Within 2 hours
Resident fails to receive medication	No, unless suspicion of a crime (criminal neglect?)	Within 24 hours, unless serious bodily injury

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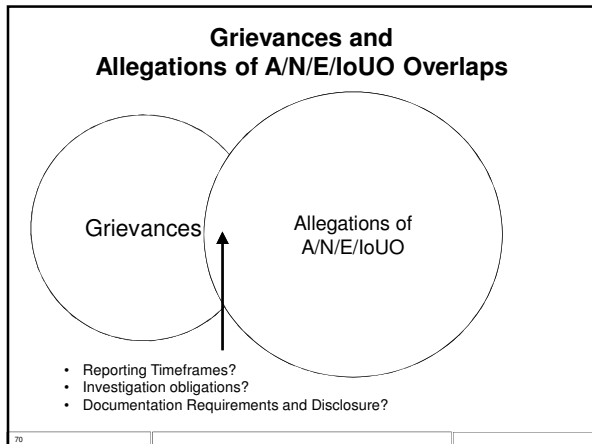
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### QAPI (Quality Assurance and Performance Improvement)

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### Quality Assurance and Performance Improvement ( § 483.75)

- CMS Final Rule (Phase 3 implementation November 2019):
  - “We are requiring all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.”
- CMS explains in the preamble discussion that proposed 42 C.F.R. § 483.75 would “establish [the] programmatic standards” “relating to facilities’ QAPI program[s]” required by Section 6102 of the Affordable Care Act (“ACA”).

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**Quality Assurance and Performance Improvement ( § 483.75)**

- 483.70(d) Governing body.  
....(3) The governing body is responsible and accountable for the QAPI program, in accordance with § 483.75(f). [ § 483.70(d)(3) will be implemented beginning November 28, 2019 (Phase 3)]

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**Quality Assurance and Performance Improvement ( § 483.75 )**

- QA&A committee – all provisions except the inclusion of the infection prevention control officer (note: this term varies throughout the rule and AHCA will request clarification from CMS);
- State may not require disclosure of the records of the committee except related to requirements of the committee (e.g., who is on committee; that committee meets as required; etc.); and
- Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

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**QAPI – Documentation and Survey Access To It**

- (a) ...The facility must—
- 1) *Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;*
  - 2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

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**QAPI – Documentation and Survey Access To It**

- (a) ...The facility must— (con't.)
- 3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and
  - 4) *Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements* to a State Survey Agency, Federal surveyor or CMS upon request.

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**CMS Excerpts in Response to Final Rule Comments (p.68805-7)**

- We have attempted to strike an appropriate balance between concerns about inappropriate use of QAPI materials and our obligation to provide effective oversight of Medicare and Medicaid participating facilities.
- The expectation that facilities will implement a QAPI program that meets those standards is clear, and facilities must be able to demonstrate that they have implemented their QAPI plan and have an effective, ongoing QAPI program.

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**CMS Excerpts in Response to Final Rule Comments (p.68805-7)**

- It is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation. At the same time, we cannot ignore our obligation to ensure that facilities implement their QAPI plan, and continue to modify and implement that plan over time. What we require is satisfactory evidence that a facility is implementing its QAPI plan and maintaining an ongoing QAPI program. We further articulated in the proposed rule what sort of evidence and documentation we believe may be necessary to demonstrate compliance.

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Compliance & Ethics

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**Compliance and Ethics Program ( § 483.85)  
Phase 3**

- Must have written standards for compliance and clear reporting path for suspected violations of compliance and ethics;
- Must designate a compliance and ethics contact;
- Must identify a high level person to oversee with the program;
- Sufficient resources and authority to oversee compliance;

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**Compliance and Ethics Program ( § 483.85)  
Phase 3**

- Effective communication of compliance standards to all staff;
- Audit and monitoring system;
- Publicize a reporting system;
- Annual review of compliance and ethics program and its efficacy;

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**Compliance and Ethics Program ( § 483.85)  
Phase 3**

- Consistent enforcement through appropriate disciplinary action;
- Mandatory annual training on compliance and ethics; and
- Designate Compliance liaisons in each facility.

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**Survey and Enforcement**

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**Terminology**

- CMP – Civil money penalty
- CMS – Centers for Medicare and Medicaid Services
- DPNA – Denial of payment for new admissions
- IJ – Immediate jeopardy
- PD – Per day
- ROPs - Requirements of Participation
- S/S –Scope and Severity
- SNF – Skilled nursing facility
- SQC – Substandard quality of care
- SSA – State survey agency
- 2567 – Statement of deficiencies

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### Poll

- Should Compliance be involved in the survey process?
- Do you get survey information?
- Does your Board get survey information?

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### Increased Enforcement a Reality

- Marked increase in citations and sanctions
- *Marked increase in CMS civil money penalties*



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### Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

- Intended to improve “effectiveness” of CMPs and maintain “deterrent effect” of CMPs
- Requires annual “adjustment” of CMPs using October Consumer Price Index for all Urban Consumers (CPI-U)
- First increase was in 2016; most recent increase effective February 3, 2017 (82 Fed. Reg. 9174, 2/3/2017)

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### Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

- Secretary of covered agency may provide lesser CMP by less than the new formula through a rulemaking only if:
  - Secretary finds that increasing penalty by required amount will have a negative economic impact or that the social costs outweigh the benefits and
  - Director of the Office of Management and Budget (OMB) concurs with this analysis

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### Impact of Inflation Adjustment Act

- CMS CMPs for surveys have increased astronomically

	Pre-August 2016	August 1, 2016	February 3, 2017
Cat.2 Per Day	\$50 - \$3,000	\$103 - \$6,188	\$105 – \$6,289
Cat. 2 Per Instance	\$1,000 - \$10,000	\$2,063 – \$20,628	\$2,097 - \$20,965
Cat. 3 Per Day	\$3,050 - \$10,000	\$6,291 - \$20,628	\$6,394 - \$20,955
Cat. 3 Per Instance	\$1,000 - \$10,000	\$2,063 – \$20,628	\$2,097 - \$20,965

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### Federal Scope and Severity Grid

	Isolated	Pattern	Widespread
Immediate Jeopardy To Resident Health Or Safety	PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	<b>J</b> PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	<b>K</b> PoC: Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2
Actual Harm That Is Not Immediate Jeopardy	PoC: Required: Cat. 2 Optional: Cat. 1	<b>G</b> PoC: Required: Cat. 2 Optional: Cat. 1	<b>H</b> PoC: Required: Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt
No Actual Harm With Potential For More Than Minimal Harm That Is Not Immediate Jeopardy	PoC: Required: Cat. 1 Optional: Cat. 2	<b>D</b> PoC: Required: Cat. 1 Optional: Cat. 2	<b>E</b> PoC: Required: Cat. 2 Optional: Cat. 1
No Actual Harm With Potential For Minimal Harm	No PoC No remedies Commitment to Correct Not on CMS-2567	<b>A</b> PoC: No remedies	<b>B</b> PoC: No remedies
Substandard Quality of Care (F221-226; F240-258; F309-334)			
Out of Compliance			
Substantial Compliance			

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### New CMS CMP Analytic Tool

- New approach to federal per day (PD) CMPs
- Begin CMP on 1<sup>st</sup> day noncompliance is documented, *even if that date precedes the first day of the current survey*
  - Unless facility can demonstrate that it corrected the noncompliance prior to the current survey (past noncompliance)

CMS Survey & Certification Memo, "Civil Money Penalty (CMP) Analytic Tool and Submission of CMP Tool Cases," S&C: 15-16-NH (Dec. 19, 2014)

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### Starting the PD CMP

- Calculate the start date for the proposed CMP with the "first supportable date of noncompliance, as determined by the evidence documented by surveyors in the statement of deficiencies (CMS form 2567)"
- Surveyors instructed to "determine the earliest date for which supportable evidence shows that the non-compliant practice began"

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### Ambiguity About Start of Deficient Practice

- CMS analysts will contact state agency if start date is ambiguous or not clearly identified and supportable, to see if start date can be determined
- CMS analysts required to document their discussions and conclusion with the state agency

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**If Start Date Not Determinable**

- If start date cannot be determined, then PD CMP would start on 1<sup>st</sup> day during the survey on which the survey team identified the noncompliant practice
  
- If the team cannot document the first day of noncompliance, then the CMP should start on the day the noncompliance was observed and documented at the time of the current survey

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**CMP Culpability Add-Ons**

- Neglect, indifference, or disregard for resident care, comfort or safety
  - SNF responsible and culpable for actions of its management and staff, and contract staff
  
- Failure to act culpability amount up to \$500
  - If management officials, e.g., administrator, director of nursing, facility owners, and/or the facility's governing body knew of problems but failed to act

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**CMS: Past Noncompliance**

- Reduce a CMP by 50% if:
  - (i) self-reported noncompliance to CMS or State before it was otherwise identified by or reported to CMS or State; and
  
  - (ii) correction of the self-reported noncompliance occurred within 15 days of the incident. 42 C.F.R. § 488.438

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**Get Credit for Correcting Past Noncompliance**

- Treat any incident that results in reporting to SSA as you would if it was on your 2567
- Develop corrective action and document monitoring and auditing for ongoing compliance
- Give evidence to surveyors at the time of the survey that a monitoring plan was implemented and maintained to assure continued compliance

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**How to Read the 2567**

- What are the deficiencies?
- What are the regulatory violations?
  - Federal
  - State
- What is the best way to respond?

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**“Required” POC Elements**

- What corrective action(s) will be accomplished *for residents affected by the deficient practice*?
- How will you identify *other residents* having the *potential to be affected by the same deficient practice* and corrective actions?
- What measures will be put in place or system changes will you make to ensure that the *deficient practice does not recur*?

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**“Required” POC Elements**

- How will the corrective action be monitored to ensure the *deficient practice will not recur, i.e.*, what quality assurance programs will be established?
  
- Dates when the corrective action will be completed.

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**Strategies for Preparing Effective POCs**

- Less is more
  
- Read the F Tags *and* the state tags
  
- Don't be afraid to have your POC rejected
  
- Be responsive and responsible
  - Don't overpromise
  - Don't admit liability

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**Strategies for Preparing Effective POCs**

- Don't go overboard with policies, procedures and plans of correction
  
- Keep your date of compliance as short as possible
  - Begin implementing corrective action during the survey and document corrections (*e.g.*, in servicing of staff)

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**Best Practices for Evaluating,  
Writing, Revising and Deleting  
Facility Policies**

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**Possible Action Plan Outline**

- Executive Level Briefing on the Rule and Requirements
  - Time Table
  - See Attachment
- Team Development – Create and Set Up Your Team
- Identify Affected Facility and Company Policies

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**Possible Action Plan Outline**

- Identify Affected Positions, Job Descriptions, or Needed New Positions
- Training (Lots of it!)
- Compliance and Ethics Program
- QAPI

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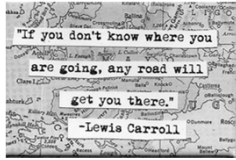
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### Best (and Worse) Practices

- Before you start walking, you better know where you are going !!!



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### Best Practice – What Do You Have / What Do You Need

- You need to have an inventory of the Facility's current policies
- Need a listing:
  - “New” policies that are needed because of new regulations/additions
  - Policy revisions that are needed because of regulation changes
- AHCA Playbook provides much of that listing

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### Best Practice – Understand What Is Required (Exactly)

- You can't draft a new policy or revise a policy if you have not read AND are not looking at the regulatory text while you do it.
- It also will help to know what changed in the new regulation and (sometimes) why CMS thought they should change the rule.
- The revised text is found in the Compliance Tool.
- The Fed. Reg. contains CMS's response to comments, S & C 17-07 has the SOM revisions, and the CMS handout has areas of emphasis.

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### Best Practice – Teamwork

- Not in a dark room
- Consider a policy Committee
- A interdisciplinary staff team is needed because:
  - Too much work for a single person
  - Many changes affect multiple areas and their input is critical (nursing and CNA, Physician and nursing, etc.)
  - Two, three, four or ten heads are better than one
  - You need buy in and investment from key staff
  - BUT – There needs to be a CAPTAIN in charge of all policies and then each policy or policy area



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### Basic Policy Elements

- Policy Title
- Rationale – briefly explains why the policy exists or why a new policy was made/changed
- Definitions – key words and terms to prevent misunderstandings
- Scope statement – explains whether the policy is limited to certain individuals, certain areas, or is applicable to whole Facility

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### Basic Policy Elements

- Policy Language or Requirements
- Reference Documents – Any regulations or cross-references to Facility or company policies
- Revision and Accountability Information

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### Best Practice – Policy Content

- KEY– WHAT IS REQUIRED ( FOR NOW ONLY THAT!!!)
- Do you even need a “new” policy ? Eliminate unnecessary or duplicate documents if you can.
- Addition through subtraction - Do you have opportunities to combine policies under the new regs?
- Don't reinvent the wheel, but know enough to know if your riding on a flat tire.

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### Best Practice – Policy Content

- Use formatting to increase readability – Section headings, bullets or lists, images or tables
- Create (and then use) a Single Template
- Limit policies to one or two pages ideally (or divide)
- Use bullets and lists

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### Best Practice – Policy Content

- Make sure the title describes the content accurately
- Keep sentences short (RoFt – 21 words) and paragraphs short (RoFt – 4 to 6 lines)
- AVOID use long multi-syllable words
- CAREFULLY USE vague modifiers like proper, appropriate, timely, normal, reasonable, etc.

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**Best Practice – Policy Draft Review**

- Draft should be reviewed by multiple individuals
- Does the Policy Comply with text of regulation?
- Can the policy be implemented by the staff you have with the staff you have ?

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**Best Practice – Policy Draft Review**

- Try to ensure these initial policies don't only work if your staff become super-humans overnight
- What ever you do – DO NOT OVERPROMISE!!!!
- Track the revisions and versions of your current and new policies

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**Best Practice – Policy Implementation**

- Your (nice and shiny) new policy does not help the Facility at all if no one knows it exists
- There should be standard process for informing staff of new policies or revisions
- Policy also doesn't help if staff are not training on what the policy does or requires

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**Best Practice – Policy Implementation**

- Training will be critical to success
- Do you have process or tool to assess staff's understanding and knowledge?
- What is the remedial "loop" when policies are not known, understood, or properly implemented?

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**Final ROP: Things You Need To Do And Suggestions On How To Get Them Done**

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# Is Your Security Incident a Data Breach? Uncle Sam Wants to Know

**Panelists:**

Patricia (PC) Shea, Partner, K&L Gates  
Laura Merten, Chief Privacy Officer, Advocate Health Care  
Asra Ali, Compliance and Risk Manager, HealthScape Advisors  
Mahmood Sher-Jan, CEO, RADAR, Inc.

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## Agenda

**Each Panelist will Discuss a Topic, Followed by a Brief Break and Open Discussion**

- Patricia (PC) Shea, Partner, K&L Gates
- Laura Merten, Chief Privacy Officer, Advocate Health Care
- Asra Ali, Compliance and Risk Manager, HealthScape Advisors
- Mahmood Sher-Jan, CEO, RADAR, Inc.
- BREAK
- Panel Discussion



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K&L GATES

### Basic Framework & Compliance Tips Navigating HIPAA

Patricia Shea

patricia.shea@klgates.com

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K&L GATES

**THE FRAMEWORK**

- Health Insurance Portability & Accountability Act of 1996 (HIPAA)
- Implementing Regulations
  - Privacy Rule – oral, documents, electronic
  - Security Rule - electronic
  - Breach Notification Rule - unsecured
  - Enforcement Rule

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K&L GATES

**OVERSIGHT**

- United States Department of Health and Human Services, Office for Civil Rights (OCR)
  - Investigate reports of breaches
  - Investigate complaints from individuals
  - Conduct compliance audits

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K&L GATES

**HIPAA'S LANDSCAPE**

- Complex
- Stressful
- Constant
- Evolving

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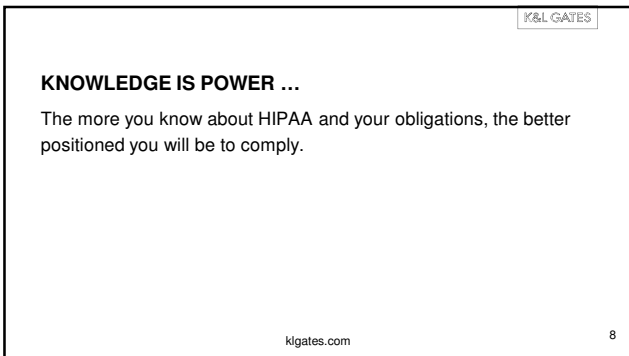
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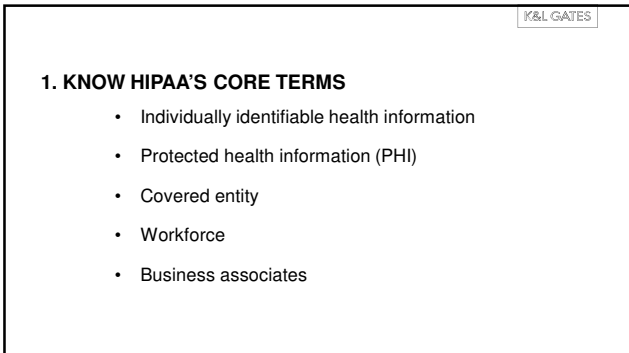
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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

*Individually identifiable health information*

- Is created or received by a health care provider, plan, or clearinghouse; or employer; and
- Relates to the past, present, or future physical or mental health or condition of an individual (or payment for health care to the individual); and
- Identifies the individual or reasonable could be used to identify the individual

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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

*Protected health information (PHI) is IHI that is:*

- Transmitted by electronic media;
- Maintained in electronic media; or
- Transmitted or maintained in any other form or medium.

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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

**PHI excludes IHI in:**

- Education records covered by the Family Educational Rights and Privacy Act
- Records described at 20 USC 1232g(a)(4)(B)(iv)
- Employment records held by a covered entity in its role as an employer

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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

*Covered entity*

- Health plan
- Health care clearinghouse
- Health care provider who transmits any health information in electronic form in connection with a standard transaction (e.g., claims for payment for services)

Most important term because it triggers HIPAA.

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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

*Workforce*

- Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity

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K&L GATES

**1. KNOW HIPAA'S CORE TERMS (CONT.)**

*Business Associates*

- Perform services **on behalf of a covered entity** that require the use or disclosure of PHI.
- Perform services **on behalf of another business associate** that require the use or disclosure of PHI.
- No limit to the number of business associates performing services on behalf of a covered entity or another business associate of the covered entity.

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**2. KNOW THE KEY PLAYERS**

- Privacy Officer
- Security Officer
- Counsel (in-house and outside)

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**3. KNOW THE KEY DOCUMENTS**

- Policies and procedures
- Notice of Privacy Practices
- Business Associate Agreements

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**4. KNOW THE GOLDEN RULE**

You may not use or disclose PHI unless HIPAA permits or requires you to do so.

- Good news = HIPAA likely permits use and disclosure for majority of covered entity's operations
- Bad news = Lots of ways to unintentionally violate the rule

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**5. KNOW WHEN YOU MUST DISCLOSE PHI**

- To the individual when requested in accordance with HIPAA's provisions
- To the Secretary of the United States Department of Health and Human Services for purposes of investigating compliance with HIPAA

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**6. KNOW WHEN YOU MAY DISCLOSE PHI**

- For treatment, payment, and health care operations purposes
- To your business associates if you have a business associate agreement in place
- Research, law enforcement and other purposes as long as requirements for those disclosures are satisfied

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**7. KNOW REQUIRED EPHI SAFEGUARDS**

Administrative, technical, and physical safeguards are specified

- Some are required
- Some are addressable (but not optional)

Safeguards are designed to protect the confidentiality, availability, and integrity of ePHI

- Risk assessment and risk management plans are key
- Must be updated appropriately

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**8. KNOW WHEN YOU HAVE A BREACH**

- Unpermitted access, acquisition, use or disclosure of PHI not permitted by HIPAA (with some limited exceptions)
- Applies to PHI not secured in the manner specified by the Secretary of the Department of Health and Human Services
- May require notification to the affected individuals, Secretary and others if the PHI has been compromised

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**9. UNDERSTAND INDIVIDUALS' RIGHTS**

- Right to access their PHI
- Right to amend inaccurate PHI
- Right to an accounting of disclosures of their PHI
- Right to complain to you or to OCR about your policies and procedures or your compliance with them
- Right to request additional restrictions on disclosures of their PHI
- Right to request confidential communications

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**10. KNOW THE PENALTIES**

Civil penalties up to \$1 million per identical penalty per year

- Typically more than one violation so the penalties can grow substantially very quickly
- Various factors affect the amount, depending on whether the violation was willful

Criminal penalties up to an including incarceration

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K&L GATES

**WHEN IN DOUBT**

Don't do anything without checking with the Privacy and/or Security Officers

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# Breach Investigation and Determination

Real World Scenarios

Asra Ali, CHC, CHPC, Compliance and Risk Manager at HealthScape Advisors



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## Breach Investigation and Determination

- Four factor analysis per HIPAA
- Collect facts as soon as possible
  - Interviews
  - Incident Intake Form
- Core Team
  - Privacy Office
  - Manager
  - Associates involved
  - If a breach is determined, involve a high level executive to determine next steps
  - Outside Counsel

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### Real World Scenario #1

- Employee Data Disclosed through Unencrypted Email
  - Email sent by HR to insurance carrier with sensitive employee data
  - Method: Unencrypted email
  - Investigation
    - Core team: Compliance, IT, HR
    - Interviews
  - Determination
    - The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification.
    - The unauthorized person who used the protected health information or to whom the disclosure was made;
    - Whether the protected health information was actually acquired or viewed;
    - The extent to which the risk to the protected health information has been mitigated.
  - Mitigation
    - Credit monitoring?
    - Notification
    - Employee training

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### Real World Scenario #2

- Stolen Laptop in combination with paper records
  - Employee left laptop in a backpack.
  - Vehicle parked on private property.
  - Vehicle is broken into and the backpack is stolen. Paper medical records are also missing.
  - Investigation
    - Police report?
    - Interviews
    - Core team: Executive presence
  - Determination
    - Was the laptop encrypted?
    - What data was included in the medical records?
    - Type of "records"?
  - Mitigation
    - Notification
    - Call center?
    - Insurance coverage?

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## Current Industry Issues

Cybersecurity/Cyberliability  
Phishing

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### Cybersecurity/Cyberliability

- Internal Practices
  - Penetration Testing
  - Mobile Devices and Wireless Networks
  - Cloud Services
  - Risk Assessments
  - Employee Data
  - Policies and Procedures
- Vendor Contracts
  - Risk Assessments
  - SOC Reports
  - Insurance Coverage
- Definition of Data
  - State level
  - Other key statutes

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### Trending Issues

- W2 Scams
- FTC email scam
- Phishing
- Ransomware

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### Phishing

- What is "Phishing"?

fISHING/  
Noun

The activity of defrauding an online account holder of financial information by posing as a legitimate company.
- 1990s: inspired by *fishing*, on the pattern of *phreaking*.



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### What Does a Phishing Email Look Like?

Hello!  
As part of our security measures, we regularly screen activity in the Facebook system. We recently contacted you after noticing an issue on your account.

Spelling

Our system detected unusual Copyrights activity linked to your Facebook account. please follow the link below to fill the Copyright Law form:

[http://www.facebook.com/application\\_form](http://www.facebook.com/application_form) Links in email

Note: If you dont fill the application your account will be permanently blocked. Threats

Regards,

Facebook Copyrights Department. Popular company

Source: <https://www.microsoft.com/en-us/safety/online-privacy/phishing-symptoms.aspx>

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### Real World Scenario #3

- Phishing
  - Scenario #1: Employee clicks on a link through email that looks like it coming from the CEO, asking for payroll information.
  - Information hacked: employee names, SSNs, 2015 wages earned, states of residence, states of work, employees' contributions to their retirement accounts, taxes withheld
  - Breach?
  - Investigation
    - Core Team
  - Remediation
    - Notification

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## Ransomware

Cybersecurity/Cyberliability  
Phishing  
Ransomware

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## Ransomware

- Ransomware
  - ran-som-ware
  - *noun*
  - a type of malicious software designed to block access to a computer system until a sum of money is paid.
  - Uses cryptotechnology to encrypt files
- Why is it so successful?
  - Victim generally do not use scrutiny when receiving emails (email overload)
  - Employees generally are not trained on what to look for
  - Email is primary vector for attacks
  - Cyber criminals getting better at creating content to trick users
  - Oversharing of personal information through public social media outlets
    - Allows cyber criminals to personalize content




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## What Does Ransomware Look Like?




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## Tips and Tools on Incident Response

- Determine basic level of severity
  - Laptop missing versus lost work badge
- Determine which team(s) you want to engage
  - Core team?
- Conduct formal risk analysis
  - Radar
- Document all steps
- Does outside counsel need to be involved?




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### External versus Internal Review and/or Investigations

- When to involve outside counsel?
  - Company culture
    - Internal role
    - Transactions and business initiatives
    - Compliance Department
    - Familiarity with privacy and state laws
  - Level of severity
  - Risk analysis
  - Policies and procedures
  - Independent review



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### Trends in Changing State Data Breach Laws

Mahmood Sher-Jan, CHPC, CEO and Founder of RADAR, Inc.



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### Overall: Increased Stringency and Growing Complexity



- 20 states and one territory now specify the contents of required notifications to individuals.
- 13 states now regulate medical information as PII.
- 22 states now require notice to the attorney general under specified circumstances.



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### Expanding Scope of Personal Information



How a state defines personal information hugely impacts what's acceptable in terms of disclosure and access. States that have recently expanded the definition of personal information:

- Montana (HB 74)
- Nevada (AB 179)
- Oregon (SB 601)



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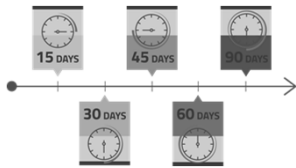
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### Increased Specificity of Timelines



Many state breach notification laws have ambiguous timelines when a breach of personal information requires notification to impacted individuals. States that have recently added more specific timelines:

- Connecticut (SB 949)
- Washington (HB 1078)
- Rhode Island (SB 134)
- Tennessee (SB 2005)



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### Specifying Notification Contents



In many states, initial data breach notification legislation didn't include guidance as to what information a notice to affected individuals should contain. States that have recently updated their notification requirements:

- California (SB 570)
- Wyoming (SF 35)
- Rhode Island (S 0134)



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## Adding the Requirement to Notify State Attorney

### General



With the number of high profile data breaches on the rise, state attorneys general are adding requirements to be notified under certain circumstances. Recently:

- North Dakota (SB 2214)
- Montana (HB 74)
- Oregon (SB 601)
- Rhode Island (SB 134)



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## The Rise of Ransomware

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### Ransomware



Ransomware attacks were up **300%** last year, occurring on average **4,000** times a day.

- Interagency guidance from the US Government  
<https://www.justice.gov/criminal-ccips/file/872771/download>



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### OCR Guidance

New OCR guidance issued this summer indicates that *even if data is encrypted*, a ransomware attack may trigger the HIPAA Breach Notification Rule and thus requires a multi-factor risk assessment:

**"However, even if the PHI is encrypted in accordance with the HHS guidance, additional analysis may still be required to ensure that the encryption solution, as implemented, has rendered the affected PHI unreadable, unusable and indecipherable to unauthorized persons."**

- Office for Civil Rights, Fact Sheet: Ransomware and HIPAA



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### Mitigating Factors for a Ransomware Attack

A ransomware attack may not be a notifiable data breach if you are able to demonstrate a *low probability that the PHI has been compromised*.



HIPAA Breach Notification Rule **Four Factor Risk:**

1. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification
2. The unauthorized person who used the PHI or to whom the disclosure was made
3. Whether the PHI was actually acquired or viewed
4. The extent to which the risk to the PHI has been mitigated



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### Ransomware Risk Assessment

A ransomware attack, like any other incident, requires a multi-factor risk assessment considering:

- Paper/electronic
- Malicious/Non malicious
- Disposition or remediation efforts

Please answer the following risk factor questions about the incident. [?]

\*What was the incident category?  
Electronic [?]

\*What was the incident subcategory?  
Network access [?]

\*What data protection measure was in place?  
Meets NIST standard, key was not compromised, and no evidence of access [?]

\*What was the nature of the incident?  
Intentional, malicious [?]

\*What was the data compromise method?  
Choose one  
 Denial of service  
 Data theft  
 Data destruction  
 Denial of service (including ransomware)  
 Theft  
 Unauthorized access  
 Unknown  
 None of the responses or one requires clarification [?]

Choose one [?]



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## Common Misconceptions in Incident Response

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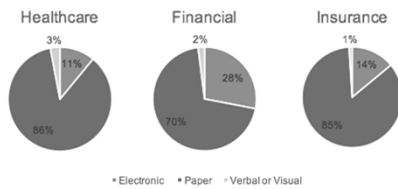
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Misconception: **In today's security threats, only your electronic data is most at risk.**



In reality, electronic incidents may expose *more records per incident*, but paper incidents – for example misdirected mail or fax – are much more commonplace.




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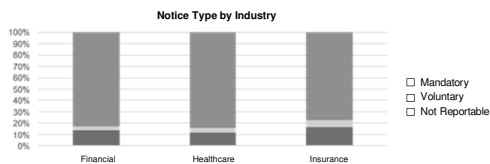
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Misconception: **If I have an incident that involves disclosure of regulated data, it's a data breach.**



In fact, the majority of incidents, when properly risk mitigated and run through a compliant multi-factor risk assessment, do not meet breach threshold in one or many jurisdictions involved.




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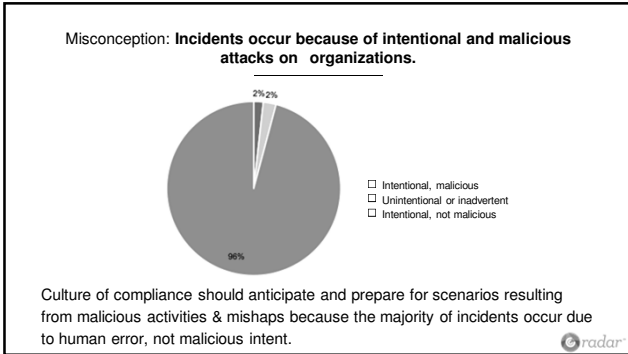
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# Operationalizing Incident Response Management

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## 1. Build Your Team

Define roles and responsibilities NOW, before an incident ever happens. Consider who will need to be pulled into Core & Extended Teams from:

- Security
- Privacy
- Information Technology (IT)
- Counsel (Inside & Outside)
- Human Resources
- Marketing or Public Relations
- Executive Team
- Board of Directors

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## 2. Gather The Facts



Document, as part of your investigation:

- Source
- Level, risk of exposure
- Nature of the data
- Protections in place
- Number of records exposed
- Remediation steps
- Malicious or non-malicious intent



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## 3. Conduct a Risk Assessment



Call upon your previously identified **Core** and **Extended** teams to plan your response, make a breach determination, and follow up your thorough investigation with necessary internal and external reporting.



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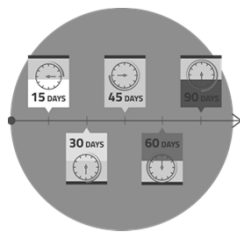
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## 4. Plan Your Breach Response - Notification



Consider possible notification requirements across jurisdictions

- Regulatory bodies
  - Federal and states
- Law enforcement
- Impacted individuals
- Pay special attention to deadlines, content, format – even font size.



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### 5. Analyze, Measure, and Improve



Perform incident type, root cause, and remediation analysis. Use the data to reduce future risks.



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### 10 Minute Break, Followed by Panelist Discussion

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### Panel Discussion

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Compliant Physician  
Documentation and Coding  
in an  
Electronic Medical Record

Kim Huey, MJ, CHC, CPC, CCS-P, PCS, CPCO  
Sandy Giangreco, RHIT, CCS, CCS-P, CHC, CPC, COC, CPC-I, COBGC  
Health Care Compliance Association  
Compliance Institute  
March 2017

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We've come a long way –  
or have we?

“By computerizing health records, we can avoid  
dangerous medical mistakes, reduce costs, and  
improve care.”

President George W. Bush,  
State of the Union Address  
January 20, 2004

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Issues

- Is meaningful use really meaningful?
- Is information available between entities?
- Is the quality of care improved – or even maintained?
- Is the health information secure?
- **Are medically necessary services provided, documented, billed for, and reimbursed appropriately?**

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### Balancing Medical Necessity and Meaningful Use

- Bringing forward medical history in an EMR is an important aspect of meaningful use
- Does this mean that you can count that comprehensive history toward the level of service for every encounter now and forevermore?
- What about medical necessity of elements? For example, vitals on every patient?

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### Physician Response

What do physicians dislike most about their EMR?

- 28.1% interferes with Face to Face/patient time
- 21.9% lack of clinical interoperability
- 18.8% slows down productivity

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### Physician Response

Study: What Do Physicians Read (and Ignore) in Electronic Progress Notes?

- Most attention given to Impression and Plan
- Very little attention given to vital signs, medication lists, and laboratory results

“Optimizing the design of electronic notes may include rethinking the amount and format of imported patient data as this data appears to largely be ignored.”

Applied Clinical Informatics  
<http://aci.schattauer.de/en/home/issue/special/manuscript/21088/show.html>

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### Concerns with electronic records and overcoding

The Center for Public Integrity –  
September 2012

“coding levels may be accelerating in part because of  
increased use of electronic health records...”

“easy to create detailed patient files with just a few clicks”

“longer and more complex visits are easier to document”

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### It's a New World

Paper Records: Not documented, not done.

Electronic Records: You documented it,  
but did you really do it?

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### Sebelius-Holder Letter

September 24, 2012

“False documentation of patient care is not just  
bad patient care; it's illegal. The indications  
include potential 'cloning' of records in order  
to inflate what providers get paid.”

<http://www.nytimes.com/interactive/2012/09/25/business/25medicare-doc.html>

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### Congressional Response

October 4, 2012 letter to HHS Secretary Sebelius  
“...your EHR incentive program appears to be doing more harm than good.”

Request –

- Suspension of EHR bonus payments and delay penalties for providers who don't use EHR
- Increase what's expected of meaningful users
- Block business practices that prevent exchange of information

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### OIG Workplan for 2012

“We will assess the extent to which CMS made potentially inappropriate payments for E/M services and the consistency of E/M medical review determinations. We will also review multiple E/M services for the same providers and beneficiaries to identify electronic health records (EHR) documentation practices associated with potentially improper payments. Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service based upon the content of the service and have documentation to support the level of service reported.”

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### Previous OIG Reports

- 2011 – measured EHR use –
- 2012 – measured EHR use and specified which system

Neither study analyzed effectiveness or impact on coding

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## OIG 2016 Compendium of Unimplemented Recommendations

ONC and CMS should collaborate to develop a comprehensive plan to address fraud vulnerabilities in electronic health records (EHR).

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## What are the auditors looking for?

- Authentication – signatures, dates/times – who did what? (metadata?)
- Contradictions – between HPI and ROS, exam elements and impression and plan
- Wording or grammatical errors/anomalies
- Medically implausible documentation

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### Code Generators

- Is the coding software programmed for the 1995 or 1997 Documentation Guidelines?
- Has the coding software been programmed to account for medical policies specific to the local Medicare contractor?
- How does the coding software manage dictated portions of the encounter such as History of Present Illness?  
How does the coding software distinguish between the levels of medical decision-making?

MORE on this later!

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### Templates

- Is the provider able to choose only part of a template or to personalize a template?
- Are there multiple templates, personalized for complaint or diagnosis?
- Are the various contributors to the encounter identified? Nursing staff, physician, etc.

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### Cloned Notes

“Documentation is considered cloned when each entry in the medical record for a beneficiary is worded exactly like or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from beneficiary to beneficiary. It would not be expected that every patient had the exact same problem, symptoms, and required the exact same treatment.

First Coast Service Options, Medicare Part B newsletter 2006  
(Definitions published by Medicare contractors as early as 1999.)

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### Cloned Notes

November/December 1999 Medicare Bulletin:  
"Cloned notes are notes that have little or no change from day to day and patient to patient. These types of notes do not support the medical necessity of a visit. More importantly, in some cases, they may not actually support that a visit occurred. Cloned notes may be construed as an attempt to defraud the Medicare program."

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### Cloned Documentation

Whether the documentation was the result of an Electronic Health Record, or the use of a pre-printed template, or handwritten documentation, cloned documentation will be considered misrepresentation of the medical necessity requirement for coverage of services due to the lack of specific individual information for each unique patient. Identification of this type of documentation will lead to denial of services for lack of medical necessity and the recoupment of all overpayments made.  
- NGS Medicare -

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### Copy and Paste

AHIMA Position Statement – March 17, 2014  
Called on industry stakeholders, EHR system developers, the public sector, and healthcare providers to work together to implement standards for the appropriate use of copy and paste

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### Why copy and paste?

“...most physicians use the functionality simply to save time. They have not been given the time and training needed to become fully proficient with their new systems, so they create workarounds to help them get through their day.”

Heather Haugen, PhD  
“Overcoming the Risks of Copy and Paste in EHRs”  
Journal of AHIMA, June 2014

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June 2014 – JAMA Internal Medicine – University of Wisconsin School of Medicine and Public Health and the University of Wisconsin Hospital and Clinics:

- “it is too easy, and often mistaken, to equate a physician’s routine use of copy-and-paste with fraud. Data replication is a feature of electronic health records; facts beyond the mere use of duplicated text are required to establish that a note may be fraudulent.”
- It can be efficient and clinically useful when used properly, and that EHRs are “not to blame for the carelessness of individual physicians.”

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### Issues with Copy and Paste

- Outdated or redundant information
- Inability to identify the author or date of origin of information
- Unnecessarily lengthy notes
- Appearance of fraudulent activity – e.g., billing twice for the same “work”
- Quality of care and medico-legal integrity are compromised

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### Coding Guidelines

Written in general – not specifically for electronic records

- Must adapt electronic documentation to existing guidelines

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### General Principles

#### of Medical Record Documentation

1. The medical record should be complete and legible.
2. The documentation for each patient encounter should include:
  - Reason for the encounter and relevant history, physical examination findings and prior diagnostic test results
  - Assessment, clinical impression or diagnosis
  - Plan for care
  - Legible identity of the observer

From CMS Evaluation and Management Documentation Guidelines – stated to be applicable to all types of medical and surgical services in all settings.

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3. If not documented, the rationale for ordering diagnostic and other ancillary services should be easily inferred.
4. Past and present diagnoses should be accessible to the treating and/or consulting physician.
5. Appropriate health risk factors should be identified.
6. The patient's progress, response to and changes in treatment, and revision of diagnosis should be documented.
7. The CPT and ICD codes reported on the health insurance claim form or billing statement should be supported by the documentation in the medical record.

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## Evaluation and Management

### Documentation Guidelines

Two sets of guidelines established by CMS

- 1995 Documentation Guidelines
- 1997 Documentation Guidelines

Providers may use whichever they choose.

Auditors are instructed to audit under both sets of guidelines and allow the physician to use whichever benefits him/her.

Are there separate CPT Documentation Guidelines?

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## Evaluation and Management

- History
- Examination
- Medical Decision-Making

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## History

- *DG: The CC, ROS and PFSH may be listed as separate elements of history or they may be included in the description of the history of the present illness.*
- *DG: A ROS and/or a PFSH obtained during an earlier encounter does not need to be re-recorded if there is evidence that the physician reviewed and updated the previous information. This may occur when a physician updates his or her own record or in an institutional setting or group practice where many physicians use a common record. The review and update may be documented by:*
  - *describing any new ROS and/or PFSH information or noting there has been no change in the information; and*
  - *noting the date and location of the earlier ROS and/or PFSH.*

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### History

- **DG: The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.**
- **DG: If the physician is unable to obtain a history from the patient or other source, the record should describe the patient's condition or other circumstance which precludes obtaining a history.**

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### History

- **DG: The medical record should clearly reflect the chief complaint.**
- The HPI is a chronological description of the development of the patient's present illness from the first sign and/or symptom or from the previous encounter to the present. It includes the following elements:
- location,
  - quality,
  - severity,
  - duration,
  - timing,
  - context,
  - modifying factors, and
  - associated signs and symptoms.

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### History of Present Illness

#### **Extended History of Present Illness**

- **DG: The medical record should describe at least four elements of the present illness (HPI), or the status of at least three chronic or inactive conditions. (1997 Guidelines)**

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### History of Present Illness

Who must document the History of Present Illness?

**DG: The ROS and/or PFSH may be recorded by ancillary staff or on a form completed by the patient. To document that the physician reviewed the information, there must be a notation supplementing or confirming the information recorded by others.**

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### History – Review of Systems

- **DG: At least ten organ systems must be reviewed. Those systems with positive or pertinent negative responses must be individually documented. For the remaining systems, a notation indicating all other systems are negative is permissible. In the absence of such a notation, at least ten systems must be individually documented.**

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### History – Past, Family, Social

- **DG: At least one specific item from two of the three history areas must be documented for a complete PFSH for the following categories of E/M services: office or other outpatient services, established patient; emergency department; domiciliary care, established patient; and home care, established patient.**
- **DG: At least one specific item from each of the three history areas must be documented for a complete PFSH for the following categories of E/M services: office or other outpatient services, new patient; hospital observation services; hospital inpatient services, initial care; consultations; comprehensive nursing facility assessments; domiciliary care, new patient; and home care, new patient.**

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### Examination

1995 – Organ Systems/Body Areas  
1997 – Specific bullet points in each Organ System  
Many EMR templates based on 1997 bullets, but are all those elements really performed?  
Is the exam related to the presenting problem?  
One click to document a completely, normal comprehensive examination?

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### Medical Decision-Making

- **DG: For each encounter, an assessment, clinical impression, or diagnosis should be documented. It may be explicitly stated or implied in documented decisions regarding management plans and/or further evaluation.**
  - For a presenting problem with an established diagnosis the record should reflect whether the problem is: a) improved, well controlled, resolving or resolved; or, b) inadequately controlled, worsening, or failing to change as expected.
  - For a presenting problem without an established diagnosis, the assessment or clinical impression may be stated in the form of differential diagnoses or as a "possible", "probable", or "rule out" (R/O) diagnosis.

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### Medical Decision-Making

- **DG: The initiation of, or changes in, treatment should be documented. Treatment includes a wide range of management options including patient instructions, nursing instructions, therapies, and medications.**
- **DG: If referrals are made, consultations requested or advice sought, the record should indicate to whom or where the referral or consultation is made or from whom the advice is requested.**

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### Medical Decision-Making

- **DG: If a diagnostic service (test or procedure) is ordered, planned, scheduled, or performed at the time of the E/M encounter, the type of service, eg, lab or x-ray, should be documented.**
- **DG: The review of lab, radiology and/or other diagnostic tests should be documented.** A simple notation such as "WBC elevated" or "chest x-ray unremarkable" is acceptable. Alternatively, the review may be documented by initialing and dating the report containing the test results.

NOTE: This is not acceptable documentation for billing for the professional interpretation of X-rays or other diagnostic services.

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### Medical Decision-Making

- **DG: A decision to obtain old records or decision to obtain additional history from the family, caretaker or other source to supplement that obtained from the patient should be documented.**
- **DG: Relevant findings from the review of old records, and/or the receipt of additional history from the family, caretaker or other source to supplement that obtained from the patient should be documented.** If there is no relevant information beyond that already obtained, that fact should be documented. A notation of "Old records reviewed" or "additional history obtained from family" without elaboration is insufficient.

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### Medical Decision-Making: Risk

- **DG: Comorbidities/underlying diseases or other factors that increase the complexity of medical decision making by increasing the risk of complications, morbidity, and/or mortality should be documented.**
- **DG: If a surgical or invasive diagnostic procedure is ordered, planned or scheduled at the time of the E/M encounter, the type of procedure, eg, laparoscopy, should be documented.**
- **DG: If a surgical or invasive diagnostic procedure is performed at the time of the E/M encounter, the specific procedure should be documented.**
- **DG: The referral for or decision to perform a surgical or invasive diagnostic procedure on an urgent basis should be documented or implied.**

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### Time-Based Coding

- **DG:** *If the physician elects to report the level of service based on counseling and/or coordination of care, the total length of time of the encounter (face-to-face or floor time, as appropriate) should be documented and the record should describe the counseling and/or activities to coordinate care.*

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### Time – Counseling and Coordination of Care

Medicare Claims Processing Manual –  
Chapter 12, Section 30.6

- The code selection is based on the total time of the face-to-face encounter or floor time, not just the counseling time. The medical record must be documented in sufficient detail to justify the selection of the specific code if time is the basis for selection of the code.
- The duration of counseling or coordination of care that is provided face-to-face or on the floor may be estimated but that estimate, along with the total duration of the visit, must be recorded when time is used for the selection of the level of a service that involves predominantly coordination of care or counseling.

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### Surgical Procedures

The Joint Commission and other accrediting agencies address standards for surgery documentation in hospital setting

- Who sets standards for in-office procedures?

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### Procedures

#### Office Procedures

- Sometimes documented as orders or CPT description without details of the procedure performed

EX: "20610 - Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance"

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### Procedure Documentation

#### Procedure:

We reviewed the procedure of joint aspiration and injection and discussed the risks, benefits, and alternative treatments. Informed consent was obtained as outlined below. I verified that the patient had no allergies to local anesthetic. We discussed the potential side effects of corticosteroids, including but not limited to local tissue breakdown, elevation of blood sugar and seizures.

A procedural pause was conducted to verify correct patient identity, procedure to be performed, correct side and site, correct patient position, availability of implants, and need for special equipment or special requirements. After verification, the was marked and then prepped in the usual sterile fashion. Using a 22 gauge 1.5 inch needle, 4 mL of lidocaine and was injected into the joint space without difficulty. After injection, the joint was passively moved through the full range of motion and a sterile dressing was applied. The patient tolerated the procedure well. Aftercare discussed.

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### Office Documentation

#### At a minimum:

- Document medical necessity
- Document specifics of procedure –
  - Site and length of laceration
  - Margins for lesion removal
  - Reason for lesion removal
  - Technique of procedure
- Details needed to support the code billed

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### Diagnosis Coding

- Have the physicians been educated in diagnosis coding?
- Has the diagnosis code listing been personalized for that practice and that physician?

As more physician payment mechanisms are based on severity of illness, correct and specific diagnosis coding becomes more important – to the physician.

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### Examples of Diagnosis Coding Errors

- Incorrect/incomplete description entered in EMR
  - “intestinal obstruction”  
K50.012 - Crohn's disease of small intestine with intestinal obstruction
  - “chronic insomnia”  
F51.04 - Psychophysiologic insomnia
- Lack of physician knowledge of coding guidelines

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### Code #s in Lieu of Diagnosis

Providers must specifically document the diagnosis, condition, and/or problem. It is not appropriate for providers to list the code # or select a code # from a list of codes in place of a written diagnosis.

Coding Clinic 4Q 2015

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### Diagnosis Documentation

- How the provider documents the diagnosis matters
- This information may be presented to patient on Visit Summary  
Does the diagnosis code description in the EMR reflect what the patient was told about their condition?

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### Scribes

- No CMS policy on scribes -
- Noridian: If the physician uses a scribe (an individual taking notes), the scribe needs to fully sign the note, with their own credentials, followed by the physician's signature and credentials.
  - WPS: "Scribe" situations are those in which the physician utilizes the services of his, or her, staff to document work performed by that physician, in either an office or a facility setting. In Evaluation and Management (E/M) services, surgical, and other such encounters, the "scribe" does not act independently, but simply documents the physician's dictation and/or activities during the visit. The physician who receives the payment for the services is expected to be the person delivering the services and creating the record, which is simply "scribed" by another person.

Beware of "Make Me The Author" functions

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### CIGNA on Scribes

If a nurse or mid-level provider (PA, NP, CNS) acts as a scribe for the physician, the individual writing the note (or history or discharge summary, or any entry in the record) should note "written by xxxx, acting as scribe for Dr. yyy." Then, Dr. yyyy should co-sign, indicating that the note accurately reflects work and decisions made by him/her. **Note: The scribe is functioning as a "living recorder," recording in real time the actions and words of the physician as they are done. If this is done in any other way, it is inappropriate. This should be clearly documented as noted, by both the scribe and the physician. Failure to comply with these instructions may result in denial of claims.**

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**Advanced Practice Providers:**

**Incident-to**

In order to bill services incident-to a physician (Medicare requirements):

- Employee of the physician
- Following a plan of care established by the physician
- Physician is in the office suite and immediately available

How do you support this in the EMR?

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**Advanced Practice Providers:**

**Split/Shared**

"When a hospital inpatient/hospital outpatient or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician's or the NPP's UPIN/PIN number. However, if there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service by only reviewing the patient's medical record) then the service may only be billed under the NPP's UPIN/PIN.

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**Advanced Practice Providers:**

**Split/Shared**

Compliant Documentation

- Identify which portions of the visit have been performed by the physician
- "Seen and agree" means no fee!
- Hospital dictation system may not allow APPs to document independently

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### Care Management Services

- Transitional Care Management – code is for 30 days of care, not just F2F visit
  - Phone call documented?
  - Overall management of patient’s needs, including psychosocial needs
- Care Plan Oversight
- Chronic Care Management
  - Time spent – every patient always requires 20 minutes
  - Generic care plan – not specific to patient’s condition/needs
- Advance Care Planning
  - Every patient documented with just the minimum time to support the code

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### Hospital

Issues –

- Unable to determine reason for visit
- Visit documentation incomplete – no history/examination/diagnosis
- Run-on visits – documentation continuous from one day to the next

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### Addenda

Are addenda done for the proper reasons and documented appropriately?

Medicare Program Integrity Manual, Chapter 3 – Section 3.3.2.5.B

“Regardless of whether a documentation submission originates from a paper record or an electronic health record, documents submitted to MACs, CERT, Recovery Auditors, and ZPICs containing amendments, corrections or addenda must:

1. Clearly and permanently identify any amendment, correction or delayed entry as such, and
2. Clearly indicate the date and author of any amendment, correction or delayed entry, and
3. Clearly identify all original content, without deletion. “

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### Signatures

Medicare Program Integrity Manual, Chapter 3 – Section 3.3.2.4.E  
“Providers using electronic systems need to recognize that there is a potential for misuse or abuse with alternate signature methods. For example, providers need a system and software products that are protected against modification, etc., and should apply adequate administrative procedures that correspond to recognized standards and laws. The individual whose name is on the alternate signature method and the provider bear the responsibility for the authenticity of the information for which an attestation has been provided. Physicians are encouraged to check with their attorneys and malpractice insurers concerning the use of alternative signature methods.”

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### Finalizing the Documentation

#### Code Selection

- Is the physician able to override the code selected by the EHR?
- Can he/she override the code to a higher level or only to a lower level of service?

#### Signatures

- Is the provider able to sign off on multiple items with one “sign-off” – multiple encounters, test results, phone calls, prescriptions

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### “Charge Passing”

Codes chosen in EMR transmit directly to Practice Management system and are then billed

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### Timing of Billing

- Is the documentation complete before the encounter is billed?
- For ancillary services, is the bill “dropped” based when the order is entered or when the test is performed and results entered?

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### Resources

- <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/electronic-health-records.html>
- Appropriate Use of the Copy and Paste functionality in Electronic Health Records  
<http://bok.ahima.org/PdfView?oid=300306>
- *Electronic Health Record Compliance Framework, Health Care Compliance Professional’s Manual*

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**Anatomy of a False Claims Act Case**

Investigation, Negotiation, Litigation, and Resolution

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**Agenda – Life-Cycle of FCA Case**

- Investigation
- Litigation
- Negotiation
- Resolution

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**Investigation**

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### Relator's Pre-Filing Investigation and Considerations

- Knowledge of facts involving clear FCA violation?
- Documentary evidence, other proof of fraud?
- Sufficient evidence of "who, what, when, and where" supporting fraud and damages?
- Specific examples of the fraud?
- Damages large enough to justify risks to relator?
- Level of government interest in specific area of law and type of fraud? Is it material to the government?

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### Investigation – DOJ's Perspective

- *Qui tam* v. non-*qui tam*
- DOJ handling of *qui tam* investigations
- Basic steps
  - Is there a violation?
  - Are there false claims?
  - Are the false claims material?
  - Did the provider act knowingly?
  - Was the government damaged?

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### Investigation – DOJ's Perspective (cont'd)

- Applicable regulations and government policy
- Internal and external audits
- Relators
- Witnesses
- OIG and agency
- Responsibility of individuals

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### Investigation - OIG's Role

- OCIG attorney assigned when OIG notified of case
- OCIG attorney coordinates with defrauded agencies, Main DOJ attorney and/or AUSA assigned
  - Evaluate whether other entities need to be involved
  - Evaluate merits of case
  - Consult with counsel and agent re investigative steps
- Individual liability issues

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### Self - Disclosures

- Intersection of self-disclosure under HHS-OIG Self-Disclosure Protocol and *qui tam* filing alleging related facts
- No bar to *qui tam*
- Impact of self-disclosure on OIG view of defendant
- Impact of self-disclosure on potential multiplier under *qui tam*

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### Investigation - Defense Perspective

- Indicators that you might be under investigation
- When to retain expert counsel
- Steps to take when you receive a subpoena/CID/request letter
  - What you can learn from the subpoena
  - Responding to the subpoena
- Consider how proactive a role to take
- Yates Memo considerations
  - Potential parallel criminal investigation
  - Focus on individuals
- Missteps to avoid
- Attempt to negotiate resolution, or litigate?

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**Litigation**

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**Key Topics**

- Overview
- Motions to Dismiss – 9(b)
- Counterclaims Against Relator
- Privilege Issues in Discovery (and Elsewhere)
- Breadth of Discovery Requests
- Sampling and Extrapolation
- Motions for Summary Judgment
- Experts

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**Rule 9(b) Motions to Dismiss**

- Question of extent to which relator/government must identify claims actually submitted
- Is description of the fraudulent scheme enough?
- Does it matter if the relator is/was an insider?
- Evolution of the law among the circuits

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## Counterclaims Against Relator

- Increased use of counterclaims against relators.
- To what extent can relator obtain documents from employer/defendant and provide to government or otherwise use for litigation?
- What guidance does government give to relators who are current employees regarding taking documents from workplace?
- What steps can employer take when it learns relator is current employee?

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## Privilege Issues in Discovery (and Elsewhere)

- Invocation of advice-of-counsel defense and resulting waiver
- Good faith reliance
- In-house counsel as relators
- Protection of pre-litigation investigation work product

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## Statistical Sampling and Extrapolation

- Use of sampling in FCA cases versus overpayment situations
- Use of sampling in different types of FCA cases
- Is there a distinction between using sampling for "damages" versus for "liability" purposes?

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## Motions for Summary Judgment

- Potential usefulness for defendant? Plaintiff?
- Motions for partial SJ
- Timing issues

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## Negotiation and Resolution

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## Overview - Negotiation

- Timing can vary
- Objectives of the various parties (DOJ, OIG, MFCU, relator, defendant)
- Key negotiating issues
  - Money
  - Scope of release
  - Existence/scope of CIA
  - Relators' share
  - Attorneys' fees

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### Negotiation – DOJ Priorities

- Make Government whole
- Deter fraud
- Consider, address views of victim agency
- Discern individual wrongdoers and proceed accordingly
- Assess strengths and weaknesses of case

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### OIG Objectives

- Appropriate program safeguards OIG
  - Exclusion
  - Reservation of authority
  - Corporate Integrity Agreements
    - Independent review organizations (IROs)
    - Legal IROs
    - Monitors

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### Relator Objectives

- Monetary resolution of FCA claims
  - Intervened
  - Non-intervened
- Relator’s share percentage
- Resolution of any retaliation claims
- Resolution of attorneys’ fee claims

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## Defendant Objectives

- Appropriate monetary resolution covering all claims
  - FCA liability
  - Attorneys' fees
- Release of **all** potential claims
- Least onerous compliance requirements possible going forward

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## Negotiation – Getting Started

- Initiation of discussions
  - When?
  - By whom?
- Mediation
- Who is at the table?
  - Intervened cases
  - Declined cases
- Roles of:
  - Relators
  - OIG

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## Alternative Dispute Resolution

- Federal government committed to ADR in "appropriate civil cases"
  - See:  
<http://www.jamsadr.com/files/Uploads/Documents/Articles/Stevens-False-Claims-Act-2012-11-20.pdf>
- Benefits of mediation
  - Objective neutral gives an important reality check
  - Use of an impartial intermediary can change the personal dynamic
- Non-binding

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## Monetary Negotiations

- Assessment of merits of the case
  - Each party's principled liability assessment
  - Each party's principled quantification of false claims and single damages at issue
- Debate over the appropriate multiplier
- Realistic assessment of the respective litigation risks of each party
- The pragmatic phase

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## Key Issues Regarding the Scope of Release

- Defining the "Covered Conduct" to be released
- Defining released parties
- Carve-outs from release
  - Criminal liability
  - Antitrust
  - Tax
- Dismissal of Complaint with prejudice
  - Non-intervened claims

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## Key Issues Relating to Corporate Integrity Agreements

- Overarching issues
  - Effectiveness of existing compliance program
  - Track record of provider
- CIA vs. Reservation of Rights
- Scope of CIA
  - Definition of issues covered by CIA
  - IRO?
  - Legal IRO?
  - Monitor?

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### Key Issues Affecting Relators

- Relators' share
  - Negotiation between DOJ and Relator
    - How much did Relator contribute
    - How much did Relators' counsel contribute to the investigation and litigation
    - Posture of the case and many other factors
- Attorneys' fees
  - Negotiation between Provider and Relator

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### Other Key Issues

- Impact of state law claims
  - State FCAs
  - States as parties
  - Role of NAMFCU
- Relationship to other litigation with Relators
- Complications resulting from increased focus on individual liability
- Clarity of rules going forward
  - Applicability to all like providers
    - "Leveling the playing field"

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### Resolution: Settlement Agreement

- DOJ sends initial draft
- Standard language
- Key terms to negotiate:
  - Covered conduct
  - Released parties
- (Mostly) Non-negotiable terms

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### Settlement – Other Considerations

- Cooperation
- Individuals
- Who signs
- Confidentiality
- Press release

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### Resolution: OIG-Specific Issues

- Administrative Remedies
- Corporate Integrity Agreement
  - OIG sends initial draft
  - Standard language
  - Also specific terms based on conduct and provider
  - Negotiated between OIG and defendant
- Timing issues

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### Resolution: Relator-Specific Issues

- Attorney fees and retaliation claims
- Relator's share
- Relator's right to object to settlement as unfair, inadequate, unreasonable

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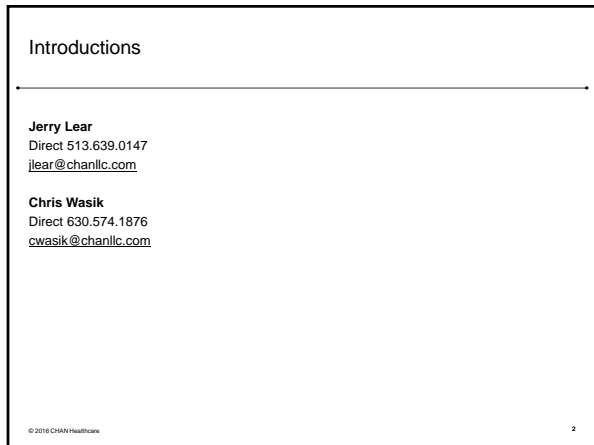
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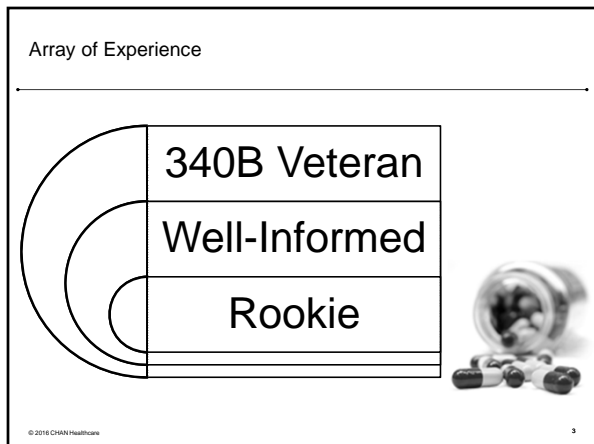
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Agenda

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Part 2

- **Most Common Audit Issues**
  - CHAN Healthcare audits
  - HRSA audits
- **Corrective Action Plans**
  - Examples for common risk categories

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340B Program Introduction

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340B Basics

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**The WHAT?**

- Drug discount program created in 1992 by the U.S. federal government that requires drug manufacturers to provide outpatient drugs to eligible health care organizations or covered entities (CEs) at significantly reduced prices

**The WHY?**

- The 340B Program enables CEs to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive care

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### 340B Basics

#### The WHO?

- The Office of Pharmacy Affairs (OPA) branch, Health Resources and Services Administration (HRSA), is responsible for Program oversight and ensuring compliance

#### The HOW?

- HRSA ensures compliance by performing CE audits.
  - 2014 – HRSA performed 99 audits
  - 2015 – HRSA performed 200 audits and committed an additional \$6M in funds to increase Program integrity
  - 2016 – HRSA has posted results for 152 audits
  - 2017 – HRSA contracts with The Bizzell Group to perform 340B audits

In this current environment, it is more a matter of 'when' rather than 'if' your organization will be selected for an audit.

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### 340B Buzzwords



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### The Foundation

- Covered Entity
- OPA Database
- Mixed-Use
- Contract Pharmacy
- Carve-in/out
- Mega-Guidance

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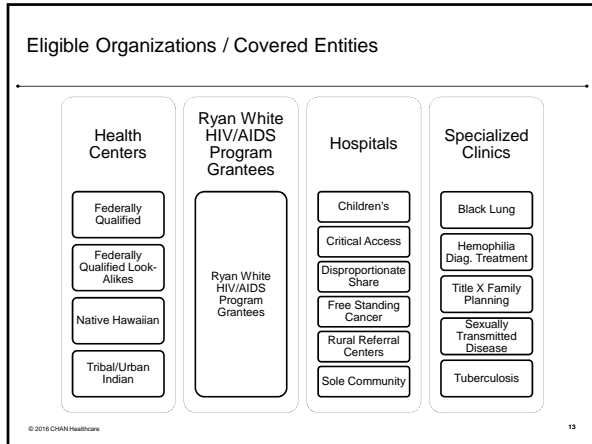
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HRSA Requirements

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Proposed Mega-Guidance Summary

- If the proposed guidance was accepted as final rule, the majority of 340B Programs could have been forced to deal with:
  - Significant software configuration and process changes
  - Overall reduction in savings
  - Increased internal and external monitoring efforts (time and money)

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### Mega-Guidance Status

"On January 30, 2017, the White House Office of Management and Budget (OMB) **withdrew the so-called 340B "mega-guidance"** (RIN:0906-AB08) that was proposed by the Department of Health and Human Services, Health Resources and Services Administration (HRSA), on August 27, 2015.

The new administration under President Donald Trump ordered a freeze on pending regulatory changes on January 20, 2017, whereupon **federal agencies cannot issue new regulations or guidance currently under review by the Office of the Federal Register.**

The OMB withdrawal of the 340B mega-guidance means that there will be no formal changes to the 340B program issues covered in the proposed mega-guidance, at least for the time being."

- American Health Lawyers Association (AHLA) – Derick Blakely

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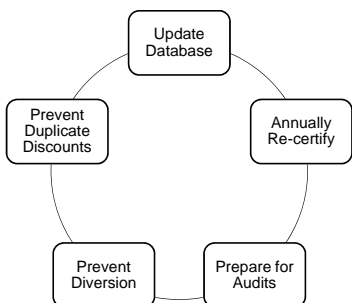
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### HRSA Requirements



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**So what should a CE do now to maintain program integrity and prepare for a potential audit?**



1. Understand what the audit process entails and specific focus areas.
2. Validate your CE has a robust compliance monitoring program.

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### Audits

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There are two types of 340B audits that CEs should understand and be prepared for:

1. HRSA audits
2. Manufacturer audits



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### 2017 – HRSA Audit Advancements

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- Beginning with the Q1 2017 audits, HRSA will utilize The Bizzell Group to conduct CE audits. Important details include:
  - Audit approach similar to prior years
  - Pre-audit research and analytics are now leveraged
  - Further depth to audit procedures
  - Enhanced auditor training, which should lead to a more consistent approach
  - Higher sophistication with many auditors having Pharmacy backgrounds

**HRSA audit advancements should provide even more reason for CEs to enhance their internal monitoring processes.**

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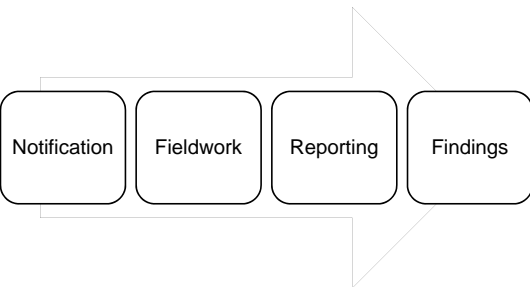
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### HRSA Audit Process

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graph LR; A[Notification] --> B[Fieldwork]; B --> C[Reporting]; C --> D[Findings];
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**HRSA Audit Process**

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- Audit notification
  - CE receives engagement letter informing them of the audit, including scope and what auditors will need onsite
  - HRSA will contact via phone and then set a longer meeting to discuss specific data requests
  - Timing from initial notification to auditors onsite varies, but can be as short as four weeks
    - We've heard that this turn-around will be reduced with the new audit team

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**HRSA Audit Process**

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- Audit fieldwork
  - Typically onsite 3-4 days
  - Procedures normally include:
    1. Confirming CE has a 340B policy/procedures and ongoing monitoring program in place
    2. Confirming CE information within the OPA database is accurate
    3. Testing a sample of 340B dispenses to validate:
      - Eligible patient
      - Eligible provider
      - Eligible location
      - Absence of duplicate discounts

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**HRSA Audit Process**

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- Exit conference
  - While onsite, HRSA typically conducts an exit meeting and shares potential findings
    - We've heard this may be eliminated with the new audit team
- Audit reporting
  - HRSA confirmation of findings and report issuance (can take weeks or months for this to be completed)
  - CE should closely review the report and respectfully challenge if there is disagreement with any findings (within 30 days of receiving the report)
  - Corrective action plan submission for each finding (within 60 days of preliminary report)



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**HRSA Audit Findings**

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- Issues identified are published on the OPA website
  - CE name, audit issue, and related sanctions
- Most common issues identified during 2016 audits surround:
  - Diversion
  - Incorrect database records
    - Child site registration (or lack thereof)
    - Inaccurate CE or contract pharmacy information
  - Duplicate Discounts
    - Dispensing
    - Billing

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**Manufacturer Audits**

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- HRSA Audits are most common, but Manufacturers also have the right to audit CE's
  - However, the audit selection process follows a different path:
    - Manufacturer notifies CE
    - CE inadequately responds to inquiry
    - Manufacturer communicates an audit request to HRSA
    - HRSA reviews and responds
    - If approved, CE is notified of the audit
  - It is anticipated that the increase in 340B savings/revenue will bring about more Manufacturer audits

**KEEP THIS IN MIND – If a Manufacturer asks questions about your 340B Program, respond in a timely fashion.**

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**Every CE's goal is an audit with no findings, how can you achieve this?**



**Evaluation**

- OUTSTANDING
- Excellent
- Very Good
- Average
- Below Average

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### Activity #1 – Monitoring Programs

- Break into small groups (4-5 people)
- Discuss and list attributes of a successful internal monitoring program
  - Include anything you deem important for compliance – some suggestions:
    - Oversight
    - Testing Procedures
    - Meeting Frequency
    - Department Participation
    - Mixed-use vs Contract pharmacy
- We'll re-convene in about 15-20 minutes and ask each group to present

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### 340B Monitoring Program

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### Creating a Monitoring Program

- CE's must be proactive in identifying where potential issues may be occurring within their 340B Program
- How do we set up a robust monitoring program?
- What procedures should be included?



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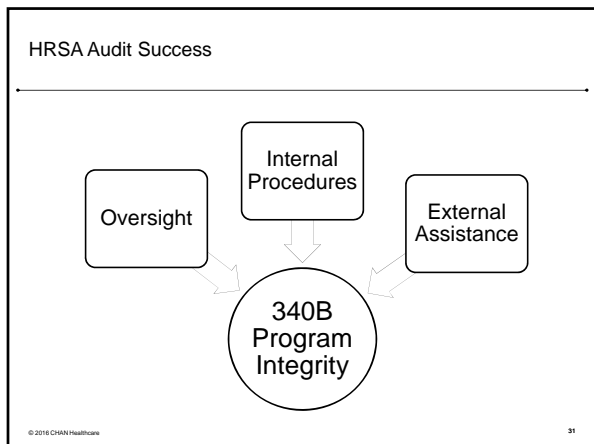
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Developing Your Self-Monitoring Strategy

**Who has responsibility for and oversight of your 340B Program?**

- Leading practice monitoring programs typically include the following attributes:
  1. **340B Committee** comprised of representatives from **various departments**
  2. A complex federal program coupled with the current healthcare landscape can lead to frequent change, so **program adaptability** is paramount
  3. Ongoing compliance is a time-consuming task, so make sure the **mechanisms used to track progress and measure results** are defined
    - Consider trending results over time
    - Document procedures in policy to show HRSA your dedication to Program compliance

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Procedures to Validate Compliance

- 5 suggested work steps:
  1. Database Review
  2. Internal Document Review
  3. Internal Auditing/Testing
  4. Independent Audits
  5. Mock HRSA Audits

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1) Database Review

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- OPA Registration Details
- Validate the information included in the OPA database is accurate and up-to-date. This includes:
  - CE information (address, authorizing official)
  - Child site completeness
  - Contract pharmacy information (address, contract in place)
  - Medicaid treatment accuracy

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2) Internal Document Review

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- 340B policy
- Confirm an entity-specific 340B policy exists
- Compare to Apexus policy example and identify areas of enhancement, such as:
  - Entity's reason for participating
  - Enrollment and recertification procedures
  - Purchasing and accumulation processes
  - Eligibility definitions
  - Internal monitoring procedures
  - CE-specific 'material breach' definition

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2) Internal Document Review

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- Other documents requiring review
- Validate your entity has a process for periodically updating the following:
  - Carve-out drug list
  - Eligible provider list
  - CDM-to-NDC crosswalk
- If utilizing a software splitter, also confirm your process includes submitting these documents to the software liaison and configuring into the software

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### 3) Internal Auditing/Testing

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- Typically performed on a sample basis
  - However, the more dispenses tested, the better chance your internal testing will identify issues that HRSA may find during an audit



- Do you want to leave it to chance?

- What if you could review all dispenses, no more 'rolling the dice' that HRSA chooses the 'right' transactions to test?

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### 3) Internal Auditing/Testing

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Utilizing data analytics can be a way to increase your sample size while bringing efficiency to the testing process



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### 3) Internal Auditing/Testing

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- Consider testing the following areas, as these are where HRSA appears to be focusing much of its audit work:
  - **Diversion** – CE providing drugs purchased utilizing 340B pricing to patients not eligible for the Program.
    - Testing procedures should include:
      - Validating the 340B qualifying drug was:
        - Related to an outpatient or an inpatient discharge script;
        - Administered at an eligible location; and
        - Prescribed by an eligible provider.
  - **Duplicate Discounts** – Manufacturers provide both a 340B discount on a drug AND pay a Medicaid rebate to the State on the same drug.
    - Testing procedures should include:
      - **Medicaid Carve-out Entities** – Validate the 340B dispense as NOT to a patient with a Medicaid payor.
      - **Medicaid Carve-in Entities** – If dispense was to a patient with a Medicaid payor, validate it meets all State requirements.
        - State requirements can include inclusion of a specific modifier or billing at the actual acquisition cost.

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### 3) Internal Auditing/Testing

- **GPO Prohibition** – purchasing covered outpatient drugs from a GPO and is prohibited at DSH, Children's hospitals and free-standing cancer centers.
- Testing procedures should include:
  - If drug was purchased through a GPO, validate the drug was dispensed to an inpatient.
  - If drug was purchased for the first time, validate it was purchased at WAC price and not 340B or GPO.
- **Policy Adherence** – HRSA also performs testing to validate your entity's 340B dispenses are in compliance with your definitions and processes detailed within your 340B policy.
- Testing procedures should include:
  - Confirm your entity's most recent carve-out list, eligible location list and eligible provider list match the lists utilized by your splitter software.
  - Validate the drugs you carve-out are not accumulating in the 340B bucket.

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### 3) Internal Auditing/Testing

- Other testing areas for consideration:
  - NDC match between dispense data and purchasing data
  - Failed data transmission identification
  - Duplicate dispense identification
  - Vaccine exclusion validation

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### 4) Independent Audits

*"...HRSA agrees that independent audits can play an important role in ensuring Program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits."*

- Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, March 2010

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#### 4) Independent Audits

"HHS believes that covered entities that do not regularly review and audit contract pharmacy operations are at an increased risk for compliance issues. An **annual audit of each contract pharmacy location** will provide covered entities a regular opportunity to review and reconcile pertinent 340B patient eligibility information at the contract pharmacy and prevent diversion. Conducting these audits **using an independent auditor will ensure the pharmacy is following all 340B Program requirements**. Additionally, as a separate compliance mechanism, the covered entity should compare its 340B prescribing records with the contract pharmacy's 340B dispensing records at least quarterly to ensure that neither diversion nor duplicate discounts have occurred."

- 340B Drug Pricing Omnibus Guidance, "Mega-Guidance," August 2015

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#### 4) Independent Audits

- Typically performed by third party audit or consulting firms.
- It is important to keep the following in mind, through each phase of the audit:
  - Firm Selection
    - Do they have previous experience with:
      - Your CE type?
      - Your splitter software?
      - Your patient financial system?
    - Have they performed work for clients who have subsequently undergone HRSA audits?
      - If so, did HRSA have additional findings?
  - Audit Methodology
    - What risks do they test? Do they include all of the HRSA focus areas?
    - How large of a sample will they test?
    - What data will be needed for them to perform their testing procedures?

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#### 4) Independent Audits

- Audit Deliverable
  - Does the deliverable include a detailed findings section?
  - Will there be recommended corrective actions for each issue identified?
  - Will the firm provide education related to the issues identified?
- After the Audit
  - Retain the audit report, as HRSA will ask for evidence of prior audits during their audit process
  - Document actions taken based on the findings identified
    - Including dates, responsible parties and additional validation
  - Begin issue resolution process ASAP

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### 5) Mock HRSA Audits

- Internal monitoring and independent audits are necessary, but planning 'dress rehearsals' of HRSA audits is a great next step
- Mock audits should consider the following:
  - Involve all departments that would be needed to completely walk through a dispense
    - Includes pharmacy, billing, IT, legal, compliance, credentialing, and finance
  - Ensure software splitter liaison understands the process and provides the same data sets HRSA would request
  - Identify a 'Mock HRSA Auditor' (this is commonly someone from Internal Audit)
  - Perform testing for a sample of dispenses and retain all supporting documentation
  - If issues are identified, draft corrective actions and follow them through to completion

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### Monitoring Program Summary

- 340B is a complex arrangement in need of near constant attention and ongoing compliance validation
- It is recommended to:
  - Periodically perform a Program review and testing procedures
  - Contract with experts to perform independent assessments and
  - Prepare for the work steps HRSA will perform when your entity is selected for an audit

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### Part 1 Summary

- HRSA has outsourced 340B audits to a third party firm. We expect the audit process to be more sophisticated and consistent than in previous years.
- Covered entities should assess their current monitoring procedures and validate HRSA-focused risks are periodically tested.
- The new administration has put the proposed Mega-Guidance on hold and there is little information as to when updated guidance may be published.



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Break – 15 Minutes

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Audit Issues Summary

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CHAN Audit Summary

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- Information in this section is based on actual audit issues:
  - Over 110 covered entity audits performed
  - Over 450 audit issues identified

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Audits Under Privilege

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# ACP Vs Non-ACP

Note – Issues identified in ACP audits are not included in this presentation.

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Activity #2 – Most Common Audit Issues

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•Rank the following risks in order of most to least number of audit issues identified:

1. Diversion
2. Duplicate Discounts
3. GPO Prohibition
4. Lost Opportunity
5. Program Management
6. Purchasing/NDC Match

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340B Risk Areas

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•Actual rankings:

- 5. Program Management
- 1. Diversion
- 4. Lost Opportunity
- 6. Purchasing/NDC Match
- 2. Duplicate Discounts
- 3. GPO Prohibition

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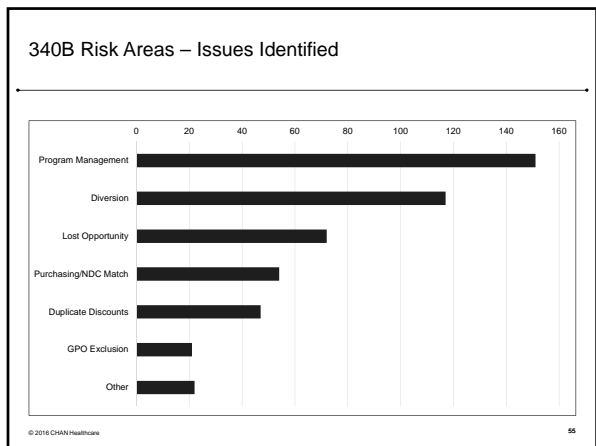
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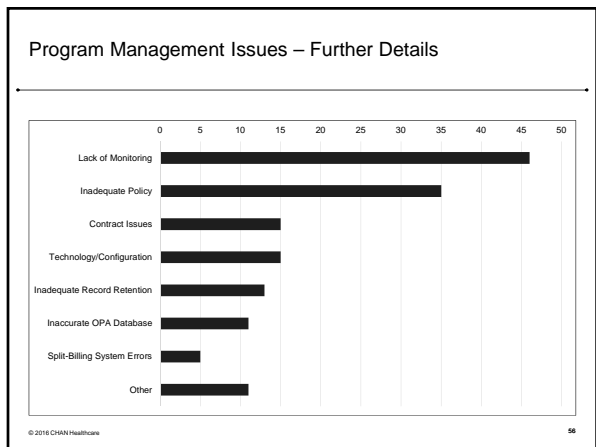
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- ### Program Management – Root Causes
- Areas with the most room for improvement:
    - Program ownership
      - Pharmacy-only focus
      - No compliance/legal presence
    - Program education
      - Initial and ongoing
      - In advance of registering
    - Splitter education
      - Configuration options
      - Qualification process
      - Reporting offerings
      - Push the vendors
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### Activity #3 – Diversion Root Causes

- Break into the same small groups (4-5 people)
- Discuss and list potential root causes of diversion – the goal is to be as detailed as possible:
  - For example, ineligible providers were found to be included in 340B dispenses/accumulation because the provider list maintenance process did not include eliminating terminated providers in a timely manner.
- We'll re-convene in about 10 minutes and ask each group to present

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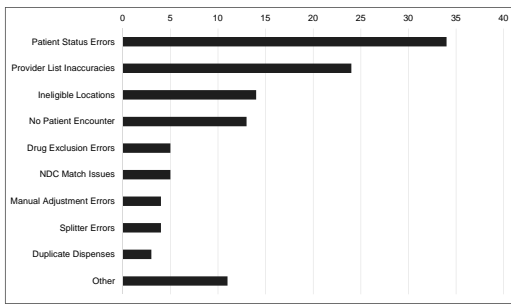
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### Diversion Issues – Further Details



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### Duplicate Discounts – Further Details

- Medicaid carve-in entities
  - Billing expectations not met
    - UD modifier
    - Actual Acquisition Cost (AAC)
- Medicaid carve-out entities
  - Medicaid payors (primary, secondary, tertiary) included in 340B

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Lost Opportunity – Further Details

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- Majority of missed opportunities relate to:

## Software Configuration

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Activity #4 – Split-billing Software Brainstorming

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- Break into groups with individuals utilizing the same split-billing vendor/system.
- Discuss current concerns, if anyone has run into similar issues previously, and how they were able to mitigate risks moving forward.
- We'll re-convene in about 10 minutes and debrief on the most common issues and related implementation strategies to reduce future risk.

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HRSA Audit Findings

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- Most common findings are similar to CHAN audit results
  - Diversion
    - Many related to ineligible sites
  - Duplicate Discounts
  - OPA Database Inaccuracies
- Interesting findings
  - Numerous issues noting lack of contract pharmacy oversight
    - Penalties include termination of contract pharmacy arrangement and termination of the entire contract pharmacy setting
  - Ineligible site qualifying 340B scripts
    - Penalties include termination of the child site from 340B
  - GPO purchasing issue, but the period extends back nine months (more than the six we typically see)
  - Contract pharmacy timing issues – registering (not qualifying scripts as 340B) prior to a contract being in place
  - Using third party audit reports to identify issues

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# Corrective Action Plans

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CHAN Audit Process

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- The following slides relate to action plans implemented based on CHAN audits, not HRSA audits. However, you'll see many could be leveraged (or at least assist) when developing HRSA corrective account plans.

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Program Monitoring and Oversight

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Compliance Risk	Example Action Plan
<b>Program Integrity (Oversight/Monitoring)</b>	Management will develop a 340B steering committee that includes a representative from each department with responsibility for maintaining 340B compliance. The committee will meet on a monthly basis, with meeting minutes compiled and sent to the group within two business days of the meeting taking place. Committee details will be recorded in the policy document.
<b>Program Management (Auditing)</b>	Management will develop a monthly audit process for each contract pharmacy arrangement and a quarterly audit process for the mixed-use setting that includes selecting a sample of 340B dispenses and validating each meets all attributes of eligibility. The internal audit process will be recorded in the policy document.
<b>Program Management (Policy)</b>	Management will update the 340B policy to include all items included in the Apexus example policy and will review the policy at least every two years.

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### Diversion

Compliance Risk	Example Action Plan
<b>Diversion (Provider Issues)</b>	Management will work with the physician credentialing and IT departments to create an initial eligible provider listing that agrees to the definition as stated in the 340B policy. This list will be updated monthly to account for new and terminated physicians and will be sent to each contract pharmacy. This provider maintenance process will be recorded in the policy document.
<b>Diversion (Eligible Encounter, Drug)</b>	Management will work with the IT department to review the current data extract file that is being uploaded into the splitter software and verify that it accurately excludes those departments and locations that do not currently qualify for the program, as stated in the OPA database. In addition, management should review the logic that is excluding certain drugs from the program to confirm that the logic is accurate given the program setup. Any modifications to the extract logic should be updated as necessary within the policy document.

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### Purchasing

Compliance Risk	Example Action Plan
<b>Purchasing (NDC-to-NDC Match)</b>	The pharmacy management department will review purchasing procedures and determine if there is a way to automate all aspects of the process in order to eliminate the ability to manually adjust the bucket in which the drug is to be purchased, as provided by the splitter. Any changes will be recorded within the policy document.
<b>Purchasing (Accumulation)</b>	The pharmacy management department will review the conversion factors currently included in the splitter software and compare them to their internal factors by NDC. Any discrepancies will be communicated to the splitter software. If discrepancies are identified, management will determine the impact on prior accumulation and 340B purchases. Management will implement a process to review periodically all changed conversion factors so that the covered entity and splitter agree.

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### Part 2 Summary

- While Compliance risks make up the majority of audit issues, Program Management and Monitoring are often found to be lacking.
  - HRSA is now taking a hard stance if oversight is not in place
- Diversion is widespread and can take on many forms – sites, providers, duplicate dispenses.
- The root cause of many audit issues is the configuration/setup within the split-billing system, which reinforces the need to fully understand the software during the implementation process.
- Corrective action plans should be detailed and many times include enhancing the policy document.

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Additional 340B Information

**HRSA Guidance**

<http://www.hrsa.gov/opa/index.html>

**OPA CE Database**

<https://opanel.hrsa.gov/340B/Views/CoveredEntity/SearchDirectory>

**HRSA Audit Results**

<http://www.hrsa.gov/opa/programintegrity/auditresults/results.html>

**Apexus Tools and Sample Documents**

<https://www.apexus.com/solutions/education/340b-tools>

**Apexus 340B University**

<https://www.apexus.com/solutions/education/340b-university>

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**21st Annual Compliance Institute – Breakout Session P22**

**Auditing Emerging Compliance Risk Areas**

Presented by:

Debi Weatherford, Executive Director, Internal Audit  
Piedmont Healthcare

Anthony Lesser, Senior Manager, Deloitte & Touche

Slide 1

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**Agenda**

- About our organizations
- Overview of emerging compliance audit issues
- Pharmacy and the 340B Drug Pricing Program
- Cybersecurity
- Provider-Based Services and Provider-Based Physician Billing
- Disaster Recovery and Business Continuity

Slide 2

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Slide 3

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### Emerging Compliance Audit Areas

- Pharmacy 340B
- Cybersecurity
- Provider-Based Services and Provider-Based Physician Billing
- Disaster Recovery and Business Continuity
- Drug Diversion/Impairment in the Work Place
- Social Media
- Medical Devices/Networked Biomedical Devices
- Construction
- Philanthropy
- Revenue Cycle

Slide 10

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### Speaker Biography



**Tony Lasser**  
 Senior Manager  
 Deloitte & Touche  
 Office: 312.498.3829  
 E-mail: [tlasser@deloitte.com](mailto:tlasser@deloitte.com)

#### Experience and qualifications

Tony is a senior manager in Deloitte & Touche's Governance, Regulatory and Risk Strategy practice. He has over twelve years of experience and expertise in the healthcare industry, mostly working with healthcare providers. He works on the national level and has devoted time to achieve experience and success across many different services and platforms in the industry. Tony has been nationally recognized for his contributions and expertise in the Incentive 340B Drug Pricing Program. He has published multiple articles in trade publications covering many topics related to 340B and regularly presents at various national events.

Prior to joining Deloitte, Tony worked for a large health plan, where he designed and implemented 340B pharmacy benefit programs between healthcare providers and pharmacies. Tony also previously served in a senior management position for a PMSA contractor, where he received all 340B technical assistance and support provided by the federal government. He gained front-line experience working for one of the largest public hospital systems in the United States, where he managed a department responsible for contracting, billing, and inventory management for the health system's \$100 million pharmaceutical budget.

#### Education and certifications

- MBA, Tulane University
- BS, Texas A&M University
- American College of Healthcare Executives (ACHE), Health Care Compliance Association (HCCA), Healthcare Financial Management Association (HFMA)

Slide 11

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## CYBER SECURITY



Slide 12

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**Overview**

- Information Security
- The Case for Change
  - In the News ...
  - Wristful Thinking?
- Cyber Security
  - Knowing Your Cybersecurity Landscape
  - Digital Eco-System
  - Understanding the existing Cybersecurity Portfolio



Slide 13 13

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**Information Security – By Definition**

- Information Security is the process by which an organization protects information and its critical elements including the systems, media, the people, and the facilities that process, store and transmit that information.
- In Healthcare: Enable and not disable empowerment of information for doctors and staff first.



Slide 14 14

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**The Case For Change**

Basic IT Security protections are no longer enough to combat the current threat environment. Internal and external threats may defeat existing protections already in place today. IT Security technologies more broadly have evolved into a much larger context than antivirus and firewalls in order to combat a newer and expansive list of potential vulnerabilities now in existence.

Privacy, confidentiality and IT assets may not be as protected as once thought. Without sophisticated monitoring, surveillance, anomaly detection and constant vulnerability assessments their relative health status is unknown and could be at risk. The new face of security breaches have changed and new threats require a far more comprehensive understanding of subtle changes in information movement. Active detection using a comprehensive integrated set of IT Security tools is essential and core to the organizations ability to detect, intervene and eradicate IT Security Breaches in the future.

Slide 15 15

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**Cyber Security**

- What is it
- Threats
- Consequences if not addressed
- Actions
- At Work and At Home
- Campus Services



Slide 16 16

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**What is Cyber Security**

- Cyber Security is a common term used to describe a set of practices, measures and/or actions you can take to protect personal information and your computer from attacks.
- Having a Cyber Security Program policy, which establishes that all devices connected to the health system electronic communications network must meet certain security standards.
- As part of this policy, all campus units provide annual reports demonstrating their level of compliance.
- Further, there are services in place to help all students, faculty and staff meet the Cyber Security standards. Specific information about these services is provided in this tutorial.

Slide 17 17

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**In the News:  
Two Cybersecurity Stories of Note**

- Level 3, which provides internet and voice services to businesses was attacked in retaliation for the rumor of Julian Assange from WikiLeaks being harmed. It is estimated that during this attack's peak, 70% of the Internet in the US and UK was virtually rendered useless. Vendors were offline during the attack and service was restored once the attack ceased. The attack only ended after Julian Assange appealed for the attack to stop.
- Texas-based Rainbow Children's Clinic was the victim of a ransomware attack on its IT systems in August, which affected more than 33,000 patients. A hacker put notice on the clinic's website and then launched a ransomware attack that began encrypting data stored on the clinic's server. Later it was discovered that some patient records have been irretrievably deleted. Destruction of records represents a new escalation in attacks on health systems.

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Wishful Thinking?



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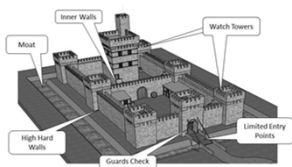
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Run From Castle Or Think!



The bad actors are coming in the front door... Via Social Engineering and Phishing

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### Creating a Cyber Resilient Environment

- Protecting everything is not only impractical it's financially not feasible for most organizations.
- Focus on the basics first:
  - Patch Management
  - Valid Backups
  - Are existing logs being monitored on the Firewalls, Anti-virus reporting, others?
- What environment can be developed to withstand attack?

slide 21

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### Knowing Your Cybersecurity Landscape

- Digital Eco-System
  - Thinking Locally and Globally
  - Sharing Threat Information in our community
  - We are electrons apart from bad actors not miles
- Understanding the existing Cybersecurity Portfolio
  - What are the Existing Protections?
  - Are the Existing Cybersecurity Assets in a Healthy State?
  - What's missing from the Portfolio?

Slide 22

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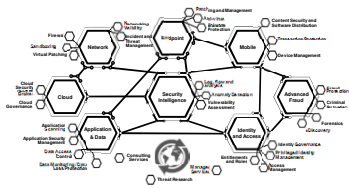
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### IT Security Portfolio – Integrated Solutions Strategy



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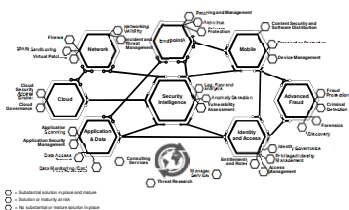
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### IT Security Portfolio – An Example



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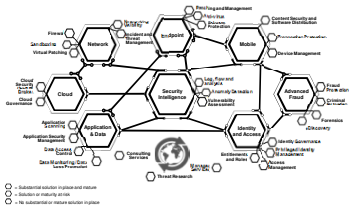
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### IT Security Portfolio – An Example



Slide 25

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### SIEM (Security Information and Event management)

- The segment of security management that deals with real-time monitoring, correlation of events, notifications and console views
- Log management aggregates data from many sources, including network, security, servers, databases, applications, providing the ability to consolidate monitored data to help avoid missing crucial events.

Slide 26

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### SIEM Components

- Data aggregation : Log management aggregates data from many sources, including network, security, servers, databases, applications, providing the ability to consolidate monitored data to help avoid missing crucial events.
- Correlation : Looks for common attributes, and links events together into meaningful bundles. This technology provides the ability to perform a variety of correlation techniques to integrate different sources, in order to turn data into useful information. Correlation is typically a function of the Security Event Management portion of a full SIEM solution.
- Alerting: The automated analysis of correlated events and production of alerts, to notify recipients of immediate issues. Alerting can be to a dashboard, or sent via third party channels such as email.
- Dashboards: Tools can take event data and turn it into informational charts to assist in seeing patterns, or identifying activity that is not forming a standard pattern.
- Compliance: Applications can be employed to automate the gathering of compliance data, producing reports that adapt to existing security, governance and auditing processes.
- Retention: Employing long-term storage of historical data to facilitate correlation of data over time, and to provide the retention necessary for compliance and eDiscovery requirements. Long term log data retention is critical in forensic investigations as it is unlikely that discovery of a network breach will be at the time of the breach occurring.
- Forensic analysis: The ability to search across logs on different nodes and time periods based on specific criteria. This mitigates having to aggregate log information in your head or having to search through thousands and thousands of logs.

Slide 27

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**Protecting the Crown Jewels**

- Determine the mission critical systems
  - Epic/Cerner, PACS, the Network, the Telephone Systems, Lawson/Peoplesoft
    - Protect
    - Monitor
    - Vulnerability Identification and Remediation
    - Focus your efforts and have the highest security standards enforced
- Build out from the center of Patient Care, Revenue Cycle and Infrastructure is one example

Slide 28 28

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**“Crown-Jewel Attack Vectors”**

Slide 29 29

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**Other Considerations...**

- Exclude whole regions of the world who you do not do business with
  - Have a process for doctors without borders, be reasonable.
- Have your Cybersecurity Portfolio “test attacked” by an independent group.
- Go on the offensive and become hunters on your own network.

Slide 30 30

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**What's the Big Deal**

- Data breaches are becoming more prevalent and costly.
- Laws are in a state of flux.
- HIPAA adds extra requirements and consequences.
- New technologies present new and varied problems.
- Amount and transmission of data is increasing at unprecedented rates!



Slide 31 31

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**Data – New Hardware**

- Google Glass
- Health wearables
- Apple Healthkit
- Google Fit
- Pill Scanning Technology



Slide 32 32

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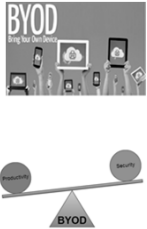
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**BYOD Policy Components**

- No expectation of privacy in the workplace
- Prohibit sharing of devices
- Must report lost or stolen devices
- Prohibit use of cloud-based storage of proprietary data
- Obtain employee consent to monitoring
- Obtain employee consent to remote wiping
- Instruction to employee to preserve data



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**Compliance Strategy**

- Understand the legal environment
- Survey the risk landscape
- Assess the benefit of cyber insurance
- Prepare for the inevitable data breach
- Organize data security teams
  - IT
  - Legal
  - Communications
  - Human Resources



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**Consequences**

- You may face a number of other consequences if you fail to take actions to protect personal information and your computer. Consequences include:

Loss of confidentiality, integrity and/or availability of valuable university information, research and/or personal electronic data

Loss of access to the campus computing network

Lawsuits, loss of public trust and/or grant opportunities, prosecution, internal disciplinary action or termination of employment

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**Top Seven Cyber Security Actions**

1. Install OS/Software Updates
2. Run Anti-virus Software
3. Prevent Identity Theft
4. Turn on Personal Firewalls
5. Avoid Spyware/Adware
6. Protect Passwords
7. Back up Important Files

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**Install OS/Software Updates**

- Updates sometimes called patches fix problems with your operating system (OS) (e.g., Windows XP, Windows Vista, Mac OS X) and software programs (e.g., Microsoft Office applications).
- Most new operating systems are set to download updates by default. After updates are downloaded, you will be asked to install them. Click yes!
- To download patches for your system and software, visit:
  - Windows Update: <http://windowsupdate.microsoft.com> to get or ensure you have all the latest operating system updates only. Newer Windows systems are set to download these updates by default.
  - Microsoft Update: <http://www.update.microsoft.com/microsoftupdate/> to get or ensure you have all the latest OS and Microsoft Office software updates. You must sign up for this service.
  - Apple: <http://www.apple.com/support>
  - Unix: Consult documentation or online help for system update information and instructions.
- Be sure to restart your computer after updates are installed so that the patches can be applied immediately.

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**Run Anti-Virus Software**

- To avoid computer problems caused by viruses, install and run an anti-virus program like Sophos.
- Periodically, check to see if your anti-virus is up to date by opening your anti-virus program and checking the Last updated: date.
- Anti-virus software removes viruses, quarantines and repairs infected files, and can help prevent future viruses.

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**Prevent Identity Theft**

- Don't give out financial account numbers, Social Security numbers, driver's license numbers or other personal identity information unless you know exactly who's receiving it. Protect others people's information as you would your own.
- Never send personal or confidential information via email or instant messages as these can be easily intercepted.
- Beware of phishing scams - a form of fraud that uses email messages that appear to be from a reputable business (often a financial institution) in an attempt to gain personal or account information. These often do not include a personal salutation. Never enter personal information into an online form you accessed via a link in an email you were not expecting. Legitimate businesses will not ask for personal information online.
- Order a copy of your credit report from each of the three major credit bureaus-Equifax, Experian, and Trans Union. Reports can be ordered online at each of the bureaus' Web sites. Make sure reports are accurate and include only those activities you have authorized.

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**Turn on Personal Firewalls**

- Check your computer's security settings for a built-in personal firewall. If you have one, turn it on. Microsoft Vista and Mac OSX have built-in firewalls. For more information, see:
  - Mac Firewall ([docs.info.apple.com/article.html?path=Mac10.4/en/mb1042.html](https://docs.info.apple.com/article.html?path=Mac10.4/en/mb1042.html))
  - Microsoft Firewall ([www.microsoft.com/windowsxp/using/networking/security/winfirewall.mspx](http://www.microsoft.com/windowsxp/using/networking/security/winfirewall.mspx))
  - Unix users should consult system documentation or online help for personal firewall instructions and/or recommendations.
- Once your firewall is turned on, test your firewall for open ports that could allow in viruses and hackers. Firewall scanners like the one on <http://www.auditmypc.com/firewall-test.asp> simplify this process.
- Firewalls act as protective barriers between computers and the internet.
- Hackers search the Internet by sending out pings (calls) to random computers and wait for responses. Firewalls prevent your computer from responding to these calls.

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**Avoid Spyware/Adware**

- Spyware and adware take up memory and can slow down your computer or cause other problems.
- Use Spybot and Ad-Aware to remove spyware/adware from your computer. Individuals can get Spybot and Ad-Aware for free on the Internet Tools CD (available from IT Express in Shields Library).
- Watch for allusions to spyware and adware in user agreements before installing free software programs.
- Be wary of invitations to download software from unknown internet sources.

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**Protect Passwords**

- Do not share your passwords, and always make new passwords difficult to guess by avoiding dictionary words, and mixing letters, numbers and punctuation.
- Do not use one of these common passwords or any variation of them: qwerty1, abc123, password1, iloveyou1, (yourname)1, baseball1.
- Change your passwords periodically.
- When choosing a password:
  - Mix upper and lower case letters
  - Use a minimum of 8 characters
  - Use mnemonics to help you remember a difficult password
  - Store passwords in a safe place. Consider using KeePass Password Safe (<http://keepass.info/>), Keychain (Mac) or an encrypted USB drive to store passwords. Avoid keeping passwords on a Post-it under your keyboard, on your monitor or in a drawer near your computer!

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**Back Up Important Files**

- Reduce your risk of losing important files to a virus, computer crash, theft or disaster by creating back-up copies.
- Keep your critical files in one place on your computer's hard drive so you can easily create a back up copy.
- Save copies of your important documents and files to a CD, online back up service, flash or USB drive, or a server.
- Store your back-up media in a secure place away from your computer, in case of fire or theft.
- Test your back up media periodically to make sure the files are accessible and readable.

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**Cyber Security AT HOME**

- Physically secure your computer by using security cables and locking doors and windows in the dorms and off-campus housing.
- Avoid leaving your laptop unsupervised and in plain view in the library or coffee house, or in your car, dorm room or home.
- Set up a user account and password to prevent unauthorized access to your computer files.
- Do not install unnecessary programs on your computer.
- Microsoft users can download the free Secunia Personal Software Inspector (<https://psi.secunia.com/>), which lets you scan your computer for any missing operating system or software patches and provides instructions for getting all the latest updates.

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**Cyber Security AT WORK**

- Be sure to work with your technical support coordinator before implementing new Cyber Security measures.
- Talk with your technical support coordinator about what Cyber Security measures are in place in your department.
- Report to your supervisor any Cyber Security policy violations, security flaws/weaknesses you discover or any suspicious activity by unauthorized individuals in your work area.
- Physically secure your computer by using security cables and locking building/office doors and windows.
- Do not install unnecessary programs on your work computer.

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### CAMPUS Cyber Security SERVICES

Protect Campus Network

Services	Software
<ul style="list-style-type: none"> <li>▪ Campus email virus filtering</li> <li>▪ Campus firewall services</li> <li>▪ Email attachment filtering</li> <li>▪ Vulnerability scanning</li> <li>▪ Intrusion prevention system</li> </ul>	<ul style="list-style-type: none"> <li>▪ Free anti-virus software: Sophos Anti-virus</li> <li>▪ Free encryption software: Pointsec for PC</li> <li>▪ Free change management software: Tripwire</li> </ul>

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#### The Internet is Hard to Secure

- Extreme complexity, minimal understanding
- High global connectivity
- Weak attribution (who's doing what?)
- Hard to tell malicious uses from legitimate ones

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#### Additional Information

- According to S.I. 1901 "Cyber Security Research and Education Act of 2002":
  - "The term cyber security infrastructure includes--
    - (A) equipment that is integral to research and education capabilities in cyber security, including, but not limited to--
      - (i) encryption devices;
      - (ii) network switches;
      - (iii) routers;
      - (iv) firewalls;
      - (v) wireless networking gear;
      - (vi) protocol analyzers;
      - (vii) file servers;
      - (viii) workstations;
      - (ix) biometric tools; and
      - (x) computers; and
    - (B) technology support staff (including graduate students) that is integral to research and education capabilities in cyber security."

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**Mobile Device Security Resource Center for Providers and Professionals**

Tips and information providers and professionals can use to:

- Protect and secure health information when using a mobile device
- Understand their organization's mobile device policies and procedures
- Five steps organizations can take to manage mobile devices

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**Materials Available Online**

Materials available for download on [HealthIT.gov/mobiledevice](http://HealthIT.gov/mobiledevice) include:

- Fact sheets
- Posters
- Brochures
- Postcard

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**Helping Providers Integrate Privacy & Security Into Their Culture**

- Designed to help health care practitioners and practice staff understand the importance of privacy and security of health information at various implementation stages
- Developed with assistance from the American Health Information Management Association (AHIMA) Foundation, with input from OCR and OGC
- Being updated to reflect HITECH changes

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### Cyber Security for Medical Devices:

- Common focus on individual medical devices is important... but misleading.
- Most medical systems can be secured simply by disconnecting them from the network.
- Unfortunately what would be lost, and what really needs to be protected, is the secure transfer of clinical information between medical systems.
- The right information, before the right people, at the right time, improves patient treatment. Security improvements must not impede that information flow.

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### Constraints on Manufacturers

- Manufacturers rarely need to get approval from FDA with regards to Cyber Security fixes. However, they always need to validate safe & effective operation after changes, including 3rd party patches.
- No one can predict impact of 3rd party changes on clinical operations in advance. Therefore, verifying and validating seemingly minor changes may take significant time.
- Determining impact of patch, or any other design change, usually requires deep understanding of medical device.
- Everyone would like to move faster, but there is no magic way to avoid necessary validation.

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### Healthcare Provider

- Traditional IT assumptions and procedures need to accommodate unique medical device realities.
- Generic IT security best practices, indiscriminately applied to medical devices without manufacturer coordination, can pose patient security risk. For example:
  - Automatic patching can and has broken medical devices.
  - Network vulnerability scans can disrupt clinical operations.
  - Antivirus software can disrupt time-sensitive clinical operations.
  - Misidentification of clinical data as a virus may interfere with clinical care.
  - Authentication schemes must fail-open (let the user in) instead of fail-closed (lock the user out).

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**Ongoing Communications**

- Cooperation between hospital IT staff and clinical personnel is critical since both parties have essential knowledge. It is dangerous when they work independently.
- Cooperation between healthcare providers and equipment manufacturers is also critical, for the exact same reasons.
- Treat security problems and concerns like any other problem with a medical device. They are hazards that need to be appropriately addressed.
- Don't reinvent the wheel or set up special channels -- use established support mechanisms.

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**Do Not wait until you have to REACT  
BE PROACTIVE**

- Review Your Policies
- Monitor the Cyber Risks
- Foster an Organizational Commitment to Security
- Conduct Regular Audits
- Understand the Legal Compliance Environment
- Train Your Team Members



Cyber Security Policy



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**WRAP UP**



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### 340B Drug Pricing Program

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#### 340B Drug Program Summary

- The 340B program requires drug manufacturers to provide outpatient drugs to qualified and participating healthcare organizations at significantly reduced prices.
- The 340B Program provides the deepest discount on pharmaceuticals in the country, trailing only the Department of Defense and Veterans Healthcare Administration contracts.
- Up to 2,048 hospitals and health systems participated as covered entities in 2014<sup>2</sup>
- 340B Entities accounted for over **\$7 billion**<sup>1</sup> in drug spend in 2013, roughly **2%** of total spend across the United States.

**The Veterans Health Care Act of 1992** requires pharmaceutical manufacturers whose drugs are covered by Medicaid to provide discounts on outpatient covered drugs purchased by specific public health services that serve the nation's most vulnerable patient populations.

The program has come under increasing levels of scrutiny since its expansion after the PPACA in 2010.

The OIG provides that reports indicating inconsistent operational practices across covered entities and limited oversight by HHS.

HHS has attempted to issue formal guidance in the past, however many unanswered questions and "gray" areas remain.

Sources: <sup>1</sup>http://www.health.gov/press/pressrel.aspx?id=2015-09-01-the-congress-overview-of-the-340b-drug-pricing-program.pdf#st=2  
<sup>2</sup>http://www.pharmaceuticalnews.com/Articles/Pharma-Act/1401642-27380

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#### 340B Program Operations Illustration

**In House:**

- Medication administered within eligible hospital/clinic
- Outpatient or "mixed use" environment
- Managed By split billing software
- ER, Observation, Infusion, etc.
- Purchases represent cost savings to the covered entity

**Contract Pharmacy:**

- Prescriptions dispensed at retail pharmacies for patients of eligible 340B entities
- Usually requires technology solution to serve as an intermediary
- Software vendor usually manages any new pharmacy chain(s)
- Discharge medications, clinic prescriptions
- Profit sharing model – revenue generating

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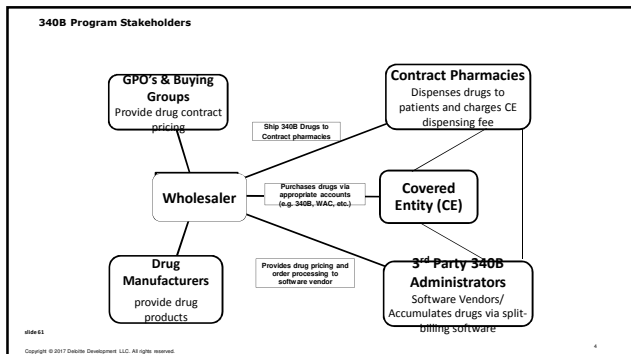
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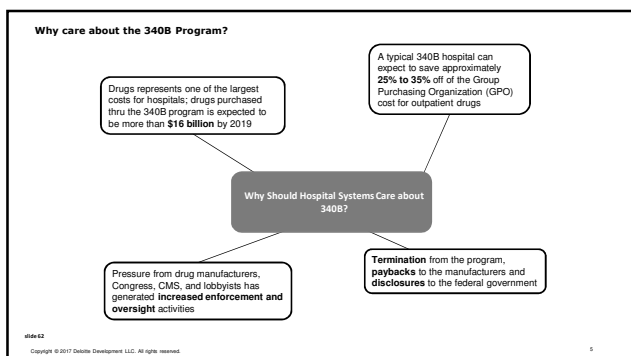
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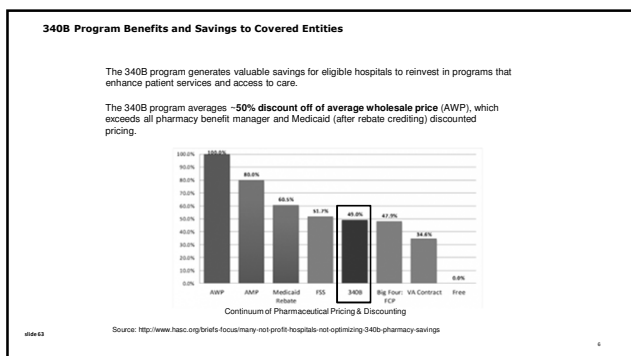
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**Key Program Prohibitions**

<b>Diversion</b>	Covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity
<b>Duplicate Discount</b>	Covered entity is prohibited from accepting a discount for a drug that would also generate a Medicaid rebate to the State. Billing requirements vary from state-to-state, but greater clarity will come in 2017.
<b>GPO Exclusion</b>	DSH hospitals, children's hospitals, and free-standing cancer hospitals may not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.
<b>Orphan Drugs</b>	Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals may not purchase selected rare disease drugs at 340B prices.

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**Illustrative 340B Program risk universe**

<p><b>Inventory Management</b></p> <ul style="list-style-type: none"> <li>Multiple distribution channels</li> <li>Drug shortages</li> <li>340B replenishment capability</li> <li>Inventory need and referral services</li> <li>Tracking, monitoring, and auditing of inventory</li> <li>Non-current spendability</li> <li>Accuracy of billings of prescription orders</li> <li>Accuracy of electronic product tracking information (tracking and judging)</li> <li>Reconciliation of medication transfers (i.e. borrow/ship)</li> </ul>	<p><b>Dispensing</b></p> <ul style="list-style-type: none"> <li>Drug diversion to non-340B patients</li> <li>Clarity and consistency of 340B "patient definition"</li> <li>Drug Enforcement Administration (DEA) compliance</li> <li>State Board of Pharmacy Regulations</li> <li>Reproducible/verifiable inventory records</li> <li>Uninsured/Charity programs</li> <li>Reconciliation of out-of-stock medication</li> <li>Patient freedom of choice</li> <li>GPO purchasing compliance</li> </ul>	<p><b>Covered Entity/Vendor Partnership</b></p> <ul style="list-style-type: none"> <li>High software costs</li> <li>Third-party vendor sophistication and performance</li> <li>Vendor selection</li> <li>Operational contractual terms</li> <li>Patient health information exchange/data breaches</li> <li>Reliance on third-party software systems</li> <li>Reliance on third-party product training information</li> </ul>
<p><b>Technology</b></p> <ul style="list-style-type: none"> <li>Completeness and verifiability of hospital IT systems</li> <li>Data integrity</li> <li>Interface between hospital and vendor systems</li> <li>Operational procedures</li> <li>Billing errors and data loss</li> <li>Software maintenance activities</li> </ul>	<p><b>Billing &amp; Reimbursement</b></p> <ul style="list-style-type: none"> <li>Medicaid claim information</li> <li>Managed Medicaid billing compliance</li> <li>Nonreimbursement/Overage 340B due to 340B volume</li> <li>Payment Collection processes</li> <li>Medicaid Payer verification and management</li> <li>Payer Auditing activity</li> <li>Variability of 340B prices</li> <li>Issues related to high-dose prescriptions</li> <li>Facility eligibility – integration with Medicare Cost Report</li> </ul>	<p><b>Legal/Regulatory/Corporate Compliance</b></p> <ul style="list-style-type: none"> <li>340B Service Customers</li> <li>DEA Tracking and Refillage regulations</li> <li>MSD/CAC anti-sharing noncompliance</li> <li>Anti-Kick Back regulations</li> <li>Patient Records Management/Retention</li> <li>Litigation and Dispute Res.</li> <li>Anti-trust</li> <li>Contract compliance</li> <li>ADA, Manufacturer audit requests</li> <li>Public disclosure of audit results/regulatory risk</li> <li>ACA implementation</li> <li>340B Registration</li> </ul>

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**340B Drug Program: "Patient Definition"**

- Drugs must be administered to a *qualified patient*:
  - Covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
  - Individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity; and
  - Individual receives health care service(s) from the covered entity which is consistent with the services(s) for which grant funding or federally-qualified health center look-alike status has been provided to the entity.
- 340B Program is intended for *Outpatient use only*
- Drugs must be administered in a hospital point of service that would qualify as a "reimbursable cost center" on the Medicare cost report:
  - Includes qualified outpatient facilities (e.g., physician clinics, surgery centers)
  - Provider-based reimbursement changes may affect new clinic enrollment



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**Duplicate Discounts**

- Covered entities may not receive a 340B discount for drugs that are subject to a Medicaid rebate:
  - Providers required to inform HRSA (by providing their Medicaid billing number) at the time they enroll if they plan to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid
  - Follow procedures established by State Medicaid agencies
- State Medicaid program may:
  - Require Covered Entities to *carve out Medicaid* patients from 340B so the State can claim the rebate
  - Allow Covered Entities to use 340B drugs for Medicaid patients, and *reduce Medicaid payment* to the Covered Entity
  - Allow Covered Entities to use 340B drugs for Medicaid patients, and *pay an increased dispensing fee*
- New CMS rules in effect beginning Summer 2017.
  - States must develop policies related to managed Medicaid
  - "acquisition cost" must be used as billing price for drugs



HRSA  
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**Contract Pharmacies**

Covered entities **must** conduct the following oversight activities for their contracted pharmacies:

**Contract Pharmacy Oversight Requirements**

- Conduct independent annual audits and/or adequate oversight mechanism.
- Documentation requirements:
  - Develop written 340B Program policies and procedures involving contract pharmacy oversight
  - Maintain auditable records at both covered entity and contract pharmacy
  - Ensure written contract pharmacy agreement lists each contract pharmacy individually and is in place before registering contract pharmacy in 340B Program
  - Contract pharmacy may not be utilized for purposes of the 340B Program until it has been registered, certified, and pharmacy is listed on the covered entity's 340B database record
- Ensure that 340B drugs are only provided to 340B-eligible patients.
- Carve-out Medicaid at contract pharmacies – or develop an alternative arrangement to work in collaboration with the state Medicaid agency to ensure duplicate discounts do not occur and report this to HRSA.
- Maintain accurate information in the HRSA 340B database, including covered entity contact information, contract pharmacy information, and Medicaid billing information.

HRSA  
Source: <http://www.hrsa.gov/opa/pdfs/contractpharmacy020514.html>

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**Contract Pharmacies Expansion**

- HRSA allows CEs to use an in-house pharmacy and contract with a retail pharmacy.
- Starting in 2010, HRSA allows CEs to utilize multiple contract pharmacies which greatly expands access to 340B drugs.
- Since 2010, percentage of CEs that use contract pharmacies has risen from 10% to 22%.



The number of unique pharmacies serving as contract pharmacies has grown by 770%, and the total number of contract pharmacy arrangements has grown by 1,245%.

HRSA  
Source: US Department of Health and Human Services, Health Resource and Services Administration, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services 10/27/2010 Federal Register Notice 66479, No. 43, March 9, 2010  
URL: <http://www.hrsa.gov/opa/programrequirements/index.html#contractpharmacyarrangements>

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**Example of Internal Monitoring and Auditing Plan Components/Areas**

<b>Eligible Provider Review</b>	Review accuracy of eligible provider list per facility to confirm proper designation	Monitoring - Bi-weekly	Pharmacies Contract pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit
<b>Eligible Payer Review</b>	Review accepted payers to validate they are in alignment with Medicaid "Care-of" or "Care-out" status and applicable Medicaid billing.	Monitoring - Monthly	Covered entity Child sites Contract pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit
<b>340B Pharmacy Claims Review</b>	Review 340B pharmacy claims per facility to confirm compliance with 340B Program requirements.	Monitoring - Monthly	Administered/dispensed outpatient locations and pharmacies Contract pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit
<b>340B Contract Pharmacy Contracts Review</b>	Review executed contracts with contract pharmacies and contract pharmacy administrators to confirm compliance with contract pharmacy contract elements	Monitoring - Annually	Contract pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit

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**Example of Internal Monitoring and Auditing Plan Components/Areas**

<b>Reversals Review</b>	Review of adjustments to confirm all submitted 340B reversals have been completed.	Monitoring - Monthly	Contract Pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit
<b>Pharmaceutical Inventory Review</b>	Review of pharmaceutical purchases orders, invoices and true-ups. Scope includes self-billing contracts and accumulators.	Monitoring - Monthly	Administered/dispensed outpatient locations and pharmacies Contract Pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit
<b>Orphan Drug Prohibition Review (if applicable)</b>	Review 340B captured prescriptions originating from the Covered Entity, from both pharmacy and contract pharmacy locations to confirm drugs are not classified as OOP for orphan drugs related to the primary indication of the orphan drug (if applicable)	Monitoring - Monthly	Administered/dispensed outpatient locations and pharmacies Contract Pharmacies	Monitoring - 340B Compliance Team Auditing - Internal Audit or Contracted External Audit

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**Overview of a Monitoring and Auditing Plan**

<b>Common Monitoring Auditing Findings</b>	<ul style="list-style-type: none"> <li>• Diversion to ineligible patients               <ul style="list-style-type: none"> <li>• Lack of documented encounter / missing assessment notes</li> <li>• "Moon-Lighting" and ineligible prescribers</li> <li>• Faxed calls vs. written date</li> <li>• Medicaid FFS processed inappropriately</li> </ul> </li> <li>• Lack of self-disclosure of known issues to HRSA/OPA</li> </ul>
<b>Monitoring / Auditing Findings Resolutions</b>	<ul style="list-style-type: none"> <li>• Quantity issue(s)</li> <li>• Clearly defines the global impact of the actual findings on your program</li> <li>• Internal Audit finding &amp; resolution documentation               <ul style="list-style-type: none"> <li>• Sample info                   <ul style="list-style-type: none"> <li>• Discovery</li> <li>• Resolution</li> <li>• Proactive steps</li> </ul> </li> </ul> </li> <li>• Communicate to all applicable parties               <ul style="list-style-type: none"> <li>• Compliance Officer/Committee</li> </ul> </li> </ul>
<b>Reporting Discoveries from Monitoring &amp; Auditing</b>	<ul style="list-style-type: none"> <li>• Entity eligibility issues               <ul style="list-style-type: none"> <li>• Report to HRSA/OPA</li> <li>• Stop purchasing</li> </ul> </li> <li>• Patient or covered drug eligibility issues               <ul style="list-style-type: none"> <li>• Work with manufacturers to determine repayment steps</li> </ul> </li> </ul>

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**Findings, Resolutions, and Reporting**

**Program Manager Job Description**

**Drug Purchasing Program Appendix**

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**Creating Tools Can Be Useful to Support 340B Compliance**

**340B Monitoring Metrics**

Monitoring	%	Jan	Feb	Mar
OPA 340B database review	99	100	100	96
Eligible Provider review	100	100	100	100
340B pharmacy claims review	99	98	99	100
Pharmacy 1	96	90	95	98
Pharmacy 2	99	100	100	95
Contract Pharmacy 1	93	80	90	100
Contract Pharmacy 2	95	90	95	100
Reversals review	100	100	100	100
Pharmacy 1	96	90	95	98
Pharmacy 2	99	100	100	95
Contract Pharmacy 1	93	80	90	100

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**Creating Tools Can Be Useful to Support 340B Compliance**

**340B Issues and Action Items Register**

Slide 81

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**Example of Internal Monitoring and Auditing Plan Components/Areas**

**340B Compliance Program Dashboard**

Quarterly Monitoring and Auditing

Monitoring Area	% Complete	Status
Medical Training	100%	Met
Medical	100%	Met
Administrative Staff	100%	Met
Medical Pharmacy	100%	Met
Medical 340B Consultant	95%	Met

**340B Compliance Key Reportable Metrics**

Category	% Complete	Status
Medical Consultant	95%	Met
Training 1	100%	Met
Training 2	100%	Met
Training 3	95%	Met

Issues/Corrective Action Status

Issue/Corrective Action	% Complete	Status
Supplier/Contract	25%	Open
Division	50%	Open
Program Center	Closed	Closed

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**Questions?**

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**Provider-Based Services and  
Provider-Based Physician Billing**

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### Agenda

- Background
- OIG Initiatives
- Provider-Based Considerations
- Monitoring Techniques to Protect Status
- Auditing for Compliance with Regulatory Requirements
- Key Controls
- Questions/ Comments

Slide 25

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### Background – Provider-Based Regulations

- Current Provider-Based Status requirements are governed by the regulations at 42 C.F.R. § 413.65
  - Describes the criteria and procedures for determining whether a facility or organization is provider-based.
- Further explained in Program Memorandum Transmittal A-03-030
- Relationship between a main provider and another facility, department or related entity, whereby the other entity is considered a subordinate part of the main provider

Slide 26

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### Background - What is Provider-Based Status?

- Refers to services rendered in an integrated hospital outpatient clinic or location
  - On-campus - within 250 yards of the main hospital (measured in a straight line)
  - Off-campus within 35 miles of the main provider
- General Rule – requirements apply to a facility if its status as provider-based or freestanding affects Medicare payment amounts and/or beneficiary liability for services furnished in the facility

Slide 27

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**Background - Potential Advantages**

- Net income benefits to the hospital for provider-based entities related to the ability to bill the hospital facility charge
- May result in higher combined reimbursement from Medicare and Medicaid
  - Commercial Payors – Problematic provisions
- Reimbursement for Medicare bad debts
- Access to hospital resources otherwise not available

Slide 18

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**Background - Potential Advantages**

- Provider may qualify as a "child site" for purposes of the 340B Drug Discount Program
- An outpatient clinic that qualifies as provider-based may be included in the commercial payor contracts applicable to services furnished in the main provider
  - Rates may be higher than those paid in freestanding outpatient clinics

Slide 19

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**Background - Potential Disadvantages**

- Negative impact on patients
  - Potentially higher charges and higher co-payments
  - Patients will receive two bills:
    - Facility Charge
    - Professional or Physician Fee Charge
  - Commercial Insurance and Other Payers
    - Higher Deductibles and Co-payments
- Greater billing complexities
- Potentially higher practice costs due to different wage scales/benefits
- Loss of physician control of hospital-based practice staff

Slide 20

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**Background – On Campus and Off Campus**

• **Licensure**

- The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except:
  - » in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or
  - » in States, where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license.
- 42 C.F.R. § 413.65(d)(1)

Slide 21

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**Background – On Campus and Off Campus**

• **Clinical Services**

- The clinical services of the facility or organization seeking provider-based status and the main provider are integrated
  - » 42 C.F.R. § 413.65(d)(2)
  - » Clinical privileges of the professional staff
  - » Monitoring and oversight by the main provider
  - » Reporting relationship of the Medical Director
  - » Medical staff committees or other professional committees
  - » Integrated medical records (unified retrieval system)
  - » Integration of inpatient and outpatient services

Slide 22

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**Background – On Campus and Off Campus**

• **Financial Integration**

- Financial operations are fully integrated within the financial system of the main provider
  - » 42 C.F.R. § 413.65(d)(3)
  - » Shared income and expense
  - » Cost reported in a cost center of the provider
  - » Financial status incorporated and readily identified in the main provider's trial balance

Slide 23

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### Background – On Campus and Off Campus

- Public Awareness
  - Held out to the public and other payors as part of the main provider
    - 42 C.F.R. § 413.65(d)(4)
  - All information (advertisements, signage, web-sites, patient registration forms, letterhead) should reflect that the site is part of the main provider
  - The name of the site should include the name of the main provider
  - CMS has said it is not sufficient for advertisements to show that the site is part of, or affiliated with, the provider's network or health care system

Slide 54

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### Background – On Campus

- Anti-dumping rules
- Bill physician services with Correct Site of Service Indicator – off-campus outpatient hospital (19) or on-campus outpatient hospital (22) versus office (11)
- Comply with all terms of the hospital's provider Agreement
- Hospital outpatient departments (other than RHCs) treat all Medicare patients for billing purposes, as hospital outpatients
- Subject to applicable payment window provisions (does not apply to CAHs)
- Meet all applicable hospital health and safety rules for Medicare-participating hospitals

Slide 55

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### Background – On Campus

- Joint Ventures
  - Partially owned by at least one provider
  - Located on the main campus of the main provider who is a partial owner
  - Be provider-based to the main provider on whose campus the facility or organization is located
  - Meet all other provider-based requirements

Slide 56

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**Background – Off Campus**

- Operation under the ownership and control of the main provider
  - 100% owned by the main provider
  - Same governing body as the main provider
  - Operate under the same organizational documents as the main provider (bylaws, etc.)
  - Final responsibility lies with the main provider for:
    - Administrative decisions
    - Final approval of contracts, personnel actions/policies and medical staff appointments

Slide 17

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**Background – Off Campus**

- Administration and Supervision
  - Maintain the same reporting relationships as other departments of the main provider
    - Facility or organization is under the direct supervision
    - Operated under the same monitoring and oversight, operated just as any other provider
    - Administrative functions are integrated with those of the provider (billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services)

Slide 18

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**Background – Off Campus**

- Location
  - Within 35 mile radius of the campus of the main provider
  - Exceptions
    - Owned and operated by a provider with DSH > 11.75%
    - Facility or organization demonstrates a high level of integration with the main provider (75% zip code test)
    - RHC located in a rural area attached to a hospital with less than 50 beds



Slide 19

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**Background – Off Campus**

- **Management Contracts**
  - A facility or organization that is not located on the campus of the potential main provider must meet all of the following criteria:
    - Main provider employs the staff
    - Administrative functions are integrated with those of the main provider
    - Main provider has significant control over operations
    - Management contract is held by the main provider itself

156b-100 100

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**Background – Off Campus**

- **HCPCS Modifier for Hospital Claims:**
  - Modifier "PO"
    - » Short descriptor – "Serv/proc off-campus pbd"
    - » Long descriptor – "Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments" Also includes drugs and lab tests packaged into an OPSS service
  - Reported with every code for outpatient hospital services furnished in an off-campus provider-based department of a hospital
  - Not required to be reported for remote locations of a hospital defined at 42 C.F.R. § 413.65 satellite facilities of a hospital defined at 42 C.F.R. § 422.22(h), or for services furnished in an emergency department (Modifier not required for Critical Access Hospitals)

156b-101 101

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**Background – Off Campus**

- **Professional Claims – POS Codes**
  - POS code 19 (Off-campus outpatient hospital)
    - Services furnished in an off-campus PBD hospital setting
  - POS code 22 (On-Campus outpatient hospital)
    - Outpatient services furnished in on-campus, remote, or satellite locations of a hospital
  - POS code 23 (Emergency Room-hospital)

156b-102 102

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**OIG Initiatives**

- HHS OIG Work Plan FY 2014:
  - Impact of provider-based status on Medicare billing
  - Comparison of provider-based and free standing clinics (new)
- HHS OIG Work Plan FY 2015:
  - Medicare oversight of provider-based status
  - Comparison of provider-based and free-standing clinics

*.....extent to which such facilities meet CMS's criteria*  
*.....provider-based status can result in additional Medicare payments and increase beneficiaries' coinsurance liabilities*

156-103 103

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**OIG Initiatives**

- HHS OIG Work Plan FY 2016:
  - Medicare oversight of provider-based status (Revised)
    - *Determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing*
    - *Determine extent to which provider-based facilities meet requirements described in 42 CFR Sec. 413.65*
  - Comparison of provider-based and free standing clinics



156-104 104

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**OIG Initiatives**

- HHS OIG Work Plan FY 2017:
  - CMS is taking steps to improve oversight of provider-based facilities, but vulnerabilities remain.
  - We will review and compare Medicare payments for physician office visits in provider-based clinics to determine the difference in payments for similar procedures.
  - We will assess the potential impact on Medicare and beneficiaries of hospitals claiming provider-based status for such facilities.

156-105 105

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**OIG Initiatives**

October 15, 2014  
Our Lady of Lourdes Memorial Hospital  
\$3.373 million settlement

*"improperly submitted claims for hyperbaric oxygen therapy over a six year period as if such services were furnished in a provider based mobile unit, event though the unit did not comply with the requirements....."*

1506-106

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**OIG Initiatives**

TrailBlazer Health Enterprises, LLC (Texas)  
\$1,051,477 settlement

*Medicare overpaid physicians due to incorrect place of service coding.*

1506-107

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**Provider-Based Considerations**

- . Emphasis on provider-based self attestations for all locations
  - Attestation limits the recoupment time frame if future issues are encountered
  - Documentation submitted for facilities located on and off campus
  - Main provider lists each facility and states its exact location
  - Must be site specific – specific offices or suites
  - Provider-based physician billing sample CMS 1500 claim forms that denote the appropriate site of service (line 24B)
- . Site of service rules the billing
  - Where the service was rendered governs billing
  - EKG performed in provider-based site but read remote must have provider-based site of service code

1506-108

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**Provider-Based Considerations**

- Notice of co-insurance liability per 42 C.F.R. § 413.65(g)(7)
  - All off-campus locations billing as provider-based must have the Medicare Coinsurance form in place.
  - Patients are notified of the coinsurance liability for the service provided by the hospital and also for any physician service
  - An Advance Beneficiary Notification (ABN) does not meet the requirement of providing written notice of beneficiary liability
  - Hospital must provide written notice to the beneficiary, before the delivery of the services, of the amount of the beneficiary's potential financial liability
  - CMS provided "Off Campus Medicare Outpatient Coinsurance Notice" shows a patient signature line while the actual regulation does not specify the requirement that the patient sign the acknowledgement

456-109

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**Provider-Based Considerations**

- Separate license/certificate required for each service or separate location
- Periodic review and update of documentation – how often, by whom, utilize shared folder
- Name of the site should include the name of the hospital (CMS rejected a provider-based entity's application because it was named "John Hopkins at Greenspring" and not "Johns Hopkins Hospital at Greenspring" *Rejected by Appeals Board but an expensive battle*)

456-110

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**Provider-Based Considerations**

- Hospital role in physician proper billing – Requirement for billing of physician services with the appropriate site-of-service indicator

Federal Register/Vol. 65, No 68 (18519) Response to comment:

We agree that physicians (or those to whom they assign their billing privileges) are responsible for appropriate billing, but note that physicians who practice in hospitals, including off-site hospital departments, do so under privileges granted by the hospital. Thus, we believe the hospital has a role in ensuring proper billing.

456-111

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**Provider-Based Considerations**

- Sharing of same space – What happens when a Medicare patient of the freestanding clinic must be seen during the block of time when it is a provider-based clinic and the treating physician insists that the provider waive its facility charge?

*A site must not treat some Medicare patients as hospital outpatients and others as physician office patients.*

4590-112

112

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**Provider-Based Considerations**

- Shared Space Concerns
  - Lack of proper signage and distinction of what space is provider-based vs. freestanding
  - Change in space from when the hospital attested to compliance with provider-based rules and received CMS approval
  - Business license should reflect hospital use of portion of the space for hospital-based

4590-113

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**Provider-Based Challenges – What's New**

- Effective 1/1/2017 CMS stopped paying hospital outpatient PPS rates for off-campus provider-based departments that began after the date the Bipartisan Budget Act of 2015 "Section 603" was signed into law.
- Going forward payments will be under the Medicare Physician fee schedule or the ambulatory Surgical Center payment system
- Payment changes do not effect on-campus provider-based departments or emergency departments

4590-114

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Provider-Based Challenges – What's New

- CMS issued preliminary guidance clarifying the 21<sup>st</sup> Century Cures Act provisions impacting off-campus provider-based hospital outpatient departments that had concrete plans for construction when the Bipartisan Budget Act of 2015 was passed on November 2. The Cure Law -
  - Extended the grandfather date
  - Clarified that the required attestation and certification documents must be received by February 13, 2017
  - Issued sub-regulatory guidance on how hospitals can request a relocation exception

450-115 115

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Provider-Based Challenges – Approach to What's New

- Review how you bill for provider-based locations based on new regulations:
  - Commercial payers – billing as provider-based or clinic
  - Medicaid – review Medicaid and Managed Medicaid plans
  - Medicare Advantage – do you contracts follow CMS

450-116 116

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**Monitoring Techniques to Protect Status**

- Annual review of documentation related to provider-based status
- Development of monitoring reports for employed physician provider-based billing
- Determine monitoring technique for non-employed provider-based physician billing



450-117 117

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### Auditing for Compliance - Regulatory Requirements

- Provider-Based Status
  - Request a listing of all locations billing as provider-based for the hospital
  - Obtain and review a copy of the attestation for each location
  - Review the confirmation letter from CMS
  - Policies and procedures exist, are followed, and comply with regulations
- Analyze sample documentation
  - Licensure/Business License/Occupational Tax Application
  - Clinical staff integration
  - Financial integration
  - Public awareness/signage
  - Patient Notifications of Coinsurance
  - Provider-based entity operates under the hospital license and is 100% owned by the hospital
  - Common bylaws and same governing body

4500-118

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### Auditing for Compliance - Regulatory Requirements

- Billing of Physician Services with the Appropriate Site-of-Service Indicator
  - Communication Protocol
  - Physician Audit Process:
    - Employed Physicians – structure reports to ensure appropriate site of service location is reflected on bill
    - Non-Employed Physicians
      - Request billing forms from sample of patients seen at provider-based facility
      - Meet with physician office manager to jointly review a sample of physician billing from list of patients seen at provider-based facility

4500-119

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### Key Controls

- ✓ Policies/Procedures
- ✓ Shared Folder with Documentary Evidence Routinely Monitored and Reviewed
- ✓ Physician Training and Education (signed attestations that they understand provider-based billing rules and will include the correct place of service code on all patient billing claims)
- ✓ Monitoring for Compliance
- ✓ Right to audit clause in all provider-based physician contracts (employed and non-employed)

4500-120

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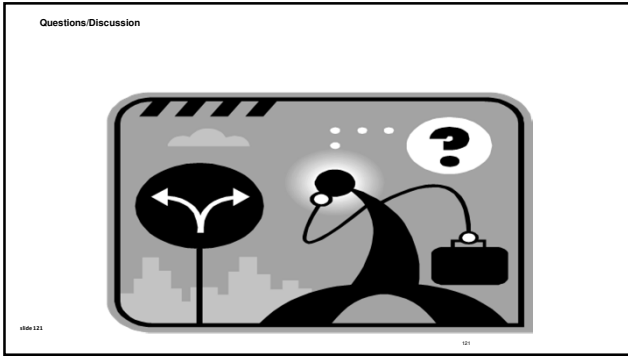
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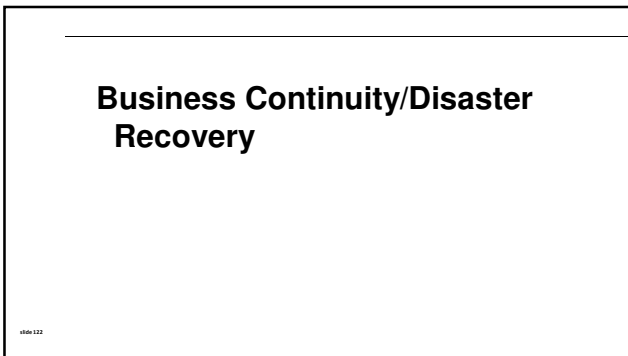
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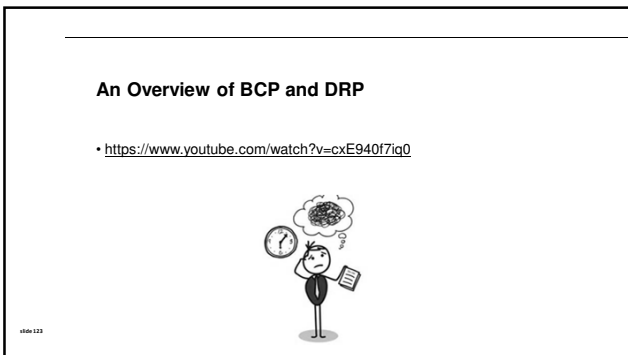
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**BCP**

Business Continuity Planning (BCP) is the processes and procedures that are carried out by an organization to ensure that essential business functions continue to operate during and after a disaster. The ultimate goal is to help expedite the recovery of an organizations critical functions. This includes disaster recovery, but also includes critical contingencies for personnel and business processes.

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**Key Elements of BCP**

- Critical business functions have been identified and prioritized.
- Recovery time objectives have been determined for critical assets.
- Recovery point objectives have been established for critical applications.
- A comprehensive risk assessment has been conducted on critical facilities.
- Succession plans exist for key employees or consultants.
- A technology backup strategy exists and is tested regularly.
- Multiple sources are available for critical supplies and processes.
- People are identified, educated and trained on their duties during a disaster.
- Tools and training are in place to provide advanced warning of incidents.

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**DRP**

Disaster Recovery Plan (DRP) is the process an organization uses to recover access to their software, data and/or hardware that are needed to resume the performance of normal business after the event of a disaster. The DRP takes care of the technology and supports the business. It lays out the process necessary to bring key IT resources - both data and systems back online.

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### Key Elements of DRP

- Remote storage and back up of data in a place that can be accessed from anywhere with an internet connection.
- Alternate communication lines for phones and email server.
- Backup people to spearhead implementation of the plan.
- An offsite location that will handle the company's computers, telecommunications, and environmental infrastructure so that critical business functions and information systems are able to resume as quickly as possible.
- List jobs that will be performed at the offsite location and who will be performing them. Be sure to have a list of the equipment they'll need to do their jobs.

ISS-127

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### Benefits of BCP and DRP

- Allows your organization to avoid certain risks or mitigate the impact of unavoidable disasters by:
  - Minimizing potential economic loss
  - Decreasing potential exposures
  - Reducing the probability of occurrence
  - Improving the ability to recover business operations
- Helps minimize disruption of mission-critical functions – and recover operations quickly and successfully – in the event of a crisis by:
  - Ensuring organizational stability
  - Reducing disruptions to operations
- Assists in identifying critical and sensitive systems
- Provides for a pre-planned recovery by minimizing decision making time
- Eliminates confusion and reduces the chance of human error due to stress reactions
- Protects your organization's assets and employees
- Minimizes potential legal liability
- Reduces reliance on certain key individuals and functions
- Provides training materials for new employees
- Reduces insurance premiums
- Satisfies regulatory requirements



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### Assess Readiness for Business Continuity and Disaster Preparedness\*

- Can you identify your critical business activities that satisfy your customers' expectations and support your overall business operations?
- Can you identify the critical business information needed for these activities to succeed?
  - Do you have information on the frequency, impact and causes of downtime?
  - Does this information allow you to identify and rank your most vulnerable business activities?
- Are your legacy systems and IT resources adequately protected against hacker intrusion and viruses?
- Have you developed a checklist, by functional area, of what your organization will need to continue business effectively in the case of a disruption or emergency?
  - Have you and your IT colleagues been successful in placing business continuity on the board agenda?
- Have you worked with your IT colleagues to develop an approved business continuity plan that accounts for all aspects of business continuity and recovery?
  - Is your business continuity plan regularly tested?
- Do you have a change control process in place to keep your continuity plan current with process, organizational and technology changes?
  - Are you confident that if a disaster were to strike this very minute, your organization could recover quickly and smoothly to prevent damage to your business?

ISS-129

\*Disaster Recovery and Business Continuity Planning: Testing an Organization's Plan", Issue 4, March, ISACA 2006

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### Audit Steps

*Define the Scope of the Audit* – What are the goals and objectives of the audit?

*Planning* – Identify and contact the primary source or auditee. Determine audit approach, such as review all plans or a sample of the plans. Develop audit checklists, questionnaires, audit programs and determine audit tests.

*Fieldwork* – Examine the individual BCP or DR program. Interview key stakeholders and participants in the program. Review planning and other IT related documents. Look for defined recovery times, verify if evidence meets the business goal. Review test plans and results.

*Analysis* – Analyze the results of tests performed and formulate recommendations.

*Reporting* – Prepare and present a formal report to management.

4500-130

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### Additional Fieldwork Steps

- Perform a health check – Review the plans and interview key stakeholders
- Assess completeness and comprehensiveness over all aspects of the BCP or DR program
- Assess the completeness of the business impact analysis (BIA)
- Observe BCP or DR tests
- Participate as formal observers of mock drills
- Compare what was planned and achieved against management's expectations. Compare to industry best practices
- Review Business Continuity Plan Attestations (see example)

4500-131

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### Examples of Key Findings

- No governance or steering committee has been established over BCP or DR
- Lack of a comprehensive enterprise wide Business Continuity Plan
- DR has not been fully tested
- No comprehensive listing of all application are tiered for criticality
- Business is not sure if recovery time objective and recovery point objective defined by Disaster Recovery Plan meets their needs
- Contact information and links noted within the Emergency Operations Plan and DR are not current
- Proximity of Data Center to the nearest facility has not been evaluated
- No formal agreement with a vendor is in place to purchase hardware if existing equipment is destroyed during a disaster
- Corporate policies that directly impact BCP and DR are not clearly defined and conflicted with facility policies (i.e. inclement weather policy)
- Accountable leader for business continuity plan attestations

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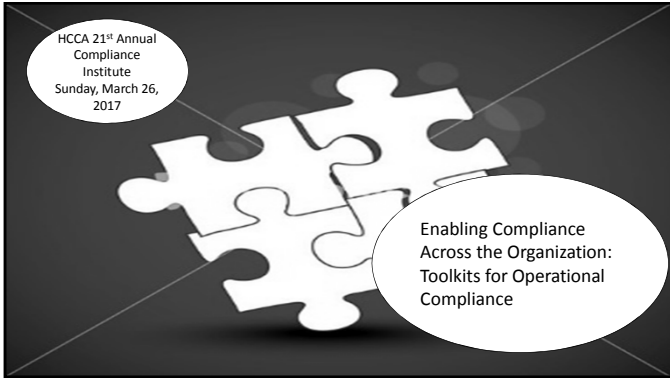
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**Session Goals**

Enable Compliance Professionals to do the following:

- Foster compliance activities by
  - Enabling operators to understand, recognize, and respond to risks of noncompliance.
  - Equipping operators with the knowledge and tools necessary to mitigate and prevent risk of noncompliance.
- Create three-part toolkits
  - Explanation of legal or regulatory requirement or concern;
  - Template for identifying and reporting compliance activity; and
  - Template for addressing compliance matter in a uniform fashion across the organization.
- Create mechanisms for tracking, trending, and reporting results of toolkit implementation
  - To involved operators to aid corrective action; and
  - To leaders / committees to empower effective oversight of compliance activities and results.

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**Hypothetical Handouts**

Three different hypothetical fact patterns, or "hypos":

1. Physician Arrangement
2. Provider-based status
3. Implantable Cardiac Defibrillator / National Coverage Determination compliance.

Each hypo contains a concern or allegation of error or misconduct.

**You are invited to consider your hypo as we discuss the next section--  
*Compliance Programs – Pieces of the Puzzle.***

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### Compliance Programs – Pieces of the Puzzle

#### U.S. Sentencing Guidelines (1991, revised 2004 and 2010)

- Controls criminal sentencing of organizations
- Sentence allows credit for “effective programs to prevent and detect violations of law”
- Risk assessments (ongoing) if credit expected
- Compliance “culture”
- Compliance standards and procedures
- Compliance obligations
- Sufficient resources
- Employee screening practices



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### Compliance Programs - Pieces of the Puzzle

#### • U.S. Sentencing Guidelines (1991, revised 2004 and 2010)

- Must have process for anonymous reporting
- “Specifically encourage prevention and deterrence of violations of the law as part of compliance programs”
- Education and Training

#### • 2010 Revisions:

- Appropriate response to the criminal conduct, including restitution to the victims, self-reporting, and cooperation with the authorities
- Organization must assess their program and make changes to make more effective.
- Encourages an independent monitor to ensure implementation of the changes.

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### Compliance Programs - Pieces of the Puzzle

#### Compliance Program Guidance Hospitals, – February 23, 1998

• **SUMMARY:** This Federal Register notice sets forth the recently issued compliance program guidance for hospitals developed by the Office of Inspector General (OIG) in cooperation with, and with input from, several provider groups and industry representatives. **Many providers and provider organizations have expressed an interest in better protecting their operations from fraud and abuse through the adoption of voluntary compliance programs.** The first compliance guidance, addressing clinical laboratories, was prepared by the OIG and published in the Federal Register on March 3, 1997. **We believe the development of this second program guidance, for hospitals, will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the health care industry.**

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### Compliance Programs - Pieces of the Puzzle

- Compliance Program Guidance Hospitals, 1998 - Compliance Program Elements**
- (1) The development and distribution of **written standards of conduct, as well as written policies and procedures** (adherence to included in evaluation of managers and employees)
  - (2) The designation of a **chief compliance officer and other appropriate bodies**, e.g., a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;
  - (3) The development and implementation of regular, **effective education and training programs for all affected employees**;
  - (4) The maintenance of a process, such as a **hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation**;

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### Compliance Programs - Pieces of the Puzzle

- Compliance Program Guidance, Hospitals 1998 - Compliance Program Elements**
- (5) The development of a **system to respond to allegations** of improper/illegal activities and the **enforcement of appropriate disciplinary action** against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
  - (6) The use of **audits and/or other evaluation techniques to monitor compliance** and assist in the reduction of identified problem area; and
  - (7) The **investigation and remediation of identified systemic problems** and the development of policies addressing the non-employment or retention of sanctioned individuals.

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### Compliance Programs - Pieces of the Puzzle

- Supplemental Compliance Program Guidance, Hospitals 2005 - Compliance Program Elements**
- January 31, 2005 - The supplemental CPG provides voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.
  - **This CPG adds Risk Assessment and evaluating effectiveness**
  - **Discusses multiple fraud and abuse risk areas**
  - **Discusses Hospital Compliance Program Effectiveness**

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017**

- In the context of a criminal investigation, a corporate compliance program is evaluated applying the “Filip Factors” – the existence and effectiveness of the pre-existing compliance program and the remedial efforts to implement an effective compliance program or to improve an existing one.
- Identified several topics and questions for use in evaluation of a corporate compliance program.
- **Topics and questions have much correlation with OIG’s Supplemental Hospital Compliance Program Guidance 2005**

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017**

• **Evaluation Sample Topics and Questions:**

1. Analysis and Remediation of Underlying Conduct
  - Root Cause Analysis—systemic issues identified? Who did RCA?
  - Prior Indications—prior (missed?) opportunities to detect? Why?
  - Remediation—specific changes to reduce risk of recurrence of issue or of missed detection?
2. Senior and Middle Management
  - Conduct at the Top—monitored? Senior leader encourage or discourage misconduct? Concrete actions?
  - Shared Commitment—Senior leaders demonstrate commitment to compliance, remediation efforts, sharing information?
  - Oversight—What compliance expertise and information is available to the Board? Executive sessions with Compliance?

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued**

• **Evaluation Sample Topics and Questions, continued:**

3. Autonomy and Resources
  - Compliance Role—Compliance involved in training and decisions relevant to misconduct?
  - Stature—Does Compliance function experience “stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers?” Turnover rate? Compliance role in “strategic and operational decisions?”
  - Experience and Qualifications—Have Compliance personnel had the appropriate experience and qualifications?
  - Autonomy—Direct reporting lines and meetings with Board? Is senior management present during meetings? Who hires, fires, reviews, gives raises or bonuses to Compliance Officer? Has company ensured independence?
  - Empowerment—Response to Compliance concerns? Transactions or deals stopped, modified, or examined?
  - Funding and Resources—how are allocations decided? Rationale? Who outsources? How overseen?
  - Outsourced Compliance Functions—Rationale? Who decided, managed, oversees, assesses effectiveness? Access level granted to external company?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 4. Policies and Procedures
  - Design and Accountability—Policies and Procedure design, implementation. Socialization?
  - Applicable Policies and Procedures—P&Ps prohibit the misconduct? Effective implementation assessed? Owners of policies held accountable for supervisory oversight?
  - Gatekeepers—Guidance or training for key gatekeepers of controls that are relevant to misconduct? Mechanism for gatekeeper communication of concerns?
  - Accessibility—P&Ps communicated to relevant employees and 3Ps? Evaluated usefulness of each P&P?
- 5. Risk Assessment
  - Risk Management Process—Method for identifying, analyzing, addressing risks faced?
  - Information Gathering and Analysis—Information, metrics used to help detect misconduct? How have the information and metrics informed the Compliance program?
  - Manifested Risk—How does the risk assessment account for the manifested risks?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 6. Training and Communications
  - Risk-Based Training—Tailored training relevant to employees function? Training where misconduct has occurred? How determine who is trained on what topic?
  - Form/Content/Effectiveness of Training—Offered in form and language effective with intended audience? Effectiveness measured?
  - Communications about Misconduct—Senior management message on misconduct? Communication of terms for failure to comply (“e.g., anonymized descriptions” of the conduct that yielded discipline)?
  - Availability of Guidance—Resources available to employees on compliance policies? Assess employee knowledge of when to seek advice? Willingness to seek advice?
- 7. Confidential Reporting and Investigation
  - Effectiveness of the Reporting Mechanism—Collect, analyze, use information from reporting mechanisms? Compliance full access?
  - Properly Scoped Investigation by Qualified Personnel—Ensure proper scope, independence objectivity, documentation, and conduct?
  - Response to Investigations—Identify root causes? System vulnerabilities? Accountability lapses? Process for responding to findings? How high into company hierarchy do investigation, accountability, and response go?

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### U.S. Department of Justice - Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 8. Incentives and Disciplinary Measures
  - Accountability—What disciplinary actions were taken? Managers held accountable? Discipline for oversight failure? Ever terminate, warn, reduce bonuses?
  - Human Resources Process—Who makes disciplinary decisions on which types of misconduct?
  - Consistent Application—Are disciplinary actions and incentives fairly and consistently applied across the organization?
  - Incentive System—Is compliant and ethical behavior incentivized? Has company considered potential negative compliance implications of what is rewarded? Have compliance or ethics considerations resulted in denial of promotions or awards?
- 9. Continuous Improvement, Periodic Testing and Review
  - Internal Audit—Risks assessed, findings, remediation reported, followed by Board, management?
  - Control Testing—Program review with testing, tracking of controls, data collection and analysis?
  - Evolving Updates—Updates to Risk Assessments? Review P&Ps?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 10. Third Party Management
  - Risk-Based and Integrated Processes—Assess enterprise risk? Procurement and vendor processes?
  - Appropriate Controls—Contract implementation, payment, work performed FMV and monitored?
  - Management of Relationships—Incentive models for 3Ps, training for relationship managers?
  - Real Actions and Consequences—Red flags from due diligence? Monitoring? Suspensions, terms?
- 11. Mergers & Acquisitions
  - Due Diligence Process—Who conducts risk review, due diligence? How? Misconduct identified?
  - Integration in the M&A Process—Is Compliance integrated into merger, acquisition, integration?
  - Process Connecting Due Diligence to Implementation—Process for tracking, remediating (risk of) misconducts identified during due diligence? How are company P&Ps implemented at acquisition?

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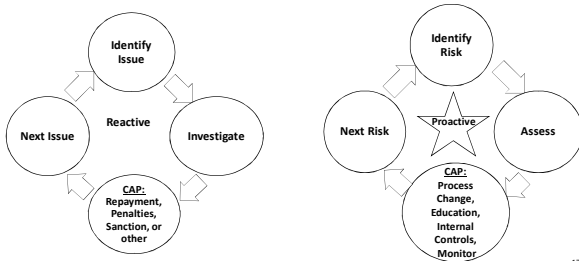
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### Hospital Compliance Program Effectiveness - Operationalize It / Complete the Puzzle

Goal: A Proactive Effective Compliance Program



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### Hospital Compliance Program Effectiveness – Operationalize It / Put The Pieces Together

A common method of assessing compliance program effectiveness is measurement of various outcomes indicators:

- Billing and coding error rates
- identified overpayments
- audit results

However, the OIG recommends examination of program outcomes and assessment of the underlying structure and process of each compliance program element. To accomplish:

- Begin with a baseline assessment using the OIG’s CPG Topics / Questions.
- Budget Time—
  - Time intensive;
  - May require a resource to remediate / identify corrective action and follow up.

Or this baseline assessment could be outsourced!

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**Example: Program Effectiveness Baseline Assessment Tool**

COMPLIANCE PROGRAM EFFECTIVENESS ASSESSMENT

In the Supplemental Compliance Program Guidance for Hospitals, the OIG identified a number of factors that may be useful when evaluating the effectiveness of a hospital's Compliance Program. The OIG instructed that hospitals consider these factors, as well as others, when assessing their compliance programs

6. Response to Detected Deficiencies

No.	Factor	Yes/ No	Description/Comments	Responsible Person
1	Has the hospital created a response team, consisting of representatives from the compliance, audit, and other relevant functional areas, which may be able to evaluate/investigate any detected deficiencies quickly?	Y	Individuals identified to assist in remediation efforts. SMEs also attend compliance committee per charter.	
2	Are all matters thoroughly and promptly investigated?	Y	Investigations policy XXX with tools implemented.	
3	Are corrective action plans developed that take into account the root causes of each potential violation?	Y	Consistent process implemented with tools.	
4	Are periodic reviews of problem areas conducted to verify that the corrective action that was implemented successfully eliminated existing deficiencies?	Y	Responsible individuals identified as part of CAP. Ongoing monitoring required in certain areas.	
5	When a detected deficiency results in an identified overpayment to the hospital, are overpayments promptly reported and repaid to the MAC?	Y	60-day policy implemented. Analysis of data, consistent process followed.	
6	If a matter results in a probable violation of law, does the hospital promptly disclose the matter to the appropriate law enforcement agency?	Y	Reportable Events policy, XXX implemented and staff trained on the policy.	

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**Toolkits for Operational Compliance**

**Process: Issue Identified > Investigation > Document > Discuss/Report > RCA > Remediate > CAP > Monitor > Periodic Reassessment**

- Create an investigative plan – who, when, where
- Pull resource materials – regulations, manuals, etc.
- Pertinent questions/intake analysis (What, Where, When, Who, How?)
- Get the facts – interview(s), group discussion(s)
- Supplemental facts – obtain data – review and analyze (billing, coding, referrals, etc.)
- Repeat fact gathering as necessary
- Risk Rating
- Root Cause Analysis – The 5 Whys
- Stop the leak (quick fix)
- Corrective Action Planning
- Monitor - defined parameters

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**Investigation Tools**

- Intake and Analysis
- Risk Rating
- Root Cause Analysis for Compliance Issues



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### Investigation Tools – Compliance Root Cause Analysis

Determine the Root Cause for ALL Compliance Issues/Investigations Using the 5 Whys technique.

- By repeatedly asking the question “Why” (five is a good rule), you can peel away the layers of symptoms which can lead to the root cause of a problem.
- Write down the specific problem. Writing the issue helps you formalize the problem and describe it completely. It also helps a team focus on the same problem.
- Ask Why the problem happens and write the answer down below the problem. Continue this step until the team is in agreement that the root cause is identified.
- Often the perceived reason for a problem will lead you to another question. Although this technique is called “5 Whys,” you may find that you will need to ask the question fewer or more times than five before you find the issue related to a problem.

#### Benefits of the 5 Whys

- Helps to identify the root cause of a problem (under the surface).
- Determine the relationship between different root causes of a problem.
- One of the simplest tools.

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### Investigation Tools - Root Cause Analysis

#### Cause-and-Effect- Relationship / Building Blocks

- Start on the left. Investigating a problem begins with the problem and then backs into the causes by asking Why questions.



- The questions begin, “Why did this effect happen?” The response to this question provides a cause (or causes).



- The cause that was written down last becomes the effect for the next Why question. This is fundamentally how causes and effects link together to create a chain of events. Writing down 5-Whys, shown below, is a great way to start an investigation because it’s so simple.



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### Activity - Hypotheticals

- Physician Arrangement
- Provider-based status
- Implantable Cardiac Defibrillator/National Coverage Determination

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### Compliance Toolkits Examples

- Physician Arrangements
- Medicare Beneficiary Notice Delivery: Important Message From Medicare
- Charging/coding/documentation: Hydration
- Specific service regulatory compliance: Swing Bed
- Specific process for NCD compliance: Implantable Cardiac Defibrillator



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### Questions

or

Feel free to contact Anne or Barb via email

- Anne Daly: [Adaly@luriechildrens.org](mailto:Adaly@luriechildrens.org)
- Barb Martinson: [Barbara.Martinson@bannerhealth.com](mailto:Barbara.Martinson@bannerhealth.com)

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## NEWS RELEASE

# Usability Testing Supports HIT Partnership's Copy and Paste Recommendations

2/6/2017

**PLYMOUTH MEETING, PA**—A report released by the National Institute of Standards and Technology (NIST) provides support for two of the *Partnership for Health IT Patient Safety's* safe practice recommendations for the use of copy and paste.

The recommendations were developed by a multi-stakeholder collaborative, the *Partnership for Health IT Patient Safety*, convened and operated by ECRI Institute. This was the *Partnership's* first set of safe practice recommendations.

NIST, in conjunction with the Fors Marsh Group (FMG), ECRI Institute, and the US Army Medical Research and Materiel Command's (MRMC) Telemedicine and Advanced Technology Research Center, conducted a human factors evaluation of the use of copy and paste to determine if the *Partnership's* recommendations were supported by provider actions and understanding.

In the just-released and publicly-available NIST report, NIST IR 8166, ["Examining the Copy and Paste Function in the Use of Electronic](#)

## CONTACT US

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Media and Press Inquiry 

### Media and Press Inquiries

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Health Records." data overwhelmingly supported two of the *Partnership's* safe practice recommendations—making copy and paste materials easily identifiable and ensuring that the provenance of the material is readily available. The study indicated that clinical users could benefit greatly from training on when and how copy and paste is appropriate to use.

Participants in the study noted that preserving integrity of the information was their primary concern despite the time saving and efficiencies derived from this functionality. Loss of integrity was identified in four areas: finding the information, copying information, understanding the information, and reusing information.

"Using outdated information, truncating information, or including a large amount of potentially extraneous information can all lead to safety issues," says Lorraine Possanza, patient safety, risk and quality program director at ECRI Institute.

All of these areas call for increased attention to how and when the copy and paste functionality is used. The *Partnership's* safe practice recommendations and implementation toolkit, released in February 2016, provides guidance on the safe use of the copy and paste feature in 4 areas:

1. Provide a mechanism to make copy and paste material easily identifiable
2. Ensure that the provenance of copy and paste material is readily available
3. Ensure adequate staff training and education regarding the appropriate and safe use of copy and paste
4. Ensure that copy and paste practices are regularly monitored, measured, and assessed

The NIST report also delivers human factors guidance, including several specific recommendations for "user interface design to ensure safety-related usability of the copy and paste function" to complete the above safe practice recommendations.

The *Partnership* is sponsored in part through a grant from the Gordon and Betty Moore Foundation and in part through a grant from the Jayne Koskinas Ted Giovanis Foundation (JKTG) for Health and Policy.

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To learn more about the *Partnership*, visit [www.ecri.org/HITpartnership](http://www.ecri.org/HITpartnership) or contact us by telephone at (610) 825-6000; by e-mail at [hit@ecri.org](mailto:hit@ecri.org); or by mail at 5200 Butler Pike, Plymouth Meeting, PA 19462.

###

### Social Sharing

- Copy & paste recommendations from Partnership for #HealthIT #Ptsafety, convened by @ECRI\_Institute, backed by @usnistgov <http://bit.ly/2k3TCqu>
- Support from @usnistgov of @ECRI\_Institute's Partnership for #HealthIT #Ptsafety copy & paste recommendations <http://bit.ly/2k3TCqu>

### About ECRI Institute

ECRI Institute ([www.ecri.org](http://www.ecri.org)), a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research to healthcare to discover which medical procedures, devices, drugs, and processes enable improved patient care. As pioneers in this science for nearly 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. Strict conflict-of-interest guidelines ensure objectivity. ECRI Institute is designated an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality. ECRI Institute PSO is listed as a federally certified Patient Safety Organization by the U.S. Department of Health and Human Services. Find ECRI Institute on Facebook ([www.facebook.com/ECRIInstitute](http://www.facebook.com/ECRIInstitute)) and on Twitter ([www.twitter.com/ECRI\\_Institute](http://www.twitter.com/ECRI_Institute)).

### For more information, contact:

Laurie Menyo, Director of Public Relations  
[lmenyo@ecri.org](mailto:lmenyo@ecri.org)  
(610) 825-6000, ext. 5310

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**Swords into plowshares**  
Leveraging clinical data quality excellence and data mining tools for promoting quality of care

Dr. Peter Pronovost, Sr. Vice President – Patient Safety and Quality, Johns Hopkins Hospital  
Aloha McBride, Principal, Ernst & Young LLP  
Marc Schulman, Executive Director, Ernst & Young LLP  
David N. Hoffman, Chief Compliance Officer, Physician Affiliate Group of New York, P.C.

JOHNS HOPKINS MEDICINE  
EY  
SIGHT TO THE LIGHT (SEEKING COST)

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**Swords into plowshares**

Page 1      Swords into plowshares

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**Course agenda and session topics**

Topic	Speakers	Time
Introduction and course objectives	All	1:30 p.m. – 1:35 p.m.
Why we need to start treating clinical data like financial data. A case study from Johns Hopkins, the value of data. Leveraging high reliability principles and financial management concept.	Dr. Peter Pronovost	1:35 p.m. – 2:20 p.m.
How do you begin to think about clinical data transactions like financial data transactions and governance: a quick overview of COSO, due diligence and ERM. How to begin to applying these concepts to clinical data quality and reporting integrity	Aloha McBride/ Marc Schulman/ Tamil Chellaiah	2:20 p.m. – 3:15 p.m.
Break	–	3:15 p.m. – 3:30 p.m.
Leveraging data mining/analytics to improve quality of care through the automated generation and distribution of actionable exception reports	David Hoffman	3:30 p.m. – 4:30 p.m.

Page 2      Swords into plowshares

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### Setting the stage on data — the never-ending struggle to determine the signal through noise

- ▶ Patient safety indicators are derived from administrative codes in billing and are broadly used in hospital ranking programs and pay-for-quality programs.
- ▶ Patient safety indicators are frequently inaccurate — missing many harms while also reporting false positives.
- ▶ Too often, hospital ratings and rankings reflect how well a hospital codes rather than how a hospital provides care.
- ▶ For instance, Johns Hopkins reduced the number of patient safety indicator (PSI) incidents it reported to CMS by 75%, thereby reducing its penalties.
- ▶ **However — only 10% of the improvement resulted from changes in clinical care. The other 90% resulted from documentation and coding that was more thorough and accurate.**

**Instead of using PSIs, there is an enormous need for valid and reliable measures that can be tested, controlled and audited, similar to financial transactions and measures.**

Page 3      Swords into plowshares       

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### Medical errors – why they occur and the role of clinical data integrity

**MEDICAL ERRORS NATION'S THIRD BIGGEST KILLER IN 2013**



Heart disease	611,000
Cancer	585,000
Medical error	251,000
COPD	149,000
Suicide	41,000
Firearm	34,000
Motor vehicle	34,000

Source: Martin Makary, Michael Daniel study at Johns Hopkins University School of Medicine  
Jim Sargent, USA TODAY

**Why do errors occur?**  
Commonly, errors are caused by systemic problems, including a lack of integrated process, technologies and governance that drive unwarranted variation.

**What is at stake when clinical data contains errors?**

- ▶ A patient's life and livelihood
- ▶ Misdiagnosis/delayed diagnosis
- ▶ Medication errors
- ▶ Performance measurement calculation errors
- ▶ Reimbursement errors
- ▶ **Trust in your organization's ability to provide safe care**

Page 4      Swords into plowshares       

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### The problem with bad data

- ▶ Can result in inappropriate clinical decision-making and creates significant patient safety risk
- ▶ Impairs evidence-based medicine and coordination across the care continuum
- ▶ Increases the risk of beneficiaries not having access to covered services
- ▶ Can result in billing, payment and performance inaccuracies
- ▶ Produces inaccurate stakeholder reporting
- ▶ Erodes consumer trust and increases legal risk

Data 'fundamentally broken' at St George's

**HOW BAD DATA HURTS QUALITY IMPROVEMENT IN HEALTHCARE**

Copy-paste use in EHRs cited for safety concerns

Page 5      Swords into plowshares       

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### How does good data become bad information?

- ▶ Methods by which it is captured and stored — manual, incomplete, etc.
- ▶ Data and system architecture lacks interoperability, resulting in blind spots.
- ▶ Cultural roadblocks across the health system prevent collaboration.
- ▶ Integrity of systems is not adequately protected, allowing for vulnerabilities and workarounds.
- ▶ Clinicians and data scientists operate in silos so reporting is not relevant or actionable in the clinical setting.
- ▶ Lack of structure and controls in underlying clinical process to manage quality data inputs.



Page 6      Swords into plowshares      JHS HOPKINS      EY

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### What is High Reliability Organizing (HRO) and how can it help us to improve clinical data integrity?




Safety culture



System integration



Zero-harm focus



High reliability engineering

HRO is the pursuit of flawless performance under complex, dynamic and oftentimes, potentially catastrophic conditions.\*

**Core characteristics**

1. Sensitivity to operations
2. Deference to expertise
3. Reluctance to simplify
4. Preoccupation with failure
5. Commitment to resilience

\*Source: Karl E. Weick and Kathleen M. Sutcliffe, *Managing the Unexpected: Resilient Performance in an Age of Uncertainty*

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### How have HROs organized for success? The advent of the *Operating Management System*

Unifying framework for structured assurance of safety, quality and reliability and an integrated approach for continuous organizational learning, innovation and improvement

For critical data, this means the utmost control, monitoring and testing to certify that all data sets are complete, accurate, interoperable, accessible, relevant and auditable.

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### Questions to ponder...

- ▶ Do you have a "Board to the Bedside" governance structure for clinical quality and patient safety measures and risks?
- ▶ Are you managing and overseeing your clinical data with the same level of rigor as your financial data?
- ▶ Do you have risk and internal control(s) owners over your clinical processes, systems and data?
- ▶ How confident are you that the clinical data residing in your systems is complete, accurate, interoperable, accessible, relevant and auditable?
- ▶ Do you understand how each clinical data element traverses through all of your systems into clinical diagnosis decisions, revenue cycle and performance reporting?
- ▶ Are you regularly testing and independently auditing clinical data, diagnosis and coding to identify control gaps, compliance gaps and training gaps?

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### Health systems must proactively *identify, understand and manage* clinical risks ... robust effective internal controls, monitoring and governance activities are crucial

Health care risk themes					
Significant cost pressures	Increased regulatory requirements	Patient safety and quality concerns	Competitive market – new business models	Growth of health insurance exchanges	Digital health/access to performance data


**Health care emerging risks**

- Increased focus by consumers on safety/quality and patient experience
- Increasing move toward evidence-based treatments and protocols and related reimbursement issues
- The need to demonstrate efficiency, leading practice and continuous improvement
- Emerging market-driven delivery models (ACOs)
- Increased regulations, government intervention and heightened compliance obligations
- The need to demonstrate ROI for technologies — that support safety, quality and patient care
- Increasing vertical integration throughout the health care value chain across traditional boundaries to deliver integrated care models
- Increased demand on IT systems for analytics, business intelligence and reporting
- Heightened focus on privacy and security lapses with the advent of mobile and digital platforms
- Consumer-driven demand for performance information and consumer-driven performance feedback

Health care top issues					
Quality	Health data/accuracy, security and use	CMS compliance	Regulatory adherence	Maximize revenue from activity	Meaningful use
Safety	Clinical innovation/ evidence-based care	Cost management and efficiency	Technology investments and value	Resource capacity/capability	Health insurance exchanges

Health care external forces					
Economic	Regulatory	Demographic	Political	Societal	Technology

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### To enable high reliability of clinical data, health systems must treat clinical data with the same rigor as financial data


**Enterprise Risk Management (ERM)**  
ERM is a discipline that addresses the full spectrum of an organization's risks, including challenges and opportunities, and integrates them into an enterprise-wide, strategically aligned portfolio view. ERM contributes to improved decision-making and performance management and supports the achievement of an organization's mission, goals and objectives.

**Internal Controls Management (ICM)**  
ICM is a process for promoting achievement of an organization's objectives in operational effectiveness and efficiency; reliable clinical performance reporting; and complying with laws, regulations and policies.

**How do we quantify enterprise risks and design internal controls that matter?**  
The impact of a risk is quantified in terms of existing performance measures and is evaluated by gauging the potential volatility the risk has on strategic goals and related business outcomes. Internal controls are designed, monitored and tested against those key clinical processes that drive critical performance and compliance measures.

**Why are ERM and ICM critical to HROs?**  
HROs must anticipate risk and mitigate harm in order to achieve mission success. In order to anticipate risk, health systems must have early warning and continuous monitoring systems in place to proactively address potential harms. ERM and ICM provide this capability and prescribe disciplined activities to root out data quality issues and test the reliability of performance and compliance reporting measures.

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### Step 6 – Future state internal controls design

6 Develop and deliver an action plan that mitigates any uncontrolled risks, while respecting the context in which the process operates

<p><b>Process</b></p> <ul style="list-style-type: none"> <li>▶ The RCM developed in the previous phase will serve as a tool to evaluate current controls, to perform a gap analysis and to make recommendations regarding the design of new controls, where applicable.</li> <li>▶ Controls are assessed so they are not excessive, in order to make the process as lean as possible. Any proposed improvements are aligned to the HRO principles and the organization's objectives.</li> <li>▶ Action plans are drafted then validated with the organization and refined.</li> <li>▶ New controls are implemented. Assistance is provided to the organization to build the capability to implement controls.</li> </ul>	<p><b>Output</b></p> <ul style="list-style-type: none"> <li>▶ Recommendations on the design of new controls and on the possible reduction of redundant controls</li> <li>▶ Action plan including improvement opportunities in case of structural deficiencies we have identified</li> <li>▶ A list of opportunities for simplification of controls where appropriate</li> <li>▶ Assistance and guidance with the design/enhancement of controls, using the RCM as tracking tool</li> <li>▶ Actions are performed in alignment with stakeholders, such as the process owners, in order for them to support and accept changes</li> <li>▶ Development of longer-term test and audit program</li> </ul>
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### Step 6 – Controls become the “day-to-day” process for managing data integrity risks

6 Risk management activities are embedded within the existing planning, analysis and reporting processes ... known as the “rhythm of the business”

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### Where to go from here?

Potential next steps to consider for your organization

- ▶ Review your governance structure relative to clinical quality and patient safety performance metric ownership – do you have alignment from the “Board to the Bedside?”
- ▶ Understand your environment – select a critical care pathway (high demand, high revenue, clinically complex) and perform a clinical data element flow review and audit – where are your control gaps and what are your most frequent data errors?
- ▶ Start with your event reporting database and spot audit clinical data element flow and integrity across a near miss event.
- ▶ Interview your clinicians to understand where their clinical data pain points, concerns and workarounds relative to clinical data capture and analysis.

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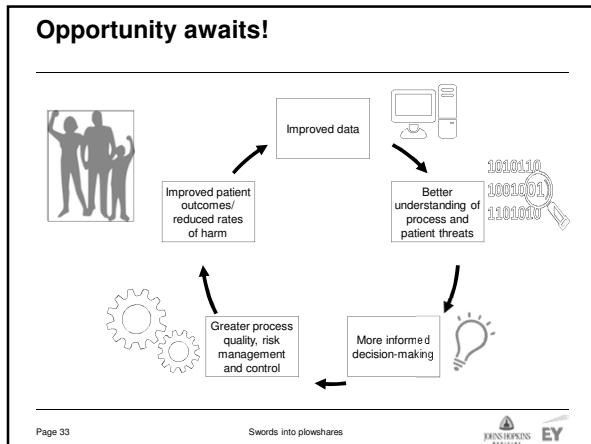
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**David N. Hoffman**  
**Chief Compliance Officer**  
**PAG<sub>NY</sub>**  
Physician Affiliate Group of New  
York, P.C.

**Leveraging data mining and analytics to drive  
quality, compliance and risk reduction**

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**What you will learn**

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- ▶ The solution is hiding in the record.
- ▶ Metadata is your friend.

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**But first, for some context**

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- ▶ First rule of corporate compliance:
  - ▶ Don't bill for care you didn't provide.
  - ▶ That's stealing.

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**Some more context**

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- ▶ Second rule of corporate compliance:
  - ▶ Don't bill for care you provided that wasn't necessary.
  - ▶ That's stealing.

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Swords into plowshares

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**And**

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- ▶ Third rule of corporate compliance:
  - ▶ Don't bill for care you provided that was necessary but was of poor quality.
  - ▶ That's \_\_\_\_\_?

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Swords into plowshares

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“Quality care” did not mean the patient got “all better.”

Doctors couldn't and were not expected to guarantee outcomes.

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With *Value-based purchasing*,  
all that has changed.

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Acronyms that have ruled our lives

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**HCAHPS**

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**Hospital Consumer Assessment of Healthcare  
Providers and Systems**

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**CAHPS**

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**Consumer Assessment of Healthcare Providers and Systems**

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**DSRIP(P)**

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**Delivery System Reform Incentive Payment Program**

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**And now**

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**VBP**

(a very special acronym)

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**VBP**

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**Value Based Purchasing**

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**MACRA**

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**Medicare Access and CHIP (Child Health Insurance Program) Reauthorization Act of 2015**

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**What is MACRA?**

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- ▶ The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) is a bipartisan legislation signed into law on April 16, 2015:
- ▶ What does Title I of MACRA do?
  - ▶ Repeals the Sustainable Growth Rate (SGR) Formula
  - ▶ Changes the way that Medicare rewards clinicians for value of volume
  - ▶ Streamlines multiple quality programs under the new Merit-Based Incentive Payments System (MIPS)
  - ▶ Provides bonus payments for participation in eligible alternative payment models (APMs)

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Now back to  
metadata

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**Two keys to survival**

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1. Data mining
2. Exception reports

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**Metadata as sword**

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Detection...

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**Metadata as sword**

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Detection...  
Followed by extrapolation...

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**Metadata as sword**

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Detection...  
Followed by extrapolation...  
And then,  
  
Repayment!

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**Metadata as tool**

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Surveillance,  
Followed by intervention,  
Followed by corrective action.

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**A simple example**

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Unread lab results,  
Or PAP smears.

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**A not-so-simple example**

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DVT prophylaxis

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What does the future hold?

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**Electronic medical records (EMR)**

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Friend or Foe?

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**Electronic medical records (EMR)**

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- ▶ Friend or Foe?
- ▶ It doesn't matter.

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**EMR as a term paper**

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- ▶ Citation, not Plagiarism.

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**EMR as a term paper**

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- ▶ "Copy and Paste"
- ▶ Is a dangerous tool we actually don't need

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**A wonderful challenge**

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Changing a flat tire on a bus ...

... while the bus is moving.

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**Thank you!**

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- ▶ (Please complete your evaluation)

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**Whistle While You Work - How to Prevent Activity Leading to Whistleblower Actions and Protect Health Organizations and Medical Practices from Whistleblower Threats**

Health Care Compliance Association's  
21<sup>st</sup> Annual Compliance Institute  
March 26-29, 2017  
National Harbor, MD  
Gaylord National

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**Presenters**

- ▶ Linda S. Woolf, Managing Partner, Goodell, DeVries, Leech & Dann
- ▶ Jacqueline N. Bloink, Instructor for UMA and CEO of Jacqueline Bloink, LLC
- ▶ Christine Zack, Senior Vice President, Chief Risk Officer, Fundamental Administrative Services LLC
- ▶ Linda W. Taetz, Senior Vice President, Chief Compliance Officer, Mariner Health Central, Inc.

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**HCCA  
March 2017**

Linda S. Woolf  
lsw@gdlldlaw.com



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### Recoveries in FCA Cases

- ▶ \$31.3 billion recovered by the DOJ under FCA since FY 2009.
- ▶ In FY 2016, the government recovered approximately \$4.7 billion in settlements and judgments.
  - ▶ Third highest in the statute's history

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### Recoveries in FCA Cases

FYI 2016 (continued)

- ▶ \$2.5 billion of the \$4.7 billion (or 53%) came from the health care industry, including drug companies, medical device companies, hospitals, nursing homes, laboratories, and physicians.
  - ▶ Seventh consecutive year where recovery exceeded \$2 billion

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### Recoveries in FCA Cases

FYI 2016 (continued)

- ▶ \$1.2 billion came from the drug and medical device industry.
  - ▶ One manufacturer paid \$413.2 million alone to resolve federal FCA allegations (and an additional \$371.4 million to state Medicaid programs).
- ▶ Hospitals and outpatient clinics accounted for \$360 million in recoveries.
  - ▶ A major hospital chain in the United States paid \$244.2 million to resolve federal FCA allegations (and \$123.7 to resolve state allegations).
- ▶ Cases involving nursing homes and skilled nursing facilities accounted for more than \$160 million in settlements and judgments.

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## Recoveries in FCA Cases

FY 2016 (continued)

- ▶ Whistleblowers filed 702 *qui tam* suits in FY 2016.
  - ▶ Average of 13.5 cases per week
- ▶ The Department of Justice recovered \$2.9 billion in FY 2016 from *qui tam* suits filed in FY 2016 or earlier.
- ▶ Whistleblowers recovered \$519 million.

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## Recoveries in FCA Cases

- ▶ From January 2009 to the end of FY 2016, the government recovered nearly \$24 billion in settlements and judgments related to *qui tam* suits.
- ▶ The government paid more than \$4 billion in whistleblower awards during the same period.

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## Recoveries in FCA Cases

A glance at FY 2017:

Since September 30, 2016, the DOJ has recovered ~\$218 million in healthcare-related *qui tam* suits.

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### Challenge for Compliance Professionals and Their Counsel

- ▶ How to develop effective internal policies to proactively protect the company from becoming the target of a whistleblower investigation
- ▶ What steps to take if you receive a compliance-related complaint
- ▶ What steps to take if a whistleblower action is filed

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### How to Develop a Culture of Compliance

- ▶ This presentation will focus in part on the steps that compliance professionals can take to create a culture within the company that protects the organization and its constituencies
  - ▶ Jacqueline Bloink - the countervailing obligations to the public, the employing organization and the profession.
  - ▶ Linda Taetz - the goals and elements of an effective compliance program.

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### Internal Investigations Initial Steps

- ▶ A whistleblower action has been filed - now what?
- ▶ What are your obligations to various constituencies?
  - ▶ Board
  - ▶ CEO/Officers
  - ▶ Shareholders
  - ▶ Patients
- ▶ What if the whistleblower is an officer of the company - how does that impact the investigation, if at all?

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## Internal Investigations Who Conducts Them?

- ▶ When should outside counsel be retained? Pros/cons
- ▶ Who should be retained?
  - ▶ Pitfalls of retaining counsel who has previously represented the company
- ▶ How should investigation results be conveyed and to whom?
- ▶ Privilege concerns and what steps should be taken to protect the privilege?

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## Obligations to the Board and Shareholders

- ▶ When does the obligation to advise the Board and Shareholders kick in?
- ▶ What information should be conveyed?
- ▶ What are the privilege issues?
- ▶ What safeguards can be put in place to protect the privilege?

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## Employee Issues

- ▶ Employees who corroborate the whistleblower's allegations
  - ▶ Do they need separate counsel?
  - ▶ Unique issues (e.g. communications with employee, depositions)
- ▶ Employees who threaten whistleblower action to gain strategic advantage in disciplinary proceeding
  - ▶ How to handle?
  - ▶ Role of in-house counsel, outside counsel, and HR department?

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## Claims by In-House Counsel

- ▶ Unique risks presented by in-house counsel/compliance professionals bringing or threatening whistleblower actions
  - ▶ Hold positions of trust
  - ▶ Have unique access to sensitive information
  - ▶ May threaten to place privileged and confidential information in the public record
  - ▶ "Self-Help" Discovery
- ▶ Blowing the whistle or just doing their job?

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## "Self-Help" Discovery

- ▶ What types of self help discovery have you encountered?
  - ▶ Theft of electronic evidence
  - ▶ Use of "moles"
  - ▶ Collusion between former employees
- ▶ How can a company protect against it?
- ▶ What can be done after it has happened?

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## Defending Against In-House Counsel as Relator

- ▶ *United States v. Quest Diagnostics* (2d Cir. 2013)
  - ▶ Former GC as Relator
  - ▶ Christine Zack will present on the intersection of state ethical rules with in-house and outside counsel's disclosure of protected client information to the government.

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Questions and Answers



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HCCA  
March 2017

Jacqueline Bloink, MBA, RHIA, CHC, CFE, CPC-I,  
CPC, CMRS  
Instructor and Compliance Specialist  
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Who Am I?



My Background ...  
My Journey

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### Today... Devil's Advocate



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### Obligations

HCCA:

1. Obligation to the Public
2. Obligation to the Employing Organization
3. Obligation to the Profession



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### Obligation 1: Public



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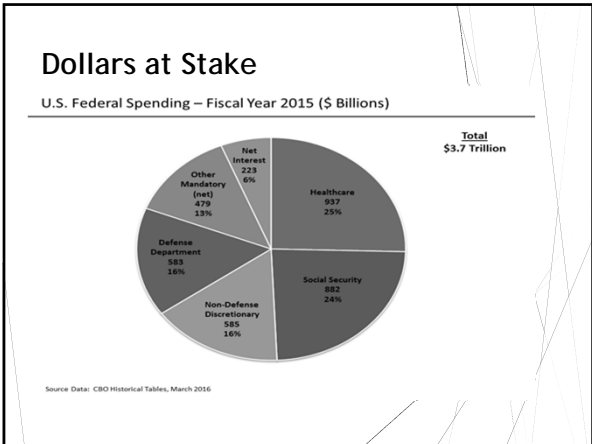
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### Fraudsters

- ▶ Tyco
- ▶ Fannie Mae
- ▶ World Com
- ▶ Lehman Brothers
- ▶ Enron

Why isn't Healthcare Fraud viewed the same way? We are passionate about our pensions and fraud... why not about healthcare fraud?

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**Obligation 2: Employer  
How To Reach the Board?**



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**Play Fair**



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**Obligation of Employer to  
YOU?**



Good Faith

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### Why Do Some Professionals Look The Other Way?



Some employees stand up to crime... *others look the other way.*  
Many reasons why...

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### Slippery Slope



ACFE Report to the Nations, 2016: "The most prominent organizational weakness. Was a lack of internal controls (29.3% of cases) followed by an override of existing internal controls (20% of cases.)"

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### Obligation 3: Compliance Profession and YOU

When life brings  
big winds of change  
that almost blow you over...  
close your eyes,  
hang on tight,  
and **BELIEVE.**



Obligation to Public, Employer and Our Self

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Time to go....

**I'm not playing wit u anymore**



**I'm going home**

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Effective Methods?



Do we change our compliance program when it is not effective? Or...do we get rid of the people that show us the flaws?

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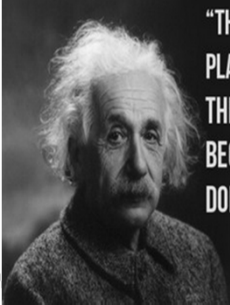
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Relators



**"THE WORLD IS A DANGEROUS PLACE TO LIVE; NOT BECAUSE OF THE PEOPLE WHO ARE EVIL, BUT BECAUSE OF THE PEOPLE WHO DON'T DO ANYTHING ABOUT IT."**

— ALBERT EINSTEIN

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### What We Permit... We Promote



Who am I? Compliance, Educator, Consumer, Patient, Employee, Fighter of Fraud, Relator.... I am *Jacqueline Bloink. Thank You for coming today!*

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### Questions and Answers



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## HCCA March 2017

Christine Zack, Senior Vice President, Chief Risk Officer  
christine.zack@fundlfc.com  
Fundamental Administrative Services LLC

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The Attorney as Whistleblower  
 A "Never Event"?

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**ABA MODEL RULES OF PROFESSIONAL CONDUCT  
 CLIENT-LAWYER RELATIONSHIP  
 RULE 1.6 Confidentiality of Information**

(a) A lawyer shall not reveal information relating to the representation of a client unless the client gives informed consent, the disclosure is impliedly authorized in order to carry out the representation or the disclosure is permitted by paragraph (b)

(b) A lawyer may reveal information relating to the representation of a client to the extent the lawyer reasonably believes necessary:

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**RULE 1.6 Confidentiality of Information (continued)**

(1) to prevent reasonably certain death or substantial bodily harm;

(2) to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer's services;

(3) to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the lawyer's services;

(4) to secure legal advice about the lawyer's compliance with these Rules;

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**RULE 1.6 Confidentiality of Information (continued)**

(5) to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client;

(6) to comply with other law or a court order; or

(7) to detect and resolve conflicts of interest arising from the lawyer's change of employment or from changes in the composition or ownership of a firm, but only if the revealed information would not compromise the attorney-client privilege or otherwise prejudice the client.

(c) A lawyer shall make reasonable efforts to prevent the inadvertent or unauthorized disclosure of, or unauthorized access to, information relating to the representation of a client.

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**Fair Laboratory Practices Associates  
v. Quest Diagnostics Inc. et al**

**United States Court of Appeals  
for the Second Circuit  
(2013)**

"The issues on appeal arise out of the tension between an attorney's ethical duty of confidentiality and the federal interest in encouraging "whistleblowers" to disclose unlawful conduct harmful to the government."

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**CONCLUSION**

1) The False Claims Act does not preempt state ethical rules governing the disclosure of client confidences; therefore N.Y. Rule 1.9(c), which generally prohibits disclosure of confidential information of a former client, governs a New York attorney's conduct as relator in a qui tam action under the False Claims Act.

(2) N.Y. Rule 1.6(b)(2), which permits a lawyer to reveal or use confidential information to the extent that the lawyer reasonably believes necessary to prevent the client from committing a crime, does not justify Bibi's disclosures in this case: Bibi reasonably could have believed in 2005 that defendants intended to commit a crime. His disclosure of Unilab's confidential information, however, went well beyond what was "necessary" within the meaning of N.Y. Rule 1.6(b)

(2) to prevent Unilab from committing a crime inasmuch as there was ample non-confidential information on which to bring an FCA action. Therefore, Bibi's conduct in this qui tam action violated his ethical obligations under N.Y. Rule 1.9(c).

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**CONCLUSION (continued)**

(3) The District Court did not err or "abuse its discretion" in dismissing the Complaint and disqualifying FLPA, all of its general partners, and its outside counsel from bringing any subsequent related qui tam action, on the basis that such measures were necessary to prevent the use of Bibi's unethical disclosures against defendants.

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"It was unnecessary for Bibi to participate in this qui tam action at all, much less to broadly disclose Unilab's confidential information . . . FLPA could have brought the qui tam action based on the information that Baker and Michaelson possessed as former executives of Unilab, or, if necessary, Bibi could have made limited disclosures. Instead, Bibi chose to participate in the action and disclose protected client confidences . . . in violation of N.Y. Rule 1.9(c).

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**ATTORNEY CHECKLIST**

- 1 Protect the Organization
- 2 Ensure compliance with Rules of Professional Responsibility/Conduct
- 3 Other Ideas?

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### Questions and Answers



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## HCCA March 2017

Linda W. Taetz, Senior Vice President, Chief  
Compliance Officer  
lwtaetz@marinerhealthcare.com  
Mariner Health Central, Inc.

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### Goals of a Compliance Program

- Creation of a "Culture of Compliance"
- Prevent, detect and correct fraud and abuse
- Compliance is doing the things necessary to run the business effectively and to provide quality care, service or product

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### Goals of a Compliance Program

- Responsibility to patients, clients, employees, vendors and business partners for Compliance oversight
- Defines government laws and regulations
- Provides consequences for illegal activity
- May result in lower penalties if wrongdoing occurs and government takes enforcement action

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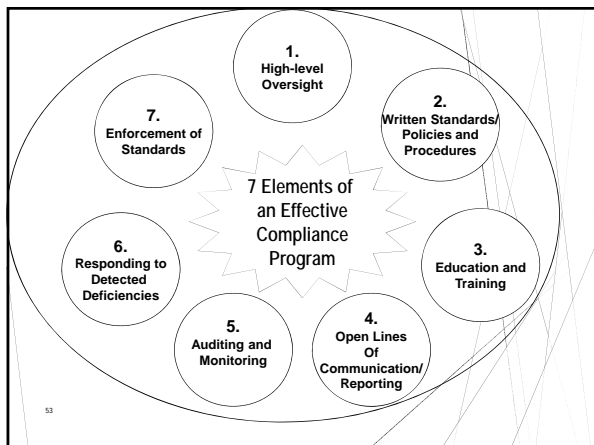
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### Benefits of an Effective Compliance Program

Compliance programs help to prevent and detect fraud and abuse and have the following benefits:

- Assists the organization in identifying and improving a weakness in internal controls or management
- Reinforces the organization's shared values
- Improves the quality of patient care or service provision
- Avoids liability and negative publicity

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### Benefits of an Effective Compliance Program (continued)

- Promotes awareness and compliance with laws and regulations
- Creates an engaged workforce by providing a process for reporting, investigating and resolving issues
- Reduces potential penalties if a violation occurs

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### Abuse and Fraud Prevention

- ▶ A robust Compliance Program is responsible for the prevention, identification, investigation, remediation and possible reporting of fraud and abusive practices or conduct

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### Abusive Practices

- ❑ BILLING FOR SERVICES NOT PROVIDED
- ❑ BILLING FOR SERVICES THAT ARE NOT MEDICALLY NECESSARY, OR PROVIDING AN INACCURATE DIAGNOSIS TO OBTAIN PAYMENT
- ❑ BILLING FOR INADEQUATE, IMPROPER OR SUBSTANDARD QUALITY
- ❑ CLAIMING UNALLOWABLE OR IMPROPER COSTS ON A MEDICARE OR MEDICAID COST REPORT
- ❑ BILLING FOR CARE OR SERVICE THAT IS NOT PROPERLY DOCUMENTED
- ❑ PAYING OR RECEIVING ILLEGAL KICKBACKS IN EXCHANGE FOR BUSINESS OR REFERRALS

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### What is Fraud?

- ▶ Fraudulent activity:
  - ▶ May involve material false statements or representations of facts in order to obtain payment or other benefit
  - ▶ Can be for one's own benefit or for the benefit of another
  - ▶ Can be knowing, willful, reckless or intentional
- ▶ Civil fraud violations usually involve sanctions and financial penalties
- ▶ Criminal fraud violations may involve fines, penalties, imprisonment or probation - including individual prosecution

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### Examples of Fraud

- ▶ Billing for services not provided
- ▶ Billing for services that are not medically necessary, or providing an inaccurate diagnosis to obtain payment
- ▶ Billing for inadequate, improper or substandard quality of care to our residents
- ▶ Claiming unallowable or improper costs on the Medicare cost report
- ▶ Billing for services that are not properly documented
- ▶ Paying or receiving illegal kickbacks in exchange for business

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### False Claims Act (FCA)

- ▶ FCA is a Civil War-era statute enacted in response to unscrupulous government contractors selling shoddy goods (e.g., mules, horses, fences)
- ▶ Now used to enforce false or fraudulent claims submitted to the government for payment in many different industries (e.g., defense, health care, homeland security)
- ▶ Civil statute providing for damages and penalties for the knowing submission of false or fraudulent claims to the government for payment

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### Written Standards/Policies and Procedures

Written standards include:

- Code of Conduct & Employee/Vendor Handbooks
- Compliance-related policies and procedures:
  - Training and Education Requirements
  - Compliance Audits
  - Quality of Care - Patient Protections & Rights
  - Vendor Relations
  - Disclosure Programs
  - Reporting Overpayments and Reportable Events

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### Code of Conduct

#### Purpose and Objectives of the Code

- Provide a framework for making the right decisions and taking appropriate action
- Create an environment that promotes the highest standard of ethics and Compliance
- Communicates commitment to furthering shared values through individual actions and responsibility
- Maintains the highest professional and ethical standards in the conduct of business

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### Scope of the Employee Code of Conduct

The Code includes guidance on a broad range of topics including:

- Legal and Regulatory Compliance
- Commitment to Quality of Care or the provision of a service
- Relationships with Referral Sources
- Business and Financial Records
- Workplace Conduct and Employment Practices
- Our Business Activities
- Conflicts of Interest and Business Relationships
- Compliance and Ethics Program
- Employee Compliance Resources and Contact Information

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### Who is Covered by the Code of Conduct?

- The Code, in addition to all statutes, regulations, guidelines and employee Policies and Procedures apply to and must be observed by everyone including:
  - Employees
  - Volunteers
  - Contractors and vendors
  - Board of Directors
  - Anyone else acting on behalf of employee

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### Quality of Care

- Hire employees, contractors, physicians and vendors with appropriate qualifications to perform in a competent and professional manner
- Pre-employment screening
- Individual responsibility to maintain appropriate licensure and other qualifications and requirements

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### Individual Rights and Privacy

Employee does not tolerate any type of abuse, discrimination or neglect, including:

- Discriminatory admission tactics or improper denial of access to care
- Verbal, mental or physical abuse, corporal punishment or involuntary seclusion
- Inappropriate use of physical or chemical restraints

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### Individual Rights and Privacy (continued)

- Denial of a resident's right to participate in care and treatment decisions
- Failure to safeguard the privacy of residents protected health information from improper use and disclosure
- Failure to safeguard residents' financial affairs

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### Education & Training

Education and Training programs include:

- Compliance training for all employees, officers and Directors
- General compliance training for new employees early in employment
- Ongoing communication
- Specialized training in certain areas for those employees with high-risk duties, such as negotiating, approving and managing transactions with referral agencies, vendors and business partners

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### Open Lines of Communication/ Reporting

Employee's open lines of communication include:

- Various resources for obtaining guidance and reporting concerns, such as:
  - Supervisors, and others in the chain of command
  - Human Resources representatives
  - Compliance and Legal personnel
  - Compliance Hotline
- On-going communication about policies, procedures and regulatory updates

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### Open Lines of Communication and Reporting

#### Compliance Hotline

- Toll-free number that is available 24/7
- Allows for confidential and anonymous reporting
- Intended to supplement, not replace other reporting channels
- Should be used when:
  - ▶ Other avenues of communication are exhausted
  - ▶ Individual is uncomfortable disclosing his or her identity when reporting a concern

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### Auditing and Monitoring

Auditing and monitoring processes should include:

- Self-monitoring
- Periodic internal reviews of key activities utilizing accepted audit tools and measurements
- Follow-up on all results to ensure action is taken and identified issues do not recur
- Regular reporting to Compliance Committee and Board of Directors

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### Responding to Detected Deficiencies

Response to allegations of improper/illegal activities includes:

- A defined timeframe for review of all reports of alleged misconduct
- An investigative process coordinated between Compliance, Law, Internal Audit and Human Resource Departments, as appropriate
- A commitment to report misconduct to the appropriate government agency if necessary
- A consistent approach to corrective action

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### Enforcement of Standards

Employee emphasizes ethical behavior in the enforcement of established standards by:

- Performing frequent reviews of the OIG and General Services Administration Exclusion Lists for:
  - All pre-hire and existing employees
  - All vendors
- Consistently documenting and enforcing compliance-related violations
- Taking appropriate disciplinary action for violations, including termination, as appropriate

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### Written Policies and Procedures

- ▶ Employee must follow written policies and
- ▶ Employee's policies and procedures are intended to govern conduct and direct relevant job functions
- ▶ Failure to follow policies and procedures potentially result in disciplinary action, including termination

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### Written Policies and Procedures

- ▶ Copies of all of employee's policies and procedures are available in each administrative office
- ▶ Questions about policies or procedures should be referred to the Chief Compliance Officer or General Counsel

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### Guidelines for Doing The Right Thing

- There may be times when there is uncertainty as to whether an activity or a situation is unethical, illegal or a violation of employee or vendor policy
- Directions should include asking for guidance from a supervisor, the Chief Compliance Officer or General Counsel, or report concerns to senior management personnel until confident that concerns have been addressed or that the right person has the facts and is addressing the situation

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### Guidelines for Doing The Right Thing

- Use caution when someone says:
  - "Well, maybe it's okay just this once."
  - "Everyone does it."
  - "We've always done it this way."
  - "No one will ever know."
- Instead, stop and ask yourself:
  - Does this activity violate a law, regulation, employee or vendor policy or Code of Conduct?

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### Report Without Fear of Retaliation

#### Remember!

No disciplinary action or retaliation will be taken against an individual for reporting a perceived issue, problem, concern or violation "in good faith"

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Questions and Answers



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## Fighting for Survival – DMEPOS

Wayne van Halem, President, The van Halem Group  
Paula Koenig, Corporate Compliance Officer, Numotion  
Ruth Krueger, Compliance Program Administrator, Sanford Health

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### Objectives

- Understand the Impact of competitive bid-derived pricing on products in non-bid areas plus future of competitive bid rounds
- Investigate Alternative payment arrangements, including the pros and cons of submitting non-assigned claims
- Learn how to manage the continued impact of Medicare/RAC audits and new program integrity contractors
- Hodge Podge of compliance issues discussions

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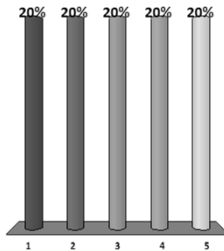
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### What type of company do you represent?

1. Hospital/Health system
2. Private/Family owned DMEPOS
3. Publically held DMEPOS
4. Insurer
5. Other



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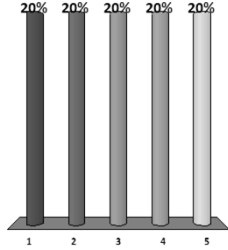
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### How long have you worked in DMEPOS?

1. <1 year
2. 1-5 years
3. 6-10
4. >10
5. DME? I'm in the wrong room!!



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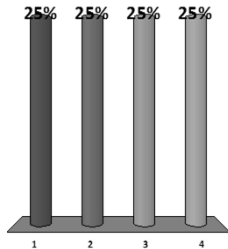
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### How many employees in your operation?

1. <20
2. 20-50
3. 51-100
4. >100



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### DMEPOS historical perspective

- DME = big business
- Customers ...then and now

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### DMEPOS Customers

- 23 million of the Greatest Generation
- 20 million of the Korean War generation
- 78 million Baby Boomers (those born between 1946 and 1964).

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### CBS News Report

- Amazing aging athletes

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**Many customers .....**

- Why the struggle to survive?



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**Wayne van Halem**

- President, The van Halem Group



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**Alternative Payment Arrangements**

HHS categorizations for health care payments:

- Category 1 – Fee-for-service - no link to quality
- Category 2 – Fee-for-service with link to quality
- Category 3 – Alternative payment models built on fee-for-service architectures
- Category 4 – Population-based payment

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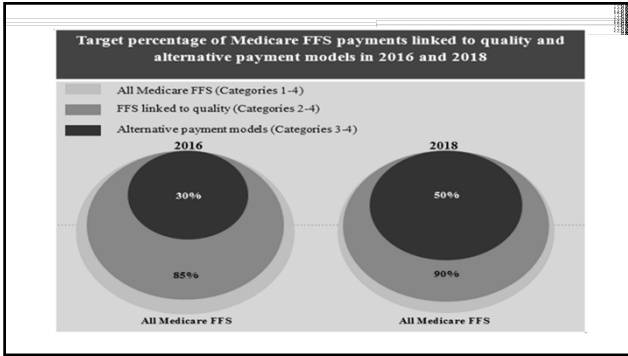
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**Alternative Payment Models**

- Accountable Care Organizations
- Bundled Payment Arrangements
- Hospital Value-Based Purchasing
- Hospital Readmission Reduction Programs

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**The Rise of Value-Based Care Delivery**

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### Healthcare Market Trends

-  **Current models of care are becoming unsustainable.** The number of people needing care is set to quadruple by 2050, placing extreme demands on access to care and creating a looming physician shortage.
-  **Patients are getting sicker.** According to the CDC, 25% of Americans have two or more chronic conditions, and the number is rising.
-  The cost of healthcare is **expected to increase annually by >5%** through 2020.
-  **Re-admission penalties** for hospitals require farther-reaching and longer-term care management capabilities.
-  **Healthcare providers are at direct financial risk** for the care of patients, requiring careful evaluation of value-based care pathways and settings.
-  **Reimbursement is shifting** to reward progress toward the "triple aim" of care: access to care, clinical outcomes, and cost-effectiveness.

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### Value-Based Reimbursement

- Value = quality / cost (over time)
- Insurers pay for value delivered, not for services rendered
- Financial risk shifts to providers for whole-patient, cost-effective care
- Health management and prevention becomes more important
- Populations are managed across providers: "It takes a village"

PAYER		PROVIDER		
Fee for Service	Pay for Performance	Bundled Payments	ACOs	Shared Risk Models
(Cost)	FINANCIAL RISK			(Value)
POPULATION MANAGEMENT				
(Traditional)	CARE MANAGEMENT			(Delegated)

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### Value-Based Plans Becoming the Norm

#### Medicare Pilot Programs

- Bundled Payment for Care Initiatives (BPCI)
- Comprehensive Care for Joint Replacement (CJR)
  - Hip and knee replacements
  - Proposing hip and femur fractures
- Cardiac Procedure Bundle (proposed)
  - Includes incentive for cardiac rehab
- Value Based Payments for Home Health
- Value Based Reimbursement for SNFs



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## Value-based plans becoming the norm

### Self Funded Employers and IDNs

- Generally bundled payments
- Cardiology and Orthopedic procedures
- Cleveland Clinic, Lowe’s, others
- Intermountain Healthcare, Kaiser

### Insurance Trend Estimates

- Medicare
  - By the end of 2016, 85% of Medicare payments tied to quality or value
  - By the end of 2018, 90% of Medicare payments tied to quality or value
- Commercial Plans
  - By the end of 2020, 75% of businesses will be operating under value-based payments.

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## Understanding Bundled Reimbursement

*A financial incentive for providers to coordinate care, keep costs down*

### How Medicare Bundling Programs Work

- Providers and suppliers bill and paid as usual under regular payment systems.
- Single “price” to hospital performing surgery (knee replacement, cardiac bypass) for any services rendered as part of that procedure (through 90-days post d/c)
- End of year reconciliation between claims payment and target “price”

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## Bundled Reimbursement, continued

### How payments are distributed

- Savings to be shared with all post-acute providers
- Hospital negotiates criteria and shared savings with each provider

### Implications of for the Industry

- Efficacy of post-acute care and appropriateness of setting is center stage
- Hospitals incented to select and work closely with most valuable post-acute partner
- PAC providers incented to deliver and demonstrate value

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### Value-Based Reimbursement

*How is this changing care delivery?*

- Conscientious discharge planning
- Cross-Provider Collaboration
- Use of protocols that deliver value over time
- Complex Care Management

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### Value-Based Reimbursement

*How is this changing care delivery?*

- “There is no standardized process for determining post-acute destination...Patients with same discharge diagnosis may be referred to different PAC settings.” *AHA Trendwatch*
- In 2014, hospitalizations for heart attacks cost Medicare over \$6 billion. Yet for every treatment, the cost could vary by as much as 50%

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**How is Value-Based Care Delivery changing the value proposition of home care providers?**



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## Hospital & Primary Care Physician Conundrum

Which setting(s), services, and provider(s) of services will:

- Provide the best long-term outcomes for my patient ...at the best price
- Prevent readmissions, ER visits, or reduce hospital LOS
- Provide the greatest level of patient satisfaction
- Be easy for me to work with

*"HCOs that do not adapt to the home care imperative risk becoming irrelevant. It seems inevitable that health care is going home."  
-New England Journal of Medicine*

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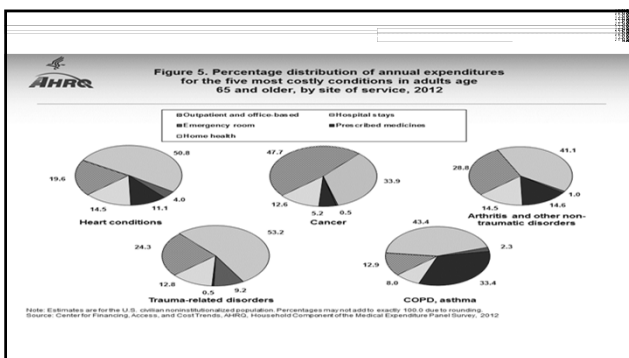
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## Impact of COPD on Health Care Costs



### WHAT ARE THE COSTS OF COPD?

While COPD receives less attention among employers compared to other chronic diseases, it is the third leading cause of death in the U.S. and seventy percent of the 24 million individuals with COPD are under age 65. COPD is one of the most burdensome diseases for employers but with half of the 24 million not properly diagnosed, the cost burden may be greater than the data reveals.

- ◆ In 2010, COPD resulted in \$49.9 billion in direct and indirect costs.<sup>1</sup>
- ◆ Commercially-insured COPD patients cost more per patient annually than those with Medicare.<sup>2</sup>
- ◆ Total costs incurred by COPD patients are approximately \$6000 higher than non-COPD patients.<sup>4</sup>
- ◆ 13-14% of COPD patients had a hospital readmission; 41-49% had a readmission within 60 days.<sup>3</sup>
- ◆ The average direct per patient costs for commercially insured increased 6% per year between 2008 and 2009.<sup>3</sup>
- ◆ Treatments that reduce frequency of COPD-related exacerbations are associated with lower COPD-related medical costs.<sup>5</sup>
- ◆ 40% of COPD costs could be avoided by preventing complications and hospitalizations.<sup>6</sup>
- ◆ Individuals with COPD had more days of lost productivity than any other chronic condition.<sup>10</sup>

The majority of COPD expenditures are due to complications and hospitalizations, many of which are preventable. As with other chronic diseases, improved health care management can reduce poor outcomes and decrease costs related to COPD.<sup>4</sup> Better care and staying on treatment can lower the avoidable costs and make patients feel better, which increases productivity and decreases absenteeism. Thus, effective management of COPD patients can result in decreased costs, increased productivity, and decreased absenteeism.

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### Chronic Conditions and Hospital Admissions

Diagnoses producing greatest number of hospital readmissions (2010)

Principal Dx for Hospital Stay	# of Stays	# of Readmissions	Readmission Rate
<b>Congestive Heart Failure</b>	847,073	209,017	25%
Septicemia	696,122	145,896	21%
<b>COPD</b>	606,186	126,443	21%
Complication of Device, Implant, Graft	596,062	121,036	20%
<b>Diabetes Mellitus, w/ complications</b>	480,958	97,784	20%

Source: HCUP/AHRQ Statistical Brief, April 2013

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### Cost Effectiveness of Homecare

- Need Cost-Effective Solutions
- Studies show home-based care is cost-effective
- Overall Medicare spending increased over 175% from 2000 – 2014.
- By contrast, DME spending only increased 3% overall in the past 5 years and actually declined 4% between 2012 and 2014.
- DME % of Medicare spending has declined for 10 years from 2.0% in 2004 to 1.25% (\$7.7 billion) of the Medicare budget in 2014.

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### Cost Effectiveness of Homecare

- Oxygen therapy can be provided for one year for the cost of one day's stay in the hospital
- For every dollar spent...
  - \$1 spent on mobility DME saves \$16.78 in fall-related recovery
  - \$1 spent on supplemental O2 therapy for COPD saves \$9.62 in complications
  - \$1 spent on CPAP therapy saves \$6.73 in Obstructive Sleep Apnea complications

Source: <http://www.vgmdlink.com/uploads/Document-Library/d1306dfcd9db67830ba14d4cd5b3be8c.pdf>

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### Redefine Your Role in the Healthcare Value Equation

- Imperatives
  - Increase patient adherence to plan of care
  - Help patient avoid exacerbations
- Leverage your core competencies: equipment selection, delivery, maintenance
  - Equipment that patients will USE
  - Equipment for full range of conditions
  - Equipment with monitoring capabilities
  - Remote monitoring / telehealth technologies; partner with home care agencies/vendors for actual monitoring
  - Be intentional and exceptional in set up, training, and follow up

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### Redefine Your Role in the Healthcare Value Equation

- Market to providers in terms of value of home care, and of YOUR CARE




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### Assigned vs. Non-Assigned Claims



- DME Suppliers have historically accepted assignment; however, increased regulatory oversight and reimbursement reductions have made suppliers question assignment.

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### Assigned vs. Non-Assigned Claims

- Participating
  - Supplier agrees to accept assignment on all claims
  - Agrees to accept the Medicare allowed amount as payment in full
  - Can only collect co-payment and deductibles and for non-covered services
  - Medicare payment is sent to the supplier
- Non-Participating – Can elect to accept assignment or not on a claim by claim basis
  - A supplier can submit either assigned or non-assigned claims
  - Beneficiary can be charged up front and be billed the difference between the billed and allowed amounts
  - Payment is sent to the beneficiary

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### Submitting Non-Assigned Claims

- You must submit claims per the mandatory claim submission rule, but you don't have to accept assignment
  - You do not have to submit claims for non-covered services
- You must be non-participating (update status with NSC during the enrollment period)
- You can charge the beneficiary up front
- You are not bound by the "limiting charge" rule

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### Mandatory Assignment Situations

- Section 114 of the Benefits Improvement and Protection Act of 2000 (BIPA) says mandatory assignment applies to Medicare-covered drugs
- Competitive Bid Suppliers must accept assignment
- Non-contract suppliers must accept assignment for competitively bid items
  - Traveling beneficiaries
  - Grandfathering
  - Repairs to bid equipment in CBAs
- Dual-Eligible Beneficiaries (Medicare/Medicaid)

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### Fragmented Billing

- A non-participating supplier accepts assignment for some services and requests payment from the beneficiary for other services performed at the same place and at the same time.
- A supplier may accept assignment on a claim by claim basis, but the decision applies to all services performed at the same place and on the same occasion.
- Exception – A supplier may choose not to accept assignment for other services as the same place or occasion in a mandatory assignment situation.

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### Oxygen

- Nonparticipating suppliers may accept assignment on a claim by claim basis. However, 42 CFR Section 414.226 (g)(3) requires that “before furnishing oxygen equipment, the supplier must disclose to the beneficiary it’s intentions as to whether it will or will not accept assignment of all monthly rental claims for the duration of the rental period.”
  - So... you cannot switch assignment for oxygen claims during the 5 year period.

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### Beneficiary Authorization

- Beneficiary Authorization – All claims require an authorization, assigned or unassigned.
  - one-time authorization - later claims for the same services can be billed without an authorization.
- One-time authorization *does not apply* to non-assigned DME rental claims;
  - requires a separate authorization for payment of each claim
  - can not have the patient sign all authorizations up front although industry is challenging this

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### Capped Rental

- Allows billing capped rental items as non-assigned, but must submit monthly rental claims just like assigned claims.
- Cannot charge the beneficiary for all months up front
- Consider getting a credit card to charge monthly

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### Advanced Beneficiary Notices

- ABNs apply to both assigned and non-assigned claims
  - Lack of medical necessity
  - Prohibited unsolicited phone contacts
  - Supplier number requirements not met
  - Denial of Advanced Determination of Medicare Coverage (ADMC) request
  - Noncontract supplier furnishing competitively bid DMEPOS items in a CBA
- Protect yourself and get an ABN when appropriate

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### Documentation Requirements

- Do not differ for assigned vs non-assigned claims
- Non-assigned claims can be audited- although probably less frequently
- If the claim is deemed to be denied and you do not have a proper ABN, the contractor could require you to refund the beneficiary
- Nothing is different, except who pays the supplier and the amount the supplier can charge

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**National DMEPOS and HHH RAC**

- November 1, 2016 – RAC contract awarded to Performant Recovery
- RAC set to begin outreach this month
- RAC audits start March 2017

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**Other RAC Program Changes**

- Establishing ADR limits based on a supplier's compliance with Medicare rules
- RACs must wait 30 days to allow for a discussion request before sending the claim to the DME MAC for adjustment
- SOW also says that RACs are expected to support CMS in a minimum of 50% of the cases that make it to the ALJ.
- CMS also says in the SOW that the agency has the authority to settle appeals without RAC approval or input.

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### Other RAC Program Changes

- No contingency fees until after 2<sup>nd</sup> level of appeal
  - Ensures RAC is properly applying Medicare rules on claims audited.
- RACs – required accuracy rate of 95% and overturn rate <10%. Failure to meet =
  - Decreased ADR limits **OR**
  - Elimination of certain reviews until problems corrected

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### What does that mean?

RACs are back -expect more active than ever;

- likely to immediately begin automated, semi-automated and complex reviews already approved
- looking at post payment claims than have been submitted within the previous 3 years from the date the claim was paid



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### Unified Program Integrity Contractors\*

- Implementation of the UPIC\* initiative began in 2016
  - Combines the audit and investigation work currently conducted by the ZPICs (and their responsibilities) with the Audit Medicaid Integrity Contractors (Audit MICs) to form the UPIC
- Contracts with ZPICs/PSCs and MICs will end as the UPIC is implemented in specific geographic regions
- Implementation of the UPICs will be over a multi-year period in order to allow current contractors to transition out
- Goal: Streamline audit structure

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### UPICs

- Umbrella contracts awarded in May 2016
- Potential 10 year, \$2.5 billion contract vehicle
- Awardees:
  - AdvanceMed
  - Health Integrity
  - Safeguard Solutions
  - Strategic Health Solutions
  - TriCenturion
  - HMS Federal
  - Noridian Healthcare Solutions

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### UPICs

- 2 task orders awarded thus far:
  - AdvanceMed on 5/24/2016 for UPIC Jurisdiction 1 (Midwest)
    - Contract amount = \$76,874,623.22
  - Safeguard Services was awarded contract for Jurisdiction 5 (Northeast) but no details have been released publicly.
    - Transitioned March 1, 2017.

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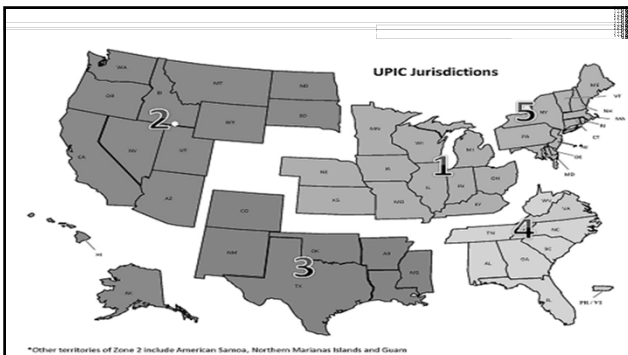
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**Managed Care Risk**

- Increased pressure on Medicare Advantage/HMO plans to conduct program integrity functions
- Applying policies consistently as Medicare
- Increased prepayment review and extrapolated overpayments
- Must be treated the same as Medicare
- December 2015 – CMS released a request for information that outlines an expansion of Medicare’s RAC program
  - ACA requires the RAC program to be expanded into Managed Care, so the plan themselves will be audited
  - Trickle-down effect to suppliers

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**Supplemental Medical Review Contractor (SMRC)**

- Strategic Health Solutions (SHS) performs a large volume of Medicare Part A, Part B, and Durable Medical Equipment reimbursement claims nationally;
- focus on lowering improper payments in Medicare Fee-For-Service programs and increasing efficiencies in medical review functions.
  - includes issues identified by the OIG, CERT and CMS internal data analysis
  - Focus on national claims data analysis versus MAC jurisdiction data

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**SMRC**

- Completed Projects
  - Power Mobility Devices
  - Vacuum Erection Devices (VED)
- Current Projects
  - Diabetic Testing Strips
  - Oxygen (50,000)
  - Nebulizers (50,000)
  - CPAP (6,000)

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**SMRC**

- Results on respiratory reviews coming in – actual overpayments
- Review results carefully
- We don't anticipate extrapolated overpayments but it can't be ruled out
- Appeal denials

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**Revocations**

NEW Final Rule for safeguards to reduce Medicare fraud – December 3, 2014

- Under authority of the ACA, CMS can and will deny or revoke enrollment of entities and individuals that pose a program integrity risk to Medicare for the following:

*"... providers and suppliers that have a pattern and practice of billing for services that do not meet Medicare requirements. This is intended to address providers and suppliers that regularly submit improper claims in such a way that it poses a risk to the Medicare program."*

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**Other High Risk Codes**

- CPAP/BiPAP
- Oxygen
- High Frequency Chest Wall Oscillation
- TENS
- Support Surfaces
- Negative Pressure Wound Therapy
- Ventilators

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### Appeal Changes

- October 1, 2015 – CMS limits scope of review at Redetermination and Reconsideration to the reason the claim was initially denied.
- Two instances where guideline does not apply
  - Claims denied in prepayment reviews (guideline applies only to post-payment denials);
  - Claims denied in post-payment review for insufficient documentation and appealed with never-before presented documents (guideline allows claims to be denied for an issue other than the issue that was initially denied).

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### Appeal Changes

- DME Pilot Program to allow for a discussion period at the Reconsideration level
- QIC will be the one to initiate
- Limited to claims for oxygen and diabetic supplies currently
- Also looking to reopen all other unfavorable claims for these products back to January 1, 2013, if they can issue a favorable decision
- Announced November 30, 2016 – program has been expanded to include all suppliers in Jurisdictions C & D; all items except PMDs

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### Appeal Changes – Final Rule

- Published 1/13/2017
- Precedential Final Decision by the Secretary
  - Decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.
- Attorney Adjudicators
  - A licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance.

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**ALJ Hearings Update**

- December 6, 2016 – Judge issued decision in American Hospital Association lawsuit
- HHS must eliminate the backlog by 2021
  - 30% by the end of 2017
  - 60% by the end of 2018
  - 90% by the end of 2019
  - Completely by the end of 2020
- Judge was asked by HHS to reconsider and he declined their request to do so.

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**Settlement Conference Facilitation Pilot**

- Pilot alternative dispute resolution process designed to bring the appellant and CMS together to discuss the potential of a mutually agreeable resolution for claims appealed to the ALJ
- If a resolution is reached, a settlement document is drafted by the settlement conference facilitator to reflect the agreement and the document is signed by the appellant and CMS at the settlement conference session

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**Settlement Conference Facilitation Pilot Phase 2**

- For the purposes of an extrapolated statistical sample, the individual claim extrapolated amount must be \$100,000 or less.
- At least 20 claims must be at issue, or at least \$10,000 must be in controversy if fewer than 20 claims are involved;
- There cannot be an outstanding request for OMHA statistical sampling for the same claims;
- Claims will not be adjusted so subsequent supply or repair claims for that patient will not get paid.

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- Compliance Programs
- Proper transferring of liability
- Getting patients requalified
- Quality Assurance
- PreScreening
- Working with beneficiaries
- Data analysis
- Innovation



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Paula Koenig

- Corporate Compliance Officer, Numotion



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### Medicare Competitive Bid

- Initial Round 1 July 1 2008-July 15 2008: 10 CBAs
  - ✓ Retracted by Congress after just 2 weeks
- Round 1 Re-Bid 01/01/2011 – 12/31/2013: 9 CBAs
  - ✓ average 32% reduction in allows
- Round 2 07/01/2013 – 06/31/2016: 100 CBAs
  - ✓ average 45% cuts
- Round 1 Re-Compete 01/01/2014 – 12/31/2016: 9 CBAs
  - ✓ average 37% cuts
- Round 2 Re-Compete 07/01/2016 – 12/31/2018: 117 CBAs
  - ✓ average 7% cuts
- Round 1 2017 01/01/2017 – 12/31/2018: 13 CBAs
  - ✓ 5% cut

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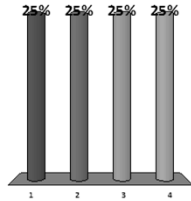
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**Is Your DME business in a Round 1 or Round 2 CBA?**

- 1. Yes, Round 1 only
- 2. Yes, Round 2 only
- 3. Yes, both Round 1 and Round 2
- 4. No, none of our customers are in a CBA
- 5. What's a CBA?




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**Regional Single Payment Amounts (RSPA)**

Medicare is using Bid rates to adjust allowables in non-bid areas

- Split into non-rural and rural rates by bene zip codes; rural gets 10% add-on
- 01/01/16 phased in rates; blended with 2015 allowables
- 07/01/16 full implementation of RSPAs
  - 2016 cuts were in many cases more than 50% lower than 2015 allowables

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**RSPA**

Cures Act rescinded July cut; claims for DOS 07/01/16 thru 12/31/16 to re-process at January rates

- Full RSPAs in effect 01/01/2017
- RSPAs reflect an average cut of 38% from 2016

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### Future Bidding

- 2019 will see new bid programs for both Round 1 and 2
- Bidding will start in 2017
- Could be different categories in Round 1 vs 2
- New Surety bond requirement
- 'lead item' groupings
- Bid ceiling at 2015 allowables

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### Can We Survive the Lower Allowables?

- Limit Products offered
- Non-assigned claims
- Re-define Service areas
- Retail
  - On-line



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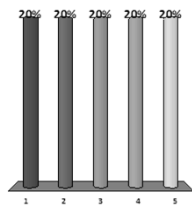
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### How have you dealt with lower payments?

1. Reduced staff
2. Changed product offerings
3. Redefined service area
4. Increased non-assigned claims
5. All of the above



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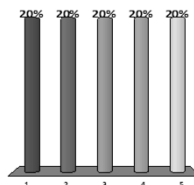
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### What are the pitfalls of cash sales?

1. Mandatory Claim Filing
2. ABNs
3. Contract obligations
4. Dual-eligibles
5. All of the above




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### Cash Sales

More 'cash' business is enticing... but

- Medicaid implications
- Commercial contract obligations
- Medicare mandatory claim filing
- Still need documentation

On-line sales:

- How do you collect insurance info?

Solution: separate entity/Tax ID  
 ✓ creates other challenges




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### Hodge-Podge: *A little of this, a little of that...*

- Medicare policy changes
- Modifiers – the new challenge
- Documentation – trends
- Prior Authorization: PWCs Ko856 & Ko861
  - starts 03/20/17
  - what items are next?

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### More... Compliance Issues

- Increase in social media activity challenges PHI management
- Email and Texting referral sources
- ✓ **01/09/2017 headline: Joint Commission prohibits secure texting for patient care orders**
- Acquisitions and closures: transferring patient files
- Contract compliance non-Medicare payers

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### Business Trends

- Direct to Beneficiary Marketing
- National mail order bracing
- Lead generation
- Scam telehealth arrangements
- Consequences
  - ZPIC Audits
  - Prepayment Reviews
  - Revocations
  - Suspensions
  - Extrapolated overpayment

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### ACA “Obamacare”

- Repeal and replace?
- Possible impact on competitive bid
- Current status of legislation/political climate




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### Exclusions

Anyone who hires an individual or entity on a sanctions list may be subject to civil monetary penalties (CMP).

- Need to verify that new hires have not been excluded
- And re-verify all staff – monthly!
- Also: need to verify that referring practitioners have not been excluded
- And that vendors/manufacturers have not been excluded



<https://oig.hhs.gov/exclusions/index.asp>

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### Medicare Enrollment

CMS appears to be getting more aggressive in revoking Medicare provider numbers

- Competitive bid contract violations
- Complaints
- Non-responses
- Patterns of 'improper' billing



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### Revocation Appeals



- Applicant/supplier must submit a CAP within 30 days from the postmark of the denial or revocation letter
- Request for reconsideration must be made within 60 days from the postmark of the denial or revocation letter
- Request must have the original signature of the authorized official, owner or partner on file

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### Final Thoughts



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### Questions?

- Wayne van Halem  
[Wayne@vanHalemGroup.com](mailto:Wayne@vanHalemGroup.com)
- Paula Koenig  
[Paula.Koenig@Numotion.com](mailto:Paula.Koenig@Numotion.com)
- Ruth Krueger  
[Ruth.Krueger@SanfordHealth.org](mailto:Ruth.Krueger@SanfordHealth.org)



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### Additional information on OIG Workplan

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**2017 OIG Work Plan – Power Mobility**

- Power mobility devices—supplier compliance with payment requirements
- OIG will review payments for power mobility devices (PMD) to determine whether such payments were medically necessary.




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**2017 OIG Work Plan - Nebulizers**

- Nebulizer machines and related drugs—supplier compliance with payment requirements
- OIG will review payments for nebulizer machines and related drugs to determine whether medical equipment suppliers' claims are medically necessary and are supported in accordance with Medicare requirements.
  - For calendar year (CY) 2014, Medicare paid approximately \$632.8 million for inhalation drugs. With an improper payment rate of 42 percent, inhalation drugs were sixth on a list of the top 20 DMEPOS services with the highest improper payments in the 2014 CERT report.

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**2017 OIG Work Plan -  
Osteogenesis Stimulators**

- From 2012 to 2014, Medicare payments for these devices were approximately \$286 million dollars.
- The OIG will examine the lump-sum purchase versus rental option to determine whether potential savings can be achieved if osteogenesis stimulators are rented over a 13-month period rather than acquired through a lump-sum purchase.

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**2017 OIG Work Plan - Orthotics**

- Orthotic braces–supplier compliance with payment requirements
- OIG will review orthotic braces to determine whether suppliers’ claims were medically necessary.
- Prior OIG work indicated that some suppliers were billing for services that were medically unnecessary (e.g. beneficiaries receiving multiple braces and referring physician did not see the beneficiary)

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**2017 OIG Work Plan – SNF Payments**

- 2009 OIG report found Medicare Part B allowed inappropriate payments of \$30 million for DMEPOS provided during non-Part A SNF stays.
- OIG intent - study the extent of inappropriate payments to nursing home patients during non-Part A stays in 2015.
- Spotlights CMS ability to determine if they have appropriate systems in place to identify improper payments and initiate recoupments.

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**2017 OIG Work Plan – PAP Supplies**

- Medicare payments for CPAP and BiPAP supplies in 2014 and 2015 -\$953 million.
- Prior OIG work found suppliers auto-shipped supplies when refills were not requested by the beneficiary and also that the physician orders were incomplete in regards to the types of supplies needed and frequency of use.
- The OIG will review supplier compliance with documentation requirements for frequency and medical necessity.

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## Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices

Colleen Shannon  
Chief Compliance and Privacy Officer



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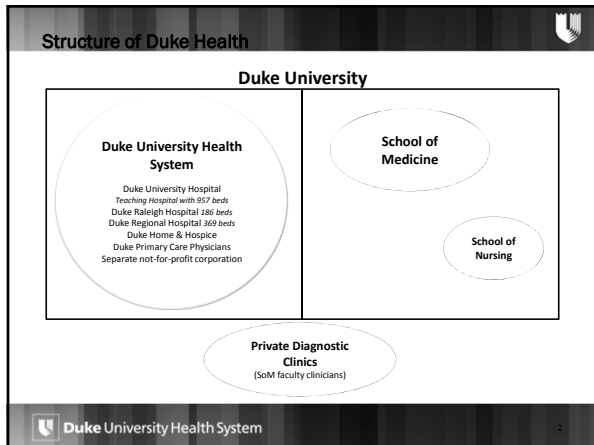
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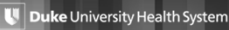
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### Compliance Effectiveness

- Open communication
- Collaboration among management, operational and compliance in evaluation of activity
- Create processes to develop compliant operations with compliance controls



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**Conflict of Interest**

- Evaluate Financial Relationships with Industry
- Benefits of Industry and Academic Medical Centers/Physicians working together
- Risk of creating bias that may affect results/ interpretations
- Risk of appearance of referral arrangements
- Evaluation of Research, Clinical and Institutional activities
- COI may affect research, faculty technology development, clinical care, purchasing and fundraising
- Compliance Control
- Policy and management plan
  - Research, Purchasing, Clinical
  - Patient Awareness/Communication

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**Conflict of Interest Scenario**

- Surgeons' creation of clinical app and considers commercialization
- Considerations
  - Research vs. Quality Improvement
  - FDA regulated
  - App meet regulatory and risk management requirements
  - Faculty owned app becomes vendor
  - Use in clinical care, efficacy
  - Patient Awareness

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**Conflict of Interest Scenario**

- Considerations
  - Self interest versus Medical Center activity
    - Use of Institutional assets
  - Is Faculty a Vendor?
    - Designation of Representative to interact with facility/physicians
    - Contract
    - Indemnification and Insurance
    - Referrals
  - IT Security
  - Privacy -- Privacy Policy/Terms and Conditions
  - Evaluation within facility
  - Patient Awareness

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**Clinical Care Conflict of Interest**

- Clinicians' activities:
  - Speaker Bureau/Promotional Speaker
  - Consultants for Device/Drug Companies
  - Development/Test new product
- Considerations:
  - Anti-kickback considerations
    - Fair Market Value
    - Services provided
  - Internal Gift policy

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**Clinical Care Conflict of Interest**

**Compliance Controls**

- Prohibit Speaker Bureau/non-CME approved Participation
  - Faculty independent material required
  - Content Expert
- Evaluation of Product Process
- Anti-kickback Settlements
  - Device/Pharmaceutical Companies
- Internal Gift policy
  - No payment for Advisory Board participation (evaluate purchasing involvement)
  - No payment for review of new product
  - No meals on or off campus

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**Warner Chilcott Settlement**

- Warner Chilcott resolved kickback investigation paying \$125 million and receiving permanent exclusion from Medicare and Medicaid participation for illegal marketing of 7 brand name drugs.
- In addition to corporate resolution, individual settlements
- Allegations that President instructed sales force to provide free expensive dinners and questionable speaker fees in exchange for prescriptions.

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**Revenue Cycle – Concurrent Surgery**

Concurrent versus Overlapping Surgery

- Concurrent surgery
  - Surgeries where **critical or key portions** performed simultaneously
- Overlapping surgery
  - Surgeries where non-critical or non-key portions performed simultaneously
  - Critical or key portions of 1<sup>st</sup> surgery complete before becoming involved in second surgery
    - Documentation of presence during critical or key portions

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**Revenue Cycle – Concurrent Surgery**

- Compliance Controls
  - Policy
    - 2<sup>nd</sup> surgeon immediately available if Attending involved in 2<sup>nd</sup> surgery
    - Patient consent of overlapping procedure
    - Definition of "Immediately Available," e.g., same surgical platform
    - Documentation of participation in critical or key portions
  - Daily scheduling review meeting
  - Documentation and Time audits

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**Revenue Cycle – Clinical Research**

- National Coverage Analysis
  - Involvement of PI and Office of Clinical Research
  - Initiation Meeting – PI, clinical research team, Revenue Cycle, Compliance and Office of Clinical Research
    - Review of protocol
    - Billing grid build -- charge assignment
    - Review of Medical necessity/coverage determinations
    - Review of CPT codes
- Use of Epic for research billing
  - Charge assignment review built into system
  - Continue 100% pre-bill review

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**Privacy – Hybrid/Affiliated Covered Entity**

- Duke Health Enterprise (Covered Entity/Components)
  - Duke University Health System
  - Duke Primary Care Physicians
  - Duke Home Care & Hospice
  - Duke School of Medicine
  - Duke School of Nursing
  - Other supporting departments
  - Administrative Services, e.g., IT, Procurement, Legal
- Established policies & procedures for sharing PHI with university components (non-covered entity)
- Established review for PHI requests

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**Privacy – Hybrid/Affiliated Covered Entity**

- Privacy Rule permits creation of ACE/Hybrid entity
  - Segregate care and non-care components of university
  - Segregate components that provide covered functions (business associate functions)
  - Covered component restricted to sharing PHI with non-covered component
    - Comply with Privacy Rule for disclosures
    - Business Associate Agreement for potential non-routine access

Duke University Health System 14

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**Privacy – Hybrid/Affiliated Covered Entity**

- Privacy Rule Requirements
  - Designated status in writing
  - Inventory of entities/services lines/administrative services
  - Comply with HIPAA Policies & Procedures
  - Orientation and Annual training
  - Risk Analysis
- Compliance Controls
  - ACE Policies & Procedures
  - Reevaluation with new entities and entity changes on a routine basis, with minimum of annually
  - Train staff of PHI restriction; not mere paper policy
  - Monitor as Big Data/Population Health activities grow

Duke University Health System 15

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**Privacy – Hybrid/Affiliated Covered Entity**

### University of Massachusetts Amherst Settlement

Resolution Agreement describes:

- Language, Speech and Hearing Center, not included in health care component, workstation infected with malware
  - Center not held to HIPAA policies and procedures
  - Center not implement technical security measures
- U Mass had not conducted thorough Risk Analysis

 **Duke University Health System** 16

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**Privacy – Access to Clinical Data**

### Governance of Clinical Data

- Activities – Population Health, Quality/Outcome Improvement, Research
- EHR seen as treasure trove
  - Internal use
    - Non-covered care component staff
      - Services to Health Care Component, e.g., statistician
      - Research
      - Desire to develop predictive analytics
  - External
    - County Health Department
    - Registries

 **Duke University Health System** 17

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**Privacy – Access to Clinical Data**

### Compliance Controls:

- Governance of Clinical Data
- Covered Entity review process
- Considerations:
  - Population Health
    - De-identified information
    - Limited data set
  - Research – Health Care IRB approval
  - Quality Improvement – Health Care approval

 **Duke University Health System** 18

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**IT Security** 

- Created database within Secure Environment
- Creation of clinical database; not direct access to EHR
- User Provisioning Categories
  - De-identified information access
  - Limited data set access
  - PHI access
- Access Approval
  - Research – IRB
  - Quality – Internal staff
    - Departmental approval
  - External – Privacy Office
- Data Analytics Oversight – implementation of data stewards

 Duke University Health System 19

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# Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practices

Ajay Vyas, Esq.  
Deputy Healthcare Compliance Officer  
University of Southern California



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## USC Health System

- 1,300 faculty physicians and scientists
- Three USC-owned private hospitals
- 9,000 patients enrolled in clinical trials and more than \$300M in research funding
- 900 medical residents – one of the largest residency programs in the U.S.
- 200 fellows and interns
- 670 medical students, 292 Ph.D. students, 300 master's students



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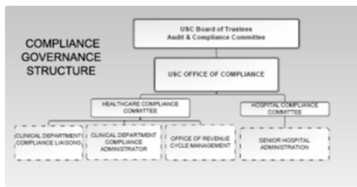
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## Compliance Governance Structure



The Keck Medicine of USC Compliance Program develops and maintains hospital and clinical compliance programs for:

- Keck Hospital of USC
- USC Norris Cancer Hospital
- USC Eye Institute – Keck Medical Center of USC in Ophthalmology
- USC Verdugo Hills Hospital
- USC Care Medical Group
- USC School of Dentistry
- USC School of Pharmacy



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## Key Issues in Academic Medical Centers



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### Key Initiative: Overlapping Surgery



**Clash in the Name of Care**

It was a battle pitting a star surgeon against a guest faculty, MD. The question: Is it right or safe for surgeons to have two operations at once in the OR with their patients? We look to find the conflict zone on the ground, and to learn more about it.



**United States Senate**  
February 17, 2016

VIA ELECTRONIC TRANSMISSION


David F. Tomlinson, MD  
President and Chief Executive Officer  
Partners Healthcare, 600 North Dearborn Street, Suite 1100  
Chicago, IL 60610-3000

Dear Dr. Tomlinson:


Recent news reports have revealed that physicians at some hospitals that participate in federal health care programs are engaging in concurrent surgery. Such behavior can compromise patient safety, compromise quality of care, and create other problems by affecting operating rooms at the same time.

**Overlapping Surgery**

When key or critical elements of the first operation have been completed and attending surgeon is performing key or critical components of a second operation in another room.



**AAMC**  
National call of Academic Medical Centers led by USC/Massachusetts General Hospital



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### Key Initiative: Overlapping Surgery



**American College of Surgeons**




**Senate Finance Committee Concluding Concerns**

**American College of Surgeons Recommendations**

- Intraoperative Responsibility of the Primary Surgeon
- Definition of Backup Surgeon
- Definition of "Immediately Available"
- Communication to Patients
- Pre-incision Timeout, Name of Backup Surgeon
- Documentation & Coding Guidelines

**Senate Finance Committee Concluding Concerns**

- Patient Safety
- Improper Payment



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**What is Overlapping/Concurrent Surgery?**

- Concurrent Surgery:
  - When critical or key components of surgeries occur all or in part at the same time.
- Overlapping surgery:
  - When key or critical elements of the first operation have been completed and attending surgeon is performing key or critical components of a second operation in another room.
  - A surgeon cannot have a third case started until the first case is completed in its entirety
    - **"OPEN TO CLOSE"**

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**Overlapping/Concurrent Surgery**

- A December 2015 Boston Globe "Spotlight" article focused on concurrent surgery practice at Massachusetts General Hospital
- Topic came to the attention of the American College of Surgeons (ACS), the Association of American Medical Colleges (AAMC) as well as the US Senate Finance Committee
- Nationwide focus on the practice of overlapping/concurrent surgery and its impact on patient safety during the perioperative process
- Keck Medical Center of USC created a workgroup to study the issue

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**Policy Highlights**

- Intraoperative Responsibility of the Primary Surgeon\*
  - Primary attending surgeon personally responsible for the patient's welfare during entire operation
  - Generally, the primary attending surgeon should be immediately available
  - When primary attending surgeon not present or immediately available, another qualified surgeon should be assigned to the patient (backup)

\* Corresponds to ACS Guidelines

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<b>Policy Highlights</b>
<ul style="list-style-type: none"> <li>• Definition of backup surgeon*             <ul style="list-style-type: none"> <li>• Attending surgeon credentialed in the same surgical specialty</li> <li>• Surgeon credentialed in the same surgical specialty and holds a Category A independent privilege</li> </ul> </li>   <li>• Definition of "Immediately Available"             <ul style="list-style-type: none"> <li>• Able to return to the OR immediately</li> <li>• Reachable through a paging system or other electronic means</li> <li>• Not involved in anything that cannot be interrupted</li> <li>• Keck Hospital                 <ul style="list-style-type: none"> <li>• Within the hospital and HCC 1-4 and Norris Cancer Hospital</li> </ul> </li> <li>• Norris Cancer Hospital                 <ul style="list-style-type: none"> <li>• Within the hospital and HCC1-4 and Keck Hospital</li> </ul> </li> </ul> </li> </ul> <p>* Corresponds to ACS Guidelines</p>


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<b>Policy Highlights</b>
<ul style="list-style-type: none"> <li>• Documentation &amp; Billing Guidelines:             <ul style="list-style-type: none"> <li>• Primary attending surgeon must personally document on each overlapping case, "I was present for the key and critical portions of the case"</li> <li>• If Fellow/Resident/NPP documenting the case, the attending must personally addend the record to note their presence during key/critical of overlapping procedures.</li> <li>• 3 overlapping or concurrent cases considered a supervisory service by the teaching physician                 <ul style="list-style-type: none"> <li>• Cannot bill 3 overlapping cases</li> </ul> </li> </ul> </li> </ul>


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<b>Importance of Documentation</b>
<p>Focused Review of Overlapping records-</p> <ul style="list-style-type: none"> <li>• OR Schedule of overlapping cases</li> <li>• OR record in Powerchart shows IN/OUT times of attending</li> <li>• Notes for overlapping procedures             <ul style="list-style-type: none"> <li>• Did the attending personally document their presence during key/critical</li> <li>• If missing, the assumption is the attending is present for entire case, which conflicts with OR records</li> </ul> </li> </ul> <p>Conflicting documentation may not support billing</p>


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<h2>Clinical Trials Research Billing at USC</h2>
<small>Keck Medicine of USC</small>

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<b>Overview</b>
<ul style="list-style-type: none"><li>• Compliant clinical trial billing requires<ul style="list-style-type: none"><li>• Substantive knowledge of complex coverage and coding rules</li><li>• Coordination across USC providers and functions</li></ul></li><li>• USC policies, procedures and processes are designed to ensure actions are consistent with coverage rules<ul style="list-style-type: none"><li>• Critical to avoid potential liability</li></ul></li></ul>
<small>Keck Medicine of USC</small>

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<b>Clinical Trial Billing Challenges: Complexity</b>
<ul style="list-style-type: none"><li>• Compliant billing for even routine medical care presents ongoing challenges for healthcare providers</li><li>• Clinical trial billing adds complexity and increases the challenge<ul style="list-style-type: none"><li>• Coverage and coding</li></ul></li><li>• No consistency among third party payors on clinical trial coverage<ul style="list-style-type: none"><li>• Medicare coverage principles may influence private health insurance</li><li>• New federal clinical trial coverage mandate applies to private health insurance but has limited applicability</li></ul></li><li>• Multiple coverage rules therefore apply to a clinical trial if subjects will be covered by multiple third party payors</li></ul>
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**Clinical Trial Billing Challenges:  
Coordination**

- Compliant billing requires coordination by multiple individuals, departments and entities
  - Research team
  - Other treating practitioners and providers
  - Patient registration
  - Finance
  - USC Clinical Research Organization
- Compliant billing requires coordination throughout clinical trial
  - Clinical trial agreement negotiation/budgeting
  - Subject enrollment/informed consent
  - Patient registration/scheduling
  - Clinical services ordering
  - Billing for services

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**Clinical Trial Billing Challenges:  
Coordination**

- Research team contribution is critical to compliant billing
  - Unique understanding of protocol and services provided under protocol
  - Often primary point of contact for patients enrolled in clinical trial
    - Notice of adverse events or complaints about billing
  - Responsible for scheduling/coordination of specific clinical trial services

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**Relationships with Industry**

Tom Bates, RN BSN MBA CPHRM LNCC  
Office of Integrated Risk Management

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<b>Fundamental USC Position</b>
<ul style="list-style-type: none"> <li>• USC supports meaningful interactions with Industry.</li> <li>• USC recognizes that these collaborations have led to the discovery of new knowledge which has directly benefited patients/public health.</li> <li>• USC seeks to maintain a culture of ethics in its business relations and to minimize conflicts of interest or even the appearance of conflicts of interest.</li> </ul>


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<b>USC Policy</b>
<p><b>Gifts</b></p> <ul style="list-style-type: none"> <li>• No gifts of any kind from Industry even if gifts are nominal</li> <li>• Food is as a gift</li> <li>• No branded items such as pens and notepads</li> <li>• No gifts to family members of Healthcare Professionals</li> </ul> <p><b>Education Grants and Trainee Scholarships</b></p> <ul style="list-style-type: none"> <li>• Education grants received from Industry must be clearly documented, signed by authorized signer for USC, and deposited in USC restricted accounts</li> <li>• Education events must comply with ACCME Standards for Commercial Support. <small>Key Questions: Budget? , Educational Objectives? , Target audience?</small></li> <li>• Education funding should not originate from company's sales/ marketing.</li> <li>• Industry can not influence educational event / content.</li> </ul>


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<b>Consulting Criteria for Chair Approval</b>
<ul style="list-style-type: none"> <li>• Is there a detailed Scope of Work?</li> <li>• Fair Market Value review</li> <li>• Is there a "quid pro quo"</li> <li>• When are services provided?</li> <li>• Conflict of Interest and Commitment Review</li> <li>• Is the faculty member involved in research with the company requesting services?</li> <li>• Paid Promotional Speaking Review</li> </ul>


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### Industry Payments Continue to be Scrutinized in the News

- ProPublica has updated the "Dollars for Docs" website to include the reported Open Payments data from 2013-2015. The application now also includes lists of the highest-earning physicians, physicians paid the most often, and teaching hospitals paid the most.  
<https://www.propublica.org/article/updated-dollars-for-docs-heres-whats-new>
- Time magazine published an article in early October discussing over \$34 million from industry to Dermatology physicians in 2014. The article discusses studies showing an increase in prescribing of brand-name prescriptions linked to receiving industry payments and meals.  
<http://time.com/4519504/dermatologists-skin-pharmaceutical-companies/>
- Modern Healthcare released a story in January of this year regarding a study on physicians tweeting about drugs or other commercial products and the lack of conflict disclosure. The researchers used the Open Payments database and the Dollars for Docs website to discover the conflicts physicians had.  
<http://www.modernhealthcare.com/article/20170117/NEWS/170119925>

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### Example of Payment Information

Summary Information for Program Year 2014 Change Program Year (2014 x)

\$354,083.10 Total General Payments	398 Total General Transactions	N/A Total Amount Invested	0 Total Invested Transactions
N/A Total Research Payments	0 Total Research Transactions	N/A Total Value of Interest	
\$29,358.70 Total Approved Research Funding	4 Total Approved Research Transactions	0 Total Disposed Payments	402 Total Undisposed Payments

General Payments Received<sup>®</sup>

Company Making Payment	Nature of Payment	Date	Amount	Third Party Payment	Disputed	Comment
Acorda Therapeutics, Inc.	Compensation for services: 2014-2015 consulting, including speaking at faculty and leadership of an education program	02/05/2014	\$2,000.00	No Third Party Payment		No
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$60.00	No Third Party Payment		No
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$300.00	No Third Party Payment		No
Acorda Therapeutics, Inc.	Travel and Lodging	02/06/2014	\$702.00	No Third Party Payment		No

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### What is a conflict of interest in research?

Researcher is conducting research related to ABC company

Researcher has a personal financial interest in ABC

COI

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**Conflicts of Interest in Research**

- Conflict of Interest in Research (COI) is a situation where financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research.
- Example: You own 10% of a start-up company called ABC Medical Devices. You are conducting research at USC on an ABC prototype or a prototype licensed to ABC.

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**Institutional Conflict of Interest (ICOI)**

- An institutional conflict of interest occurs when a financial interest of the university has the potential to bias research conducted by its employees or students.
- Such financial interests include, but are not limited to, receipt of licensing payments or royalties from the outside entity, or an ownership interest in the outside entity.

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**Institutional Conflict of Interest (ICOI) cont.**

An ICOI is deemed a "Significant Conflict" when a research project includes human subjects and any of the following conditions applies:

- The university holds any private equity in the outside entity,
- The university has the potential to receive cash payments from existing licensing arrangements with the outside entity;
- The university maintains an ownership interest or an entitlement to equity in a publicly-traded sponsor of human subject research as a result of technology licensing activities.

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### HIPAA for Hybrid Entities -University of Massachusetts Amherst (UMass)

- November 22, 2016 the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") reported a settlement for a malware infection that penetrated a covered entity's entire system.
- Infection started in a system that was not designated as a "health care component" in a hybrid entity which means there were no HIPAA Privacy and Security policies in place to prevent the breach.
- The settlement included a \$650k monetary penalty and corrective action.
- Of note is the designation of the organization as a "hybrid entity," a single entity with both covered and non-covered business activities.
- A health care component would be any component or combination of components that are involved in covered business practices.
- Hybrid entities must ensure that there are policies and procedures to ensure a separation between the health care and non-health care components.

Source: [https://www.hhs.gov/ohcr/default/files/umass\\_ra\\_cip.pdf](https://www.hhs.gov/ohcr/default/files/umass_ra_cip.pdf)

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### HIPAA for Hybrid Entities

- Covered entities that perform covered and non-covered functions that have not elected the hybrid entity designation should consider whether the designation is appropriate for the organization. The designation may help focus its HIPAA compliance efforts and reduce HIPAA compliance costs.

Source: <http://www.healthcare.com/2016/12/02/ocr-settlement-announced-hybrid-entity-hipaa-breach-2/>

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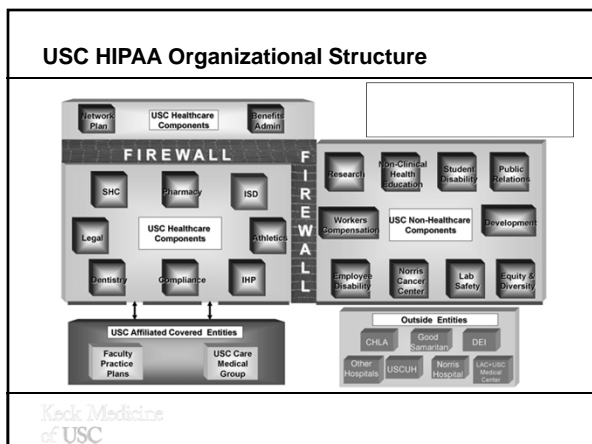
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Questions?
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UC San Diego Health

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**Academic Medical Center Compliance: Tips, Traps, and Emerging Best Practice**

Daniel J. Weissburg, JD, CHC  
 Chief Compliance & Privacy Officer  
 University of California San Diego Health

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UC San Diego Health

**University of California Health**

**5 UC MEDICAL CENTERS**

**4<sup>th</sup> largest health care delivery system in CA**

TRAINS **50%** OF STATE'S MEDICAL STUDENTS & RESIDENTS

GENERATES **\$16.7B** IN ECONOMIC ACTIVITY

PERFORMS **50%** OF ALL TRANSPLANT SURGERIES IN CA

**60%** OF PATIENTS ON MEDICARE, MEDI-CAL OR LACK INSURANCE

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**UC San Diego Health – Academic Enterprise**

**2**  
Professional Schools: Medicine and Pharmacy

**1,431**  
Faculty Members

**2,370**  
Students, Postdocs, Residents & Fellows

**\$577 Million**  
2015 Faculty Research Awards

**6<sup>th</sup>**  
Highest NIH Funding in Nation<sup>1</sup>

**50**  
National Academy of Medicine Members<sup>2</sup>

1. Based on total campus NIH awards  
 2. Based on total campus members, current and emeritus

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### Case Study: Overlapping surgeries and a FCA Whistle Blower

- Ganesh Elangovan, M.D., a resident at Medical College of Wisconsin
- Became a whistleblower after he allegedly was put in the position of operating on patients without the presence of the teaching physician.



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### Case Study: Overlapping surgeries and a FCA Whistle Blower

- Medical College of Wisconsin agreed to pay \$840,000 to settle a false claims allegations that two of its teaching physicians charged Medicare for performing more than one neurosurgery at the same time.
- Dr. Elangovan received up to **30%** of the government's recovery



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### Case Study: Overlapping surgeries and a FCA Whistle Blower

- Allegation: Medical College of Wisconsin scheduled two neurosurgery patients at the same time and billed Medicare and TRICARE as if teaching physicians performed the surgeries and were immediately available during them.

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**Case Study: Overlapping surgeries and a FCA Whistle Blower**

- The Medicare teaching physician billing rule allows separate billing only if the teaching physician personally performs the service or is physically present for at least the key portions of the service and immediately available when the resident performs the service.
- A single teaching physician cannot be responsible for two simultaneous surgeries.

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**Case Study: Overlapping surgeries and a FCA Whistle Blower**

- The resident-turned-whistleblower found himself in the middle of the alleged misconduct.
- Ten examples of two surgeries scheduled simultaneously by neurosurgeons who were named in the complaint.

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**Case Study: Overlapping surgeries and a FCA Whistle Blower**

- Allegation: Dr. Elangovan personally witnessed the routine occurrence of simultaneous surgeries and was forced to participate in the fraud — frequently performing one of those surgeries without any back-up.

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**BAD PUBLICITY**  
JUST AHEAD

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**Department of Justice**  
U.S. Attorney's Office  
Eastern District of Wisconsin

FOR IMMEDIATE RELEASE  
Friday, January 9, 2015

**Medical College of Wisconsin, Inc. Pays \$840,000 to Settle Alleged False Claims for Neurosurgeries**

United States Attorney James L. Santelle of the Eastern District of Wisconsin announced today that the Medical College of Wisconsin, Inc. (MCW) has paid the federal government \$840,000 to resolve allegations that it violated the False Claims Act. MCW is alleged to have knowingly billed federal healthcare programs for neurosurgeries involving residents who did not receive the required level of supervision from teaching physicians.

MCW is a medical school in Milwaukee, Wisconsin, that employs teaching physicians who provide medical care to patients and supervise residents. The civil settlement resolves a lawsuit filed under the *qui tam*—or whistleblower—provisions of the False Claims Act, which allows private citizens with knowledge of fraud to bring a civil action on behalf of the United States and share in any recovery. As part of the resolution, the whistleblower will receive a share of the settlement.

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## The Government's Goal

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"The settlement we are announcing today reflects the focused, sustained, and purposeful efforts of the Justice Department, together with our partnered federal agencies, to investigate and redress fraud in our healthcare system....Under the authority of the False Claims Act, we are aggressive yet even-handed in pursuing health care fraud to ensure that taxpayer dollars are spent lawfully and that federal monies that should not have been paid are returned with an appropriate penalty."



- US Attorney's Office, Eastern District of Wisconsin (January 9, 2015).

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### COI vs COC

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- Related challenges best managed from a single data set/single process?
  - Faculty satisfier: Ease/efficiency of interface
  - Sunshine is the best disinfectant, but to what extent and for how long will the Physician Payments Sunshine Act be a paper tiger?
  - If the future is "uber-transparency," should AMCs go there fast and make a marketing tool out of it?

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### Privacy & Data Security vs Academic Freedom

- The joys of being a HIPAA Hybrid Entity: How to get tangential "healthcare people" to think and act like people who are under or close to a Healthcare Component.
- Broad-based tumor boards and like conferences: Technology is not quite our friend (yet?)
- The power of the boogie man – case study-driven privacy compliance education.

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### Case Study: NY Presbyterian and Columbia U

- Columbia University College of Physicians and Surgeons:
  - 655 Students
  - \$1.46 billion annual budget
  - \$1.6 billion endowment
  - First MD graduate in 1769
- New York Presbyterian Hospital:
  - 2,478 beds (six locations)
  - \$4.3 billion annual revenue (2013)
  - 6<sup>th</sup> on America's Best Hospitals (U.S. News)



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### Case Study: NY Presbyterian and Columbia U

- Physician had a **personally-owned computer server** on the network containing NYP patient PHI.
- Due to a lack of technical safeguards, PHI was accessible on internet search engines, including **Google**.
- An individual found the PHI of their deceased partner, a former patient of NYP, on the internet and complained.
- Breach report to HHS – Office for Civil Rights (OCR) regarding the disclosure of the PHI of **6,800 individuals**, including patient status, vital signs, medications, and laboratory results.

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### Case Study: NY Presbyterian and Columbia U

- Neither entity:
  - made efforts prior to the breach to assure that the network was secure and that it contained appropriate software protections.
  - had conducted an accurate and thorough risk analysis that identified all systems that accessed PHI.
  - had developed an adequate risk management plan that addressed the potential threats and hazards to the security of PHI.
- NYP failed to implement appropriate policies and procedures for authorizing access to its databases and failed to comply with its own policies on information access management.

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### Case Study: NY Presbyterian and Columbia U

- NYP and Columbia agreed to settle charges that they violated HIPAA
- NYP paid \$3.3 million
- Columbia paid \$1.5 million
- Largest HIPAA settlement to date (May 2014)

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### Case Study: NY Presbyterian and Columbia U

- Both NYP and Columbia agreed to a 3 year Corrective Action Plan, which includes:
  - Undertaking a risk analysis
  - Developing a risk management plan (submitted to the OCR for approval)
  - Revising policies and procedures (submitted to the OCR for approval)
  - Training staff (within 30 days and annually)
  - Providing incident and annual progress reports to the OCR

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UC San Diego Health

**What does all this mean?**

- Deep violation of patient privacy
- Massive reputational harm to both entities
- High cost of privacy/data security compliance, on a compressed time table

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UC San Diego Health

**Daniel J. Weissburg, JD, CHC**

Email: [dweissburg@ucsd.edu](mailto:dweissburg@ucsd.edu)

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**OIG Work Plan FY2017 Overview**

- The Work Plan highlights the priorities that the OIG's more than 1,700 employees will have as they:
  1. Conduct audits, evaluations, investigations;
  2. Provide guidance; and
  3. Impose civil monetary penalties, assessment and administrative sanctions.
- Familiarity with the focus of the OIG work plan is crucial. For FY 2016, the OIG reported
  1. 3,635 exclusions (individuals and entities);
  2. 844 criminal actions; and
  3. 708 civil actions.
- For FY 2016, the OIG
  - Reported expected recoveries of over \$5.66B, consisting of nearly \$1.2B in audit receivables and about \$4.46B in investigative receivables; and

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**OIG Work Plan FY2017**

CMS Other Providers and Suppliers

- **Data Brief on Financial Interests Reported Under the Open Payments Program (New)**

The Physician Payments Sunshine Act requires that manufacturers disclose to CMS payments made to physicians & teaching hospitals. Manufacturers & group purchasing organizations must also report ownership & investment interests held by physicians. OIG will analyze 2015 data extracted from the Open Payments website to determine:

1. The number & nature of financial interests;
2. How much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations; and
3. The volume and total dollar amount associated with drugs & DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.

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**OIG Work Plan FY2017**

CMS Other Providers and Suppliers

- **Review of Financial Interests Reported Under the Open Payments Program**

OIG will determine:

1. The extent to which data in Open Payments System is missing or inaccurate;
2. The extent to which CMS oversees manufacturers' and group purchasing organizations' compliance with data reporting requirements; and
3. Whether the required data for physician & teaching hospital payments are valid.

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**OIG Work Plan FY2017**

Public Health Reviews - CDC

- CDC - Oversight of the Federal Select Agent Program**

OIG will examine CDC's inspections of entities registered with the program & CDC's oversight of entities' annual internal inspections. In specific, OIG will:

1. Examine number, frequency & results of CDC inspections and CDC's response to and follow-up on noncompliance with regulatory requirements identified during inspections (Part 1); and
2. Examine extent to which CDC ensures that sampled entities comply with annual internal inspection requirements & that identified observations are corrected. OIG will also identify any differences and/or similarities b/t observations identified in CDC's and the entities' inspections for sampled entities (Part 2).

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**OIG Work Plan FY2017**

National Institutes of Health (NIH)

- Review of NIH Data Controls to Ensure Privacy & Protection of Volunteers in Precision Medicine Initiative (New)**

Precision Medicine Initiative plans to have more than 1 million volunteers provide their personal health information to NIH so researchers, providers and patients can develop individualized care. Maintaining data security and privacy is paramount to retaining the volunteer's trust and participation in the initiative. OIG will determine the controls that NIH has developed to ensure privacy and protection of the volunteer's personal health information.

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**OIG Work Plan FY2017**

NIH

- Controls Over Subcontracting of NIH Grant and Contract Work**

OIG will assess colleges' and universities' controls over the subcontracting of NIH grant and contract work. Specifically, OIG will determine whether colleges and universities effectively monitor the services subcontracted to other organizations and ensure that Federal funds are spent on allowable goods and services in compliance with selected cost principles and the terms and conditions of the grants and subcontracts. Cost principles for Educational Institutions at 45 CFR 75 are used in determining the allowable costs of work performed by colleges and universities under sponsored agreements.

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**OIG Work Plan FY2017**

NIH

- **Colleges' and Universities' Compliance with Cost Principles**

OIG will assess colleges' and universities' compliance with selected cost principles. OIG will conduct reviews at selected colleges and universities on the basis of the dollar value of Federal grants received and input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration.

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
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**OIG Work Plan FY2017**

NIH

- **Superfund Financial Activities for FY2015 - Mandatory Review**

The NIH National Institute of Environmental Health Sciences (NIEHS) provides Superfund Research Program funds for university-based multidisciplinary research on human health and environmental issues related to hazardous substances. Federal law and regulations require OIG to conduct an annual audit of the Institute's Superfund activities. OIG will review payments, obligations, reimbursements, and other uses of Superfund money by NIEHS.

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**OIG Work Plan FY2017**

NIH

- **Review of NIEHS' Funding for Bisphenol A (BPA) Research**

OIG will determine the extent to which NIH's NIEHS has conducted and funded research on the safety of BPA since 2000 as well as roles that other HHS programs and agencies play in planning, funding and conducting NIEHS's BPA research. OIG will also determine the extent to which NIEHS followed its grant application processes related to peer review when awarding funds for BPA research.

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## Slide 11

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- A1** May want to add the OHRP audit initiative. I believe the audience would be interested in this topic. See page  
Author, 12/1/2015

**OIG Work Plan FY2017**

Public Health Legal Activities

- **Violations of Select Agent Requirements**

In 2005, HHS issued final regulations on possession, use and transfer of select (biological) agents and toxins that applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. 42 CFR Part 73. The final regulations authorize OIG to conduct investigations and impose civil monetary penalties against individuals or entities for violations of 42 CFR Part 73. OIG is continuing to coordinate efforts with CDC, FBI, and USDA to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

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**OIG Work Plan FY2017**

Financial Reviews

- **OIG Reviews of Non-Federal Audits**

Pursuant to the Uniform Grant Guidance at 2 CFR Part 200, certain entities receiving Federal awards are required to have annual organization-wide audits of all Federal funds that they receive. OIG will continue to review the quality of audits conducted by non-Federal auditors, such as public accounting firms and State auditors, in accordance with the uniform grant guidance.

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**Research Related Rules/Guidance Documents/FAQs/Q&A Documents**

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## FDA Categorization of IDE Devices to Assist CMS with Coverage Decisions

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### FDA Categorization of IDE Devices - Draft Guidance

- Modifies FDA's policy on categorizing investigational device exemption (IDE) devices into either Category A (experimental/investigational) or Category B (non-experimental/investigational) which will assist CMS in determining whether an IDE device should be reimbursed by CMS.
- New guidance needed because:
  1. FDA's 1995 policy regarding categorization of IDE devices did not adequately articulate criteria relevant to categorizing certain studies involving IDE devices such as feasibility studies;
  2. FDA's 1995 policy did not provide sufficient guidance regarding how a category designation may change from A to B;
  3. FDA's previous criteria did not consider all applicable regulatory pathways. (e.g. de novo submission);
  4. CMS changed from local Medicare Administrative Contractor review/approval of IDE studies to centralized review approval of IDE studies effective January 1, 2015; and
  5. Interactions between FDA and CMS since that time have highlighted a need for changes to categorization in order to improve consistency.

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### FDA Categorization of IDE Devices - Draft Guidance

- New Category A: Experimental Guidelines - ...device for which 'absolute risk' of device type has not been established, i.e., initial safety and effectiveness (S&E) questions have not been resolved, & FDA is unsure whether device type is safe and effective. (42 CFR 405.201(b))
- FDA will consider a device to be in Category A if one or more of following:
  1. No PMA approval, 510(k) clearance or de novo request has been granted for proposed or similar device, and non-clinical and/or clinical data on proposed device do not resolve initial S&E questions.
  2. Proposed device has different characteristics compared to legally marketed device & information related to marketed device does not resolve initial S&E questions of proposed device. Available non-clinical and/or clinical data on proposed device also do not resolve these questions.
  3. Proposed device is being studied for a new indication/intended use for which information from proposed or similar device related to the previous indication does not resolve initial S&E questions. Available non-clinical and/or clinical data on proposed device relative to the new indication/intended use also do not resolve these questions.

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## FDA Categorization of IDE Devices - Draft Guidance

■ New Category B: Nonexperimental/Investigational Guidelines - ...device for which incremental risk is primary risk in question (i.e., initial S&E questions are resolved) or it is known that device type can be safe and effective because, e.g., other manufacturers obtained FDA premarket approval or clearance for device type. (42 CFR 405.201(b))

- FDA will consider a device to be in Category B if one or more of following:
1. No PMA approval, 510(k) clearance or de novo request granted for proposed or similar device; but available clinical data (e.g., feasibility study data) and/or non-clinical data for proposed or similar device resolve initial S&E questions.
  2. Proposed device - similar characteristics to legally marketed device & information related to marketed device resolve initial S&E questions for proposed device.\*
  3. Proposed device being studied for new indication/intended use; but information from proposed or similar device related to previous indication resolves initial S&E questions.\*

\*Additional non-clinical and/or clinical data on proposed device may be used in conjunction with the leveraged information to resolve these questions.

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## FDA Categorization of IDE Devices - Draft Guidance

1995 Interagency Agreement		Draft Guidance
Changes	Detailed criteria were used to designate an IDE device category.	Criteria have been simplified to ensure that devices fall into the correct category.
	Limited or no visibility to how a category change may occur as knowledge is gained.	Draft guidance provides an explanation of how a category change may occur.
	No examples provided.	Examples provided.
The same	FDA review team makes the category designation.	Unchanged
	Category designation is to be based on the degree to which initial questions of safety and effectiveness are resolved.	Unchanged
	The categorization will then be used by CMS as part of its determination of whether or not items and services will be covered.	Unchanged

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## Expanded Access to Investigational Drugs for Treatment Use - Qs & As

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## FDA Expanded Access to Investigational Drugs for Treatment Use - & As

■ Expanded access - use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient (with a serious or immediately life-threatening disease or condition who lacks therapeutic alternatives) rather than obtain information about a drug generally derived from clinical trials

■ In 2009, FDA revised its IND regulations by removing the existing regulations on treatment use and creating subpart I of part 312 to consolidate and expand the various provisions regarding expanded access to treatment use of investigational drugs

■ Under FDA's regulations, there are three categories of expanded access:

1. Expanded access for individual patients, including emergency use (21 CFR 312.310);
2. Expanded access for intermediate-size patient populations (generally smaller than those typical of a treatment IND or treatment protocol (21 CFR 312.315); and
3. Expanded access for widespread treatment use through a treatment IND or treatment protocol (designed for use in larger patient populations) (21 CFR 312.320)

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## FDA Expanded Access to Investigational Drugs for Treatment Use - Qs & As

■ Document developed to provide information to interested parties about most FAQs pertaining to implementation of FDA's regulations on expanded access to investigational drugs for treatment use under an IND. Document provides answers to 31 FAQs, including:

1. What is expanded access?
2. Which regulatory submissions can be used to obtain expanded access to a drug under the 3 expanded access categories?
3. When should an expanded access protocol vs. an new expanded access IND be used?
4. What information should be included in an expanded access submission?  
See 21 CFR 312.305(b) and 312.310(b) for individual patient submissions or 312.315(c) for intermediate-size patient population submissions or 312.320(b) for treatment submissions.
5. Whether prospective IRB review/approval is required for all expanded access categories?

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## FDA Expanded Access to Investigational Drugs for Treatment Use - Qs & As

6. Whether expanded access submissions are subject to informed consent requirements?
7. How FDA categories/subcategorizes expanded access submissions?
8. Who can make a submission for individual patient expanded access? Either the sponsor of an existing IND or a licensed physician.
9. What are the roles of the patient's physician and FDA in determining if expanded access of an individual patient is appropriate?
10. Whether there can be more than one intermediate-size patient population expanded access IND or protocol for a particular drug for the same disease or condition?
11. When can access for emergency use begin?
12. When can treatment begin under expanded access protocols not for emergency use?

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## NIH Single IRB Policy

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## NIH Single IRB Policy

- June 21, 2016 - NIH Single IRB (sIRB) Policy for multi-site research of non-exempt human subjects research protocols funded by NIH and are carried out at more than one site in the United States
- Applies “only to studies where the same research protocol is being conducted at more than one site; it does not apply to studies that involve more than one site but the sites have different roles in carrying out the research.”
- Per NIH email correspondence (12/2/16): If one site involved in a study has a different role than other sites, that site may elect to use a different IRB for reviewing and approving research; however, exception does not exempt remaining sites from the expectation that they will use a single IRB.

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## NIH Single IRB Policy (cont'd)

- Policy criticism - Little guidance provided to facilitate Policy implementation
- NIH will issue guidance and provide resources to assist awardees in adapting to the change before policy's effective date and post guidance at: <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review>

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**NIH Single IRB Policy (cont'd)**

- Guidance will address:
  - How costs are charged as direct vs. indirect costs;
  - sIRB selection considerations;
  - Content of sIRB plan submitted with applications/proposals;
  - Exemption request process;
  - Roles and responsibilities of the sIRB and participating sites;
  - Model authorization agreement, e.g., SMART IRB Model;
  - Models for gathering and evaluating information from reliant sites re: community attitudes and acceptability of proposed research;
  - Model communication plan identifying documents to be completed and shared with those involved
- December 2016: NIH announced a revised effective date from May 25, 2017 to September 25, 2017

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**IRB Written Procedures**

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**FDA/OHRP Draft Guidance - IRB Written Procedures**

- Highlights that written IRB procedures should:
  - Be detailed so IRB members/staff understand how to carry out duties consistently and effectively in ways that ensure that the rights and welfare of subjects are protected, and that the IRB operates in compliance with the regulations;
  - Identify who carries out specific duties by reference to position title (e.g., IRB Administrator) rather than by employee name;
  - Be available to investigators so investigators are aware of IRB's requirements and facilitate investigator compliance with IRB requirements; and
  - Help regulators understand how IRB operates/fulfills its regulatory responsibilities.
- Includes an IRB Written Procedures Checklist that incorporates both HHS and FDA regulatory requirements for IRB written procedures and additional topics that FDA and OHRP recommend including in IRB written procedures, including IRB Scope and Authority; IRB Membership; IRB Functions and Operations; and IRB Records.

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## NIH GCP Training Policy

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## NIH GCP Training Policy

■ Scope: Applies to NIH-funded **investigators** and **clinical trial staff** who are responsible for the conduct, management and oversight of NIH-funded **clinical trials** ("CTs")

- Investigator: Individual responsible for the conduct of CT at a site. If CT conducted by a team of individuals, investigator is responsible leader, e.g., principal investigator
- CT staff: Individuals responsible for study coordination, data collection and data management, e.g., manage participant recruitment and enrollment, maintain consistent study implementation, data management, ensure integrity and compliance with regulatory/reporting requirements; seek informed consent; enroll and meet with research participants; collect/record information from research participants
- CT: Research study in which one or more human subjects are prospectively assigned to one or more interventions (including placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

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## NIH GCP Training Policy

■ GCP Training Requirements

- **Content:** Principles of ICH GCP outlined In Section 2 ICH GCP (R2)
- Acceptable GCP courses include the NIAID GCP Learning Center website (<http://gcplearningcenter.niaid.nih.gov>) and National Drug Abuse Treatment Clinical Trials Network (<https://gcp.nihtraining.com/>)
- **Outcome:** Demonstrates individual have attained knowledge of CT quality standards for designing, conducting, recording and reporting trials that involve human research participants
- **Effective Date:** January 1, 2017 to have either taken steps to meet the expectation, e.g., signed up to take a course, or have received training\*
- **Refresher:** Every 3 years
- **Documentation:** Training recipients must retain documentation of training

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## Use of Electronic Informed Consent

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## Use of Electronic Informed Consent - Qs and As

■ Provides answers to 16 common questions about using electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof

■ Focuses on procedures to be followed when using electronic informed consent (eIC) to help:

1. Ensure protection of the rights, safety and welfare of human subjects;
2. Facilitate the subject's comprehension of the information presented;
3. Ensure appropriate documentation is obtained when multiple electronic media are used; and
4. Ensure the quality and integrity of eIC data included in FDA applications and made available to FDA during inspections.

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## Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

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## Why Change?

- Amendments were needed to:
  - Encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and data integrity; and
  - Update standards regarding electronic records and essential documents standards in order to increase clinical trial quality and efficiency
- November 2016 - Adoption by the Regulatory Members of the ICH Assembly


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## Major Changes

- ALCOA "C" source document requirements
- Sponsor focused risk-based trial quality management guidance, including risk based monitoring (RBM)
- Investigator oversight responsibilities
- Sponsor oversight responsibilities regarding vendors
- Sponsor responsibilities regarding serious breaches
- Computer validation, electronic record and essential document standards

Source:  
[http://www.therqa.com/assets/is/tiny\\_mce/plugins/filemanager/files/Publications/Online\\_Articles/ICH\\_E6\\_rewritten\\_to\\_reflect\\_recent\\_GCP\\_findings.pdf](http://www.therqa.com/assets/is/tiny_mce/plugins/filemanager/files/Publications/Online_Articles/ICH_E6_rewritten_to_reflect_recent_GCP_findings.pdf)


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## Clinical Trials Registration & Results Final Rule & NIH Complimentary Policy


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## Clinical Trials Registration and Results

- September 2016 HHS issued a final rule and NIH issued a new policy to increase the availability of information about clinical trials via ClinicalTrials.gov
  - HHS final rule describes requirements for registering and submitting summary results information for certain clinical trials to ClinicalTrials.gov.
  - NIH Complementary Policy expands the scope of the final rule to apply to *all* clinical trials funded by NIH, regardless of whether they are subject to the Final Rule
  
- Both initiatives aim to help ensure that information about clinical trials and their results are made publicly available in a timely manner

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## Clinical Trials Registration and Results (cont'd)

Element	HHS Final Rule	NIH Policy
<b>Scope Applicability</b>	Applies to applicable CTs of FDA-regulated drug, biological & device products & pediatric post-market surveillance studies of devices required by FDA  Applicable CTs (1) CTs of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations, of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA  Does not apply to phase 1 trials or small feasibility device studies  Applies to public and private sector sponsors and other entities who meet the definition of a responsible party	All NIH funded CTs including phase 1 CTs & trials that do not involve FDA regulated products, e.g. behavioral intervention trials  Applies to NIH-funded CT applications or proposals received by NIH on or after effective date.  Applies to NIH-conducted CTs initiated on or after policy effective date.
<b>When register</b>	NI.T 21 days after enrollment of first participant	Same
<b>Required registration data elements</b>	Descriptive information, recruitment information, location & contact information, as well as administrative data.	Same

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## Clinical Trials Registration and Results (cont'd)

Element	HHS Final Rule	NIH Policy
<b>Time trial results submitted</b>	NI.T 12 months after primary completion date; Possible delay of up to an additional 2 years for trials of unapproved products or of products when initial FDA marketing approval/clearance is sought or approval/clearance of a new use is sought.	Same
<b>Results information elements submitted</b>	Includes participant flow, demographic & baseline characteristics, outcomes & statistical analyses, adverse events, the protocol and statistical analysis plan & administrative information.	Same
<b>Potential Non-compliance Consequences</b>	Identify CT record as non-compliant in ClinicalTrials.gov  Federal grant funding can be withheld if required reporting cannot be verified.  Civil monetary penalties of up to \$10,000/day (amount to be adjusted going forward)	Same  May lead to suspension or termination of grant or contract funding  Considered in future funding decisions
<b>Effective Date</b>	January 18, 2017	January 18, 2017

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## Revised Common Rule

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## History

- **July 26, 2011** – HHS and OMB, Office of Science and Technology Policy (OSTP) issued an ANFRM in the *Federal Register*
  - Requested comment on how to modernize/revise Common Rule
  - Asked public to answer 74 questions
  - 1,051 comments received
- **September 8, 2015** – 16 Common Rule agencies published NPRM in *Federal Register*
  - Asked an additional 88 questions
  - Referenced multiple not yet developed decision tools, guidance documents, model agreements & document templates
  - Received 2,186 comments
- **January 19, 2017** – 16 Common Rule agencies published Final rule in *Federal Register*

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## Revised Common Rule

- **Compliance Dates**
  - Cooperative Research/Single IRB – January 19, 2020
  - Research initially IRB approved, waived or deemed exempt before January 19, 2018 need not comply with New Common Rule; comply with the old Common Rule (Revised January 15, 2009)
  - Research initially IRB approved, waived or deemed exempt on or after January 19, 2018 shall comply with the new Common Rule (Revised January 19, 2017)

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## Revised Common Rule Highlights

- Regulatory Oversight of IRBs Unaffiliated with Engaged Institutions
- Revised Exempt Categories
- Limited IRB Review
- New Approval Criteria
- Informed Consent
  - Broad Consent
  - Public Accessibility of Informed Consent Forms
  - Waiver of Informed Consent for Recruitment
- Changes to Continuing Review
- Single IRB Review of Multisite Research

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## National Academies of Sciences, Engineering and Medicine Report

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## Report Overview

- Optimizing the Nation's Investment in Academic Research - A New Regulatory Framework for the 21st Century
- Recommendations:
  - Congress authorize/President appoint independent national commission to examine and update the frameworks governing research involving human subjects (Belmont 2.0);
  - Withdraw NPRM Revising the Common Rule and not revise the Rule until a national commission issues recommendations and public has opportunity to comment;
  - Make changes to current regulations governing research involving select agents, export controls and intellectual property

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## The 21<sup>st</sup> Century Cures Act

*“An innovation game-changer, a once-in-a-generation, transformational opportunity to change the way we treat disease”*



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## 21<sup>ST</sup> CENTURY CURES ACT

*Expedites the DISCOVERY, DEVELOPMENT and DELIVERY of new treatments and cures and maintains America's global status as the leader in biomedical innovation*

### ■ DISCOVERY

- Provides NIH with \$4.8B in new research funding to:
  - ❖ Advance Precision Medicine Initiative (\$1.5B)
  - ❖ Bolster “Cancer Moonshot” (\$1.8B)
  - ❖ Invest in the BRAIN initiative to improve understanding of diseases like Alzheimer’s

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## 21<sup>ST</sup> CENTURY CURES ACT

### ■ DEVELOPMENT

- Modernizes clinical trials and how safety and efficacy data is accumulated/analyzed;
- Incorporates patient perspectives into drug development/regulatory review process;
- Supports broader, more collaborative development and utilization of biomarkers, which help assess how therapy is working, earlier in the process;
- Streamlines regulations and provides more clarity and consistency for innovators developing health software and mobile medical apps, combination products, vaccines, and regenerative medicine therapies;
- Incentivizes development of drugs for pediatric diseases and medical countermeasures, and empowers FDA to utilize flexible approaches in reviewing medical devices that represent breakthrough technologies;
- Provides FDA with \$500m for regulatory modernization and gives the agency the ability to recruit and retain the best and brightest scientists, doctors, and engineers.

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## 21<sup>ST</sup> CENTURY CURES ACT

### ■ DELIVERY

- Improve delivery of new drugs and devices to the right patients at the right time by:
  - ❖ Ensuring electronic health record systems are interoperable for seamless patient care and help fully realize the benefits of a learning health care system; and
  - ❖ Improving education for health care providers and help facilitate seniors' access to the latest medical technology

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## 2016 Legislative Actions to Reduce Research Regulatory Burden

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## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, Signed into Law Dec. 13)	American Innovation and Competitiveness Act (Passed Senate Dec. 12 and House on Dec. 16)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
<p><b>Research Policy Board</b> A public-private entity recommended by the National Academies "to foster more effective conception, development and harmonization of research regulations." The NAB similarly recommended an interagency, intersector committee with stakeholder and OMB/ORA representation.</p>	<p>Established by the Director of OMB, 10 or fewer federal members (ORA, OSTP, HHS, NSF and others that support or regulate research), 9-12 representatives of academic or other non-profit research institutions or organizations with relevant expertise. Agreed through a formal process including nomination by members of the research community. The process would be established by the Secretary (in consultation with the Federal membership). This is likely in error, as in previous iterations the RPB was established by the HHS Secretary due to HELL jurisdiction, now the OMB Director. The board is charged with coordinating and improving regulations and policies; discussing policy and regulatory gaps and challenges; and ongoing assessment of regulatory burden. Expert subcommittees can be formed as needed. Not explicitly tasked with addressing prospective regulations and policies. Report to Congress and OIG evaluation. Senate 9/30/20.</p>	<p>Not addressed.</p>	<p>Not addressed.</p>

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## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, President Obama to sign.)	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 14)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
<b>Interagency Working Group on Research Regulations</b>	Not addressed.	To be established by OMB in coordination with OSTP. Charged with reviewing existing regulations and making recommendations for eliminating, streamlining or improving regulations and processes with the goal of reducing burden on researchers and IRBs. Directed to consult with stakeholders, an improvement over the existing research business models (management) working group. Requires a report to congressional committees annually for the first four years.	Not addressed.
<b>Subrecipient Monitoring - reduce unnecessary or redundant oversight. Recommendations: National Academies - amend the US to clarify applicability of IRB only for project and performance monitoring. GAO - target higher risk subrecipients.</b>	NIH Director directed to reduce administrative burden, including possible exemption where the subrecipient is subject to single audit and use of collaborative grant models or other structures allowing for multiple prime awardees.	Not addressed.	Not addressed.

Council on Governmental Relations - December 15, 2016

## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, President Obama to sign.)	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 14)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
<b>Micropurchase Threshold - increase to \$10,000 with the opportunity for higher thresholds. Recommendations - National Academies, GAO - target higher risk purchases.</b>	Not addressed.	\$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with audit findings, institutional risk assessment, or State law. Applicable only to NSF, NASA and NIH.	\$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with (a) audit findings, institutional risk assessment, or State law. Grants, cooperative agreements, and contracts for all federal agencies.
<b>Review Financial Conflict of Interest Policies - harmonizing policies and reducing burden. Recommendations: National Academies - Federal-wide policy to be developed by Congress and OSTP, NIH and GAO - evaluation of the 2011 revisions to the PHS COI regulations.</b>	Within two years of enactment, Led by the HHS Secretary. Review to include the minimum threshold for reporting and just-in-time reporting.	Not addressed.	Not addressed.
<b>Evaluation of Financial Reporting Procedures and requirements with the goal of minimizing burden.</b>	Specific to HHS/NIH. Avoid duplication between HHS and NIH and minimize burden.	Not addressed.	Not addressed.

Council on Governmental Relations - December 15, 2016

## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, President Obama to sign.)	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 14)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
<b>Review Animal Research Regulations - goal of reducing administrative burden. Recommendations - National Academies, OSTP to convene - goal of unified federal approach. NIH - engage all regulatory, independent and certification bodies.</b>	Within two years of enactment, NIH, USDA and FDA are charged with identifying and eliminating inconsistent, overlapping or unnecessarily duplicative regulations and policies and improving coordination.	Not addressed.	Not addressed.
<b>Clarify or Affirm Alternatives to Effort Reporting - Recommendations - NSB: OMB issue a memo of clarification indicating that the payroll certification method is acceptable to the Federal Government. National Academies: OMB affirm that IRBs may take advantage of the flexibility of the US for documentation of personnel expenses.</b>	Directs the HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses. It would be our understanding that the intent is that the HHS Secretary offers the flexibility under the US in documenting personnel expenses.	Not addressed.	Not addressed.

Council on Governmental Relations - December 15, 2016

## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, President Obama to sign.)	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 14)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
Unified Grant Format - Recommendations - National Academies	Not addressed.	Working group to consider a simplified, unified grant format for use by all agencies.	Not addressed.
Preliminary Proposals - Recommendations - NSB and GAO	Not addressed.	Consideration by interagency WG	Not addressed.
Simplified Budget Proposals - Recommendations - NSB; GAO	Not addressed.	Consideration by interagency WG	Not addressed.
Greater Use of Just-in-time - Recommendations - NSB and Academies reports	Not addressed.	Working Group to consider	Not addressed.
Create a Centralized Researchers Profile Database - Recommendations - National Academies	Not addressed.	WG to establish a centralized database for biosketches, CVs, licenses, and related documents. Consider incorporating existing databases. To be utilized for all grant proposals "to the extent practicable."	Not addressed.

Council on Governmental Relations - December 15, 2016

## Legislative Actions Taken to Reduce Research Regulatory Burden

Actions	21st Century Cures (Passed House and Senate, President Obama to sign.)	American Innovation and Competitiveness Act (Passed Senate Dec. 10 and House on Dec. 14)	National Defense Authorization Act (Passed House and Senate, Conference report language adopted by Senate on Dec. 8)
Create a Centralized Assurances Repository - Recommendations - National Academies "similar to the Single Audit Clearinghouse of the FDO."	Not addressed.	For all assurances required for federal grants.	Not addressed.
Review and Simplify Progress Reports - Recommendations - NSB, National Academies; single uniform format.	Not addressed.	Consider limiting reports to performance outcomes. The RRM working group has created the Research Performance Progress Report, a unified federal progress report. Potential for further simplification and linking to performance outcomes.	Not addressed.

Reports cited include the National Science Board report "Reducing Investigators' Administrative Workload for Federally Funded Research;" "The National Academies Report: Optimizing the Nation's Investment in Academic Research;" and the GAO report "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements"

Council on Governmental Relations - December 15, 2016

## Human Research Subjects Protections Enforcement Actions



### FDA and OHRP Enforcement Actions

Type of Action	FDA	OHRP
<b>Inspections</b> ■ Conducted by FDA in FY2015 ■ Opened by OHRP in FY2015	CI - 822 IRB - 138 Sponsor - 117	For cause - 7 Not for cause - 4
<b>Noncompliance Letters Issued</b> ■ FDA Warning Letters (OAI) ■ OHRP Determination Letters (Noting Noncompliance)	CI - 6 IRB - 4 Sponsor - 2	FWA Holding Institution - 9
Disqualifications (CIs/IRBs/Sponsors)	1	0
Debarments (CIs/IRBs/Sponsors)	1	0
IRB Restrictions or Suspensions	0	0

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### FDA Common Findings - CIs

- Failure to follow the investigational plan and/or regulations
- Protocol deviations
- Inadequate recordkeeping
- Inadequate accountability for the investigational product
- Inadequate communication with the IRB
- Inadequate subject protection - failure to report AEs and informed consent issues

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### FDA Common Findings – IRBs <sup>Ad</sup>

- Inadequate initial and/or continuing review
- Inadequate SOPs
- Inadequate membership rosters
- Inadequate meeting minutes
- Quorum issues
- Subpart D issues
- Inadequate communication with CI/institution
- Specific to devices - lack of or incorrect SR/NSR determination

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## Slide 66

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**A4** Based on FY2014 Bimo stats; may need to revise when we get FY2015 Bimo stats.  
Author, 11/23/2015




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### Human Research Protections OHRP Determination Letters

Date	Institution	Issue(s) Summary
10/13/15 2/2/16	San Diego State University	<ul style="list-style-type: none"> <li>Informed consent documents (i.e., telephone screening consent script and informed consent forms) failed to include basic elements</li> <li>Investigator implemented changes to research without prior IRB review</li> <li>IRB approved an advertisement that overpromised or gave a false impression of the likelihood of benefit in violation of 45 CFR 46.116(a)(3)</li> <li>IRB lacked sufficient information to make determinations required for approval of research, i.e., IRB conditionally approved a study when it should have deferred its approval</li> </ul>
12/23/15	Oregon Health and Science University	<ul style="list-style-type: none"> <li>IRB lacked sufficient information to make determinations required for approval of research</li> </ul>
1/7/16	Tulane University	<ul style="list-style-type: none"> <li>Informed consent document for one study did not include an adequate explanation of the purposes of the research in language understandable to the subject or representative</li> <li>Informed consent document for another study did not describe the risks of a research indicated biopsy</li> </ul>
1/28/16	Baylor College of Medicine	<ul style="list-style-type: none"> <li>Informed consent documents for a study that were reviewed and approved by the IRB failed to include or adequately address certain applicable basic elements</li> </ul>
2/23/16	University of Texas, San Antonio	<ul style="list-style-type: none"> <li>IRB lacked sufficient information to make determinations required for approval of research</li> <li>Research conducted without IRB review and approval</li> <li>Failure to report serious noncompliance to OHRP</li> </ul>

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### Human Research Protections OHRP Determination Letters

Date	Institution	Issue(s) Summary
4/8/16	University of Virginia	<ul style="list-style-type: none"> <li>No findings of noncompliance</li> </ul>
5/5/16	Suffolk University	<ul style="list-style-type: none"> <li>Institution did not have written IRB procedures that adequately described certain activities</li> </ul>
5/5/16	University of Nebraska Medical Center	<ul style="list-style-type: none"> <li>Failure of investigator to obtain the legally effective informed consent of subjects when the IRB did not waive obtaining informed consent</li> <li>Changes to research initiated without IRB review and approval</li> </ul>
5/16/16	University of New Orleans	<ul style="list-style-type: none"> <li>No findings of noncompliance</li> </ul>
7/14/16	Northwestern University	<ul style="list-style-type: none"> <li>No findings of noncompliance</li> </ul>
9/27/16	George Washington University	<ul style="list-style-type: none"> <li>No findings of noncompliance</li> </ul>
9/27/16	North Carolina, Chapel Hill	<ul style="list-style-type: none"> <li>IRB approved research contingent upon substantive modifications or clarifications directly relevant to IRB approval criteria without requiring additional review by the convened IRB</li> </ul>
9/27/16	West Virginia School of Osteopathic Medicine	<ul style="list-style-type: none"> <li>No findings of noncompliance</li> </ul>

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## Human Research Protections OHRP Investigations

Ongoing priorities for the OHRP's Division of Compliance Oversight

■ Findings in recent determination letters....

- Research conducted without IRB review and/or approval
- Failure of IRB to review HHS grant applications
- Lacking sufficient information to make determinations required for approval
- Inadequate review at convened meetings
- IRB members lacking expertise to make thoughtful determinations required for approval
- Approval of research not approved by the IRB
- Contingent approval of research with substantive changes expected, yet no additional review by convened IRB
- Meetings convened without quorum (i.e., not enough members present, no non-scientist present, etc.)
- Meeting convened by IRB members with a COI
- Inadequate continuing review
- Failure to conduct continuing review at least once a year
- Inappropriate use of expedited review procedures
- Failure to advise IRB members of expedited approvals
- Expedited review conducted by someone other than an IRB member


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## Human Research Protections OHRP Investigations

Ongoing priorities for the OHRP's Division of Compliance Oversight

■ Findings in determination letters (cont)

- Failure to report unanticipated problems, noncompliance, suspensions, terminations, etc. to IRB, IO, or OHRP
- Changed to researcher initiated without IRB review and approval
- Inappropriate application of exempt categories of research
- Failure of investigator to obtain legally effective and/or to document Informed Consent or of the IRB to waive requirements
- Failure to provide a copy of the signed ICF to the subject (or their representative)
- Inadequate ICF (e.g., lacks key elements, language too complex, exculpatory language, etc.)
- IRB membership is not aligned with standards/rules/guidance
- Poor documentation (minutes, records, files, retention of information)
- Lack of appropriate written policies and SOPs
- Lack of OHRP-approved FWA
- IRB failure to determine that criteria for IRB approval are satisfied
- Failure of IRB to make required findings when reviewing research involving children or prisoners.
- Failure to notify Investigator / Institution of IRB actions
- Failure of signatory official to fulfill obligations


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## DOJ/HHS OIG Actions

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### Lexington Couple Pleads Guilty to Grant Fraud

- 2/10/16: DOJ announces that a Lexington couple admitted in federal court that they submitted false claims related to federal grants from NIH and defrauded the government out of hundreds of thousands of dollars.
  - According to court documents, Ms. Brue certified on behalf of Telehealth Holdings, LLC, a company owned by Jerome Hahn, that company incurred expenses totaling \$222,037 relating to two federal grants Telehealth received from NIH
  - Ms. Brue falsely certified that funds had been spent in accordance with grant rules and regulations
  - Ms. Brue plead guilty to making a false claim against the United States
  - Mr. Hahn plead guilty to conspiracy to defraud the United States
  - On March 30, 2016, U.S. District Judge sentenced Brue to seven months in prison, and an additional seven months on home detention. Brue was also ordered to pay \$222,037 in restitution to NIH.
  - On June 13, 2016, U.S. District Judge sentenced Hahn to four months in prison and an additional six months on home detention. Hahn was also ordered to pay \$222,037 in restitution to NIH.

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### U.S. District Court Orders \$4.5M Civil Judgement Against Lexington Women and Her Medical Device Companies for Committing Grant Fraud

- 7/13/16: U.S. District Court enters a civil judgement against Vesta Brue and her companies, Life Techniques, Inc. and Care Team Solutions, LLC, to resolve False Claims Act allegations regarding defrauding NIH of millions of dollars over 8 years
  - NIH awarded Ms. Brue and her companies five (5) SBIR grants to support development of electronic pillboxes customized for specific patient populations
  - Ms. Brue acknowledged that they:
    - ❖ Made false statements in grant applications about company personnel, facilities and accounting systems;
    - ❖ Falsely stated on grant reports that they had spent grant funds for purposes of the grants and in compliance with grant regulations when in fact spent money on personnel expenses; and
    - ❖ Used grant money on business expenses not allowed under grant regulations, e.g., marketing and promotion expenses.
  - Government complained that Ms. Brue also falsified entries in her companies' accounting ledgers to conceal from NIH auditors that federal funds had been misspent.

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## Columbia University Agrees to Pay \$9.5 Million to Settle Civil Fraud Allegations

- 7/14/16: DOJ and HHS OIG announces \$9.5 Million settlement with Columbia University ("Columbia") for improperly seeking and receiving excessive cost recoveries in connection with research grants funded by NIH
  - The United States' Complaint alleged that from July 1, 2003, through June 30, 2015, Columbia impermissibly applied its "on-campus" indirect cost rate - instead of the much lower "off-campus" indirect cost rate - when seeking federal reimbursement for 423 NIH grants where the research was primarily performed at off-campus facilities owned and operated by the State of New York and New York City
  - The Complaint also alleged that Columbia failed to disclose to NIH that it did not own or operate these facilities and that Columbia did not pay for use of the space for most of the relevant period.
  - Columbia Admitted to Seeking and Receiving Cost Recoveries at the Higher "On-Campus" Rate for 423 Research Grants Even Though the Research Was Primarily Performed in Space Not Owned or Operated by Columbia

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## Lexington KY Man and his Medical Device Company Sued for Grant Fraud

- 7/29/16: United States Government sued a Lexington man, Jerome Hahn, and the Lexington-based medical device company he owns, Telehealth Holdings, LLC, for violations of the False Claims Act alleging that they defrauded the government by submitting false claims in connection with federal grants.
  - According to the Complaint, Telehealth received three grants from the government worth over \$600,000 to develop a sleep apnea monitoring system and for the development of pillboxes customized for specific patient populations.
  - The Complaint alleges Hahn and Telehealth did the following:
    - Made false statements in the grant applications about Telehealth's personnel, facilities and accounting systems;
    - Falsely stated on grant reports that they had spent grant funds for purposes of the grants and in compliance with grant regulations when in fact spent money on personnel expenses;
    - Used grant money on business expenses not allowed under grant regulations, e.g., marketing and promotion expenses;
    - Spent over \$100,000 in grant funds for foreign goods and services, when grant regulations require recipients to use American goods/workers; and
    - Falsified accounting ledgers entries and created false invoices in order to conceal that federal funds had been misspent

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## Research Misconduct

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**Recent ORI Administrative Actions**

- **Andrew R. Cullinane, Ph.D., NIH:** ORI found that Dr. Cullinane, former postdoctoral fellow, Medical Genetics Branch, National Human Genome Research Institute (“NHGRI”), NIH, engaged in research misconduct (“RM”) by knowingly reporting falsified and/or fabricated data and related images in two (2) publications and one (1) submitted manuscript by altering and/or reusing and/or relabeling experimental data.
- **Dr. Cullinane agreed for 3 years to:**
  - Have his research supervised and not participate in PHS-supported research until a supervision plan is submitted to/approved by ORI;
  - Have any institution employing him submit to ORI a certification that data provided by Dr. Cullinane is based on actual experiments and accurately reported; and
  - Be excluded from providing advisory services to PHS.
- Dr. Cullinane also agreed to retract or correct 2 of the publications.

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**Recent ORI Administrative Actions**

- **Karen M. D'Souza, Ph.D., University of Chicago (UC):** ORI found that Dr. D'Souza, former Research Professional Associate, Department of Surgery, UC, engaged in RM in research supported by NHLBI, NIH grants K08 HL081472 and R01 HL107949 by including falsified and/or fabricated data in one (1) funded NIH grant, two (2) publications, two (2) posters, and one (1) presentation.

Specifically, ORI found that Respondent reused and falsely relabeled and/or falsely spliced Western blot images, falsified the related densitometry measurements based on the falsified Western blots, and falsified and/or fabricated data for experiments that were not performed or from unrelated experiments.

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**Recent ORI Administrative Actions**

- **Dr. D'Souza has agreed for 2 years to:**
  - Have her research supervised and not participate in any PHS-supported research until a supervision plan is submitted to/approved by ORI; supervision plan must ensure the scientific integrity of Dr. D'Souza's PHS-supported research contribution and include specific elements;
  - Have any institution employing her submit to ORI a certification that data provided by Dr. D'Souza is based on actual experiments and accurately reported; and
  - Be excluded from providing advisory services to PHS.
- Dr. D'Souza also agreed to retract 1 publication.

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## Recent ORI Administrative Actions

- **Meredyth M. Forbes, Albert Einstein College of Medicine:** ORI found that Ms. Meredyth M. Forbes, former Graduate Student, AECM, engaged in RM in research supported NIGMS, NIH grants R01 GM089979, T32 GM007491, R01 GM55101, and R01 GM88202 and NICHD, NIH grant T32 HD007502 by intentionally falsifying and/or fabricating data reported in the three (3) published papers and four (4) meeting presentations.

ORI found that Ms. Forbes intentionally falsified and/or fabricated data for germ-cell development in zebrafish *Dazap2* maternal-effect mutants (*MDazap2*) in one (1) paper and two (2) presentations when the mutants were not produced nor the data derived from them;

ORI found that Ms. Forbes intentionally fabricated and/or falsified data for zebrafish embryogenesis and oocyte polarity in two (2) papers and two (2) presentations when the data were not obtained from actual experiments.

F T I CONSULTING 85

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## Recent ORI Administrative Actions

- **Ms. Forbes has agreed for 3 years to:**
  - Exclude herself from contracting/subcontracting with any US agency and from eligibility or involvement in US Government non-procurement programs;
  - Neither apply for nor permit her name to be used on any application, proposal, or other request for funds to the United States Government or any of its agencies
  - Neither receive nor be supported by funds of the United States Government made available through grants, subgrants, cooperative agreements, contracts, or subcontracts; and
  - Exclude herself from providing advisory services to PHS.

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## Recent ORI Administrative Actions

- **Zhiyu Li Ph.D., Mount Sinai School of Medicine:** ORI found that Dr. Zhiyu Li, former Postdoctoral Fellow, MSSM, engaged in RM in research that was supported by NCI, NIH grant R21 CA120017 by intentionally, knowingly, and recklessly including falsified and/or fabricated data in 10 published papers, submitted manuscript, poster presentation, and grant applications.

ORI found that Dr. Zhiyu intentionally, knowingly, and recklessly claimed to have generated recombinant *Clostridium perfringens* (Cp) strains, Cp/sod-, Cp/sod-/PVL, and Cp/plc-/sod-/PVL, to depict the effects of recombinant Cp strains on their ability to destroy cancer cells in a murine model, when these bacterial strains were not produced nor the data derived from them, and by falsifying histopathological data reported in fifty-seven (57) images in two (2) published papers, one (1) submitted manuscript, two (2) poster presentations, and seven (7) of Respondent's supervisor's grant applications and fabricating the corresponding nineteen (19) summary bar graphs that were based on those false images.

F T I CONSULTING 87

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## Recent ORI Administrative Actions

- ORI implemented the following administrative actions for a period of five (5) years:
  - ORI debarred Dr. Zhiyu from contracting/subcontracting with any US Government Agency and from eligibility for, or involvement in, US Government Non-procurement Programs; and
  - ORI prohibited Dr. Zhiyu from providing advisory services to PHS.


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## Recent ORI Administrative Actions

- **Ricky Malhotra, Ph.D., University of Michigan and University of Chicago:** ORI found that Dr. Ricky Malhotra, former Research Assistant Professor, Department of Internal Medicine, UM, from 2005-2006, and Research Assistant Professor, Department of Surgery, UC, from 2007-2011, engaged in RM in research supported by NHLBI, NIH grants K08 HL081472 and R01 HL107949 by including falsified and/or fabricated data were included in three (3) NIH grant applications, one (1) NIH grant progress report, one (1) publication, seven (7) presentations, and one (1) image file by reusing and falsely relabeling Western blot gel images, falsifying the related densitometry measurements based on the falsified Western blots, and falsified and/or fabricated data for experiments that were not performed.
- Dr. Malhotra continued this falsification at UC, after the UM RM investigation was completed.


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## Recent ORI Administrative Actions

- **Dr. Malhotra agreed to the following administrative actions:**
  - If within five (5) years of the effective date of Agreement, Dr. Malhotra receives or applies for PHS support, he agreed to have research supervised for ten (10) years and to notify his employer/institution(s) of the terms of supervision; any supervision plan must be submitted to/approved by ORI; supervision plan must ensure the scientific integrity of Dr. Malhotra's PHS-supported research contribution and include specific elements;
  - If within five (5) years from the effective date of the Agreement, Dr. Malhotra receives or applies for PHS support, Dr. Malhotra agreed that for (10) years any institution employing him shall submit to ORI at six (6) month intervals certifications that data provided by Dr. Malhotra is based on actual experiments and accurately reported;
  - If no supervisory plan is provided to ORI, Dr. Malhotra agreed to provide certification to ORI on a quarterly basis for five (5) years that he has not engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds without prior notification to ORI.
  - For five years (5) exclude himself from providing advisory services to PHS.
- Dr. Malhotra also agreed to retract his publication.


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## Recent ORI Administrative Actions

■ **John G. Pastorino, Ph.D., Rowan University School of Osteopathic Medicine:** ORI found that Dr. John G. Pastorino, Associate Professor, Department of Molecular Biology, RUSOM, engaged in RM in research supported by NIAAA, NIH grant R01 AA012897 and NCI, NIH grant R01 CA118356 by intentionally falsifying and/or fabricating data reported in eight (8) published papers, one (1) unpublished manuscript, and one (1) NIH grant application.

Specifically, ORI found that he duplicated images, or trimmed and/or manipulated blot images from unrelated sources to obscure origin & relabeled them to represent different experimental results.

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## Recent ORI Administrative Actions

■ **Dr. Pastorino has agreed for a period of five (5) years to:**

- Exclude himself from contracting/subcontracting with any US Government Agency and from eligibility or involvement in US Government Non-procurement Programs;
- Neither apply for nor permit his name to be used on any application, proposal, or other request for funds to the United States Government or any of its agencies;
- Neither receive nor be supported by funds of the United States Government and its agencies; and
- Exclude himself from providing advisory services to PHS.

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## Recent ORI Administrative Actions

■ **Kenneth Walker, Ph.D., University of Pittsburgh:** Based on admission, ORI found that Dr. Kenneth Walker, former postdoctoral fellow, Department of Pediatrics, University of Pittsburgh (UP), engaged in RM in research supported by NIDDK, NIH grant R01 DK081128 by falsifying and/or fabricating data that were included in two (2) publications, one (1) submitted manuscript, and two (2) grant applications submitted to NIDDK, NIH.

Specifically, ORI found that he falsified and/or fabricated quantitative real-time polymerase chain reaction (qPCR) data to demonstrate a statistically significant or “trend” of statistical difference in the expression of renal or bladder urothelium and muscle developmental markers between control and experimental (mutant) mice, when there was none.

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**Recent ORI Administrative Actions**

- Dr. Walker has agreed for 3 years to:
  - Have his research supervised and not participate in PHS-supported research until a supervision plan is submitted to/approved by ORI;
  - Have any institution employing him submit to ORI a certification that data provided by Dr. Walker is based on actual experiments and accurately reported; and
  - Be excluded from providing advisory services to PHS.
- Dr. Walker also agreed to retract and/or correct two publications, as determined by the corresponding author.

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**RESEARCH MISCONDUCT RESOURCES**

- ORI website: <http://ori.hhs.gov/>
- Statutes and Regulations
  - ORI Statutory Authority - 42 U.S.C. § 289b
  - Public Health Service (PHS) Policies on Research Misconduct - 42 CFR Part 93 – June 2005
  - HHS Debarment Regulations - 45 CFR Part 76
  - Federal Whistleblower Protection Act of 1989 - 5 U.S.C. § 1201
  - Freedom of Information Regulation - 45 CFR Part 5
  - Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct, HHS/OASH/ORI. 74 Fed. Reg. 44847 (2009)
- ORI Sample Policy and Procedures for Responding to Research Misconduct Allegations
- ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research
- ORI Handbook for Institutional Research Integrity Officers

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**Removing Barriers to Clinical Research Act of 2016**

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**Removing Barriers to Clinical Research Act of 2016**

- **March 3<sup>rd</sup>, 2016:** The House of Congress introduced a bill to amend title XVIII of the Social Security Act to ensure Medicare coverage of certain costs associated with FDA-approved clinical trials involving medical devices.

In summary, this Bill

- Clarifies Medicare Coverage of routine services and Category B devices
- Provides the industry with welcome guidance going forward

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**Removing Barriers to Clinical Research Act of 2016**

- **The amendment clarifies the following points:**
  - Medicare coverage for clinical trials in which a Category A or Category B medical device is involved;
  - Which “routine costs” are covered for research using either a Category A or Category B medical device;
  - Assuming there is medical necessity and the use is consistent with routine standards, Category B devices are also covered; and
  - Clinical trials automatically meet the “Category A and Category B” definitions when the trial is conducted under an Investigation Device Exemption filing.

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
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**Questions?**

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**Critical Thinking at the Critical Time™**

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How to **WILDLY**  
Be a **EFFECTIVE**  
Compliance Officer

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	<h2>Kristy Grant-Hart</h2>
	<p>"An accomplished compliance professional and true expert in her field." – Risk Universe Magazine</p> <hr/> <ul style="list-style-type: none"><li>– Author</li><li>– Consultant</li><li>– Speaker</li><li>– Professor</li><li>– Former Chief Compliance Officer</li></ul> <p>World-Class Program Assessments ISO 37001 Anti-Bribery Management Systems Certification</p> 

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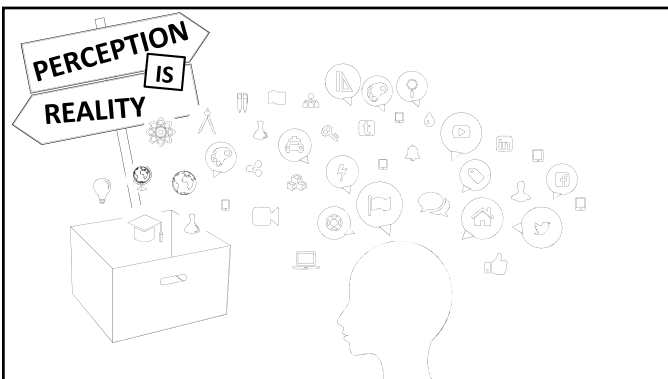
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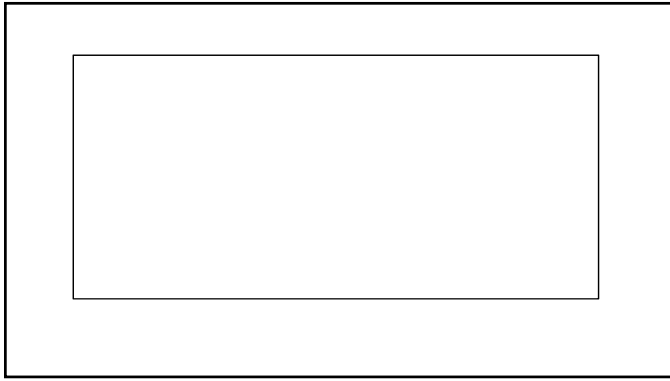
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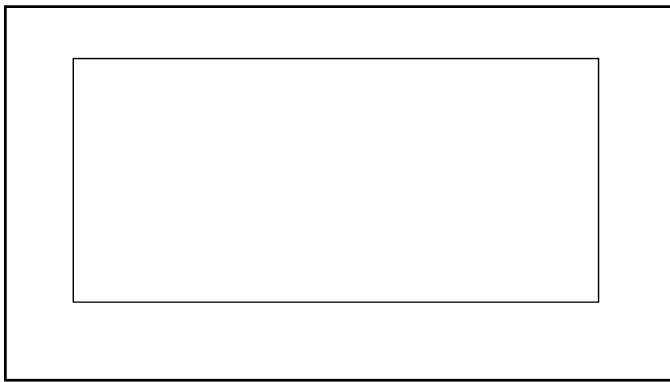
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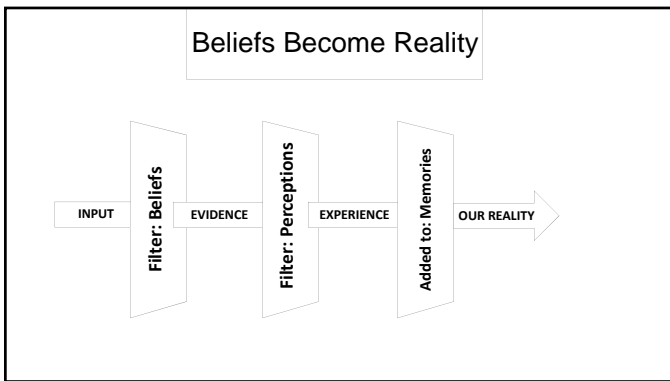
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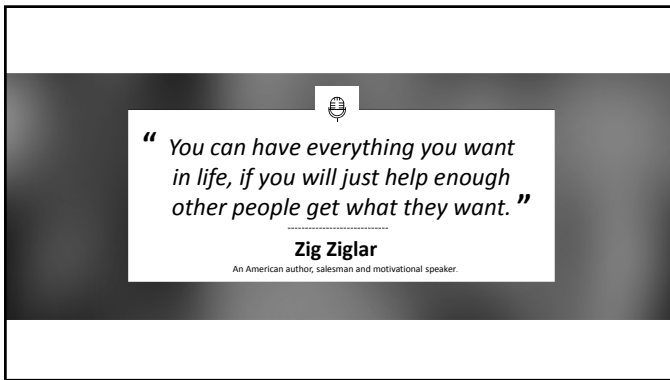
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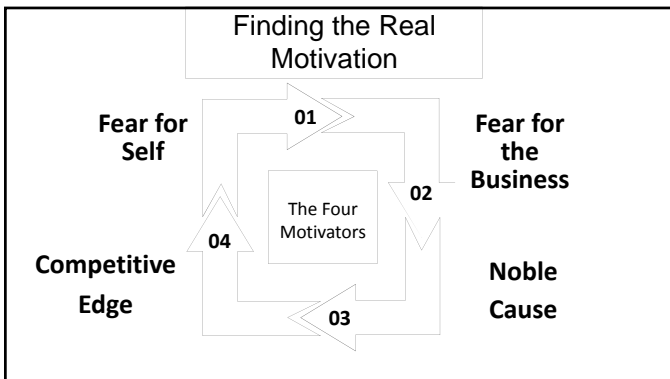
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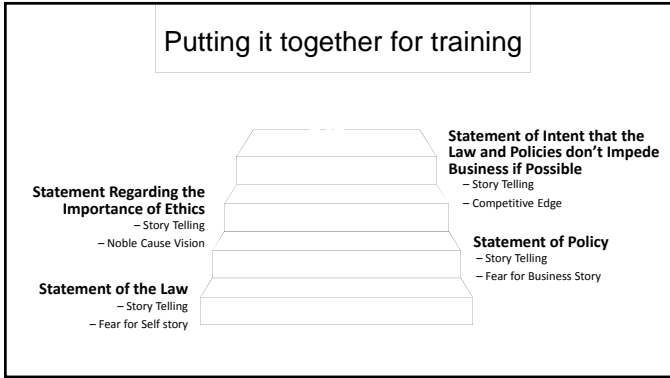
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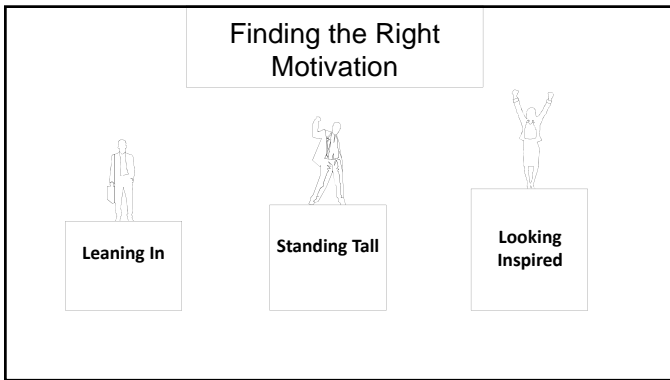
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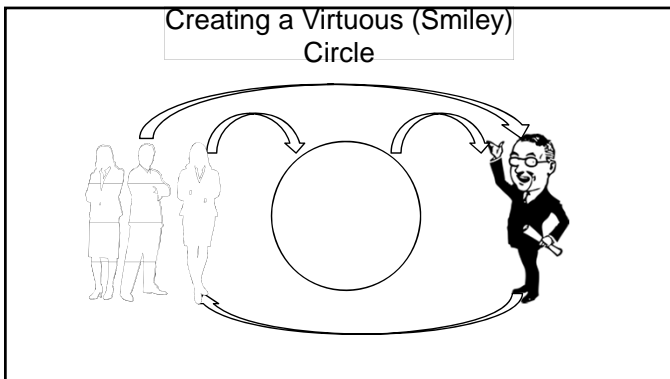
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Who are you?



Bulldog  Labrabull  Labrador

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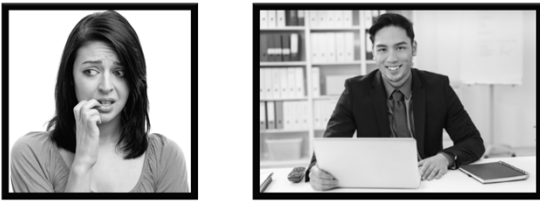
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Insecure Irene      Compliant Kevin

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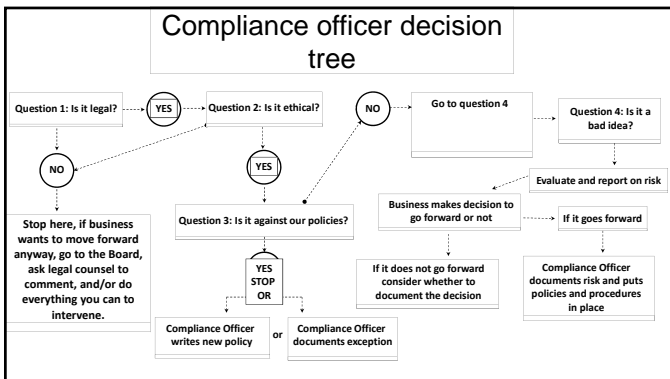
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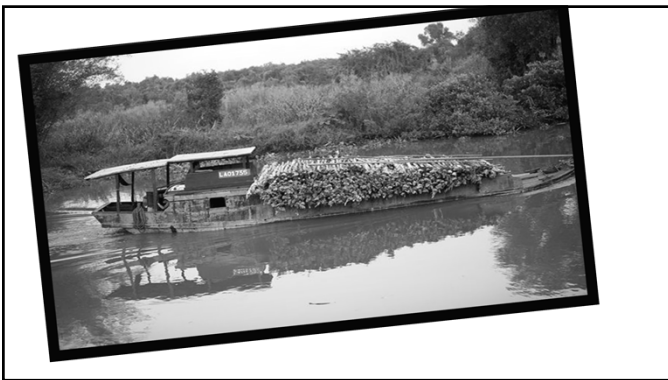
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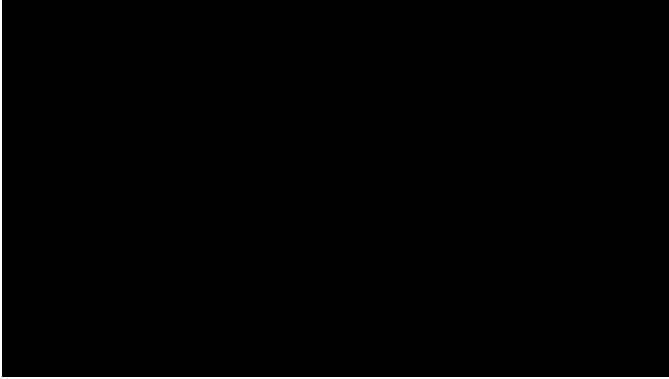
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**Thank you!**

Let's Stay In Touch!

**Kristy Grant-Hart**

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🐦 Twitter: @KristyGrantHart

How to Be a Wildly Effective  
Compliance Officer,  
available at  
<http://amzn.to/1VP64pZ>

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## 340B Compliance

LIFE AFTER A HRSA AUDIT  
AND IMPLEMENTING A CORRECTIVE ACTION PLAN

HCCA Compliance Institute

March 27, 2017

Presented by:

Melissa Singleton

Sarah Bowman, CHC®

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## Overview

- 340B Program Background
- Athens Regional Medical Center's ("ARMC") Experience
- Corrective Action Plan
- Independent Assessment
- Industry Best Practices and Areas of Caution

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## 340B Program Background



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## Why Is 340B Important?

The 340B Program was created in 1992 by President Bush, and requires drug manufacturers to provide covered **outpatient** drugs to eligible Covered Entities ("CEs") at significantly reduced prices. The CEs benefit from the difference between the drug's reduced cost and the full reimbursement received from payers.

*"The 340B Program enables Covered Entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*  
- Health Resources and Services Administration ("HRSA")

Many CEs use these funds towards providing additional community benefit programs to patients who are poor, uninsured, or underinsured. Currently, the 340B Program does not restrict the use of the 340B savings for certain purposes; however, it is important that CEs document and demonstrate their use of savings annually.

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## 340B Impact

**\$3.8 Billion**

Estimated annual savings attributed to 340B in 2013

**32,071**

Total Registered Sites participating in the 340B Program as of October 1, 2015

HRSA's Increased Focus on Compliance

**+ \$7M**

in additional budgetary funding for **FY 2017**



**Goal: 100**

**Additional**  
Onsite CE HRSA Audits in FY 2017

Source: HRSA Fiscal Year 2017 Budget Justification Document.

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## Who is Eligible to Participate?

- Safety-net healthcare organizations serving vulnerable patient populations, which are classified into two main categories:



### Hospitals

- Children's Hospital
- Critical Access Hospital ("CAH")
- Disproportionate Share Hospital ("DSH")
- Free Standing Cancer Center
- Rural Referral Center ("RRC")
- Sole Community Hospital ("SCH")



### Federal Designees/Grantees

- Community Health Centers ("CHC")
- Federally Qualified Health Centers ("FQHCs")
- FQHC Look-Alikes
- Tribal/Urban Indian Health Centers
- Ryan White HIV/AIDS Program Grantees
- Sexually Transmitted Disease Clinics
- Family Planning Clinics
- Tuberculosis Clinics
- Hemophilia Treatment Centers
- Black Lung Clinics

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## ARMC's Experience

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## Background

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- Athens Regional Medical Center ("ARMC") has participated in the 340B Program since 2005 and qualifies as a DSH (ID DSH110074).
- HRSA conducted an audit in August 2013:
  - Audit period was January 1, 2013 through June 30, 2013.
  - The auditor was on site for four days.
- HRSA audit report of findings was provided on July 14, 2014.
- The report's findings required ARMC to develop a corrective action plan.



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## Background (cont'd)

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- At the time of the audit, ARMC had the following locations listed on the OPA database as participating in the 340B Program:
  - Hospital
  - Home Infusion



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### HRSA Audit: Key Findings

- 1. Diversion: 340B drugs were dispensed to ineligible individuals.
  - The dispensation sample included 13 (340B eligible) prescriptions at the home infusion location.
  - All patients of home infusion were treated as eligible by ARMC, regardless of where patient received healthcare services.
  - Prescriptions were written by ineligible providers at ineligible sites.
    - Prescriber must be employed by or under a contractual or other arrangement with the CE.
  - ✓ Ineligible sites include those hospitals and/or private physician offices not reimbursable on ARMC's Medicare cost report without an arrangement demonstrating that the responsibility for care remained with the entity.

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### HRSA Audit: Key Findings (cont'd)

- 2. Diversion: 340B drugs were not properly accumulated. Adequate controls to prevent diversion of 340B drugs were not in place.
  - The hospital pharmacy replenished 340B drugs with substitutes (different NDC numbers and manufacturers).
  - The replenishment system could not ensure proper accumulation (exact match – NDC and manufacturer).
  - ✓ Auditable records demonstrating proper accumulation in a replenishment model are required.



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### HRSA Audit: Key Findings (cont'd)

- 3. Duplicate Discounts: Adequate controls were not in place to prevent duplicate discounts.
  - A drug purchase cannot be subject to both a 340B discount and a Medicaid rebate.
    - ARMC had "carve-in" status to include billing Medicaid for drugs purchased at 340B prices.
    - Incorrect Medicaid numbers were listed in the Medicaid Exclusion File for both the parent and home infusion (child) sites.



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### HRSA Audit: Areas for Improvement\*

1. ARMC obtained covered outpatient drugs through a GPO.
  - GPO Prohibition: DSH CEs may not "obtain covered outpatient drugs through a GPO or other group purchasing arrangement".<sup>1</sup>
  - Audit discovered that ARMC was replenishing using a GPO.
  - "ARMC should immediately stop using this replenishment model or be found in violation of GPO prohibition." - HRSA Audit Report
    - ARMC was not in compliance with GPO prohibition prior to July 9, 2013.
    - ARMC was taking proactive steps to become compliant.

\*Note: An area for improvement does not identify any specific violations of the 340B Program requirements.  
<sup>1</sup> Source: 42 U.S.C. 256b(a)(4)(3)(B) <https://www.gpo.gov/fdsys/pkg/USCDOE-2010-09-04/ps/USCDOE-2010-09-04-chap4-subchap1-partD-subpart1-sec256b.pdf>

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### HRSA Audit: Areas for Improvement (cont'd)

2. HRSA recommended that ARMC develop written 340B Program policies and procedures to describe appropriate oversight of each contract pharmacy's compliance with ARMC's 340B Program.
  - ARMC **had** written 340B Program policies and procedures for contract pharmacy arrangements.
  - Policies and procedures did not reflect all oversight activities and did not include specific **controls to verify eligibility or prevent diversion** of 340B drugs.
  - ✓ Policies and procedures should describe monitoring procedures, to include effective eligibility **determination** process and **reconciliation** of dispensing and purchasing records.

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### HRSA Audit: Areas for Improvement (cont'd)

3. HRSA recommended that ARMC remove the 3 contract pharmacies currently registered until the use could be compliant with all 340B Program requirements.
  - **No oversight of contract pharmacies** through independent annual audits had occurred since contract agreements had commenced.
  - ✓ HRSA expects all CEs using contract pharmacies to perform **annual independent audits of all contract pharmacies**.

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## Post-HRSA Audit Activities

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- Corrective Action Plan
- Manufacturer Repayment
- Independent Assessment



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## Post-Audit Corrective Action Plan ("CAP")

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- The report's findings required ARMC to develop a CAP
- Initial CAP provided to HRSA on October 19, 2014
- OPA representative was in frequent contact with ARMC
- Revised CAP issued on January 8, 2015



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## Post-Audit CAP (cont'd)

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1. Diversion: ARMC dispensed 340B drugs to ineligible individuals.
  - ARMC performed a review after receiving the HRSA audit report. Dispensations were re-qualified for 340B based on the patient definition.
  - Pharmacists were educated on the qualification process and criteria (including prescriber and location elements)<sup>1,2</sup>.
  - A 340B Program compliance training module was also completed.
  - Policy and procedures were developed and internal monitoring was implemented.

Note:

1) Prescriber must be employed by or under a contractual or other arrangement with the CE.

2) Ineligible sites include those hospitals and/or private physician offices not reimbursable on ARMC's Medicare cost report without an arrangement demonstrating that the responsibility for care remained with ARMC.

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## Post-Audit CAP (cont'd)

2. Diversion: 340B drugs were not properly accumulated. Adequate controls to prevent diversion of 340B drugs were not in place.



- ARMC's pharmacy software vendor assisted with an 11-digit NDC replenishment system.
- A wholesale acquisition cost ("WAC") account was established with the vendor.
- Electronic accumulator software was implemented to apply qualified purchases to the 340B account.

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## Post-Audit CAP (cont'd)

3. Duplicate Discounts: Adequate controls were not in place to prevent duplicate discounts.

- Director of Pharmacy at Georgia Medicaid confirmed all Medicaid numbers were correct as updated in the OPA database for hospital and home infusion locations.
- ARMC worked closely with Georgia Medicaid to determine if any duplicate discounts were received.
- Internal Audit began to monitor pharmacy records quarterly to assess compliance with Medicaid billing for 340B drugs. Reports were provided to Senior Leadership.

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## Post-Audit CAP: Areas for Improvement\*

1. ARMC obtained covered outpatient drugs through a GPO.
  - ARMC began purchasing all drugs at WAC, and began replenishing after 340B eligibility was confirmed.
  - ARMC's Internal Audit department began conducting random quarterly audits to document compliance with non-GPO account.
  - ARMC selected an external independent firm for its 340B Program assessment.
  - ARMC began conducting staff education based on role/responsibility.



\*Note: An area for improvement does not identify any specific violations of the 340B Program requirements

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## Post-Audit CAP: Areas for Improvement (cont'd)

2. HRSA recommended that ARMC develop written 340B Program policies and procedures to describe appropriate oversight of each contract pharmacy's compliance with ARMC's 340B Program. Additionally, HRSA recommended that ARMC remove the 3 contract pharmacies currently registered until the use could be compliant with all program requirements.
- Contract pharmacies were removed from the 340B Program.
  - Quarterly internal reviews of in-house retail pharmacy patient qualification process with review by ARMC and pharmacy leadership.

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## Manufacturer Repayment



- After the HRSA audit, ARMC worked with GA Medicaid to confirm no duplicate discounts were received.
- ARMC issued a letter to drug manufacturers:
  - Initial refunds occurred within the first 12 months.
  - ARMC continues to work through the refund process with manufacturers (low dollar amounts).

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## Manufacturer Repayment Process – Lessons Learned



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## Independent 340B Program Assessment



- ARMC engaged PYA to assist with an independent assessment of its 340B Program.
- PYA's review included the hospital (parent), home infusion, and outpatient surgery center (child site) locations.
- ARMC's in-house retail pharmacy was also included in the review.
- PYA's review was conducted in May 2016.

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## Independent Assessment: Key Findings

- Centralized 340B compliance committee
- Standardized pharmacy processes
- Home infusion and retail pharmacy patient and prescriber eligibility
- Non-covered outpatient drug definitions
- Limitations related to home infusion software and reporting functions



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## Current State – Piedmont Athens Regional

- ARMC is now Piedmont Athens Regional (effective October 1, 2016):
  - DSH Parent Site
  - Inpatient/Outpatient Surgery Center child site
  - Home Infusion child site **terminated** as of June 2016



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## Industry Best Practices and Areas of Caution

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## Infrastructure

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### Things to Watch For:



- The CE should be able to produce a dispensation report that includes all necessary information to monitor compliance with eligibility criteria.
- Policies & procedures which are not comprehensive, or which do not match the processes in place at all locations.
- Lack of formal and/or regular auditing and monitoring processes.

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## Entity Eligibility

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### Things to Watch For:

- Accuracy of child site and contract pharmacy registration on cost report
- Missing child sites which should be registered
- Changes in qualifying DSH percentage
- Non-reimbursable locations on cost report
- Processes for identification and tracking of 340B eligibility – are the child site processes the same as within the parent site, or different?

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## Prescription Eligibility

### Things to Watch For:

- Is eligibility identified within the split-billing software, or through another data source like the Admissions, Discharges, and Transfers ("ADT") feed?
- How often does the hospital ADT feed interface with split-billing software? How are ADT changes applied (e.g., patient status changes from observation to inpatient)?



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## Prescription Eligibility (cont'd)

### Things to Watch For:

- What filters is the CE utilizing to determine prescription eligibility?
  - How does the CE define its eligible prescribers?
  - Are there any date parameters for prescription eligibility?
  - Are there any controls in place related to observation patients?
  - How does the CE treat Medicaid-pending and Medicaid MCO patients?
- Employees are not an exception to the patient definition, they must still meet all requirements to be eligible.
- When reviewing documentation, locate a physician order for the prescription, not just documentation that it was administered.
  - If all filters are not in place, a drug may be incorrectly qualified as eligible.

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## Contract Pharmacy Arrangements

### Things to Watch For:

- Written Contract Pharmacy agreement, which addresses HRSA's 12 Essential Compliance Elements
- Accuracy of OPA Database registration
- Detailed policies and procedures
- Lack of monitoring by CE and/or Contract Pharmacy
- Maintenance of records, and reporting of information to CE

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## Procurement and Inventory

### Things to Watch For:

- Purchasing accounts are appropriate for entities subject to GPO Prohibition
- Internal controls are in place and records are maintained to support accumulations for 340B and GPO accounts
- Is there a process for reversal of inaccurate accumulations?



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## Determining Prescription Eligibility

As a best practice, CEs should identify 340B eligibility at the prescription level, and take into account each of the following factors:

### Prescriber Eligibility:

- CE's definition of eligible prescriber should meet current HRSA guidance.
- All prescriptions purchased under 340B should be ordered by prescriber on CE's eligible listing.

### Patient Eligibility:

- Does the CE maintain records for the patient's care?
- Did the patient receive a health care service other than the dispensing of a drug?

### Drug Eligibility:

- Is the CE subject to the Orphan Drug Exclusion?
- Confirm that orphan drugs have not been purchased under 340B after October 10, 2015; if prior to this date, CE must have documentation of non-orphan indication for 340B eligibility.

*\*Note: considerations are based upon current guidance only.*

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## Determining Prescription Eligibility (cont'd)

As a best practice, CEs should identify 340B eligibility at the prescription level, and take into account each of the following factors (cont'd):

### Location of Prescription Origination:

- Was the patient seen within the four walls of the hospital, or at an eligible child site?
- Confirm that the encounter where the drug was prescribed is not related to a visit to the private practice of an eligible prescriber.

### Patient Status:

- Was the prescription dispensed while the patient was in outpatient or observation status?
- Confirm that an order to admit to inpatient status was not entered prior to drug dispensation.

### Payer Status:

- Medicaid Carve-Out: Confirm that no patients with a Medicaid payer type received 340B dispensations.
- Medicaid Carve-In: Review Medicaid exclusion file for accuracy.

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## What's Next?

- HRSA made an attempt to impose stricter 340B requirements and clarify some of the historically "gray" areas through proposed Mega Guidance.
- HRSA withdrew its Guidance on January 30, 2017.
- Current guidance still stands.
- CEs should look to HRSA's Frequently Asked Questions, Apexus resources and recent audit findings for assistance with program planning and internal program monitoring.

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## Protect Your Program, Protect Your Savings

*"The 340B Program enables Covered Entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*

- HRSA

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## THANK YOU!



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U.S. Department of Health & Human Services  
Office of Medicare Hearings and Appeals

**Latest Policy and Regulatory Changes  
to the Medicare Appeals Process**  
*Update from OMHA*

Nancy J. Griswold  
Chief Administrative Law Judge  
Office of Medicare Hearings and Appeals  
<http://www.hhs.gov/omha>  
[Medicare.Appeals@hhs.gov](mailto:Medicare.Appeals@hhs.gov)

Health Care Compliance Association, Annual Compliance Institute; March 26–29, 2017

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### OMHA by the Numbers

Fiscal Year	Appeals	Claims
FY07	7.2	9.8
FY08	11.9	11.1
FY09	11.1	11.1
FY10	11.1	11.1
FY11	11.1	11.1
FY12	11.1	11.1
FY13	11.1	11.1
FY14	11.1	11.1
FY15	11.1	11.1
FY16	11.1	11.1

Fiscal Year	Appeals	Claims
FY07	6.4	8.4
FY08	11.2	10.5
FY09	10.5	10.5
FY10	10.5	10.5
FY11	10.5	10.5
FY12	10.5	10.5
FY13	10.5	10.5
FY14	10.5	10.5
FY15	10.5	10.5
FY16	10.5	10.5

Fiscal Year	Appeals	Claims
FY07	4.4	6.4
FY08	11.2	10.5
FY09	10.5	10.5
FY10	10.5	10.5
FY11	10.5	10.5
FY12	10.5	10.5
FY13	10.5	10.5
FY14	10.5	10.5
FY15	10.5	10.5
FY16	10.5	10.5

Fiscal Year	Processing Time
FY07	186.4
FY08	183.9
FY09	184.9
FY10	181.9
FY11	184.5
FY12	220.6
FY13	414.9
FY14	661.6
FY15	877.2

Note: Receipts include appeals involving the Settlement and Disposition appeals combined; appeals remainder appeals. Data current as of January 31, 2017.

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### Departmental Initiatives

- ☛ **QIC Formal Telephone Discussion Demonstration**
  - DME QIC conducts voluntary telephone discussions with suppliers in MAC Jurisdictions C & D
  - Suppliers given opportunity to present facts of case & provide additional documentation to support resolution of appeal at QIC
  - QIC also reviews closed reconsiderations pending with OMHA; identifies cases that can be resolved favorably via QIC reopening in light of discussion

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**Departmental Initiatives**

**QIC Formal Telephone Discussion Demonstration**

- If a fully favorable determination is warranted, QIC requests remand from OMHA and notifies DME MAC to pay claim
- 5,683 appeals\* have been resolved favorably via demonstration process prior to reaching OMHA
- 16,208 appeals\* have been remanded from OMHA for QIC to process reopening/resolve claim favorably
- Recently expanded to include all claims for DME submitted by Jurisdictions C and D suppliers

\*Data current as of February 2, 2017 (confirmed with CMS)

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**OMHA Initiatives**

**Settlement Conference Facilitation (SCF)**

- Appeals resolved since June 2014: 10,838

**Adjudication through Statistical Sampling**

- Appeals for which the appellant selected statistical sampling since June 2014: 6,287
- New process implemented in the coming month
  - No date restrictions
  - Sample units will be assigned among multiple adjudicators

**Senior Attorney On the Record (OTR)**

- Appeals resolved since July 1, 2015: 3,338

\*Data current as of February 15, 2017

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**OMHA Initiatives**

**Electronic Case Adjudication Processing Environment (ECAPE)**

- Release 1 (Spring 2017)
  - Case Intake/Appellant Public Portal (Phase I)
- Release 2
  - Phase 1 (Spring /Summer 2017) - Appellant-Initiated Requests for Withdrawals/Remands Associated with Backlog Initiatives
  - Phase 2 (Winter/Spring 2018) - Appeals Adjudication
- Release 3 (Summer 2018)
  - Enhanced Appellant Public Portal (Phase II)

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**Medicare Appeals Final Rule**

- ✎ Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures (82 FR 4974 (Jan. 17, 2017))
- ✎ 68 comments to July 5, 2016, proposed rule (81 FR 43790)
- ✎ Published effective date: March 20, 2017

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**Medicare Appeals Final Rule**

- ✎ Precedential Decisions (§401.109)
- ✎ Attorney Adjudicators—authorities
  - Decide appeals for which a decision can be issued without a hearing
  - Review dismissals issued by a CMS contractor
  - Issue remands to CMS contractors
  - Dismiss requests for hearing when an appellant withdraws the request
- ✎ CMS and CMS Contractor Participation (§§405.1010, 405.1012, 423.2010)

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**Medicare Appeals Final Rule**

**Review of New Evidence (§405.1028(a)(2))**

- ✎ With §405.1018, implements §1869(b)(3) of Social Security Act
- ✎ Four new examples of when good cause may be found for submission of new evidence:
  - Material to a new issue identified after QIC decision
  - Unable to be obtained prior to QIC’s decision, and evidence that reasonable attempts were made
  - Previously submitted but missing evidence.
  - Any other circumstance where party could not have obtained evidence before the QIC issued its reconsideration
- ✎ Clarified that limitation does not apply to CMS or its contractors, Medicaid State Agencies, or Plans

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**Medicare Appeals Final Rule**

**Increased Efficiencies**

- ✎ Revised request for information (§405.1034) and remand (§405.1056) procedures and authority of Chief ALJ or designee to review remands
- ✎ Adjudication time frame for cases remanded from Medicare Appeals Council (§405.1016(b)(2))
- ✎ Authority of ALJ or attorney adjudicator to vacate his or her own dismissals (§405.1052(e))
- ✎ Stipulated decisions (§405.1038(c))

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**Medicare Appeals Final Rule**

**Reduced Confusion**

- ✎ Replaces references to "MAC" and "DAB" with "Council"
- ✎ Clarifies application of part 405 regs to other parts
- ✎ Clarifies §405.1014 requirement to send copies of request for hearing to other parties

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**Medicare Appeals Final Rule**

**Proposals That Were Not Finalized**

- ✎ (Section IV of Final Rule 82 FR 5102)
- ✎ Changes to calculation methodology for amount in controversy
- ✎ Required disclosure on request for hearing of pending OIG or law enforcement investigations or proceedings

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## Latest Policy & Regulatory Changes to the Medicare Appeals Process

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**Judge Nancy Griswold**  
 Chief Judge  
 Office of Medicare Hearings and Appeals

HCCA Compliance Institute  
March 2017

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## Medicare Appeals Backlog

- “Despite significant gains in OMHA ALJ productivity..., and CMS and OMHA initiatives to address the increasing number of appeals, the number of requests for an ALJ hearing...continue to exceed OMHA’s capacity to adjudicate requests.” 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017)
- As of September 30, 2016, OMHA had over 650,000 pending appeals. 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017)
- What has been done and what needs to be done to rectify the backlog?
- How will these activities impact providers’ and suppliers’ audit and appeal strategies?

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## Judicial Relief: Medicare Appeals Backlog

*Hospice Savannah, Inc. v. Burwell* (4:15-cv-00253-JRH-GRS) (Sept. 21, 2015)

- District court awarded Hospice Savannah a temporary restraining order (TRO) enjoining HHS from withholding, recouping, offsetting, or otherwise failing to pay any current Medicare receivables
  - Substantial likelihood of success on the merits based on a “questionable extrapolation”
  - Hospice Savannah will be irreparably harmed by being forced to close and being unable to provide ongoing care to current hospice patients who by definition are terminally ill and disabled
  - Little or no risk to HHS because, at worst, the TRO will only defer its ability to pursue collection efforts
  - Public has an interest in seeing that terminally-ill patients continue to have access to Hospice Savannah’s services

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## Judicial Relief re: Appeals Backlog

*American Hospital Association, et. al. v. Burwell* (No. 14-cv-00851) (Feb. 9, 2016)

- AHA sought a writ of mandamus compelling HHS to act within the specified appeal time frames
  - “[ALJs] shall conduct and conclude a hearing . . . and render a decision . . . by not later than the 90-day period beginning on the date a request for hearing has been timely filed.” 42 U.S.C. § 1395ff(d)(1)(A)
- District court concluded mandamus relief was unwarranted
- Reversed and remanded by United States Court of Appeals for the District of Columbia Circuit
  - “[C]ommon sense suggests that lengthy payment delays will affect hospitals’ willingness and ability to provide care.”
  - Statute imposes a clear duty on HHS to comply with the statutory deadlines, statute gives AHA a corresponding right to demand compliance with the deadlines, and escalation is an inadequate alternative remedy in the circumstances of this case
  - “In the end, although courts must respect the political branches and hesitate to intrude on their resolution of conflicting priorities, our ultimate obligation is to enforce the law as Congress has written it. Given this, and given the unique circumstances of this case, the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time—say, the close of the next full appropriations cycle.”

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## Judicial Relief re: Appeals Backlog

*American Hospital Association, et. al. v. Burwell* (Case 14-cv-00851-JEB) (September 19, 2016)

- D.C. District Court concluded that absent any intervention the OMHA backlog at the end of FY2020 will be over 1,900,000
- Required “significant progress toward a solution” but clarified that this must mean “real movement towards statutory compliance” and not just slowing down the backlog,
- Concluded that HHS’ suggested administrative fixes do not demonstrate the needed “real movement towards statutory compliance.”
- The Court accepted reduction in appeal thresholds as proposed by AHA to reduce the backlog of ALJ appeals by certain intervals:
  - 30% by 2018;
  - 60% by 2019;
  - 90% by 2020;
  - 100% by 2021

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## New RAC Program Enhancements

**Effective May 15, 2015**

- Required to maintain an overturn rate of less than 10% at the first level of appeal
  - Failure will result in CMS placing the RAC on a corrective action plan, that could include decreasing the ADR limits, or ceasing certain reviews until the problem is corrected.
- Required to maintain an accuracy rate of at least 95%.
  - Failure will result in a progressive reduction in ADR limits.
- Limited the look-back period to 6 months from the date of service for patient status reviews in cases where the hospital submits the claim within 3 months of the date of service
- Incrementally apply the ADR limits to new providers under review

**Effective January 1, 2016**

- ADR limits are diversified across all claim types of a facility (e.g., inpatient, outpatient) to ensure that a provider with multiple claim types is not disproportionately impacted by a RAC’s review in one claim type
- ADR limits based on a provider’s compliance with Medicare rules
  - Providers with low denial rates will have lower ADR limits while providers with high denial rates will have higher ADR limits
  - ADR limits will be adjusted as a provider’s denial rate decreases

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## New RAC Program Enhancements

**October 31, 2016:** CMS awarded the next round of RAC contracts to:

- **Region 1 – Performant Recovery, Inc.**
- **Region 2 – Cotiviti, LLC**
- **Region 3 – Cotiviti, LLC**
- **Region 4 – HMS Federal Solutions**
- **Region 5 – Performant Recovery, Inc.**
- RACs in Regions 1-4 will perform postpayment reviews that were made under Part A and B for all providers other than DMEPOS and home health/hospice.
- Region 5 will focus on postpayment reviews for DMEPOS and home health/hospice nationwide.

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## Medicare Appeals Backlog

- HHS approach to address the backlog:
  - Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog;
  - Take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog;
  - Propose legislative reforms that provide additional funding and new authorities to address the volume of appeals

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## Activities to Address Appeals Backlog

- AFIRM Act – Announced in December 2015 and not passed as of February 2017
- Settlement Conference Facilitation Pilot Program
- CMS 66% Inpatient Hospital Claim Settlement
- OMHA Case Processing Manual  
<https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>
- MLN Matters SE1521 (May 9, 2016): For redeterminations and reconsiderations of claims denied following a complex prepayment review, a complex post-payment review, or an automated post-payment review by a contractor, CMS instructed MACs and QICs to limit their review to the reason(s) the claim or line item at issue was initially denied.

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**CMS Final Rule: New Regulations to Address Backlog**

- “Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures”
  - 82 Fed. Reg. 4974 (January 17, 2017)
  - Effective March 20, 2017 (Further delay possible)

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**CMS Final Rule: New Regulations to Address Backlog**

- **Overview of the Final Rule**
  - Reforms and changes to the Medicare appeals process to encourage efficiency;
  - All reforms support HHS’ three-prong approach to addressing the increasing number of appeals and the backlog of appeals at the OMHA level of appeal;
  - Rule includes a variety of changes to language within the Code of Federal Regulations

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**CMS Final Rule: New Regulations to Address Backlog**

- **Major changes in the Final Rule include:**
  - Precedential authority to selected Medicare Appeals Council decisions
  - Attorney Adjudicators at OMHA
  - Submission of Evidence for Medicare appeals
  - Appointed Representatives
  - CMS Contractors participation in ALJ proceedings

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**CMS Final Rule: New Regulations to Address Backlog**

- **Precedential authority to Medicare Appeals Council decisions**
  - Under previous regulations, Medicare Appeals Council ("Council") decisions were binding on the parties to the particular appeal;
  - The revised regulation, 42 C.F.R. 401.109, provides the Chair of the Departmental Appeals Board ("DAB") the authority to designate a final decision of the Council as precedential;
  - Purpose: to provide appellants with consistent precedential decisions to utilize in seeking appeals, to assist appeal adjudicators at all levels of appeal by providing clear direction on common legal and policy issues and in some circumstances, factual questions.

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**CMS Final Rule: New Regulations to Address Backlog**

- **Precedential authority to Medicare Appeals Council decisions**
  - Application to factual issues: Where precedential decisions apply to a factual question, it would apply only in limited situations where the relevant facts are the same and the evidence presented demonstrates that the factual circumstances have not changed since the precedential decision was issued;

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**CMS Final Rule: New Regulations to Address Backlog**

- **Precedential authority to Medicare Appeals Council decisions**
  - Factors DAB Chair may consider in determining to designate a specific decision as precedential:
    - Primary goal is to identify Council decisions with wide applicability where the precedent is likely to materially improve predictability and consistency in decisions;
    - Whether the precedential decision would have wide applicability to a broad number of cases or if the decision analyzes a legal issue of general public interest;
    - Whether the appeal's record was fully developed at lower levels of review;

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**CMS Final Rule: New Regulations to Address Backlog**

- **Precedential authority to Medicare Appeals Council decisions**
  - Notice of selected precedential decisions will be provided within a reasonable amount of time after the issuance of the decision and provided through publication in the Federal Register as soon as possible to the time the decision is selected to be precedential.
- **Effect on providers and suppliers:**
  - Monitor for appeal strategies
  - Monitor for prospective compliance

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**CMS Final Rule: New Regulations to Address Backlog**

- **Attorney Adjudicators at OMHA**
  - Regulations provide authority to attorney adjudicators to render decisions when an ALJ hearing is not necessary because:
    - The decision can be issued without one;
    - To dismiss appeals when an appellant withdraws his or her request for an LJ hearing;
    - To remand certain appeals pursuant to regulatory standards or at the direction of Council;
    - To conduct reviews of QICs' and IREs' dismissals.
  - Attorney adjudicators specifically trained to handle appeals regarding issues only within the written record that do not require an oral hearing.
  - Attorney adjudicators may refer a case for an ALJ hearing if determine a hearing is warranted and the ALJ will independently determine if a hearing is necessary.

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**CMS Final Rule: New Regulations to Address Backlog**

- **Attorney Adjudicators at OMHA**
  - The goal is to utilize ALJs for hearing cases on the merits, including fact-finding and reaching conclusions of law;
  - Utilizing attorney adjudicators will decrease ALJ's workload by transferring non-hearing, non-substantive claims to attorneys trained in the Medicare system;
  - Any final determination, including those from an attorney adjudicator, may be appealed to the Medicare Appeals Council.

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**CMS Final Rule: New Regulations to Address Backlog**

- **Submission of Evidence for Medicare Appeals**
  - Current 42 C.F.R. 405.1028: Submission and Examination of New Evidence
    - Good cause requirement
    - If no good cause, the evidence is excluded from the record and not considered in reaching a decision.

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**CMS Final Rule: New Regulations to Address Backlog**

- **Submission of Evidence for Medicare Appeals**
  - Newly revised regulations include specific instances for when an ALJ may consider permitting introduction of new evidence:
    - Evidence is material to an issue which was not identified as a material issue prior to the issuance of the reconsideration decision;
    - The new evidence is material to an entirely new issue addressed in the reconsideration decision;
    - The party was unable to obtain the evidence prior to the reconsideration decision, and the party has supplied evidence to establish its reasonable attempts to obtain evidence prior to reconsideration;
    - The evidence was submitted before reconsideration and the party can show evidence to prove the submission and the fact that it was not included in the administrative record;
    - ALJ's discretion

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**CMS Final Rule: New Regulations to Address Backlog**

- **Submission of Evidence for Medicare Appeals**
  - Revised regulations will reflect that evidence submitted after reconsideration that does not meet good cause criteria will be preserved in the administrative record;
  - Purpose of the new regulations:
    - To clearly indicate that providers and suppliers should submit all evidence that is relevant to their appeal as early as in the appeal process as possible and to clarify instances where an ALJ or attorney adjudicator may find good cause for introduction of new evidence at the OMHA level.

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**CMS Final Rule: New Regulations to Address Backlog**

- **Appointed Representatives**
  - New regulations provide clarity regarding required information on an Appointed Representative form for beneficiaries and providers.
  - Previous Appointment of Representative form included a field that stated "Medicare Number or National Provider Identifier Number"
  - Appeals submitted on providers' behalf that included the provider's NPI were improperly dismissed or returned because the beneficiary's HICN was not included on the

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**CMS Final Rule: New Regulations to Address Backlog**

- **Appointed Representatives**
  - Revised regulations will specifically state that where the party appointing the representative is a beneficiary, the beneficiary's HICN must be included and where the party appointing the representative is the provider, the provider's NPI will be included.
- **Impact on Appeals Backlog**
  - Unnecessary/incorrect denials cause administrative delays and waste of resources

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**CMS Final Rule: New Regulations to Address Backlog**

- **CMS Contractors Participation in ALJ Proceedings**
  - Current regulations permit CMS and CMS contractors to participate in ALJ hearings
    - 42 C.F.R. 405.1010: When CMS or its contractors may participate in an ALJ hearing;
    - 42 C.F.R. 405.1012: When CMS or its contractors may be a party to a hearing;

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**CMS Final Rule: New Regulations to Address Backlog**

- **CMS Contractors Participation in ALJ Proceedings**
  - Newly revised regulations: limit participation in ALJ hearings to either CMS or a single CMS contractor, unless ALJ finds that participation of both parties are necessary.
  - If multiple CMS entities file for participation in an ALJ hearing where one party is eligible, "only the first entity to file a response to the notice of hearing...may participate in the oral hearing."
  - CMS and/or multiple contractors may submit position papers or other written testimony for the ALJ hearing without limitation.

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**Best Practices for Providers and Suppliers for Appeals**

**Best practices for Lower Level Appeals**

- Preparation of substantive appeals early in the appeals process
  - Challenges with appeal deadlines to prevent recoupment
- Retain experts
  - Statistician
  - Clinical experts
  - Coding experts

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**Best Practices for Appeals: OMHA Case Processing Manual**

- OMHA Case Processing Manual available at: <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>
- Purpose: to provide direction for processing appeals at the OMHA level of adjudication and establish day-to-day procedures for carrying out adjudicative functions.

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**Best Practices for Appeals: OMHA Case Processing Manual**

- Useful information for appellants including:
  - Addresses and instructions for communicating with OMHA Central Options and specific ALJs
  - Information regarding OMHA's processes for handling requests and submissions;
  - Organization of the administrative record and OMHA's instructions for handling requests for the administrative record;
  - CMS and CMS Contractor Involvement in ALJ hearings;

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**Best Practices for Providers and Suppliers for Appeals**

**Best practices for ALJ appeals**

- Prominently list Medicare Appeal Number on your request
- Ensure beneficiary information matches Medicare Appeal Number
- List beneficiary's full HICN
- Include first page of QIC decision or prominently list full name of QIC
- Document Proof of Service to other parties
- Do not submit courtesy copy to QIC
- Submit only one request per Medicare Appeal Number
- Mail request via tracked mail to OMHA Central Operations
- Issue regarding evidence previously submitted lower level
- Do not attach evidentiary submissions or submit additional filings to OMHA Central Operations
- Wait until an ALJ is assigned and submit directly to ALJ

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**Questions?**

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# Highlights of the CMS Final Rule: The Impact on Compliance

21<sup>st</sup> Annual Compliance Institute  
March 27, 2017

Presenters: Kris D'Ann Maples and Lyn Bentley

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**Kris D'Ann Maples, Esq.**

- 19 years in Healthcare field
- Currently In-House Counsel and Compliance Officer at Hillcrest Health Services. Hillcrest is a mid-size, aging service provider in eastern Nebraska and western Iowa providing independent living, assisted living, memory support, skilled nursing, post-acute/outpatient rehab, home care and hospice services. Operates the first CCRC in the region.
- Prior to joining Hillcrest, served as general counsel at multi-state, multi-national intellectual disability services provider.
- Also worked as the VP Risk Management/Compliance Officer and VP of Human Resources at large multi-state human, social and aging services providers.



Enhancing the Lives of Aging Adults  
Hillcrest Home Care • Hillcrest Hospice Care • Hillcrest Respite Care  
Hillcrest Health & Rehab • Hillcrest Physical Therapy • Hillcrest Training  
Hillcrest Home Care • Hillcrest Home Care • Hillcrest Home Care

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**Lyn Bentley, MSW**  
Vice President, Quality & Regulatory Affairs  
AHCA

- 28 years focused on Aging Policy/Long Term Care
- Assisted Living Specialist, FL Dept. of HRS; Aging Policy Specialist in Florida Senate; Director of Government Affairs, Marriott Senior Living Services
- Since 2001, AHCA/NCAL: Senior Policy Director, NCAL; Senior Director Regulatory Services, AHCA; VP, Quality & Regulatory Affairs



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## Overview of Requirements of Participation

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### Themes of the Rule

- Person-Centered Care
- Facility-Based Responsibility
  - Assessment/Staffing, Competency-Based Approach
    - Know Your Center, Know Your Patients, Know Your Staff
- Quality of Care & Quality of Life
  - New/changed evidence-based practice
  - Care Planning
    - Patient goals
    - Patient as the locus of control

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IMPROVING LIVES by DELIVERING SOLUTIONS for QUALITY CARE

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### Themes of the Rule

- Changing Patient Population
  - Acuity
  - Behavioral Health
- Reflects dramatic cultural & technology changes over three decades

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IMPROVING LIVES by DELIVERING SOLUTIONS for QUALITY CARE

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**Alignment with HHS Priorities**

Advancing Cross-Cutting priorities:

- Reducing unnecessary hospitalizations
- Reducing the incidences of healthcare acquired infections/adverse events
- Improving behavioral healthcare

**AHCA** **NCAL** *IMPROVING LIVES by DELIVERING SOLUTIONS for QUALITY CARE*

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**Alignment with HHS Priorities**

Advancing Cross-Cutting priorities:

- Safeguarding nursing home residents from the use of unnecessary psychotropic (antipsychotic) medications
- Care Planning
- Quality Assurance & Performance Improvement
- Health Information Technology/IT Interoperability

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**Impact of New RoPs on Survey Process**

- CMS developing a new survey process
  - Merges QIS with traditional survey
  - Incorporates new RoPs
  - Goes into effect in Nov 2017

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### Implementation Timeline

Implementation Date	Type of Change	Details of Change
Phase 1: November 2016	Effective date of new LTC Requirements for Participation	New Regulatory Language under current F Tags
Phase 2: November 2017	<ul style="list-style-type: none"> <li>Appendix PP of State Operations Manual</li> <li>Implement new survey process</li> </ul>	<ul style="list-style-type: none"> <li>New F Tag numbers</li> <li>Interpretive Guidance (IG) Changes</li> <li>Begin surveying with the new survey process</li> </ul>

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### Added New Definitions

- “abuse”
- “adverse event”
- “exploitation”
- “misappropriation of resident property”
- “mistreatment”
- “neglect”
- “person-centered care”
- “resident representative”
- “sexual abuse”

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### Resident/Patient Rights (\$483.10)

- Grievances, inform how to file and who may be contacted to file
- Identify a **grievance official** responsible for the process, including:
  - Receiving & tracking;
  - Leading investigations;
  - Maintaining confidentiality;
  - Issuing official decisions to the resident;

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### Resident/Patient Rights (§483.10)

(Grievance Official responsibilities)

- Coordinating with State and Federal agencies;
- Preventing further violations while investigations are taking place;
- Documentation requirements; and
- Meeting all applicable State and Federal, laws and regulations.
- Facility must establish a grievance policy

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### Freedom From Abuse, Neglect & Exploitation (§483.12)

- Formerly "Resident Behavior & Facility Practices"
- Definition of abuse: actions such as the **willful** infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.
  - Includes verbal, sexual, physical, and mental abuse including abuse facilitated or enabled through the use of technology.

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### Freedom From Abuse, Neglect & Exploitation (§483.12)

- Use of "**willful**" in the definition means the individual must have acted deliberately, not that they must have intended to inflict injury or harm.

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### Freedom From Abuse, Neglect & Exploitation (§483.12)

- Report violations to State Agency and Adult Protective Services (per state law) immediately/not later than 2 hours if allegation of abuse or if serious bodily injury—24 hours, if no abuse and does not result in bodily injury.
- Expands employment ban to professional who has current disciplinary action against their license.
- Phase 2: Establish policies and procedures to ensure the reporting of crimes in accordance with section 1150 B of the act, with associated penalties for failure to act (Elder Justice Act).




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### Notifications (in Resident Rights) (§483.10)

- Must send a copy of all notices of transfer or discharge to LTCO including reasons for the move
- Notification **60 days prior** to increase in **any** charges not paid by Medicare or Medicaid
- At time of admission, and periodically during resident's stay, services available in the facility and any associated charges




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### Regulatory Timing

- Proposed Rules were published July 16, 2015
- Final Rules published October 4, 2016.
  - Phase I regulations effective November 28, 2016
  - Phase II regulations effective November 28, 2017
  - Phase III regulations effective November 28, 2019



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### Compliance & Ethics

- There is now a new section in the Rules of Participation for SNFs entitled "Compliance and Ethics Program" - §483.85
- *Note:* With the change in the administration and plan to abolish ACA, be on alert to changes in the regulations prior to the implementation dates for each phase.



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### Compliance & Ethics



- Past OIG Guidance for nursing centers was published in 2000 and 2008 have now been codified and compliance will be part of survey process
- The operating organization for each facility must have a compliance and ethics program that meets the requirements outlined in §483.85 (a) & (c) **by November 28, 2017.**
  - However, the entire Compliance and Ethics section [presumably that includes §483.85 (d) and (e) as well as (a) and (c)] must be implemented **by November 28, 2019.**



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### Minimum Components of Program

- Written compliance and ethics standards, policies and procedures that are "reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the act and promote quality of care"
- Corrective/Disciplinary standards that outline consequences of committing violations
  - Which are enforced consistently for all of the operation's staff, contractors, and volunteers
  - Includes consequences for failure to detect or report a violation



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### Minimum Components of Program

- Designate "appropriate" compliance and ethics program contact
  - Can report suspected violations
  - Means to report anonymously without fear of retaliation
- Designated contact reports to "high level" individual in organization who oversees compliance and ethics program for the organization.
  - CEO
  - Board
  - Director "of major division"



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### Minimum Components of Program

- Devote "Sufficient resources and authority" to the designated contact and designated high level overseer to "reasonably assure" program standards, policies and procedures are being met.
  - Level in organization and authority granted that individual?
  - Time devoted to compliance and ethics program?
  - Budget?



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### Minimum Components of Program

- Take "due care" to not delegate discretionary authority to individuals in the organization who the organization knew or should have known had a propensity to engage in potential civil or criminal violations under the FCA.
  - Background checks?
  - Past behavior?



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### Minimum Components of Program

- Take steps to “effectively” communicate standards, policies and procedures “in a practical manner”
  - Mandatory one time training for all new and existing staff, contractors and volunteers
  - Mandatory annual training if organization operates 5 or more facilities



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### Minimum Components of Program

- Response taken after a violation:
  - All “reasonable steps” to respond “appropriately” to prevents future similar violations
  - Includes tweaking monitoring and auditing practices to detect violations



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### Annual Review of Program

By Phase III effective date:

- Annual review of program to make changes to:
  - Reflect any changes in applicable laws and regulations
  - Improve performance in “detering, reducing and detecting” FCA violations
  - Improve performance in promoting quality of care



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### Additional Requirements

By Phase III effective date:

- Additional requirements if have 5 or more facilities:
  - Annual compliance training for all staff members outlined in §483.95(f)
  - Designated compliance officer whose “major responsibility” in operating the organization’s compliance program.
    - Must report directly to organization’s “governing body”
    - CANNOT report to General Counsel, CFO or COO
  - “Compliance Liaisons” at each facility



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### Questions



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# Playbook

This booklet was developed to support members and provide guidance on necessary actions for each of the three phases of implementation of the Requirements of Participation for States and LTC Facilities. It uses as a reference [Part 483](#)- Requirements for States and LTC Facilities.

The timeline is based on the phases created by CMS.

- Phase 1 which begins on November 28, 2016
- Phase 2 which begins on November 28, 2017
- Phase 3 which begins on November 28, 2019

This document is intended to provide a high level overview of the various regulatory sections affected by the Reform of Requirements of Participation. It does not reflect all aspects of the regulatory requirements. The necessary actions listed for each section are a starting point. Several other actions may be necessary to adequately prepare. For example, changes to Policies & Procedures may also require changes in other documentation, training staff of the new policy, helping to develop systems that allow for that policy to become fluid etc.) Employing an organized process improvement approach to guide the effective implementation of the various steps will help to produce desired results.

NOTE: This document has not been approved by the Centers for Medicare & Medicaid Services (CMS) or any other federal or state agency. This document is not intended as legal or operational advice and should not be used as or relied upon as legal or operational advice. It is for general informational purposes only in light of the modified requirements of participation found at 42 C.F.R. § 483.1 et seq. and may not be substituted for legal or operational advice. Specific legal and operational advice is crucial when ensuring compliance with the requirements of participation found at 42 C.F.R. § 483.1 et seq. ALWAYS SEEK THE ADVICE OF KNOWLEDGEABLE COUNSEL TO PROVIDE ADVICE THAT IS TAILORED TO THE ACTUAL FACTS AND CIRCUMSTANCES AND TAKES INTO ACCOUNT ALL RELEVANT LAW.

Section	Phase	Page #	Necessary Action
<b>§483.1 Basis and scope.</b>	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68848	

CMS Summary: We have added the statutory authority citations for sections 1128I(b) and (c) and section 1150B of the Social Security Act (the Act) to include the compliance and ethics program, quality assurance and performance improvement (QAPI), and reporting of suspicion of a crime requirements to this section.

Section	Phase	Page #	Necessary Action
<b>§483.5 Definitions.</b>	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68848	<input type="checkbox"/> Familiarize staff at all levels of the organization with these terms  <input type="checkbox"/> Modify language to include resident representative

**CMS Summary:**

We have added the definitions for “abuse”, “adverse event”, “exploitation”, “misappropriation of resident property”, “mistreatment”, “neglect”, “person-centered care”, “resident representative”, and “sexual abuse” to this section.

Section	Phase	Page #	Necessary Action
<b>§483.10 Resident rights.</b>	<b>Phase 1</b> The section will be implemented in Phase 1 with the following exception:	68849	<input type="checkbox"/> Review and modify language in P&P related to Advance directives §483.10(b)(8)  <input type="checkbox"/> Develop P&P related to Grievance policy (new)  <input type="checkbox"/> Identify a “grievance official” who oversees the process  <input type="checkbox"/> Establish a process for responding to grievances by family and or residents

<p><b>CMS Summary:</b></p>		<ul style="list-style-type: none"> <li><input type="checkbox"/> Furnish a written description of legal rights to the resident and resident’s representative</li> <li><input type="checkbox"/> Update the Notification of the resident’s rights with all new required notifications and information</li> <li><input type="checkbox"/> Develop P&amp;P related to Visitation rights of residents (new)</li> <li><input type="checkbox"/> Post survey results</li> <li><input type="checkbox"/> Assure staff’s readiness and ability to accommodate the needs of LGBT residents and their families</li> </ul>
	<p><b>Phase 2</b>                  (g)(4)(ii) – (v) Providing contact information for State and local advocacy organizations, Medicare and Medicaid eligibility information, Aging and Disability Resources Center and Medicaid Fraud Control Unit</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Furnish a list of names, addresses (mailing and email), and telephone numbers of all pertinent State regulatory and informational agencies, resident advocacy groups such as the State Survey Agency, the State licensure office, the State Long-Term Care Ombudsman program, the protection and advocacy agency, adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community and the Medicaid Fraud Control Unit;</li> </ul>
	<p><b>Phase 3</b></p>	

We are retaining all existing residents’ rights and updating the language and organization of the resident rights provisions to improve logical order and readability, clarify aspects of the regulation where necessary, and updating provisions to include advances such as electronic communications.

Section	Phase	Page #	Necessary Action
§483.12 Freedom from abuse, neglect, and exploitation.	Phase 1 with the following exceptions:	68855	<input type="checkbox"/> Have a process for ensuring that residents are free or at the least restrictive level of chemical restraints <input type="checkbox"/> Have a process for ensuring that staff are qualified and in good standing <input type="checkbox"/> Develop P&P related to the prohibition of abuse, neglect and exploitation <input type="checkbox"/> Train staff on abuse, neglect and exploitation
	Phase 2 •(b)(5) Reporting crimes/1150B		<input type="checkbox"/> Modify P&P to include expressed topics found on page 68855
	Phase 3 •(b)(4) Coordination with QAPI Plan		<input type="checkbox"/> Integrate abuse, neglect and exploitation into QAPI program

CMS Summary: We are requiring facilities to investigate and report all allegations of abusive conduct. We also are specifying that facilities cannot employ individuals who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of their property.

Section	Phase	Page #	Necessary Action
§483.15 Admission, transfer, and discharge rights.	Phase 1 This section will be implemented in Phase 1 with the following exceptions:	68855	<input type="checkbox"/> Review and modify language in P&P related to Admissions Policy3 §483.12(d)3



<b>Phase 2 • (c)(2) Transfer/Discharge Documentation</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Review and modify language in P&amp;P related to Bed hold policy3 §483.12(b)(1)</li> <li><input type="checkbox"/> Review and modify specific language permitting resident’s return to the center after a hospitalization or therapeutic leave (page 648)</li> <li><input type="checkbox"/> Review Discharge policy. Align with care plan requirements found on pages 68856</li> <li><input type="checkbox"/> Update the documentation of a residents discharge to include all items found on page 68856</li> </ul>
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CMS Summary: We are requiring that a transfer or discharge be documented in the medical record and that specific information be exchanged with the receiving provider or facility when a resident is transferred.

Section	Phase	Page #	Necessary Action
<b>§483.20 Resident assessment.</b>	<p><b>Phase 1</b></p> <p>This entire section will be implemented in Phase 1.</p>	68857	<ul style="list-style-type: none"> <li><input type="checkbox"/> Document the resident’s involvement in completing the RAI.</li> <li><input type="checkbox"/> Review and modify documents and process to address resident’s needs, strengths, goals, life history and preferences</li> </ul>

CMS Summary: We are clarifying what constitutes appropriate coordination of a resident’s assessment with the Preadmission Screening and Resident Review (PASARR) program under Medicaid. We are also adding references to statutory requirements that were inadvertently omitted from the regulation when we first implemented sections 1819 and 1919 of the Act.

Section	Phase	Page #	Necessary Action
<b>Comprehensive Person-</b>	<b>Phase 1</b>	68858	<ul style="list-style-type: none"> <li><input type="checkbox"/> Ensure that the Comprehensive Care Plan meets the criteria set forth on page 68858.</li> </ul>

<b>Centered Care Planning (§483.21)</b>  <b>*New Section*</b>	This section will be implemented in Phase 1 with the following exceptions:	<input type="checkbox"/> Develop a discharge plan for each resident that is included in the Comprehensive Care Plan and evaluated regularly
	<b>Phase 2</b> •.Baseline care plan	<input type="checkbox"/> Develop or modify and implement a baseline care plans that includes instructions to provide effective person-centered care. Specifics of the care plan can be found on page 68858  <input type="checkbox"/> Furnish the resident and representative with a summary of the baseline care plan
	<b>Phase 3</b> •(b)(3)(iii) Trauma informed care	

**CMS Summary:**

- We are requiring facilities to develop and implement a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.
- We are adding a nurse aide and a member of the food and nutrition services staff to the required members of the interdisciplinary team that develops the comprehensive care plan.
- We are requiring that facilities develop and implement a discharge planning process that focuses on the resident’s discharge goals and prepares residents to be active partners in post-discharge care, in effective transitions, and in the reduction of factors leading to preventable re-admissions. We are also implementing the discharge planning requirements mandated by The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) by revising, or adding where appropriate, discharge planning requirements for LTC facilities.

Section	Phase	Page #	Necessary Action
§483.24 Quality of life.	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68859	<input type="checkbox"/> Establish a process to determine that residents are being given the appropriate treatments and services to maintain or improve their function  <input type="checkbox"/> Review the activities program to ensure the on-going activities support resident’s choice

		<p>through group, individual and independent activities</p> <p><input type="checkbox"/> Assure the qualifications of the Director meet the definition of qualified professional</p>
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**CMS Summary:**

- We are requiring that each resident receive and the facility provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident’s comprehensive assessment and plan of care.

Section	Phase	Page #	Necessary Action
<b>§483.25 Quality of care.</b>	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exception:	68860	<p><input type="checkbox"/> Ensure staff competency in providing treatment and care in accordance with professional practice.</p> <p><input type="checkbox"/> Review the current processes around vision &amp; hearing, skin integrity, mobility, incontinence, colostomy, urostomy &amp; ileostomy, assisted nutrition &amp; hydration, parenteral fluids, respiratory care, prostheses, pain management, dialysis, trauma informed care, and bed rails</p>
	<b>Phase 2</b>		
	<b>Phase 3•(m) Trauma-informed care</b>		<p><input type="checkbox"/> Provide training to staff related to trauma-informed care</p>

**CMS Summary:**

- We are requiring that each resident receive and the facility provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident’s comprehensive assessment and plan of care.

Section	Phase	Page #	Necessary Action
§483.30 Physician services.	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68861	<input type="checkbox"/> Review new requirements with center physician

**CMS Summary:**

- We are allowing attending physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals and therapy orders to therapists.

Section	Phase	Page #	Necessary Action
§483.35 Nursing services.	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exception:  <b>Phase 2.</b> • Specific usage of the Facility Assessment at §483.70(e) in the determination of sufficient number and competencies for staff	68861	<input type="checkbox"/> Review current written information (e.g., job descriptions, job expectations, etc.) and update as necessary to include “assuring resident safety.”  <input type="checkbox"/> Review any facility documents to ensure “other nursing personnel” includes nurse aides.  <input type="checkbox"/> Develop and implement processes to assess competencies of nursing staff.  <input type="checkbox"/> Develop and implement processes to determine “sufficient nursing staff” to meet requirements for nursing services, based on facility assessment.

**CMS Summary:**

- We are adding a competency requirement for determining the sufficiency of nursing staff, based on a facility assessment, which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of individual care plans.

Section	Phase	Page #	Necessary Action
<b>§483.40 Behavioral health services.</b>	<b>Phase 1</b> (b)(1), (b)(2), and (d) Comprehensive assessment and medically related social services	68862	<input type="checkbox"/> Develop and implement process to meet requirements at §483.40 (b)(1) and (b)(2) related to providing services to a resident to correct an assessed problem related to mental disorder or psychosocial adjustment difficulty and, if an assessment did not reveal a mental or psychosocial adjustment difficulty, prevent an occurrence of such in a resident if clinically avoidable.
	<b>Phase 2</b> This section will be implemented in Phase 2 with the following exceptions:		<input type="checkbox"/> Assure medically related social services are provided as necessary. (see current Interpretive Guidelines at F250)
	<b>Phase 3</b> •(a)(1) As related to residents with a history of trauma and/or post-traumatic stress disorder		<input type="checkbox"/> Develop and implement a process to assess staff competencies and skills sets as related to caring for residents with a history of trauma and/or post-traumatic stress disorder.

**CMS Summary:**

- We are adding a new section to subpart B that focuses on the requirement to provide the necessary behavioral health care and services to residents, in accordance with their comprehensive assessment and plan of care.
- We are adding “gerontology” to the list of possible human services fields from which a bachelor degree could provide the minimum educational requirement for a social worker.

Section	Phase	Page #	Necessary Action
<b>§483.45 Pharmacy services.</b>	<b>Phase 1</b>  This section will be implemented in Phase 1 with the following exceptions:	68863	<input type="checkbox"/> Review and modify as necessary, documents/policies, etc. referencing “psychotropic drugs” to ensure they are consistent with new definition of psychotropic drug.  <input type="checkbox"/> Develop policies and procedures for the monthly drug regimen review and include the required information.
	<b>Phase 2</b> (c)(2) Medical chart review (e) Psychotropic drugs		

**CMS Summary:**

- We are requiring that a pharmacist review a resident’s medical chart during each monthly drug regimen review.
- We are revising existing requirements regarding “antipsychotic” drugs to refer to “psychotropic” drugs and define “psychotropic drug” as any drug that affects brain activities associated with mental processes and behavior. We are requiring several provisions intended to reduce or eliminate the need for psychotropic drugs, if not clinically contraindicated, to safeguard the resident’s health.

Section	Phase	Page #	Necessary Action
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<b>§483.50 Laboratory, radiology, and other diagnostic services.</b>  <b>*New Section*</b>	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68863	<input type="checkbox"/> Facility policies and procedures must identify process for notifying the ordering professional of lab, radiology and other diagnostic services when results fall outside of clinical reference ranges.
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**CMS Summary:**

- We are clarifying that a physician assistant, nurse practitioner or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope-of-practice laws.

Section	Phase	Page #	Necessary Action
<b>§483.55 Dental services.</b>	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exceptions:	668864	
	<b>Phase 2</b> (a)(3) and (a)(5) Loss or damage of dentures and policy for referral (b)(3) and (b)(4) Referral for dental services regarding loss or damaged dentures		<input type="checkbox"/> Develop a policy related to Loss or damage of dentures  <input type="checkbox"/> Establish a system to ensure denture replacement within 3 days
	<b>Phase 3</b>		

**CMS Summary:**

- We are prohibiting SNFs and NFs from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility’s responsibility, and we are adding a requirement that the facility have a policy identifying those instances when the loss or damage of dentures is the facility’s responsibility. We are requiring NFs to assist residents who are eligible to apply for reimbursement of dental services under the Medicaid state plan, where applicable.
- We are clarifying that with regard to a referral for lost or damaged dentures “promptly” means that the referral must be made within 3 business days unless there is documentation of extenuating circumstances.

Section	Phase	Page #	Necessary Action
<b>§483.60 Food and nutrition services.</b>	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exceptions:	68864	<input type="checkbox"/> Develop a policy for use and storage of foods brought to residents by family and other visitors (new)
	<b>Phase 2</b> <ul style="list-style-type: none"> <li>• a) As linked to Facility Assessment at §483.70(e) Implemented in Phase 2.</li> <li>• (a)(1)(iv) Dietitians hired or contracted with prior to effective date—Built in implementation date of 5 years following effective date of the final rule.</li> <li>• (a)(2)(i) Director of food &amp; nutrition services designated to serve prior to effective—Built in implementation date of 5 years following the effective date of the final rule.</li> </ul>		<input type="checkbox"/> Assess the qualifications and competencies of dietary staff leadership

**CMS Summary:**

- We are requiring facilities to provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident.



- We are also requiring facilities to employ sufficient staff, including the designation of a director of food and nutrition service, with the appropriate competencies and skills sets to carry out the functions of dietary services while taking into consideration resident assessments and individual plans of care, including diagnoses and acuity, as well as the facility’s resident census.

Section	Phase	Page #	Necessary Action
<b>§483.65 Specialized rehabilitative services.</b>	<b>Phase 1</b> This entire section will be implemented in Phase 1.	68865	<input type="checkbox"/> Review new regulatory language at §483.65 (a) and §483.65 (a)(2) to ensure any relevant written information and facility policies/programs are updated.

**CMS Summary:**

- Current regulations set forth the services that a facility must provide if a resident needs specialized rehabilitative services including, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for a mental disorder. We have added respiratory services to those services identified as specialized rehabilitative services.

Section	Phase	Page #	Necessary Action
<b>§483.70 Administration.</b>	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exceptions:	68866	<input type="checkbox"/> Review admissions policy/package to ensure a pre-dispute agreement for binding arbitration agreement is not included.  <input type="checkbox"/> Review final regulations to ensure all requirements are included in facility’s operations. Modify as necessary  <input type="checkbox"/> Review job qualifications for a facility social worker to include additional of “gerontology” as specified in §483.70(p).

	<b>Phase 2</b> (e) Facility assessment—Implemented in Phase 2.	<input type="checkbox"/> Develop and implement a process for conducting and updating as necessary an annual facility assessment.
	<b>Phase 3</b> d)(3) Governing body responsibility of QAPI program	<input type="checkbox"/> Include responsibility and accountability for the QAPI program to the obligations of the governing body.

**CMS Summary:**

- We have largely relocated various portions of this section into other sections of subpart B as deemed appropriate.
- We require facilities to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies.
- Facilities are required to address in the facility assessment the facility’s resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.
- Binding Arbitration Agreements: We are requiring that facilities must not enter into an agreement for binding arbitration with a resident or their representative until after a dispute arises between the parties. Thus, we are prohibiting the use of pre-dispute binding arbitration agreements.

Section	Phase	Page #	Necessary Action
§483.75 Quality assurance and performance improvement.	This section will be implemented in Phase 3 with the following exceptions: <ul style="list-style-type: none"> <li>• (g)(1) QAA committee—All requirements of this section will be implemented in Phase 1 with the exception of subparagraph (iv), the addition of the ICPO, which will be implemented in Phase 3.</li> <li>• (h) Disclosure of information—Implemented in Phase 1.</li> <li>• (i)Sanctions—Implemented in Phase 1.</li> </ul>	68867	<input type="checkbox"/> Compare new requirements for the QAA committee with facility’s current QAA committee and update as necessary.

	<b>Phase 2</b> <ul style="list-style-type: none"> <li>(a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey—Implemented in Phase 2.</li> </ul>	<input type="checkbox"/> Facility must develop a QAPI Plan by November 27, 2017 and submit to the Survey Agency at the first annual recertification survey
	<b>Phase 3</b>	

**CMS Summary:**

- We are requiring all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.

Section	Phase	Page #	Necessary Action
<b>§483.80 Infection control.</b>	This section will be implemented in Phase 1 with the following exceptions:		68868
	Phase 2 (a) As linked to Facility Assessment at §483.70(e) (a)(3) Antibiotic stewardship		<input type="checkbox"/> Review new requirements and compare to facility’s current infection control program and update/revise/include additional information as necessary.  <input type="checkbox"/> Ensure all required standards, policies and procedures include at least the items identified at §483.80 (2)(i) – (iv).
	Phase 3 (b) Infection preventionist (IP)—Implemented in Phase 3. (c) IP participation on QAA committee—Implemented in Phase 3.		<input type="checkbox"/> Align the infection control program with the results of the facility assessment.  <input type="checkbox"/> Incorporate an antibiotic stewardship program into the infection control program.  <input type="checkbox"/> Hire/designate one or more infection preventionist(s) who is responsible for the Infection Prevention and Control Program.

- Add the infection preventionist (or at least one, if there are more than one) to the quality

**CMS Summary:**

- We are requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP).

Section	Phase	Page #	Necessary Action
§483.85 Compliance and ethics program.  *New Section*	This entire section will be implemented in Phase 3  <u>NOTE: The final rule contains conflicting information about implementation: this will be required in either Phase 2 or Phase 3. AHCA will obtain clarification.</u>	68869	
	Phase 2		<input type="checkbox"/> Review current policies and procedures to determine inclusion of what is required by this new section.  <input type="checkbox"/> Develop a plan for developing and implementing the required components of this program (§483.85(c)(1) -(8).  <input type="checkbox"/> Develop a schedule for an annual review and update to the compliance and ethics program.  <input type="checkbox"/> If you are an organization with five or more facilities, review specific requirements at §483.85(d)(1) -(3).
	Phase 3		

**CMS Summary:**

- We are requiring the operating organization for each facility to have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.

Section	Phase	Page #	Necessary Action
<b>§483.90 Physical environment.</b>	<b>Phase 1</b> This section will be implemented in Phase 1 with the following exceptions:	68870	<input type="checkbox"/> Any facility newly certified or approved for construction (including remodeling) must have a private bath including at least a toilet and sink for <b>each</b> resident room. [NOTE: a bathroom that is located between two patient rooms and accessible from each does not meet this requirement.]
	Phase 2(h)(5) Policies regarding smoking		<input type="checkbox"/> Develop smoking policy that incorporates smoking safety and takes into account nonsmoking residents. Policy must be in accord with applicable federal, state, and local laws and regulations re: smoking and smoking areas.
	Phase 3 (f)(1) Call system from each resident’s bedside		<input type="checkbox"/> Confirm that each resident’s bedside has a call system that will allow the resident to request staff assistance and the call goes directly to a staff member or a centralized staff work area.

**CMS Summary:**

In the proposed rule we indicated that the facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. Many of these provisions relate to Life Safety Code (LSC) requirements. We are requiring facilities that are constructed, re-constructed, or newly certified after the effective date of this regulation to accommodate no more than two residents in a bedroom. We are also requiring facilities that are constructed, or newly certified after the effective date of this regulation to have a bathroom equipped with at least a commode and sink in each room.

Section	Phase	Page #	Necessary Action
<p><b>§483.95 Training requirements.</b></p> <p><b>*New Section*</b></p>	<p>This entire section will be implemented in Phase 3 with the following exceptions:</p> <p><b>Phase 1</b></p> <p>Training on:</p> <ul style="list-style-type: none"> <li>(c) Abuse/Neglect/Exploitation,</li> <li>(g) (2) Dementia Management expanded beyond nurse aides to other direct staff</li> <li>(g) (4) Care of the cognitively impaired</li> <li>(h) Feeding Assistant requirement.</li> </ul>	68870	<ul style="list-style-type: none"> <li><input type="checkbox"/> Develop the required new training.</li> <li><input type="checkbox"/> Incorporate required new training into your annual training schedule.</li> <li><input type="checkbox"/> Add into your training schedule any individuals newly required by the rule.</li> <li><input type="checkbox"/> Have a system to document completed training of required individuals.</li> </ul>
	Phase 2		
	<p>Phase 3 •</p> <p>There are eight required training topics that centers are responsible for training new and existing staff, as well as contractors, and volunteers. The topics are communication; resident’s rights and facility responsibility; abuse, neglect and exploitation; quality assurance and performance improvement; infection control; compliance and ethics; and behavioral health.</p>		<ul style="list-style-type: none"> <li><input type="checkbox"/> Implement required new trainings</li> </ul>

**CMS Summary:**

We are adding a new section to subpart B that sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles.

Additional Highlights:

- 
- There are eight required training topics that centers are responsible for training new and existing staff, as well as contractors, and volunteers. The topics are communication; resident's rights and facility responsibility; abuse, neglect and exploitation; quality assurance and performance improvement; infection control; compliance and ethics; and behavioral health.

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**21<sup>st</sup> Century Cures Act**

Calls for additional guidance:

- Accessing and sharing PHI for research purposes, including prep to research
- w/ONC, common legal, governance and security barriers that prevent trusted exchange of health info
- w/ONC, improving individual access to health information, including from BAs
- Ability to disclose treatment-related information about persons with mental health disorders, such as with close friends and family

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**Long-term Regulatory Agenda**

- HITECH provision re: providing individuals harmed by violations of the HIPAA regulations with a percentage of any civil monetary penalties or settlements collected.
- HITECH provisions re: changes to HIPAA Accounting of Disclosure provisions.

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**Upcoming Guidance/FAQs**

- Privacy and Security for “All of Us” (PMI) research program
- Text messaging
- Social Media
- Use of CEHRT & compliance with HIPAA Security Rule (w/ONC)
- RA/CMP Process
- Update of existing FAQs to account for Omnibus and other recent developments
- Minimum necessary

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**Recent Guidance:  
Ransomware and Cloud Computing**

- Ransomware:
  - <http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html>
- Cloud Computing:
  - <https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html>

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**Monthly Guidance:  
Cybersecurity Newsletters**

February 2016	Ransomware, “Tech Support” Scam, New BBB Scam Tracker
March 2016	Keeping PHI safe, Malware and Medical Devices
April 2016	New Cyber Threats and Attacks on the Healthcare Sector
May 2016	Is Your Business Associate Prepared for a Security Incident
June 2016	What’s in Your Third-Party Application Software
September 2016	Cyber Threat Information Sharing
October 2016	Mining More than Gold (FTP)
November 2016	What Type of Authentication is Right for you?
December 2016	Understanding DoS and DDoS Attacks
January 2017	Audit Controls
February 2017	Reporting and Monitoring Cyber Threats

<http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html>

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**Audit Purpose:  
Support Improved Compliance**

- Identify best practices; uncover risks & vulnerabilities; detect areas for technical assistance; encourage consistent attention to compliance
  - Intended to be non-punitive, but OCR can open up compliance review (for example, if significant concerns are raised during an audit or an entity fails to respond)
- Learn from this next phase in structuring permanent audit program
- Develop tools and guidance for industry self-evaluation and breach prevention

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**Audit Program Status**

- Desk audits underway
  - ✓ 166 Covered Entities
  - ✓ 43 Business Associates
- Business Associate selection pool largely drawn from over 20,000 entities identified by audited CEs
- On-site audits of both CEs and BAs in 2017, after completion of the desk audit process, to evaluate against a comprehensive selection of controls in protocols
- A desk audit subject may be subject to on-site audit
- OCR beginning distribution of draft findings

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**Desk Audit Reporting: Process**

**After review of submitted documentation:**

- Draft findings shared with the entity
- Entity may respond in writing

**Final audit reports will:**

- Describe how the audit was conducted
- Present any findings, and
- Contain any written entity responses to the draft

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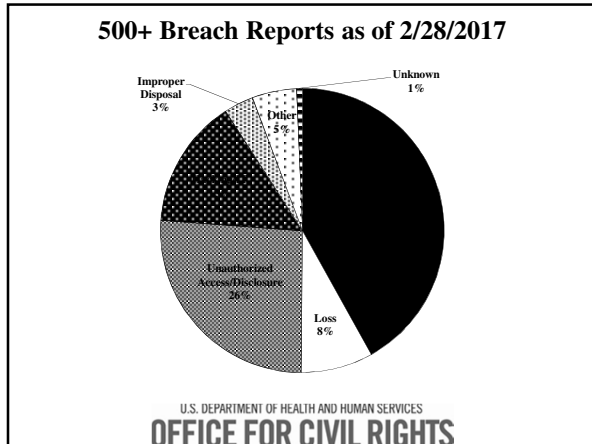
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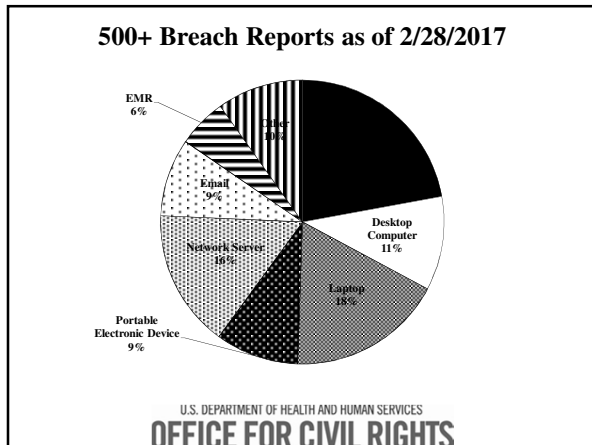
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### Complaints Received and Cases Resolved

- Over 150,507 complaints received to date
- Over 24,879 cases resolved with corrective action and/or technical assistance
- Expect to receive 17,000 complaints this year

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**Enforcement Guidance:  
How OCR Closes Cases**

- <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/index.html>
- Cases that OCR closes fall into five categories:
  - Resolved after intake & review (no investigation)
  - Technical Assistance (no investigation)
  - No Violation (investigated)
  - Corrective Action Obtained (investigated; includes Resolution Agreements)
- OCR may decide not to investigate a case further if :
  - The case is referred to the Department of Justice for prosecution.
  - The case involved a natural disaster.
  - The case was pursued, prosecuted, and resolved by state authorities.
  - The covered entity or business associate has taken steps to comply with the HIPAA Rules and OCR determines enforcement resources are better/more effectively deployed in other cases.

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**Recent Enforcement Actions**

- <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>
- 2/16/2017: HIPAA settlement shines light on the importance of audit controls
- 2/1/2017: Lack of timely action risks security and costs money
- 1/18/2017: HIPAA settlement demonstrates importance of implementing safeguards for ePHI

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**Continuing Enforcement Issue:  
Affirmative Disclosures Not Permitted**

The HIPAA Privacy Rule provides that Covered Entities or Business Associates may not use or disclose PHI except as permitted or required. See 45 C.F.R. § 164.502(a). Examples of Potential Violations:

- Covered Entity permits news media to film individuals in its facility prior to obtaining their authorization.
- Covered Entity publishes PHI on its website or on social media without an authorization from the individual(s).
- Covered Entity confirms that an individual is a patient and provides other PHI to reporter(s) without authorization from the individual.
- Covered Entity faxes PHI to an individual’s employer without authorization from the individual.

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**Continuing Enforcement Issue:  
Lack of Business Associate Agreements**

HIPAA generally requires that covered entities and business associates enter into agreements with their business associates to ensure that the business associates will appropriately safeguard protected health information. See 45 C.F.R. § 164.308(b).  
Examples of Potential Business Associates:

- A collections agency providing debt collection services to a health care provider which involves access to protected health information.
- An independent medical transcriptionist that provides transcription services to a physician.
- A subcontractor providing remote backup services of PHI data for an IT contractor-business associate of a health care provider.

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**Continuing Enforcement Issue:  
Incomplete or Inaccurate Risk Analysis**

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the [organization]. See 45 C.F.R. § 164.308(a)(1)(ii)(A).
- Organizations frequently underestimate the proliferation of ePHI within their environments. When conducting a risk analysis, an organization must identify all of the ePHI created, maintained, received or transmitted by the organization.
- Examples: Applications like EHR, billing systems; documents and spreadsheets; database systems and web servers; fax servers, backup servers; etc.); Cloud based servers; Medical Devices Messaging Apps (email, texting, ftp); Media

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**Risk Analysis Guidance**



- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html>
- <http://scap.nist.gov/hipaa/>
- <http://www.healthit.gov/providers-professionals/security-risk-assessment>

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**Continuing Enforcement Issue:  
Failure to Manage Identified Risk**

- The Risk Management Standard requires the “[implementation of] security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with [the Security Rule].” See 45 C.F.R. § 164.308(a)(1)(ii)(B).
- Investigations conducted by OCR regarding several instances of breaches uncovered that risks attributable to a reported breach had been previously identified as part of a risk analysis, but that the breaching organization failed to act on its risk analysis and implement appropriate security measures.
- In some instances, encryption was included as part of a remediation plan; however, activities to implement encryption were not carried out or were not implemented within a reasonable timeframe as established in a remediation plan.

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**Mobile Device Security**



<http://www.healthit.gov/mobiledevices>

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**Continuing Enforcement Issue:  
Lack of Transmission Security**

- When electronically transmitting ePHI, a mechanism to encrypt the ePHI must be implemented whenever deemed appropriate. See 45 C.F.R. § 164.312(e)(2)(ii).
- Applications for which encryption should be considered when transmitting ePHI may include:
  - Email
  - Texting
  - Application sessions
  - File transmissions (e.g., ftp)
  - Remote backups
  - Remote access and support sessions (e.g., VPN)

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**Continuing Enforcement Issue:  
Lack of Appropriate Auditing**

- The HIPAA Rules require the “[implementation] of hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.” See 45 C.F.R. § 164.312(b).
- Once audit mechanisms are put into place on appropriate information systems, procedures must be implemented to “regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.” See 45 C.F.R. § 164.308(a)(1)(ii)(D).
- Activities which could warrant additional investigation:
  - Access to PHI during non-business hours or during time off
  - Access to an abnormally high number of records containing PHI
  - Access to PHI of persons for which media interest exists
  - Access to PHI of employees

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**Continuing Enforcement Issue:  
Patching of Software**

- The use of unpatched or unsupported software on systems which access ePHI could introduce additional risk into an environment.
- Continued use of such systems must be included within an organization’s risk analysis and appropriate mitigation strategies implemented to reduce risk to a reasonable and appropriate level.
- In addition to operating systems, EMR/PM systems, and office productivity software, software which should be monitored for patches and vendor end-of-life for support include:
  - Router and firewall firmware
  - Anti-virus and anti-malware software
  - Multimedia and runtime environments (e.g., Adobe Flash, Java, etc.)

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**Continuing Enforcement Issue:  
Insider Threat**

- Organizations must “[i]mplement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information ... and to prevent those workforce members who do not have access ... from obtaining access to electronic protected health information,” as part of its Workforce Security plan. See 45 C.F.R. § 164.308(a)(3).
- Appropriate workforce screening procedures could be included as part of an organization’s Workforce Clearance process (e.g., background and OIG LEIE checks). See 45 C.F.R. § 164.308(a)(3)(ii)(B).
- Termination Procedures should be in place to ensure that access to PHI is revoked as part of an organization’s workforce exit or separation process. See 45 C.F.R. § 164.308(a)(3)(ii)(C).

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**Continuing Enforcement Issue:  
Disposal of PHI**

- When an organization disposes of electronic media which may contain ePHI, it must implement policies and procedures to ensure that proper and secure disposal processes are used. See 45 C.F.R. § 164.310(d)(2)(i).
- The implemented disposal procedures must ensure that “[e]lectronic media have been cleared, purged, or destroyed consistent with *NIST Special Publication 800–88: Guidelines for Media Sanitization*, such that the PHI cannot be retrieved.”
- Electronic media and devices identified for disposal should be disposed of in a timely manner to avoid accidental improper disposal.
- Organizations must ensure that all electronic devices and media containing PHI are disposed of securely; including non-computer devices such as copier systems and medical devices.

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**Continuing Enforcement Issue:  
Insufficient Backup and Contingency Planning**

- Organizations must ensure that adequate contingency plans (including data backup and disaster recovery plans) are in place and would be effective when implemented in the event of an actual disaster or emergency situation. See 45 C.F.R. § 164.308(a)(7).
- Leveraging the resources of cloud vendors may aid an organization with its contingency planning regarding certain applications or computer systems, but may not encompass all that is required for an effective contingency plan.
- As reasonable and appropriate, organizations must periodically test their contingency plans and revise such plans as necessary when the results of the contingency exercise identify deficiencies. See 164.308(a)(7)(ii)(D).

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**Questions**

- <http://www.hhs.gov/hipaa>
- Join us on Twitter @hhsocr

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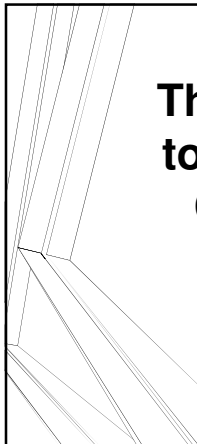
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# The Best Approach to Design Effective Corrective Action Plans (CAP)

Deann Baker, Compliance Officer, Sutter Health  
Christos G. Arvanitis, Compliance Officer, Sutter Health

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## Disclaimer

The views shared today are not necessarily the view of our organizations and are our personal views.

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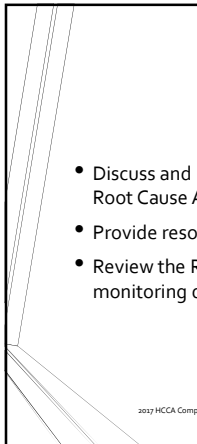
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## Overview

- Discuss and review the CMS Guidance for Performing Root Cause Analysis (RCA)
- Provide resources tools and techniques
- Review the RCA, Corrective Action Plan (CAP) and monitoring documentation best practices

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## Background - Compliance Program Effectiveness

**US Federal Sentencing Guidelines (Ch. 8): Effective Compliance and Ethics Programs**

- Exercise due diligence to prevent and detect criminal conduct
- Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law
- After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.

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## Root Cause Analysis Background

- A method to identify underlying cause(s) of a failure(s).
- Assists in identification of solutions to mitigate further instances of failure.
- Provides a systematic organized and unbiased approach to evaluate causes.
- A structured facilitated team process.

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## Root Cause Analysis Steps

Steps	Explanation
1. Identify the event to be investigated and gather preliminary information	Events and issues can come from many sources (e.g., incident report, risk management referral, resident or family complaint, health department citation). The facility should have a process for selecting events that will undergo an RCA.
2. Charter and select team facilitator and team members	Leadership should provide a project charter to launch the team. The facilitator is appointed by leadership. Team members are people with personal knowledge of the processes and systems involved in the event to be investigated.
3. Describe what happened	Collect and organize the facts surrounding the event to understand what happened.
4. Identify the contributing factors	The situations, circumstances or conditions that increased the likelihood of the event are identified.
5. Identify the root causes	A thorough analysis of contributing factors leads to identification of the underlying process and system issues (root causes) of the event.
6. Design and implement changes to eliminate the root causes	The team determines how best to change processes and systems to reduce the likelihood of another similar event.
7. Measure the success of changes	Like all improvement projects, the success of improvement actions is evaluated.

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### Describe What Happened

- Everyone should be in agreement that they have the information necessary to accurately define what happened.
- The five whys helps ensure nothing is missed and that everything is factual about the event.
- Be careful about leaping to conclusions and solutions!



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### Contributing Factors

- First need to understand the facts surrounding the event that lead to the problem.
- Assess what conditions existed to produce the effect.
- Assess sequence of events to understand the condition that influenced the effect or effects of the problem. Interview those involved in the incident.

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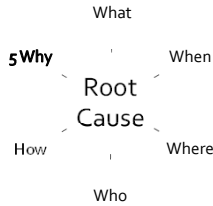
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### Technique – Root Cause Analysis



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### Root Cause and The 5 Why's

<b>Problem Statement</b>	<b>One sentence description of event or problem:</b> <i>Your 14 year old received a D in geometry.</i>
Why? →	Because not all the assignments were turned in.
Why? →	Because the assignments were incomplete.
Why? →	Because geometry is a struggle to understand.
Why? →	Because it is necessary to ask for additional support.
Why? →	Because it is embarrassing to get more classroom support.
Root Cause(s)	Your 14 year old is afraid to ask for help because they're embarrassed for struggling with geometry and they've never struggled before.
Corrective Actions	Get a Tutor to work with your teenager.  <b>To validate root causes, ask the following: If you removed this root cause, would this event or problem have been prevented?</b>

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### Scenario

- The Hospital's Director of Patient Financial Services informs you that they have received a letter from a Recovery Audit Contractor (RA) requesting a refund for \$500,000 overpayment and that they exceeded 60 day overpayment rule.
- You contact the Health Information Management (HIM) Director to inquire if CMS made any record requests.
- The Director of HIM discloses that CMS requested 20 records a few months back and then a few months later requested an additional 100 records.
- The focus of the audit was for 96 hours of ventilation services.
- You contact Coding leadership to inquire about any recent DRG audits from the RACs. They confirm the recent activity and that they are working on a coding education plan for mechanical vent procedure code.

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### Root Cause and The 5 Why's

<b>Problem Statement</b>	<b>One sentence description of event or problem:</b> <i>A letter from CMS regarding an overpayment of \$500,000.00 for incorrect billing of ventilation services was not repaid within 60 days of identification.</i>
Why? →	The ventilation services were incorrectly coded.
Why? →	The ventilation hours were incorrectly counted.
Why? →	The Coders were struggling with workload.
Why? →	The Coders have productivity requirements to meet.
Why? →	The Coders were new to the organization and coding for this service.
Root Cause(s)	1. Discussion 2. Discussion
	To validate root causes, ask the following: If you removed this root cause, would this event or problem have been prevented?

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## Cause and Affect Diagrams

A technique that helps think through all of the possible causes and complete a thorough analysis.

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## Intake - Assessment - Reporting

- Key information to build a Corrective Action Plan (CAP)
  - Understand and define your Root Cause(s)
  - Define the factors of Root Cause(s):
    - Regulatory
    - Environmental
    - Equipment
    - Processes/activities
    - Human
  - Define the mitigation of each effect

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## Sample Tool

Incident Overview					Initial Assessment of Weaknesses		
Describe Incident	Report Origin	Incident Date	Risk Rank	Program Areas	Describe Activities evaluated	Describe Factors (Physical, Human or Organizational)	Describe Data/Records Assessment

Final Assessment, Conclusions & Mitigation				
Problem Statement	Mitigation Activities (education, revise or create policies, repayment or disclosure)	Define Responsible Person, Activities and Timelines	Describe Reporting Oversight & Frequency	Describe Monitoring and Timelines

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## Corrective Action Plan

- Corrective Action Plan
  - Define the cause and effects
  - Management to develop the CAP
  - Compliance to approve the CAP
  - CAP elements
    - Assignment of responsibilities of mitigation of effects
    - Define effects, mitigation and timelines to address effects
    - Reporting structure to provide status of mitigation
  - Compliance establish a time to monitor results (did the fix stick?)



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## Accountability for Success

**Establish the Expectation & Processes of RCA & CAP**

- Development of policies and toolkits
- Communicate benefits and alignment with corporate strategy
- Define accountability

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## Accountability Helps Build Trust

- "An organization that wants to empower its team members doesn't give out power haphazardly, like writing blank checks. Instead, empowerment needs to come with terms attached, so people *know how their results will be measured. Trust grows*, on the other hand, when *expectations are clear*, when people know what they've been empowered to do, and when they can focus on doing it."

"Joel Peterson, Chairman, JetBlue Airways"

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## Promote a Compliant & Ethical Culture

Incentivize, Performance, and Culture

The USFSG's state, "The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program".

PROMOTING RESPONSIBLE  
& ETHICAL BEHAVIOUR

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## Incentives Considerations

**Strategy:** Increase Corporate Responsibility and Commitment.

**Risk:** Compliance risks not mitigated may lead to fines, penalties, and loss of reputation.

**Goal:** Reward and recognize involvement in RCAs and successful implementation of CAPs.

**Performance Measures:** % CAPs completed and implemented effectively OR % of participation in training or acknowledgments of policies as part of CAP.

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## Tools and Resources



- Guidance resources:
  - ThinkReliability <https://www.thinkreliability.com>
  - AHRQ (Agency for Healthcare Research and Quality) <https://healthit.ahrq.gov/health-it-tools-and-resources/workflow-assessment-health-it-toolkit/all-workflow-tools/flowchart>
  - Quality Assurance (QA) and Performance Improvement (PI) <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework.pdf>
  - MindTools [https://www.mindtools.com/pages/article/newTMC\\_80.htm](https://www.mindtools.com/pages/article/newTMC_80.htm)

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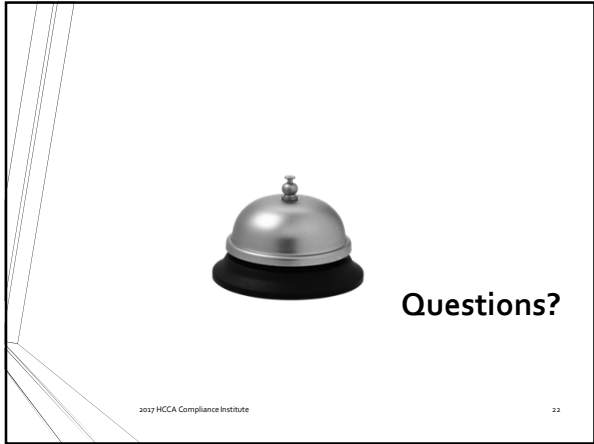
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**Overview:** Root cause analysis is a structured team process that assists in identifying underlying factors or causes of an adverse event or near-miss. Understanding the contributing factors or causes of a system failure can help develop actions that sustain the correction.

A cause and effect diagram, often called a “fishbone” diagram, can help in brainstorming to identify possible causes of a problem and in sorting ideas into useful categories. A fishbone diagram is a visual way to look at cause and effect. It is a more structured approach than some other tools available for brainstorming causes of a problem (e.g., the Five Whys tool). The problem or effect is displayed at the head or mouth of the fish. Possible contributing causes are listed on the smaller “bones” under various cause categories. A fishbone diagram can be helpful in identifying possible causes for a problem that might not otherwise be considered by directing the team to look at the categories and think of alternative causes. Include team members who have personal knowledge of the processes and systems involved in the problem or event to be investigated.

### **Directions:**

The team using the fishbone diagram tool should carry out the steps listed below.

- Agree on the problem statement (also referred to as the effect). This is written at the mouth of the “fish.” Be as clear and specific as you can about the problem. Beware of defining the problem in terms of a solution (e.g., we need more of something).
- Agree on the major categories of causes of the problem (written as branches from the main arrow). Major categories often include: equipment or supply factors, environmental factors, rules/policy/procedure factors, and people/staff factors.
- Brainstorm all the possible causes of the problem. Ask “Why does this happen?” As each idea is given, the facilitator writes the causal factor as a branch from the appropriate category (places it on the fishbone diagram). Causes can be written in several places if they relate to several categories.
- Again asks “Why does this happen?” about each cause. Write sub-causes branching off the cause branches.
- Continues to ask “Why?” and generate deeper levels of causes and continue organizing them under related causes or categories. This will help you to identify and then address root causes to prevent future problems.

### **Tips:**

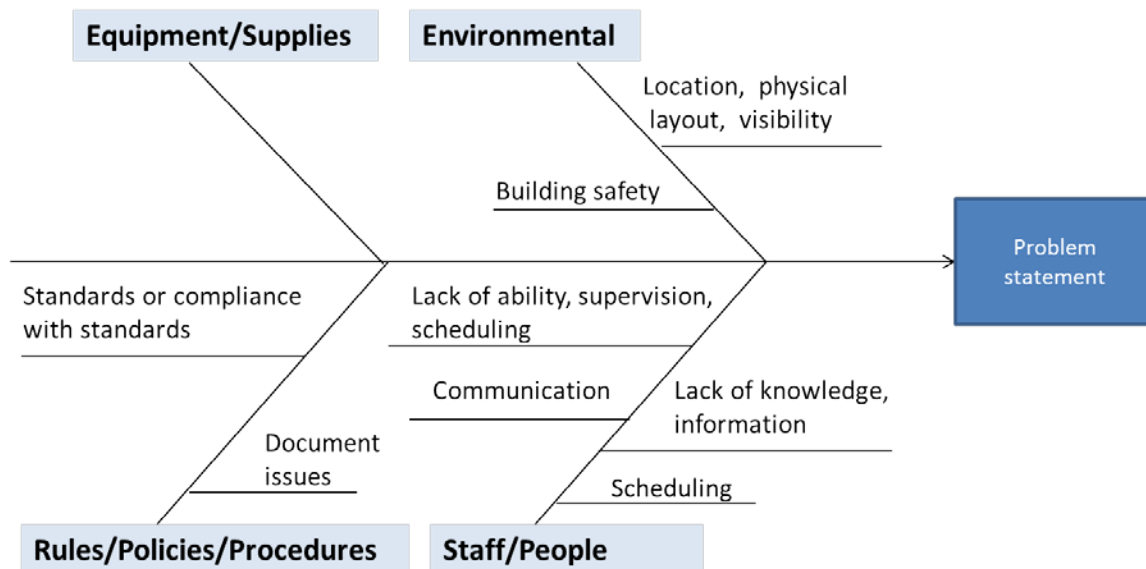
- Use the fishbone diagram tool to keep the team focused on the causes of the problem, rather than the symptoms.
- Consider drawing your fish on a flip chart or large dry erase board.
- Make sure to leave enough space between the major categories on the diagram so that you can add minor detailed causes later.
- When you are brainstorming causes, consider having team members write each cause on sticky notes, going around the group asking each person for one cause. Continue going through the rounds, getting more causes, until all ideas are exhausted.

**Disclaimer:** Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.

- Encourage each person to participate in the brainstorming activity and to voice their own opinions.
- Note that the “five-whys” technique is often used in conjunction with the fishbone diagram – keep asking why until you get to the root cause.
- To help identify the root causes from all the ideas generated, consider a multi-voting technique such as having each team member identify the top three root causes. Ask each team member to place three tally marks or colored sticky dots on the fishbone next to what they believe are the root causes that could potentially be addressed.

**Examples:**

Here is an example of the start of a fishbone diagram that shows sample categories to consider, along with some sample causes.

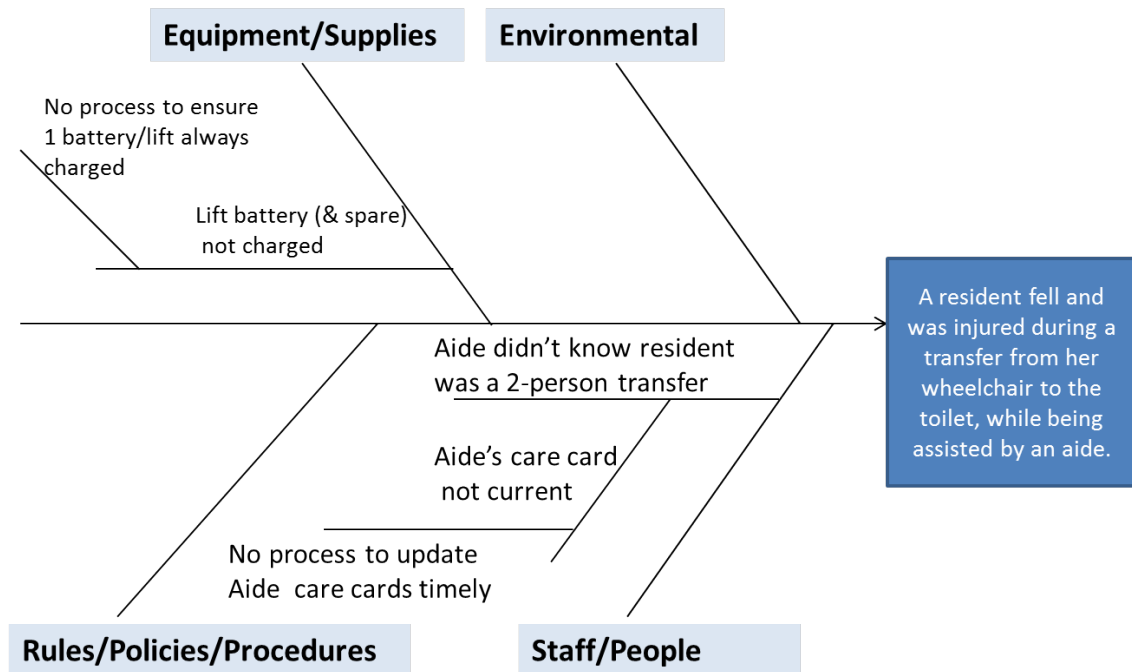


Here is an example of a completed fishbone diagram, showing information entered for each of the four categories agreed upon by this team. Note, as each category is explored, teams may not always identify problems in each of the categories.

**Facts gathered during preliminary investigation:**

- Time of fall: change of shift from days to evenings
- Location of fall: resident’s bathroom
- Witnesses: resident and aide
- Background: the plan of care stipulated that the resident was to be transferred with two staff members, or with one staff member using a sit-to-stand lift.
- Information from interviews: the resident was anxious and needing to use the bathroom urgently. The aide was helping the resident transfer from her wheelchair to the toilet, without using a lift, and the resident fell, sustaining an injury. The aide stated she did not use the lift because the battery was being recharged, and there was no extra battery available. The aide stated she understood that the resident could be transferred with assist of one.
-

With this information, the team proceeded to use the fishbone diagram to better understand the causes of the event.



The value of using the fishbone diagram is to dig deeper, to go beyond the initial incident report, to better understand what in the organization's systems and processes are causing the problem, so they can be addressed.

In this example, the root causes of the fall are:

- There is no process in place to ensure that every lift in the building always has a working battery. (One battery for the lift on this unit is no longer working, and the other battery was being recharged.)
- There is no process in place to ensure timely communication of new care information to the aides. (New transfer information had not yet been conveyed to the aide. The aide's "care card" still indicated transfer with assist of one for this resident.)

The root causes of the event are the underlying process and system problems that allowed the contributing factors to culminate in a harmful event. As this example illustrates, there can be more than one root cause. Once you have identified root causes and contributing factors, you will then need to address each root cause and contributing factor as appropriate. For additional guidance on following up on your fishbone diagram findings, see the [Guidance for Performing RCA with Performance Improvement Projects tool](#).



## Five Elements

### Element 1: Design and Scope

A QAPI program must be ongoing and comprehensive, dealing with the full range of services offered by the facility, including the full range of departments. When fully implemented, the QAPI program should address all systems of care and management practices, and should always include clinical care, quality of life, and resident choice. It aims for safety and high quality with all clinical interventions while emphasizing autonomy and choice in daily life for residents (or resident's agents). It utilizes the best available evidence to define and measure goals. Nursing homes will have in place a written QAPI plan adhering to these principles.

### Element 2: Governance and Leadership

The governing body and/or administration of the nursing home develops a culture that involves leadership seeking input from facility staff, residents, and their families and/or representatives. The governing body assures adequate resources exist to conduct QAPI efforts. This includes designating one or more persons to be accountable for QAPI; developing leadership and facility-wide training on QAPI; and ensuring staff time, equipment, and technical training as needed. The Governing Body should foster a culture where QAPI is a priority by ensuring that policies are developed to sustain QAPI despite changes in personnel and turnover. Their responsibilities include, setting expectations around safety, quality, rights, choice, and respect by balancing safety with resident-centered rights and choice. The governing body ensures staff accountability, while creating an atmosphere where staff is comfortable identifying and reporting quality problems as well as opportunities for improvement.

### Element 3: Feedback, Data Systems and Monitoring

The facility puts systems in place to monitor care and services, drawing data from multiple sources. Feedback systems actively incorporate input from staff, residents, families, and others as appropriate. This element includes using Performance Indicators to monitor a wide range of care processes and outcomes, and reviewing findings against benchmarks and/or targets the facility has established for performance. It also includes tracking, investigating, and monitoring Adverse Events that must be investigated every time they occur, and action plans implemented to prevent recurrences.

### Element 4: Performance Improvement Projects (PIPs)

A Performance Improvement Project (PIP) is a concentrated effort on a particular problem in one area of the facility or facility wide; it involves gathering information systematically to clarify issues or problems, and intervening for improvements. The facility conducts PIPs to examine and improve care or services in areas that the facility identifies as needing attention. Areas that need attention will vary depending on the type of facility and the unique scope of services they provide.

### Element 5: Systematic Analysis and Systemic Action

The facility uses a systematic approach to determine when in-depth analysis is needed to fully understand the problem, its causes, and implications of a change. The facility uses a thorough and highly organized/ structured approach to determine whether and how identified problems may be caused or exacerbated by the way care and services are organized or delivered. Additionally, facilities will be expected to develop policies and procedures and demonstrate proficiency in the use of Root Cause Analysis. Systemic Actions look comprehensively across all involved systems to prevent future events and promote sustained improvement. This element includes a focus on continual learning and continuous improvement.

## Guidance for Performing Root Cause Analysis (RCA) with Performance Improvement Projects (PIPs)



**Overview:** RCA is a structured facilitated team process to identify root causes of an event that resulted in an undesired outcome and develop corrective actions. The RCA process provides you with a way to identify breakdowns in processes and systems that contributed to the event and how to prevent future events. The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made. It can be an early step in a PIP, helping to identify what needs to be changed to improve performance. Once you have identified what changes need to be made, the steps you will follow are those you would use in any type of PIP. Note there are a number of tools you can use to perform RCA, described below.

**Directions:** Use this guide to walk through a Root Cause Analysis (RCA) to investigate events in your facility (e.g., adverse event, incident, near miss, complaint). Facilities accredited by the Joint Commission or in states with regulations governing completion of RCAs should refer to those requirements to be sure all necessary steps are followed.

Below is a quick overview of the steps a PIP team might use to conduct RCA.

Steps	Explanation
1. Identify the event to be investigated and gather preliminary information	Events and issues can come from many sources (e.g., incident report, risk management referral, resident or family complaint, health department citation). The facility should have a process for selecting events that will undergo an RCA.
2. Charter and select team facilitator and team members	Leadership should provide a project charter to launch the team. The facilitator is appointed by leadership. Team members are people with personal knowledge of the processes and systems involved in the event to be investigated.
3. Describe what happened	Collect and organize the facts surrounding the event to understand what happened.
4. Identify the contributing factors	The situations, circumstances or conditions that increased the likelihood of the event are identified.
5. Identify the root causes	A thorough analysis of contributing factors leads to identification of the underlying process and system issues (root causes) of the event.
6. Design and implement changes to eliminate the root causes	The team determines how best to change processes and systems to reduce the likelihood of another similar event.
7. Measure the success of changes	Like all improvement projects, the success of improvement actions is evaluated.

Steps two through six should be completed as quickly as possible. For facilities accredited by the Joint Commission, these steps must be completed within 45 days of occurrence of the event.

## Step 1: Select the event to be investigated and gather preliminary information

Events that may be investigated using the RCA process can be identified from many sources (e.g., incident report, risk management referral, staff, resident, or family feedback, health department citation). High priority should be given to events that resulted in significant resident harm or death and other events the facility is required by regulation to investigate. Also consider doing an RCA for “near miss” or “close call” events that could have resulted in harm to the resident, but did not, either by chance or timely intervention. The latter types of events represent high risk situations that could, in the future, cause a resident to be harmed.

Once an event is selected for a Performance Improvement Project (PIP) involving RCA, someone involved in the facility QAPI program can begin gathering preliminary information, including the incident report and any documentation from the preliminary investigation, for later discussion by the team. This may include interviews with those involved including the resident or family members, collection of pertinent documentation or photographs, review of relevant policies and procedures, quarantine of defective equipment, etc. This preliminary information is also useful for deciding which individuals should be invited to serve as members of the team as described in Step 2.

### ✓ Helpful Tips:

- Involve facility leaders in the prioritization and decision to proceed with an RCA. There will be greater cooperation in completing RCAs when the process is viewed as leadership-driven.
- Be sure to start with a problem and not the solution. It is tempting to assume we know what will fix the problem before we’ve thoroughly examined it. Assumptions are often wrong and may hinder complete analysis of the underlying causes.
- Don’t define the problem as a need for something. The problem statement should objectively state what went wrong, not why, or how. An example of an effective problem statement is, “Resident X continued to receive a medication one week after the order was given for discontinuation.” A good problem statement will facilitate a more thorough examination of the problem.
- If the event represents a liability concern or questionable practices by an employee, the leadership team can initiate a risk management review or an employee performance review to start simultaneous with, but separate, from the RCA process. The RCA process should focus on systems rather than individual performance.

## Step 2: Select the event to be investigated and gather preliminary information

Next, leadership designates a facilitator for the PIP team, and works with the facilitator to create a charter that will help guide the team in managing the scope of the project and making changes that are ultimately linked to the root causes identified in the RCA process. Together, leadership and the facilitator select staff to participate on the PIP team.

As managers and supervisors gain experience in doing RCAs, more people in the facility can be trained to serve as team facilitators. The facilitator is responsible for assembling and managing the team, guiding the analysis, documenting findings and reporting to the appropriate persons.

The number of team members depends on the scope of the investigation. Individuals selected to serve as team members must be familiar with the processes and systems associated with the event. People who have personal knowledge of what actually happened should be included as team members or given an opportunity to contribute to the investigation through interviews.

✓ Helpful Tips:

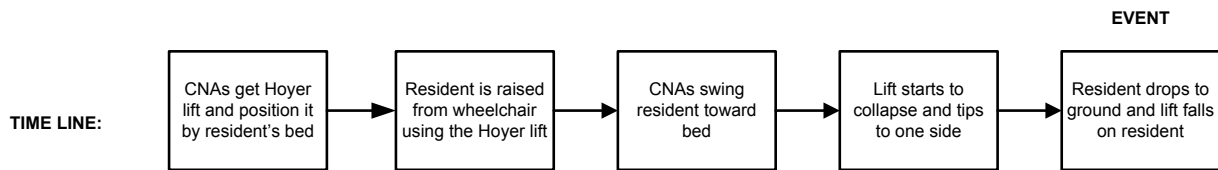
- Team members should be selected for their ability to discuss and review what happened during the event in an objective and unbiased manner. In some situations, staff members personally involved in the event are the best people to serve as team members. In other situations, staff members not personally involved in the event are the best people to serve as team members with the people personally involved asked to share their experience during interviews. This may be appropriate if the people directly involved in the event are dealing with emotions and are not able to be objective. However, if this is the case, it is a good idea to provide those staff persons directly involved with counseling and support so that they are able to participate in the RCA process. Participating in the RCA process and hearing other's objective viewpoints can help them to deal with the situation in a positive manner.
- Keep the number of management or supervisory level individuals on the team to a minimum. Staff members may be inhibited from speaking up or being completely candid during discussions about what happened if their direct supervisor is in the room. If this is not possible, the facilitator should explain the need for members to be free to discuss the process honestly, as it is actually carried out in the facility.
- Make it clear to everyone involved that the RCA process is confidential. This reassurance helps people feel safer discussing the process and system breakdowns that may have caused an inadvertent mistake.

### Step 3: Describe what happened

At the first meeting of the team, a time line of the event under review is created. The preliminary information gathered in step 1 is shared with the team and other details about the event are elicited from team members. If the people personally involved in the event are not part of the team, their comments about what happened are shared with team members. All of this information is used to create a time line of the event – the sequence of steps leading up to the harmful event.

Below is a time line for a situation involving a resident that suffered a serious injury during his transfer from a wheelchair back to his bed. This tall and larger man (300-pound) was placed in a Hoyer lift and elevated into the air above his wheelchair. As the CNAs turned the lift toward the bed it began to sink because the lift arm couldn't handle the resident's weight. In an attempt to complete the transfer before the patient was below the level of the bed, the CNAs swung the lift quickly toward the bed. The lift tilted dangerously to the side and the legs started to move together, narrowing the base of support. The resident dropped to the ground and the lift fell on top of him.





Use a flipchart or sticky notes to draw a preliminary time line. Before proceeding to Step 4 of the RCA, be sure that everyone agrees that the time line represents what actually happened. Now is the time for the team to add missing steps or clarify “factual” inconsistencies about the event.

✓ Helpful Tips:

- The time line of the event should describe just the facts – not what caused the facts to happen. For instance, the CNAs may have mistakenly used a Hoyer lift that was not strong enough to move a tall resident weighing 300 lbs. This factor may have contributed to the event, but it is not documented in the time line. Only the facts of what happened should be included in the time line, the causal factors are added in a later step.
- Once the preliminary time line has been created, the facilitator finalizes the time line by asking the team:
  - Does the time line adequately tell the "story" of the incident? If not, the scope of the timeline may need to be extended further back in time or expanded to include what happened after the event.
  - Does each step in the time line derive directly from the step it precedes? If each step is not derived logically from the one preceding it, it usually indicates that one or more steps in the sequence have been left out. Add missing steps to the time line.
  - Is each step in the timeline pertinent to the incident under investigation? The answer may be "yes", "no," or "not sure." Include only the "yes" and "not sure" steps in the final event line.
- In rare situations the team cannot identify a sequence of steps leading up to the harmful event. For instance, when a resident develops an intravenous (IV) catheter–related infection it may not be possible to pinpoint the exact steps preceding the infection event. The infection appears to have occurred despite staff members apparently doing all the right things (e.g., following good hygiene when inserting catheters and caring for catheterized residents). In these situations, a time line is not created – however don’t jump to this conclusion too quickly. It is harder to find all the root causes of an undesirable event if the team does not have a time line to guide their decisions.
- Resist the temptation to skip right to step 5 of the RCA process, which is “Identify the root causes.” Team members may insist the root causes of the event are already understood and it is not necessary to go through steps 2 through 4. Jumping to conclusions about root causes increases the likelihood the team will end up with “quick-fix” solutions that do not address the underlying systems gaps, or contributing factors, and fail to prevent similar events in the future.

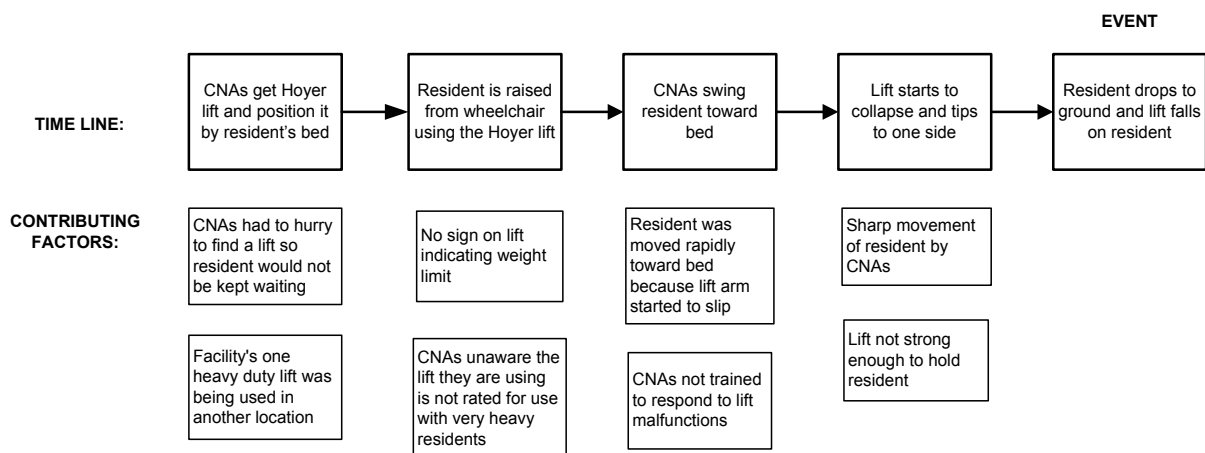
## Step 4: Identify the contributing factors

Here is where the knowledge gained during step 3 is used by the team to dig deeper into what happened to discover why it happened.

Step 4 involves the team looking at each step of time line and asking, “What was going on at this point in time that increased the likelihood the event would occur?” These are the contributing factors – situations, circumstances or conditions that collectively increased the likelihood of an incident. By itself a contributing factor may not have caused the incident, but when they occur at the same time, the probability an incident will occur increases.

As mentioned in Step 2, it is important to get the perspective of people personally involved in the event when identifying the contributing factors at each step. These may be the only individuals aware of the actual circumstances affecting what happened. For instance, the CNA who chose the wrong type of lift might have felt pressured by her supervisor to find a lift as quickly as possible so the resident would not be kept waiting. Team members not personally involved in the event might be unaware this contributing factor existed.

Below are examples of contributing factors that might be identified for each step of the time line for the event involving a resident injury during transfer from wheelchair to bed.



### ✓ Helpful Tips:

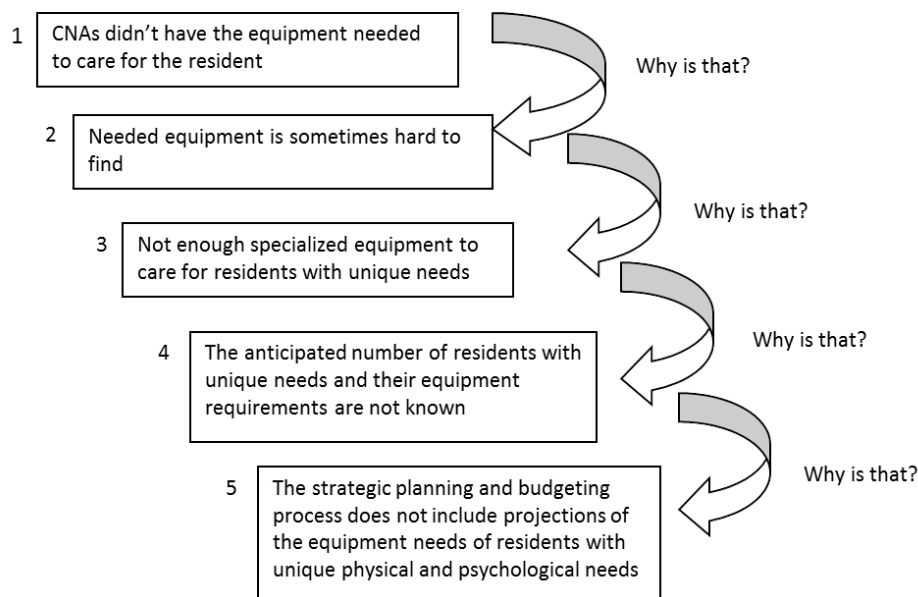
- Consider what was happening at each step in the time line to ensure the team does not overlook some important factors. Whenever possible, use a time line as the basis for identifying contributing factors.
- Brainstorming can be an effective tool to identify contributing factors by asking, “What might have happened that would increase the likelihood the event would occur?” Consider what recommended practices might not have been followed, e.g. sterile dressing changes not done for IV-catheter sites. Consider what procedure “work-arounds” might have occurred. Consider how staffing at the time of the event might have impacted the eventual outcome.
- When identifying contributing factors be careful to avoid “hindsight bias.” Knowing the eventual outcome of a time line can influence how team members view activities leading up to the event. Remember to consider only those factors that were actually present and known to those involved at the time – not what was only realized after-the-fact.

## Step 5: Identify the root causes

All incidents have a direct cause. This is the occurrence or condition that directly produced the incident. In the resident incident described in Step 3, the tilting and collapsing Hoyer lift is the direct cause of the accident. However, the direct cause is not the root cause.

Root causes are underlying faulty process or system issues that lead to the harmful event. Often there are several root causes for an event.

Contributing factors are not root causes. The team needs to examine the contributing factors to find the root causes. This can be done by digging deeper – asking repeated “why” questions of the contributing factors. This is called the “five why’s” technique, which is illustrated below.



This questioning process is continued until all the root causes are found. It is common to find the same root cause for two or more contributing factors.

### ✓ Helpful Tips:

- The team must determine if they’ve truly identified a root cause, versus a contributing factor which requires the team to do more digging. Ask the questions below about each potential root cause identified by the team. If the answers are NO, then the team has identified root causes and they can stop the questioning process. If the answer to any question is YES, then the team may not have identified true root causes and needs to ask more “why” questions to get to the root causes. Keep asking these until you get to root causes.
  - Would the event have occurred if this cause had not been present?
  - Will the problem recur if this cause is corrected or eliminated?
- The team should not make judgments about whether an individual did the right thing. This judgment is to be made by the manager responsible for evaluating the employee’s performance. The facilitator may need to remind team members that the RCA process is not where these judgments are to be made.

- The team facilitator should watch out for discussion “manipulation” during this stage. Some team members may try to divert attention from root causes originating in their department or direct the discussion away from root causes that will require additional resources or necessitate significant changes to how work is now being done. A successful RCA process requires frank and open discussions of the causes of the event.
- A fishbone diagram can also be used to determine root causes; see the CMS QAPI website for more information on this tool.

## Step 6: Design and implement changes to eliminate the root causes

In this step the team evaluates each root cause to determine how best to reduce or prevent it from triggering another harmful event. The key is to choose actions that address each root cause. These actions will generally require creating a new process or making a change to a current process. The steps to accomplish this are the same as those used in any type of PIP. Note that at this point, you may want to reevaluate the composition of your team to make sure you have included people who are part of the process being changed. It is a good idea throughout a project to make sure you have the right people on the team and to adjust membership as needed.

At least one corrective action should be developed to reduce or eliminate each root cause. Some action plans will be short-term solutions to fix a contributing factor, e.g. purchase an additional Hoyer lift rated for use by residents weighing over 250 lbs. But short-term solutions rarely fix root causes. For instance, in the example event the team also needs to recommend that a formal evaluation of future specialized equipment needs for residents be regularly incorporated into the facility strategic planning and budgeting process.

When developing corrective actions consider questions such as:

- What safeguards are needed to prevent this root cause from happening again?
- What contributing factors might trigger this root cause to reoccur? How can we prevent this from happening?
- How could we change the way we do things to make sure that this root cause never happens?
- If an event like this happened again, how could we stop the accident trajectory (quickly catch and correct the problem) before a resident was harmed?
- If a resident were harmed by this root cause, how could we minimize the effect of the failure on the resident?

Aim for corrective actions with a stronger or intermediate rating, based on the categories of actions below. Corrective actions that change the system and do not allow the errors to occur are the strongest.

### Stronger Actions

- Change physical surroundings
- Usability testing of devices before purchasing
- Engineering controls into system (forcing functions which force the user to complete an action)
- Simplify process and remove unnecessary steps
- Standardize equipment or process

- Tangible involvement and action by leadership in support of resident safety; i.e., leaders are seen and heard making or supporting the change

### Intermediate Actions

- Increase staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions
- Checklist/cognitive aid
- Eliminate look alike and sound alike terms
- “Read back” to assure clear communication
- Enhanced documentation/communication

### Weaker Actions

- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training
- Additional study/analysis

For example, suppose staff members cannot locate the equipment to use when lifting larger residents, because the specialty equipment is not kept in the same location. The strongest action to prevent another accident would be to keep all equipment designed for special needs residents in just one storage area (change physical surroundings). Staff members will no longer need to differentiate “usual” equipment from “specialized” equipment. If this action is not feasible, consider placing a sign on the lift equipment – *“DO NOT USE FOR RESIDENTS OVER 250 LBS.”* This is an example of a warning or label (sometimes called a visual cue). It is a weak action because staff members might overlook the warning, but if no other stronger action is available, a weak action is better than none at all.

When designing corrective actions, clearly state what is to be done, by whom, and when. Satisfactory implementation of the corrective actions will be monitored so it is important to have clearly defined plans.

#### ✓ Helpful Tips:

- The team leader should encourage team members to come up with as many intermediate and strong actions as possible. It is helpful to involve supervisory and management staff in the action planning discussions. Designing intermediate and strong actions often requires an understanding of various resident care systems and the facility’s resource allocation priorities. Staff members on the team may not possess this knowledge.
- Because the feasibility and costs associated with corrective actions must also be considered it is helpful to include facility management in the corrective action discussions, if they are not already members of the team.
- If a particular action cannot be accomplished due to current constraints (e.g. lack of resources), the team should look for other ways of changing the process to prevent a similar event from occurring in the future. Doing nothing should not be an option.

## Step 7: Measure the success of changes

Concurrent with implementation of action plans, mechanisms are established to gather data that will be used to measure the success of the corrective action. The RCA should reduce the risk of future harmful events by minimizing or eliminating the root causes. What you measure should provide answers to three questions:

1. Did the recommended corrective actions actually get done? (e.g., Did the warning signs get put on the Hoyer lifts? Did a formal equipment evaluation step get added to the annual budgeting process?)
2. Are people complying with the recommended changes (e.g., How often is the wrong type of Hoyer lift used for residents weighing over a predetermined weight? Is staff provided an opportunity to participate in an equipment needs assessment during the budgeting process?)
3. Have the changes made a difference? (Has another resident been harmed by equipment unsuited for their physical condition?)

Evaluating the success of the PIP usually occurs after the team has been disbanded, and will become the responsibility of the person designated to monitor the corrective action/s. The QAA committee is responsible for overseeing all QAPI activities, which includes reviewing data on the effectiveness of all improvement projects. Ideally, all of the following criteria should be met to conclude a PIP has been successful:

- Measures of success were monitored over time.
- The goal was attained (process changes were made and sustained, no recurrent events).
- You are confident that the change is permanent.

## RCA PIP Template

This template can be used to document the completed RCA PIP process, including follow-up actions and measures. Revise it as necessary to meet your needs.

**Team Facilitator:** \_\_\_\_\_ **Date RCA Started:** \_\_\_\_\_ **Date Ended:** \_\_\_\_\_

### Team Members:

Name	Position	Name	Position

**Brief Narrative Description of Event** (include time line if available):

### Root Causes and Contributing Factors

Conduct your systematic analyses to determine your contributing factors and root causes. Use techniques such as the five whys, flowcharting, or the fishbone diagram to assist in identifying the root causes. Additional tools are available that guide the use of each of these techniques. It is helpful to keep any of these analyses with your PIP documentation for future reference. Describe each root cause as identified by the team. Enter these in the table below.

### Corrective Action Plans

For each root cause identified, enter the corrective action plans intended to prevent the root cause from causing another harmful event. There can be more than one action plan for each root cause. Some action plans may be short-term interventions which can be accomplished quickly and some action plans require more long-term implementation steps. For each action plan designate the individual or group responsible for completing the action and the time frame for completion.

Root Cause	Corrective Action	Responsible Individual/Group	Completion Deadline



## Measures of Success

Corrective Action	<b>Measures of Success (How we will know if this action is successful)</b> Consider measures of how often recommended processes are not followed and the incidence of similar adverse events.	<b>Reporting Schedule and Individual or Group Responsible for Reviewing Results</b>

Signature of RCA team leader \_\_\_\_\_ Date \_\_\_\_\_

Acknowledgement: This guide draws on information from the *VHA National Patient Safety Improvement Handbook* (March 2011), *Error Reduction in Health Care: A Systems Approach to Improving Patient Safety*, 2<sup>nd</sup> ed. (Jossey-Bass, 2011) and the *Minnesota Adverse Health Events Measurement Guide* (Minnesota Department of Health, 2010).

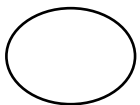
**Overview:** Performance Improvement Project (PIP) teams frequently must study an existing or new process in order to better understand each step and identify where improvements can be made. A flowchart is a tool that allows you to break any process down into individual events or activities and shows the logical relationships between them. Flowcharting is often used by PIP teams when conducting root cause analysis (RCA) and/or failure mode effects analysis (FMEA) (See [Guidance for Performing RCA with PIPs](#), and/or [Guidance for Performing FMEA with PIPs](#)).

### A flowchart:

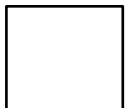
- Facilitates the team's common understanding of the steps in a process
- Highlights decision points and decision outcomes
- Helps a team understand whether a process occurs in one or multiple ways
- Promotes system-thinking about how the work is made up of interacting steps
- Provides visualization of complexity, rework, and problem areas; this insight can suggest where simplification, elimination of unnecessary steps, and standardization may be possible
- Enables comparison of the way the process actually occurs with the planned or ideal flow

### How do you develop a flowchart?

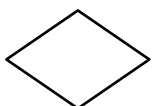
Flowcharts are diagrams that use shapes to show the types and flow of steps in a process. The shapes represent different types of steps or actions.



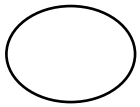
= beginning and end of a process



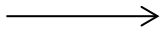
= a task or activity performed in the process



= a decision point (yes/no)



= beginning and end of a process



= direction or flow of the process

To draw the flow chart, brainstorm the steps in the process, and list them in the order they occur. Ask questions such as "What really happens next in the process?" and "Does a decision need to be made before the next step?"

Work through your whole process, showing actions and decisions in the order they occur, linking these together using arrows to show the flow of the process. Decisions are represented as diamonds and reflect a condition that impacts the process (e.g., if yes, then...; if no, then...). At each decision diamond, draw an arrow for each decision outcome. Typically there are two decision outcomes such as, yes/no or true/false. Continue charting the process as it would be performed as a result of the decision.

If you find that your process occurs in multiple ways; i.e., different people or units do things differently, you may want to flow chart the process in each of the different ways it occurs. This can help you to understand what, when, and why variation is occurring, and informs any process improvement changes you plan.

Finally, review your flowchart. Work through each step asking your team if you have correctly represented the sequence of actions and decisions involved in the process. And then (if you're looking to improve the process) look at the steps identified and think about whether work is duplicated, whether other steps should be involved, where gaps or breakdowns occur, where you can make improvements in your process.

**Tips:**

- When developing a flowchart, include people with personal knowledge of the process being discussed.
- Many teams find it easy to flowchart on large poster size sheets, using sticky notes for process steps, or on white boards. This allows you to move steps around and add steps as you define the process.

# QAPI Self-Assessment Tool



**Directions:** Use this tool as you begin work on QAPI and then for annual or semiannual evaluation of your organization’s progress with QAPI. This tool should be completed with input from the entire QAPI team and organizational leadership. This is meant to be an honest reflection of your progress with QAPI. The results of this assessment will direct you to areas you need to work on in order to establish QAPI in your organization. You may find it helpful to add notes under each item as to why you rated yourself a certain way.

Date of Review: \_\_\_\_\_ Next review scheduled for: \_\_\_\_\_

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
<p>Our organization has developed principles guiding how QAPI will be incorporated into our culture and built into how we do our work. For example, we can say that QAPI is a method for approaching decision making and problem solving rather than considered as a separate program.</p> <p>Notes:</p>					
<p>Our organization has identified how all service lines and departments will utilize and be engaged in QAPI to plan and do their work. For example, we can say that all service lines and departments use data to make decisions and drive improvements, and use measurement to determine if improvement efforts were successful.</p> <p>Notes:</p>					
<p>Our organization has developed a written QAPI plan that contains the steps that the organization takes to identify, implement and sustain continuous improvements in all departments; and is revised on an ongoing basis. For example, a written plan that is done purely for compliance and not referenced would not meet the intent of a QAPI plan.</p> <p>Notes:</p>					
<p>Our board of directors and trustees (if applicable) are engaged in and supportive of the performance improvement work being done in our organization. For example, it would be evident from meeting minutes of the board or other leadership meetings that they are informed of what is being learned from the data, and they provide input on what initiatives should be considered. Other examples would be having leadership (board or executive leadership) representation on performance improvement projects or teams, and providing resources to support QAPI.</p> <p>Notes:</p>					

QAPI SELF-ASSESSMENT TOOL

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
<p>QAPI is considered a priority in our organization. For example, there is a process for covering caregivers who are asked to spend time on improvement teams.</p> <p>Notes:</p>					
<p>QAPI is an integral component of new caregiver orientation and training. For example, new caregivers understand and can describe their role in identifying opportunities for improvement. Another example is that new caregivers expect that they will be active participants on improvement teams.</p> <p>Notes:</p>					
<p>Training is available to all caregivers on performance improvement strategies and tools.</p> <p>Notes:</p>					
<p>When conducting performance improvement projects, we make a small change and measure the effect of that change before implementing more broadly. An example of a small change is pilot testing and measuring with one nurse, one resident, on one day, or one unit, and then expanding the testing based on the results.</p> <p>Notes:</p>					
<p>When addressing performance improvement opportunities, our organization focuses on making changes to systems and processes rather than focusing on addressing individual behaviors. For example, we avoid assuming that education or training of an individual is the problem, instead, we focus on what was going on at the time that allowed a problem to occur and look for opportunities to change the process in order to minimize the chance of the problem recurring.</p> <p>Notes:</p>					
<p>Our organization has established a culture in which caregivers are held accountable for their performance, but not punished for errors and do not fear retaliation for reporting quality concerns. For example, we have a process in place to distinguish between unintentional errors and intentional reckless behavior and only the latter is addressed through disciplinary actions.</p> <p>Notes:</p>					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
<p>Leadership can clearly describe, to someone unfamiliar with the organization, our approach to QAPI and give accurate and up-to-date examples of how the facility is using QAPI to improve quality and safety of resident care. For example, the administrator can clearly describe the current performance improvement initiatives, or projects, and how the work is guided by caregivers involved in the topic as well as input from residents and families.</p> <p>Notes:</p>					
<p>Our organization has identified all of our sources of data and information relevant to our organization to use for QAPI. This includes data that reflects measures of clinical care; input from caregivers, residents, families, and stakeholders, and other data that reflects the services provided by our organization. For example, we have listed all available measures, indicators or sources of data and carefully selected those that are relevant to our organization that we will use for decision making. Likewise, we have excluded measures that are not currently relevant and that we are not actively using in our decision making process.</p> <p>Notes:</p>					
<p>For the relevant sources of data we identify, our organization sets targets or goals for desired performance, as well as thresholds for minimum performance. For example, our goal for resident ratings for recommending our facility to family and friends is 100% and our threshold is 85% (meaning we will revise the strategy we are using to reach our goal if we fall below this level).</p> <p>Notes:</p>					
<p>We have a system to effectively collect, analyze, and display our data to identify opportunities for our organization to make improvements. This includes comparing the results of the data to benchmarks or to our internal performance targets or goals. For example, performance improvement projects or initiatives are selected based on facility performance as compared to national benchmarks, identified best practice, or applicable clinical guidelines.</p> <p>Notes:</p>					
<p>Our organization has, or supports the development of, employees who have skill in analyzing and interpreting data to assess our performance and support our improvement initiatives. For example, our organization provides opportunities for training and education on data collection and measurement methodology to caregivers involved in QAPI.</p> <p>Notes:</p>					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
<p>From our identified opportunities for improvement, we have a systematic and objective way to prioritize the opportunities in order to determine what we will work on. This process takes into consideration input from multiple disciplines, residents and families. This process identifies problems that pose a high risk to residents or caregivers, is frequent in nature, or otherwise impact the safety and quality of life of the residents.</p> <p>Notes:</p>					
<p>When a performance improvement opportunity is identified as a priority, we have a process in place to charter a project. This charter describes the scope and objectives of the project so the team working on it has a clear understanding of what they are being asked to accomplish.</p> <p>Notes:</p>					
<p>For our Performance Improvement Projects, we have a process in place for documenting what we have done, including highlights, progress, and lessons learned. For example, we have project documentation templates that are consistently used and filed electronically in a standardized fashion for future reference.</p> <p>Notes:</p>					
<p>For every Performance Improvement Project, we use measurement to determine if changes to systems and process have been effective. We utilize both process measures and outcome measures to assess impact on resident care and quality of life. For example, if making a change, we measure whether the change has actually occurred and also whether it has had the desired impact on the residents.</p> <p>Notes:</p>					
<p>Our organization uses a structured process for identifying underlying causes of problems, such as Root Cause Analysis.</p> <p>Notes:</p>					

Rate how closely each statement fits your organization	Not started	Just starting	On our way	Almost there	Doing great
<p>When using Root Cause Analysis to investigate an event or problem, our organization identifies system and process breakdowns and avoids focus on individual performance. For example, if an error occurs, we focus on the process and look for what allowed the error to occur in order to prevent the same situation from happening with another caregiver and another resident.</p> <p>Notes:</p>					
<p>When systems and process breakdowns have been identified, we consistently link corrective actions with the system and process breakdown, rather than having our default action focus on training education, or asking caregivers to be more careful, or remember a step. We look for ways to assure that change can be sustained. For example, if a policy or procedure was not followed due to distraction or lack of caregivers, the corrective action focuses on eliminating distraction or making changes to staffing levels.</p> <p>Notes:</p>					
<p>When corrective actions have been identified, our organization puts both process and outcome measures in place in order to determine if the change is happening as expected and that the change has resulted in the desired impact to resident care. For example, when making a change to care practices around fall prevention there is a measure looking at whether the change is being carried out and a measure looking at the impact on fall rate.</p> <p>Notes:</p>					
<p>When an intervention has been put in place and determined to be successful, our organization measures whether the change has been sustained. For example, if a change is made to the process of medication administration, there is a plan to measure both whether the change is in place, and having the desired impact (this is commonly done at 6 or 12 months).</p> <p>Notes:</p>					













**Telehealth Legal and Compliance Issues**

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 Health Care Compliance Association

 **FOLEY**  
FOLEY & LARDNER LLP

Anna Whites  
Law Office

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**Overview**



- Licensure and exceptions
- Online Second Opinions
- Multi-state telemedicine services
- Medicare coverage
- Medicare mysteries

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**Overview**



- Telehealth medical practice standards
- Telehealth in mental health and crisis management
- HIPAA privacy and security
- Medicaid coverage and billing

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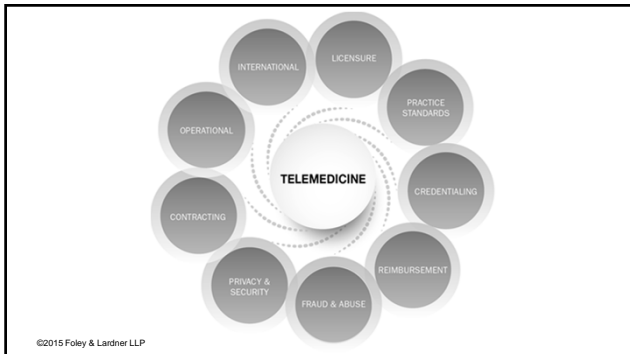
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### Telehealth and Licensure

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**Basic rule:**  
**Physician must be licensed in the state where the patient is located at the time of the consult.**

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### Licensure Exceptions

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Consultation	Bordering State	Special License or Registration	Follow-Up Care	FSMB Compact
<ul style="list-style-type: none"> <li>• Allows unlicensed physician to practice medicine in peer to peer consultation with a physician licensed in the state</li> </ul>	<ul style="list-style-type: none"> <li>• Allows practice of medicine by out-of-state physicians who are licensed in a bordering state.</li> </ul>	<ul style="list-style-type: none"> <li>• Abbreviated license or registration for telemedicine-only care</li> </ul>	<ul style="list-style-type: none"> <li>• Allows physician to provide follow-up care to his/her patient (e.g., post-operation)</li> </ul>	<ul style="list-style-type: none"> <li>• Allows reciprocity in participating Compact states.</li> </ul> <div style="text-align: center; font-size: x-small; margin-top: 5px;"> </div>

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## Telehealth and Destination Medicine

*“Ten years from now, there will emerge just a few medical centers with the reputation for health care excellence and patient-focused outcomes that will attract patients from all over the world.”*

John H. Noseworthy, M.D.  
President and CEO of Mayo Clinic

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## Online Second Opinions

- Patient desires 2<sup>nd</sup> opinion via provider's website
- Patient's PCP completes a request for a consult
- PCP provides charts and records

### 2<sup>nd</sup> Opinion Request

### 2<sup>nd</sup> Opinion Consult Performed

- Provider's coordinator reviews materials and selects physician to perform 2<sup>nd</sup> opinion consult
- Physician reviews materials and writes opinion

- Provider's coordinator sends 2<sup>nd</sup> opinion to PCP to discuss with the patient

### Consult Sent to PCP

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## International Telehealth Arrangements

The Health Care Provider's Guide to Building United States to China Telemedicine Arrangements



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### Multi-State Telehealth Services

■ **Fraud & Abuse Considerations Under State Law**

- Fee-Splitting Laws
- State Self-Referral Laws
- Patient Brokering & All Payer Kickback
- Corporate Practice of Medicine
- Insurance Laws

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### Telehealth and Medicare

1. Patient in a qualifying rural area
2. Patient at one of eight qualifying facilities ("originating site")
3. Service provided by one of ten eligible professionals ("distant site practitioner")
4. Technology is real-time audio-video (interactive audio and video telecommunications system that permits real-time communication between the beneficiary and the distant site provider)
5. The service is among the list of CPT/HCPCS codes covered by Medicare

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### Telehealth and Medicare

1. GT vs GQ modifier
2. POS Code 02
3. GY modifier

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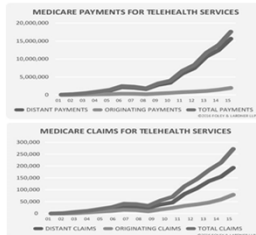
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## Medicare Mysteries

- Charging beneficiaries out of pocket for telehealth services?
- Reassignment to originating site hospital?
- Interjurisdictional reassignment of claims?
- Overseas providers?
- Enrollment of national physician group?



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## Telehealth and Medicare

- Telehealth services billed through a single physician group but the physicians themselves are physically located throughout the country.
- The group provides Medicare telehealth services to patients located at various originating sites across the country.
- Physicians reassign claims to the group, which does all the billing itself.

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## Telehealth and Medicare

- **Enrollment**
- **Interjurisdictional reassignment of claims**
  - 42 CFR § 414.65(a)(2), (3); 424.80(b)(2), (d)
  - Program Integrity Manual Ch. 15, section 15.5.20.1, 15.5.4.2.D
  - Claims Processing Manual Ch. 12 § 190 et seq.
  - CMS 855-R
  - The reassigned claims are billed by the originating site hospital to the A/B/MAC(B) located in the distant site physician's jurisdiction.

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## Kentucky Statutes

- Kentucky Revised Statute 205.510 defines terms used in healthcare coverage. Subsection (15) provides that "Telehealth consultation" means a medical or health consultation, for purposes of patient diagnosis or treatment, that requires the use of advanced telecommunications technology, including, but not limited to:
  - Compressed digital interactive video, audio, or data transmission;
  - Clinical data transmission via computer imaging for teleradiology or telepathology;
  - Other technology that facilitates access to health care services or medical specialty expertise.

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## Direct to patient services

- In 2016 a modification was proposed to Kentucky Revised Statute Chapter 216 which would have defined "Telehealth" as:

"Tele-health" and "Tele-Communication Services" refers to a mode of delivering health care, counseling and public health services by way of federally compliant information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management and self-management of a patient's healthcare while the patient or consumer is at an originating site, including but not limited to the patient's or consumer's home, and a health care provider at a distant site.

- Medicaid was uncomfortable with expansion that would have permitted "direct to patient" services in the patient's home. The direct to patient language was stricken from the statutory amendments. Many providers are using direct to patient services, but are not billing for them.

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## Covered providers

- 907 KAR 3:170 is the administrative regulation addressing reimbursement for telemedicine in Kentucky. At Section 2 (b) the Regulation affirms that a Medicaid Managed Care entity may, but is not required to reimburse for care provided via telehealth.
- Section 2(b)(2) outlines when telehealth is not required to be reimbursed. This section provides:
  - (2) A telehealth consultation shall not be reimbursed by the department if:
    - (a) It is not medically necessary;
    - (b) The equivalent service is not covered by the department if provided in a face-to-face setting;
    - (c) It requires a face-to-face contact with a recipient in accordance with 42 C.F.R. 447.371;

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- Cont.

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### Covered providers

- (d) The telehealth provider of the telehealth consultation is:
  1. Not currently enrolled in the Medicaid program pursuant to 907 KAR 1:672;
  2. Not currently participating in the Medicaid program pursuant to 907 KAR 1:671;
  3. Not in good standing with the Medicaid program;
  4. Currently listed on the Kentucky DMS List of Excluded Providers, which is available at <http://chfs.ky.gov/dms/provEnr>; or
  5. Currently listed on the United States Department of Health and Human Services, Office of Inspector General List of Excluded Individuals and Entities, which is available at <https://oig.hhs.gov/exclusions/>; or
- (e) It is provided by a telehealth practitioner or telehealth provider not recognized or authorized by the department to provide the telehealth consultation or equivalent service in a face-to-face setting.

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### Cost control

- One provider can treat more patients via telemedicine than with separate in-person visits. Cost-effective counseling model. Expenses of travel are reduced, it's easier for patients to keep scheduled appointments, there is increased access to care, and reduced stigma for patients who don't want to be seen at a counselor's office. Benefits include improved and faster care delivery, expanded staff capacity, enhanced training for providers, cost savings for payors.
- <https://www.hrsa.gov/publichealth/guidelines/BehavioralHealth/behavioralhealthcareaccess.pdf> (2012)

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### Who may provide services

- Medicaid in Kentucky has a spoke and hub coverage model which requires both sides of the telehealth encounter to be at sites (usually a hospital or CMHC) approved by the state telehealth board. See: 907 KAR 3:170(3)(a) holding that:
 

A telehealth provider shall:

  - Be an approved member of the Kentucky Telehealth Network; and
  - Comply with the standards and protocols established by the Kentucky Telehealth Board.

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## Reimbursement

- The Administrative regulation specifies which provider types can bill for telehealth services. 907 KAR 3:170 Section (3)(2) allows reimbursement to:
  - (A) A physical health evaluation or management consultation provided by:
    - 1. A physician including a physician:
      - a. With an individual physician practice;
      - b. Who belongs to a group physician practice; or
      - c. Who is employed by a federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;
    - 2. An advanced practice registered nurse including an advanced practice registered nurse:
      - a. With an individual advanced practice registered nurse practice;
      - b. Who belongs to a group advanced practice registered nurse practice; or
      - c. Who is employed by a physician, federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;
    - 3. An optometrist; or
    - 4. A chiropractor;

- Cont.

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## Reimbursement, con't

- (B) A mental health evaluation or management service provided by:
  - 1. A psychiatrist;
  - 2. A physician in accordance with the limit established in 907 KAR 3:005;
  - 3. An APRN in accordance with the limit established in 907 KAR 1:102;
  - 4. A psychologist.

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## Billing

- 907 KAR Section 5 (1)(a) states that the department shall reimburse a telehealth provider who is eligible for reimbursement from the department for a telehealth consultation an amount equal to the amount paid for a comparable in-person service in accordance with:
  - 1. 907 KAR 3:010 if the service was provided:
    - a. By a physician; and
    - b. Not in the circumstances described in subparagraphs 3., 4., 5., or 6. of this paragraph;
  - 2. 907 KAR 1:104 if the service was provided:
    - a. By an advanced practice registered nurse; and
    - b. Not in the circumstances described in subparagraphs 3., 4., 5., or 6. of this paragraph;
  - 3. 907 KAR 1:055 if the service was provided and billed through a federally-qualified health center, federally-qualified health center look-alike, rural health clinic, or primary care center;

- Cont.

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## Billing, con't

- 4. 907 KAR 1:015 if the service was provided and billed through a hospital outpatient department;
- 5. 907 KAR 1:031 if the service was provided and billed through a home health agency; or
- 6. 907 KAR 1:065 if the service was provided and billed through a nursing facility.
- (b)1. Reimbursement for a telehealth consultation provided by a practitioner who is employed by a provider or is an agent of a provider shall be a matter between the provider and the practitioner.
- 2. The department shall not be liable for reimbursing a practitioner who is employed by a provider or is an agent of a provider.
- (c) A managed care organization shall not be required to reimburse the same amount for a telehealth consultation as the department reimburses, but may reimburse the same amount as the department reimburses if the managed care organization chooses to do so.
- (2) A telehealth provider shall bill for a telehealth consultation using the appropriate two (2) letter "GT" modifier.

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## Informed Patient Consent

- 907 KAR 1:170 outlines the requirements for informed consent for telehealth services in Kentucky. Before providing a telehealth consultation to a recipient, a telehealth provider or telehealth practitioner shall document written informed consent from the recipient and shall ensure that the following written information is provided to the recipient in a format and manner that the recipient is able to understand:
  - The recipient shall have the option to refuse the telehealth consultation at any time without affecting the right to future care or treatment and without risking the loss or withdrawal of a Medicaid benefit to which the recipient is entitled;
  - The recipient shall be informed of alternatives to the telehealth consultation that are available to the recipient;
  - The recipient shall have access to medical information resulting from the telehealth consultation as provided by law;
  - The dissemination, storage, or retention of an identifiable recipient image or other information from the telehealth consultation shall comply with 42 U.S.C. 1301 et seq., 45 C.F.R. Parts 160, 162, 164, KRS 205.566, 216.2927, and any other federal law or regulation or state law establishing individual health care data confidentiality policies;
  - The recipient shall have the right to be informed of the parties who will be present at the spoke site and the hub site during the telehealth consultation and shall have the right to exclude anyone from either site; and
  - The recipient shall have the right to object to the video taping of a telehealth consultation.

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## Prescribing

- Kentucky law does not specifically address prescribing. Remote prescribing is generally believed to be at the discretion of the prescribing physician and is held to equivalent standards for in-person encounters. Prescribing may be limited where federal law prohibits internet prescriptions of controlled substances

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## Remote Prescribing

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 governs dispensing of controlled substances by means of the internet. The law specifically exempts practitioners of telemedicine from the Act's prohibitions under certain conditions. See: Subsection 309(e) (3)(A) of that Act. The Ryan Haight Act expressly provides that a physician who is acting in accordance with applicable state law and is registered with the state as a telehealth provider or is exempt from such registration, may prescribe after seeing a patient via telehealth. See: Section 53(A)(II) and (III). The Act allows that a patient evaluation permitting prescribing where appropriate need not be in-person if the provider employs technology sufficient to accurately diagnose and treat the patient in conformity with the applicable standard of care and the provider is licensed in the state in which the services are being provided. 42 C.F.R. § 482.22(a)(3)(iii)

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## Fraud Concerns

- Fraud concerns include services being rendered by unqualified providers, services being billed that are not actually rendered, HIPAA breaches, and business arrangements that breach federal fraud and abuse laws, including the Anti-Kickback Statute and the Stark Law. 42 U.S.C. § 1320a-7b. 42 U.S.C. § 1395nn

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## Confidentiality and Privacy

- 907 KAR 3:170 Section 6. Confidentiality and Data Integrity governs the way Kentucky Medicaid wants telehealth privacy and HIPAA concerns managed.
- (1) A telehealth consultation shall be performed on a secure telecommunications line or utilize a method of encryption adequate to protect the confidentiality and integrity of the telehealth consultation information.
- (2) Both a hub site and a spoke site shall use authentication and identification to ensure the confidentiality of a telehealth consultation.
- (3) A telehealth provider or telehealth practitioner of a telehealth consultation shall implement confidentiality protocols that include:
  - (a) Identifying personnel who have access to a telehealth transmission;
  - (b) Usage of unique passwords or identifiers for each employee or person with access to a telehealth transmission; and
  - (c) Preventing unauthorized access to a telehealth transmission.
- (4) A telehealth provider's or telehealth practitioner's protocols and guidelines shall be available for inspection by the department upon request.

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## Emergency Treatment and Evaluation

- For patients who may be in crisis, telemedicine provides regular mental health check-ins or quick access to reassurance. In an interactive video format, the provider can observe patient condition as well as speak directly to the patient. This can reduce in-patient care needs since the provider can be reassured as often as daily that the patient is safe and compliant and does not have to be in a hospital or facility.
- In an emergency situation, such as an involuntary commitment or emergency room situation where a mental health expert analysis is required via telehealth, the Kentucky Administrative Regulations hold that the informed consent requirements do not apply "if the recipient is unable to provide informed consent and the recipient's legally-authorized representative is unavailable." 907 KAR 1:170 Section 7(3).

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## Pilot Programs

- In 2006, Kentucky piloted a school telehealth program between three hospitals and five schools in which primary care providers used videoconferencing technology to treat and assess elementary, middle and high school students remotely while the children remained in school. The goals were to reduce costs to the Medicaid program while simultaneously reducing absenteeism and increasing access for the young patients. This program was successful as a pilot but was not expanded after the pilot year due to cost.
- In 2015 Humana began using telehealth and direct contact between a patient and a primary care provider or mid-level provider as a means of fostering access to care by patients while encouraging reduced use of hospital emergency departments. The insurer used that coverage to supplement it's "ask a nurse" telephone programs and other educational means of controlling cost for care.
- In 2017, a pilot program between several Home Health entities and patients with chronic conditions such as diabetes, dementia and heart disease will allow providers to videoconference with the patients daily and use remote patient monitoring to capture health data to evaluate. The goal is to reduce readmission for those patients in a cost-effective manner.

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## TELEHEALTH: TAKE FLIGHT!



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## Tools and Handouts Galore!

- Telemedicine Business & Legal Considerations
- Telehealth Compliance Checklist
- Telemedicine Malpractice Insurance Checklist
- Telemedicine and Controlled Substances Handout
- Hospital Telemedicine Credentialing by Proxy Agreement
- Sample Patient Consent Form
- Kentucky Telehealth Medicaid Statute
- Kentucky Telehealth Medicaid Regulations

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## Ask Us Anything\*

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#### News & Resources

[www.foley.com/telemedicine](http://www.foley.com/telemedicine)  
[www.healthcarelawtoday.com](http://www.healthcarelawtoday.com)

\*Almost!

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### OIG's New Model Corporate Integrity Agreement

**(1) Evolution of CIAs**

OIG priorities and monitoring experience  
 Feedback from providers and IROs  
 The progression of compliance in the health care industry  
 Trends in health care, and fraud, waste, and abuse

**(2) Big Picture**

Most providers have the basics and don't need to be micromanaged by OIG  
 OIG is focused on early detection of risks and fraud through audits, disclosures, and risk assessments

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### Goals of the CIA

<input type="checkbox"/>	Efficient and effective oversight
<input type="checkbox"/>	Basic elements apply to most providers
<input type="checkbox"/>	Time spent negotiating should decrease
<input type="checkbox"/>	Provider must certify that it is in compliance with these elements
<input type="checkbox"/>	More useful and relevant IRO reviews
<input type="checkbox"/>	Careful and targeted risk assessments and internal audits
<input type="checkbox"/>	Focus on risks particular to that provider type
<input type="checkbox"/>	Simpler Annual Reports

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### Basic Elements of a CIA

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**CIA Claims Reviews**

1	Targeted to risks, not necessarily the covered conduct
2	Removes the "Discovery Sample" in favor of one 100-claim sample
3	Requires that the error rate be extrapolated as part of the Claims Review Report, but provider determines what "reasonable diligence" is required, to comply with the 60-day rule
4	Repayment of extrapolated overpayment, further investigation, full sample review, or repayment of sample overpayment only
5	"Medically necessary and appropriately documented" means medical review—IRO must use a medical reviewer

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**Claims Reviews, cont.**

6	<p>Each year, the Population can be determined based on risk</p> <ul style="list-style-type: none"> <li>• Recommendations from provider</li> <li>• OIG data mining and analysis           <ul style="list-style-type: none"> <li>• Volume of types of claims compared to peers</li> <li>• Claim types at various locations</li> </ul> </li> <li>• Risks in the industry</li> </ul>
7	For hospitals, the risk-based determination is the default Claims Review process
8	OIG Compliance Monitor, Provider's Compliance Officer, and IRO will begin discussing risk areas with many months left in the year

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**How to Negotiate Successfully**

✓	Involve the compliance officer
✓	Suggest creative Claims Reviews that the provider will find useful
✓	Accept that the body of the CIA will be largely standard
✓	We are asking, "Why did the conduct happen?"
✓	Be transparent about corporate structure and relationships
✓	Think broadly about risk
✓	Think positively about compliance goals

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**CCO**

*JoAnne Little*

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**LHC Group's CIA: Lessons Learned**

✓	Engage the right IRO
✓	Collaborate with the OIG and IRO on an ongoing basis
✓	Involve the Board
✓	Build a Culture of Compliance
✓	Concurrent Auditing and Monitoring
✓	Ensure adequate preparation for IRO activities

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**Engage the Right IRO**

- 1 Reputable
- 2 Experienced in issues that form the basis of CIA
- 3 Right fit for the organization
- 4 Cost shouldn't be sole determining factor

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### Ongoing Collaboration with the OIG and IRO

- 1 Issues pertaining to CIA
- 2 Issues not pertaining to CIA but within their expertise
- 3 Ongoing compliance program changes

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### Involve the Board

- 1 Board Training
- 2 Quarterly Reports to the Board on CIA Compliance
- 3 Quarterly Reports on Other Compliance Data
- 4 Annual in Person Reports from the IRO

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### Build a Culture of Compliance

- 1 Starts at top and includes all levels of organization
- 2 Compliance part of overall management strategy
- 3 Compliance has a seat at the table in all meetings/on all agendas
- 4 All levels of organization involved in compliance risk assessment
- 5 Provide guidance based on regulation; don't just give opinion
- 6 Compliance Department as a resource
- 7 Constant feedback and training:
  - Newsletters
  - Email "tips"
  - Regional/Divisional Presentations
  - Discussion topics in staff meetings
  - Audit reports/calls to discuss
- 8 Compliance Week

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**Concurrent Auditing and Monitoring**

- 1 Develop expertise in regulations surrounding the items being audited
- 2 Ongoing internal auditing of conditions of payment
- 3 Internal auditing of issues identified through risk assessment hotline, exit interviews, etc.
- 4 Constant feedback to field of findings/opportunities
- 5 Individual and companywide feedback

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**Ensure Adequate Preparation for IRO Activities**

- 1 Ongoing communication with IRO prior to their specific activities
- 2 Organization and preparation in advance
- 3 Break annual activities and reporting requirements into manageable pieces

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**IRO**

*Peter Dressel*

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

- 1 Knowledge of the IRO process
- 2 Subject matter expertise
- 3 The necessary technical skills
- 4 The ability to scale up if need be
- 5 Scheduling availability

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

- 1 Language may be overly broad or impractical
- 2 Work to resolve common issues (e.g.; timing, scope, inconsistencies, sample frame, definition of an "error")
- 3 Consider an "Early Work Plan" Submission
  - These are not usually required by the CIA
  - OIG will not formally "bless" it, but will provide input on areas of concern
  - Helps to avoid problems at the back-end
  - Creates an early opportunity to build rapport

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

- Be mindful of "Over-Disclosure"**

  - Some issues require the IRO to exercise judgment or to choose a particular interpretation
  - Be mindful of the overall objectives of the CIA and of the CIA's language
  - Provide logic and rationale for key decisions
- Formally Define Communication Process**

  - Need to identify key stakeholders in the various processes
  - Need to decide when/how potential issues will be raised
  - Need to decide when/how potential issues will be dealt with
  - Consider communication with board and management on an ongoing basis

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

- Early Site Visit**

  - After the Implementation Report and before year-end
  - Focus on things that might facilitate a more efficient IRO review
- Data Acquisition "Dry Run"**

  - Obtaining data can often be more difficult than expected
  - Reconciling/validating data can also be challenging
- Define the Strike Zone**

  - Consider all forms of an exception based on the language of the CIA & related policies
  - Determine what will constitute a reportable exception
  - Ensure management buy-in – **but** – set reasonable expectations

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### Elements to a Successful IRO engagement

Elements					
1	2	3	4	5	6
IRO team	Early Involvement	Communication Protocols	Pre-Work	Reporting	Independence

- Don't simply report what is wrong**

  - Provide information on underlying causes
  - Provide information on severity
  - Provide information on trending
- Explain whether the company had already identified the issue, and/or what actions have already been**

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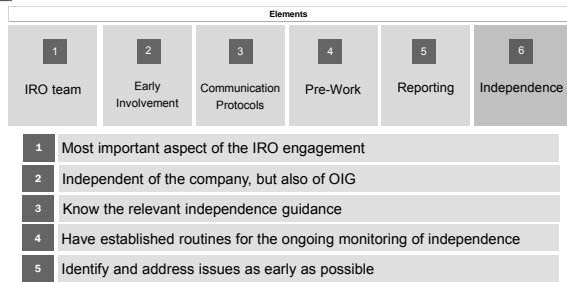
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### Elements to a Successful IRO engagement



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Thank You for Your Time

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## Leveraging Internal Audit to Improve Quality of Care Metrics

Shawn Steverson, CPA, CHC,  
CRMA, CGMA

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### Internal Audit Considerations

#### Pros – Reasons to Use Internal Audit

- Independent
- Analytical
- Focused on Risk-Based Areas
- Understand the inter-relation of Quality metrics and Reimbursement patterns.
- Able to process through source data and various interfaces and iterations

#### Cons – Areas to Watch For

- May not be clinically trained
- Fairly black and white in interpretation

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### Quality Areas of Focus

- Falls Risk Prevention
- Restraints
- Surgical Never Events
- Catheter Associated Urinary Track Infection (CAUTI)
- Central Line Associated Blood Stream Infection (CLABSI)
- Ventilator Associated Pneumonia (VAP)

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### Falls Risk Prevention Audit



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### Falls Risk Prevention Audit

- Evidence Based Practice Sources:
  - Joint Commission Guidance
  - Centers for Disease Control and Prevention (CDC) guidelines
  - Stopping Elderly Accidents, Deaths and Injuries (STEADI) Initiative

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### Falls Risk Prevention Audit

- Internal Source Guidance:
  - Internal Policies and Procedures;
  - Internal Toolkits;
  - Education and Training of Staff
  - Quality Department

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### Falls Risk Prevention Audit

Steps:

1. Policy and Procedure Review
2. Data Mining
3. Observation and Walkthrough
4. Chart Reviews



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### Falls Risk Common Findings

1. Documentation Issues
2. Bed Alarm/Alarm Fatigue
3. Practices inconsistent with policy
4. Over-use of restraints



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### Restraints

TYPES OF RESTRAINTS



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 **Restraints Audit**

- CMS Regulations Clearly Define Requirements
- On-going scrutiny of practices
- Difficulty with certain aspects relative to behavioral health

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 **Restraints Audit**

1. Data Mining
  1. Restraint products charged
  2. Restraint documentation in EHR
2. Targeted walkthroughs on identified units
3. Documentation review for alignment with regulatory requirements

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 **Restraint Audit Common Findings**

- Documentation issues
  - F2F in behavioral
  - Periodic reassessment in correct timeframe
- Misclassification of activities as non-restraints
  - Use of medications
  - Use of bedrails

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**Surgical Never Events**



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**Types of Surgical Never Events**

- Wrong Site/Procedure/Patient
- Object left in body
- Surgical Fires
- Wrong blood product
- Anesthesia Complications – airway, etc.

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**Surgical Never Event Audit**

External Sources:

- CMS Conditions of Participation
- Joint Commission
- Agency for Healthcare Research and Quality
- National Quality Forum

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 **Surgical Never Event Audit**

Internal Resources:

- Policies and Procedures
- Checklists
- Protocols

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 **Surgical Never Event Audit**

1. Benchmark of Policy, Procedure and Protocol to leading practices.
2. Observational Audit – in Operating Rooms for all Types of Procedures
3. Documentation Review – Surgical Time Outs, Anesthesia Time Outs, Fire Safety, etc.

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 **Surgical Never Event Audit**

Common Findings:

1. Failure to complete Time-out;
2. Failure to complete count prior to closure;
3. Change in use of supply resulting in change in fire risk
4. Fear of physicians; Fear of speaking out

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### HAIs: CAUTI, CLABSI, VAP

- Select a sample of charts to review documentation:
  - Date and time of placements and equipment/supplies utilized;
  - Frequency of care provided aligns to the EBP for that device (Catheter, Central Line, Vent); and
  - Assessments for removal at earliest possible time.

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### Common Findings: CAUTI, CLABSI & VAP

- Supplies purchased and used don't align to EBP in place – changes made without vetting.
- Training on EBPs “on the job” by individuals who don't follow EBP protocols.
- Excessive time in use.
- Other miscellaneous...

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### Questions?



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 In Summary

Internal Audit provides an independent, non-clinical approach to compliance with specified evidence-based practices.

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**Top 10 Things a Compliance Professional Needs to Know About Coding**

Melissa McCarthy, RHIT, CCS, CHC

**Northwell Health**

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**Disclaimer**

The views in this presentation are the presenter's personal views and do not necessarily represent the views of her employer.

**Northwell Health**

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**Agenda**

- ✓ What is Coding?
- ✓ Abbreviations
- ✓ ICD-10
- ✓ Prospective Payment Systems
- ✓ Coding Lingo
- ✓ When Do I Use What?
- ✓ Medicare Alphabet
- ✓ Documentation, Coding and Reimbursement
- ✓ My Coding Top 10
- ✓ Overlap of Issues
- ✓ Coding/Audit Tips
- ✓ Compliance Audit Process

**Northwell Health**

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**What is Coding?**

Medical coding is the transformation of healthcare diagnosis, procedures, medical services, and equipment into universal medical alphanumeric codes. The diagnoses and procedure codes are taken from medical record documentation, such as transcription of physician's notes, laboratory and radiologic results, etc.

-American Academy of Professional Coders (AAPC)



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**Abbreviations**

ICD=International Classification of Diseases

- 9-ninth revision
- 10-tenth revision
- CM-Clinical Modification
- PCS-Procedural Coding System

CPT=Current Procedural Terminology

- 4-fourth revision
- Also called HCPCS level I

HCPCS Level II=Healthcare Common Procedural Coding System

E/M=Evaluation and Management

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**ICD-10**

Replaced ICD-9-CM

In the U.S., ICD-10 was effective on October 1, 2015

Procedural coding in the inpatient setting uses ICD-10-PCS

Procedural coding in the outpatient setting and Physician services use CPT

ICD-10-CM and ICD-10-PCS significantly increased the specificity of codes and expanded many codes

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**Prospective Payment Systems**

A Prospective Payment System (PPS) is a method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service.

-CMS

Some Examples:

- Medical Severity Diagnosis Related Group (MSDRG)-Inpatient Hospital Claims
- All-Payer Group (APG)-Outpatient Hospital Claims (ED/ASU/Clinic)
- Home Health Resource Group (HHRG)-Home Health Claims
- Resource Utilization Group (RUG)-Skilled Nursing Facility Claims
- Case Mix Group (CMG)-Inpatient Rehabilitation Facility

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**Coding Lingo**

**Principal Diagnosis**=Defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."

**Complication/Comorbidity (CC) and Major Complication/Comorbidity (MCC)**= *complication* is a condition that develops while in the hospital that prolongs the length of stay. A *comorbidity* is a pre-existing medical condition that impacts the treatment a patient may receive and could also prolong the length of stay.




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**Coding Lingo (continued)**

**Chief Complaint (CC)**=a concise statement that describes the symptom, problem, condition, diagnosis, or reason for the patient encounter. The CC is usually stated in the patient's own words. For example, patient complains of upset stomach, aching joints, and fatigue. The medical record should clearly reflect the CC.

**Medical Decision Making (MDM)**=refers to the complexity of establishing a diagnosis and/or selecting a management option, which is determined by considering these factors:

- The number of possible diagnoses and/or the number of management options that must be considered
- The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be obtained, reviewed, and analyzed
- The risk of significant complications, morbidity, and/or mortality as well as comorbidities associated with the patient's presenting problem(s), the diagnostic procedure(s), and/or the possible management options

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**When Do I Use ICD-9, ICD-10, ICD-10-PCS, CPT, HCPCS?**

ICD-9-CM-extinct however when auditing inpatient hospital and outpatient hospital claims, you need to use this system for claims billed before 10/1/2015.

ICD-10-CM-for inpatient hospital, outpatient hospital and physician office diagnosis coding beginning 10/1/2015

ICD-10-PCS-for inpatient hospital procedure coding beginning 10/1/2015

CPT-for outpatient hospital and physician services coding

HCPCS-for outpatient hospital and physician office coding of health care equipment and supplies not identified by the HCPCS level I, CPT codes (Drugs, Supplies, etc...)

-Majority of modifiers live here

**Remember-no matter what codes you are using, you must always code from Physician or applicable physician extender documentation**



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**Medicare Alphabet**

**Part A**= certain inpatient services in hospitals and Skilled Nursing Facilities and some Home Health services

**Part B**= designated practitioners' services. Outpatient care and certain other medical services, equipment, supplies and drugs that Part A does not cover

**Part C**= Medicare Advantage Plans

**Part D**= Medicare prescription drug coverage



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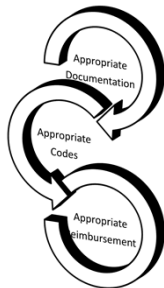
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**Documentation, Coding and Reimbursement**



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**My Coding Top 10**

10. Kwashikor
9. Radiation Therapy
8. Infusion and Injection Coding
7. Post Acute Services
6. Sepsis
5. Cardiac Catherizations
4. Unbundling
3. Modifiers
2. Time-Based Evaluation and Management Codes
1. Documentation



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**10-Kwashikor**

Kwashikor	Setting/Medicare Part	Problem	Controls
Severe malnutrition. Rarely seen in the U.S.	Mainly Inpatient coding (Part A).	Extremely high reimbursement for this diagnosis.  in ICD-9-CM "malnutrition" indexed to Kwashikor, it wasn't until you looked in the tabular portion of the book that the coder realized that it was incorrect.	<ul style="list-style-type: none"> <li>Run population of billed inpatient Part A claims to see if Kwashikor diagnosis is billed.</li> <li>If so, audit documentation to see if documented diagnosis is consistent with billed codes.</li> <li>Refund overpayments.</li> <li>Educate coders and physicians.</li> <li>Query policies.</li> </ul>

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**9-Radiation Therapy**

Radiation Therapy	Setting/Medicare Part	Problem	Controls
Treatment of a disease with x-ray radiation.	Can be Inpatient and outpatient coding Part A and Part B.	Can be highly complex treatment with equally complex coding rules.	<ul style="list-style-type: none"> <li>Make sure that when choosing to audit any part of the Radiation Therapy billing/coding the auditor is well versed in Radiation therapy; preferably certified in coding of this specialty.</li> </ul>

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8-Infusion and Injection Coding			
Infusion and Injection Coding	Setting/Medicare Part	Problem	Controls
<p>Infusion: Administration of diagnostic, prophylactic, or therapeutic intravenous (IV) fluids and/or drugs given over a period of time. -AHIMA</p> <p>Injection: Injection delivers a dosage in one "shot" rather than over a period of time. -AHIMA</p>	Outpatient-ED, Observation, Medicare Part A.	<ul style="list-style-type: none"> <li>• Can be difficult to determine administration method.</li> <li>• Need to understand and use AMA Hierarchy.</li> <li>• Infusions must have start and stop times documented.</li> <li>• Heavily reliant on documentation of physician, PA, NP and nurses.</li> </ul>	<ul style="list-style-type: none"> <li>• Run population of billed outpatient Part A claims with Infusion/Injection CPT codes billed.</li> <li>• Audit documentation to see if documentation supports billed codes (time and hierarchy)</li> <li>• Refund overpayments.</li> <li>• Educate coders and physicians.</li> <li>• Validate policy.</li> </ul>

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7-Post Acute Services			
Post Acute Services	Setting/Medicare Part	Problem	Control
Skilled Nursing Facilities, Home Health, and Hospice.	SNF, Home Health, Hospice Part A & Part B.	<p>Often times have different rules for Medicare than traditional "Part A".</p> <p>Own prospective payment system (HHRGs, RUGs).</p>	<ul style="list-style-type: none"> <li>• Make sure that when choosing to audit billing/coding the auditor is well versed in the specialty; preferably certified in coding of this specialty.</li> </ul>

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6-Sepsis			
Sepsis	Setting/Medicare Part	Problem	Control
A complication caused by the body's overwhelming and life-threatening response to infection, which can lead to tissue damage, organ failure, and death.-CDC.	Most likely Part A; inpatient hospital.	<ul style="list-style-type: none"> <li>• Can be difficult to diagnose.</li> <li>• Documentation of sepsis can take many forms.</li> <li>• Sepsis definition is ever-changing.</li> <li>• Don't need definitive proof to have a diagnosis of sepsis- can be clinical picture.</li> </ul>	<ul style="list-style-type: none"> <li>• Run population of billed inpatient Part A Sepsis claims.</li> <li>• Audit documentation to see if documented diagnosis is consistent with billed codes.</li> <li>• Refund overpayments.</li> <li>• Educate coders and physicians.</li> <li>• Validate policy.</li> </ul>

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5-Cardiac Catherizations			
Cardiac Catherization	Setting/Medicare Part	Problem	Control
A procedure used to diagnose and treat cardiovascular conditions. A tube (catheter) is inserted into the heart to conduct diagnostic tests. Coronary angioplasties, also are done using cardiac catheterization.	Part A (outpatient hospital) and Part B (physician services).	<ul style="list-style-type: none"> <li>Highly scrutinized area by the government.</li> <li>Room for documentation and coding errors.</li> <li>Patient must meet medical necessity.</li> </ul>	<ul style="list-style-type: none"> <li>Run population of billed outpatient Part A and Part B claims.</li> <li>Audit documentation to see if documented diagnosis and procedure is consistent with billed codes.</li> <li>Refund overpayments.</li> <li>Educate coders and physicians.</li> <li>Validate policy.</li> </ul>

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4-Unbundling			
Unbundling	Setting/Medicare Part	Problem	Control
Occurs when multiple procedure codes are billed for a group of procedures that are covered by a single comprehensive code.-CMS	Part A (outpatient hospital) and Part B (physician services).	<ul style="list-style-type: none"> <li>Highly scrutinized area by the government.</li> <li>Room for coding errors related to documentation.</li> <li>Very easy to unbundle-just add modifier -59.</li> </ul>	<ul style="list-style-type: none"> <li>Run population of billed outpatient procedures for Part A and Part B claims.</li> <li>Audit documentation to see if documented procedures are consistent with billed codes and procedures are coded appropriately according to NCCI edits.</li> <li>Make sure modifier -59 is used appropriately.</li> <li>Refund overpayments.</li> <li>Educate coders and physicians.</li> <li>Validate policy.</li> </ul>

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3-Modifiers			
Modifier	Setting/Medicare Part	Problem	Control
Two digit numeric or alphanumeric characters that are appended to CPT and HCPCS Level II codes. A modifier provides a means to indicate that a service or procedure was altered by specific circumstances, without changing the definition of the code.	Part A (outpatient hospital) and Part B (physician services).	<ul style="list-style-type: none"> <li>Highly scrutinized area by the government.</li> <li>Room for coding errors related to documentation.</li> <li>Many modifiers have similar meanings.</li> </ul>	<ul style="list-style-type: none"> <li>Run population of billed outpatient procedures for Part A and Part B claims.</li> <li>Audit documentation to see if documented procedures are consistent with billed codes and are coded appropriately.</li> <li>Make sure modifiers are used appropriately.</li> <li>Refund any overpayments.</li> <li>Educate coders and physicians.</li> <li>Validate policy.</li> </ul>

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2-Timed E/M Codes			
Timed E/M Codes	Setting/Medicare Part	Problem	Control
The more complex the visit, the higher the level of code you may bill within the appropriate category. The three key components when selecting the appropriate level of E/M services provided are history, examination, and medical decision making. Visits that consist predominately of counseling and/or coordination of care are an exception to this rule. For these visits, time is the key or controlling factor to qualify for a particular level of E/M services. -CMS	Part B (physician services).	<ul style="list-style-type: none"> <li>Highly scrutinized area by the government.</li> <li>If time is not documented, it is not billable.</li> </ul>	<ul style="list-style-type: none"> <li>Run population of billed timed E/M codes.</li> <li>Audit documentation to see if required time is appropriately documented.</li> <li>Refund any overpayments.</li> <li>Educate coders and physicians.</li> <li>Validate policy.</li> </ul>

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1-Documentation			
Documentation	Setting/Medicare Part	Problem	Control
Clear and concise medical record documentation is critical to providing patients with quality care and is required for you to receive accurate and timely payment for furnished services. -CMS	Part A (inpatient and outpatient hospital) and Part B (physician services).	<ul style="list-style-type: none"> <li>Documentation counts!</li> </ul>	<ul style="list-style-type: none"> <li>Run population of billed claims</li> <li>Audit documentation to see if documentation matches the codes billed.</li> <li>Refund any overpayments.</li> <li>Educate coders and physicians.</li> </ul>

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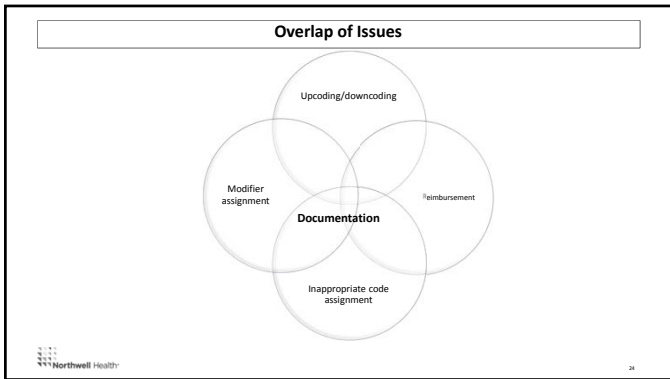
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**Coding / Audit Tips**

People generally feel nervous when audited

- Transparency is key

Try to look at the whole picture

- Not just the task at hand

Limit the timeframe/objectives of the audit

- Audit should be a snapshot in time
- Don't bite off more than you can chew
- Clear and concise objectives

Choose an appropriate audit sample

- Probe audits are best to start routine audits
- Implement routine monitoring


Understand the subject matter

- Use knowledgeable coders/auditors

Used recognized resources

- AHA Coding Clinic
- CPT Assistant
- Official Coding Guidelines

When in doubt about documentation...Query



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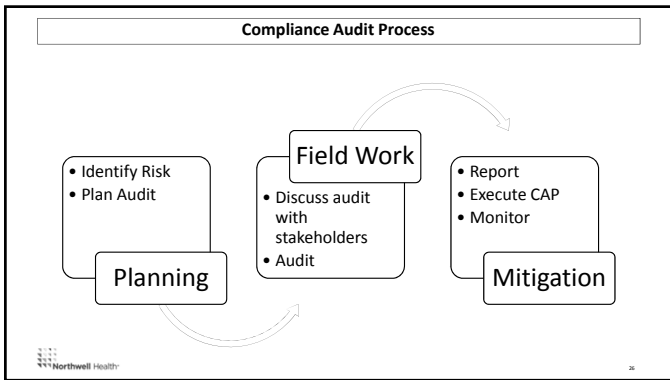
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**Resources**

[www.cms.gov](http://www.cms.gov)

[www.aapc.com](http://www.aapc.com)

[www.ahima.org](http://www.ahima.org)

[www.cdc.gov](http://www.cdc.gov)

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Questions?



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**Thank You**

**Melissa McCarthy**  
**Northwell Health**  
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**BEHAVIORAL HEALTH COMPLIANCE**  
IT DOESN'T NEED TO BE A MYSTERY



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**OUTLINE**

- I. RISK AREAS
  - Documentation, Medical Necessity, Supervision, Credentials, Background Checks/Exclusion Screening, Privacy of Behavioral Health & Substance Abuse Records, Opioid Treatment
- II. CURRENT REGULATORY AND OPERATIONAL CHANGES IMPACTING LANDSCAPE
  - Telemedicine Developments & Challenges
  - Utilization of Advanced Practice Practitioners (APPs)
  - Opioid Prescription Regulation
- III. STRATEGIES & MECHANISMS FOR AUDITING BEHAVIORAL HEALTH RECORDS TO ACHIEVE COMPLIANCE

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**ABANDON THE NOTION THAT BEHAVIORAL HEALTH IS "DIFFERENT."**

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**ENFORCEMENT**

Department of Justice  
U.S. Attorney's Office  
Western District of Texas

FOR IMMEDIATE RELEASE Thursday, February 9, 2017

**El Paso Behavioral Health Facility Pays \$860,000 to Resolve False Claims Act Allegations Under Civil Settlement with United States**

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**ENFORCEMENT**

Department of Justice  
U.S. Attorney's Office  
Western District of Oklahoma

FOR IMMEDIATE RELEASE Friday, July 29, 2016

**United States and State Of Oklahoma Obtain \$4.7 Million Judgment Against Behavioral Health Counseling Company and Its Owner for Submitting False Claims**

**Both Company and Owner Excluded from Participation in Medicaid/Medicare Programs for Five Years**

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**ENFORCEMENT**

Department of Justice  
U.S. Attorney's Office  
Northern District of New York

FOR IMMEDIATE RELEASE Monday, August 1, 2016

**ST. Joseph's Hospital To Pay \$3.2 Million For Billing MEDICAID For Mental Health Services Rendered By Unqualified Staff**

**St. Joseph's Comprehensive Psychiatric Emergency Program's Mobile Crisis Outreach Team Failed To Meet Mental Health Staffing Requirements**

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# ENFORCEMENT

Department of Justice  
Office of Public Affairs

SHARE 

FOR IMMEDIATE RELEASE

Friday, April 1, 2016

**Houston Psychiatrist Sentenced to 144 Months in Prison for Role in \$158 Million Medicare Fraud Scheme**

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# ENFORCEMENT

Department of Justice  
U.S. Attorney's Office  
Northern District of Illinois

SHARE 

FOR IMMEDIATE RELEASE

Friday, March 11, 2016

**Chicago Psychiatrist Who Took Kickbacks to Prescribe Mental Health Medication Sentenced to Nine Months in Federal Prison**

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# ENFORCEMENT

Department of Justice  
U.S. Attorney's Office  
Eastern District of Pennsylvania

SHARE 

FOR IMMEDIATE RELEASE

Monday, July 20, 2015

**Civil Complaint Alleges Fraud By Operators Of Community Mental Health Clinics**

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## ENFORCEMENT

Department of Justice  
Office of Public Affairs

SHARE 

FOR IMMEDIATE RELEASE

Wednesday, May 6, 2015

**Houston Doctor and Group Home Owner Indicted for Alleged Roles in \$5.2 Million Medicare Fraud Scheme**

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## RISK AREAS

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## TOP RISK AREAS

1. DOCUMENTATION
2. MEDICAL NECESSITY
3. SUPERVISION
4. CREDENTIALS
5. BACKGROUND CHECKS/ EXCLUSION SCREENING
6. PRIVACY OF BEHAVIORAL HEALTH & SUBSTANCE ABUSE RECORDS
7. EMTALA

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## COMPLIANCE STANDARDS

- CMS REGULATIONS
- MEDICARE CONDITIONS OF PARTICIPATION (COPS)
- ACCREDITING BODY STANDARDS
- STATE MENTAL HEALTH OR SUBSTANCE ABUSE TREATMENT LAWS
- STATE MEDICAID REQUIREMENTS
- STATE HEALTHCARE PROGRAM AND PROFESSIONAL LICENSURE LAWS/REGULATIONS
- COMMERCIAL PAYOR REQUIREMENTS

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## DOCUMENTATION

- GENERAL - ADEQUATELY DESCRIBE THE SERVICE AND JUSTIFY IT
  - ASSESSMENT
  - CERTIFICATIONS
  - TREATMENT PLANS
  - PROGRESS NOTES
  - CORRECT CODING
- OIG REPORTS ON MENTAL HEALTH DOCUMENTATION
- 2017 OIG WORK PLAN - INPATIENT PSYCH OUTLIER PAYMENTS

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## MEDICAL NECESSITY

- MEDICALLY NECESSARY SERVICES
  - APPROPRIATE AND INDIVIDUALIZED
  - OF QUALITY THAT MEETS PROFESSIONALLY RECOGNIZED STANDARDS OF HEALTH CARE
  - SUPPORTED BY EVIDENCE IN THE MEDICAL RECORD
  - REASONABLE EXPECTATION OF IMPROVEMENT
- ISSUES:
  - POOR DOCUMENTATION OF SERVICES RENDERED • LACK OF MEDICAL NECESSITY • INAPPROPRIATE OR SUBSTANDARD CARE • UNNECESSARY SERVICES • NON-COVERED SERVICES

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## SUPERVISION

- INPATIENT PSYCH FACILITIES (IPFS)
  - SERVICES MUST BE SUPERVISED AND PERIODICALLY EVALUATED BY A PHYSICIAN TO DETERMINE THE EXTENT TO WHICH TREATMENT GOALS ARE BEING REALIZED
  - THE EVALUATION MUST BE BASED ON PERIODIC CONSULTATION AND CONFERENCE WITH THERAPISTS AND STAFF, REVIEW OF MEDICAL RECORDS, AND PATIENT INTERVIEWS
  - PHYSICIAN ENTRIES IN MEDICAL RECORDS MUST SUPPORT THIS INVOLVEMENT
  - THE PHYSICIAN MUST ALSO PROVIDE SUPERVISION AND DIRECTION TO ANY THERAPIST INVOLVED IN THE PATIENT'S TREATMENT
  - PHYSICIAN MUST SEE THE PATIENT PERIODICALLY TO EVALUATE THE COURSE OF TREATMENT AND TO DETERMINE THE EXTENT TO WHICH TREATMENT GOALS ARE BEING REALIZED AND WHETHER CHANGES IN DIRECTION OR EMPHASIS ARE NEEDED
- STATE PROGRAM REQUIREMENTS
- PROFESSIONAL LICENSURE REQUIREMENTS
- REIMBURSEMENT REQUIREMENTS

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## CREDENTIALS

- MULTIPLE PRACTITIONERS
  - PHYSICIANS / PSYCHIATRISTS
  - CLINICAL PSYCHOLOGISTS (CP)
  - CLINICAL SOCIAL WORKERS (CSW)
  - CLINICAL NURSE SPECIALISTS (CNS)
  - NURSE PRACTITIONERS (NP)
  - PHYSICIAN ASSISTANTS (PA)
- CREDENTIALS:
  - LICENSED OR CERTIFIED TO PERFORM MENTAL HEALTH SERVICES BY THE STATE IN WHICH THEY PERFORM THE SERVICES
  - QUALIFIED TO PERFORM THE SPECIFIC MENTAL HEALTH SERVICES RENDERED
  - WORKING WITHIN THEIR STATE SCOPE OF PRACTICE ACT
- ROUTINELY REVIEW AND UPDATE DOCUMENTATION / AUDIT CREDENTIAL FILES

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## BACKGROUND CHECKS / EXCLUSION SCREENING

- STATE REGULATED BACKGROUND CHECKS
  - WHO?
  - HOW?
  - WHERE?
  - WHEN / FREQUENCY?
- MONTHLY OIG SCREENINGS
  - ALL STAFF, CONTRACTORS, PHYSICIANS



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## PRIVACY – BEHAVIORAL HEALTH / SUBSTANCE ABUSE

- HIPAA
  - DISCLOSURE OF BEHAVIORAL HEALTH RECORDS
  - PATIENT RIGHT TO ACCESS
- SUBSTANCE USE DISORDER REGULATIONS
  - 42 CFR PART 2 (REVISED 2.17.17)
  - APPLICABILITY
  - KEY HIGHLIGHTS
- STATE PRIVACY LAWS AND REGULATIONS
  - SPECIAL PROTECTIONS



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## EMTALA

- APPLICABILITY
- CONFLICTS WITH STATE LAWS
  - ASSESSMENTS
  - TRANSFERS
- WHEN IS A BEHAVIORAL HEALTH EMC STABILIZED
- GROWING EPIDEMIC – FREQUENT FLYERS AND DRUG SEEKING BEHAVIOR IN THE ED
  - PAIN MANAGEMENT AGREEMENTS, PRESCRIPTION LENGTH MANAGEMENT, STATE PRESCRIPTION MONITORING PROGRAM CHECKS
  - CONFLICTS WITH EMTALA

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## CURRENT REGULATORY & OPERATIONAL CHANGES IMPACTING LANDSCAPE

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## TELEMEDICINE DEVELOPMENTS & CHALLENGES

- MEDICARE –
  - TECHNOLOGY, LOCATION, PRACTITIONERS, ELIGIBLE SERVICES
- MEDICAID/COMMERCIAL –
  - COVERAGE, PARITY LAWS, LOCATION
- CHALLENGES –
  - COMPLEXITY AND DIFFERENTIATION IN PAYMENT POLICIES, LICENSURE, CREDENTIALING, SCOPE OF PRACTICE

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## UTILIZATION OF ADVANCED PRACTICE PRACTITIONERS

- INPATIENT V. OUTPATIENT
- LEVEL OF PHYSICIAN INVOLVEMENT
- PAYOR REQUIREMENTS
- APP STATE SCOPE OF PRACTICE, SUPERVISION, AND LICENSURE REQUIREMENTS
- CREDENTIALING & POLICIES

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## OPIOID PRESCRIPTION REGULATION

- "OUR NATION IS IN THE MIDST OF AN UNPRECEDENTED OPIOID EPIDEMIC."
- MORE PEOPLE DIED FROM DRUG OVERDOSES IN 2014 THAN IN ANY YEAR ON RECORD. TOP PRIORITY FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS).
  - IMPROVING PRESCRIBING PRACTICES.
  - EXPANDING ACCESS TO AND THE USE OF MEDICATION-ASSISTED TREATMENT, AND
  - EXPANDING THE USE OF NALOXONE.
- COMPREHENSIVE ADDICTION AND RECOVERY ACT
- 21<sup>ST</sup> CENTURY CURES ACT
- CDC GUIDELINES
- CHANGING STATE LAWS

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## STRATEGIES & MECHANISMS FOR AUDITING BEHAVIORAL HEALTH RECORDS

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## AUDITING AGAINST REQUIREMENTS

- DETERMINE THE PARTICULAR LAWS, REGULATIONS, AND OTHER REQUIREMENTS THAT APPLY TO YOUR PROGRAM AND SERVICES - FEDERAL / STATE / ACCREDITATION / PRIVATE PAYOR FOR EACH IDENTIFIED RISK AREA
  - CONDITIONS OF PARTICIPATION
  - LICENSURE
  - ACCREDITATION
  - REIMBURSEMENT
- DETERMINE WHETHER POLICIES AND PROCEDURES TRACK THESE REQUIREMENTS
- DEVELOP AN AUDIT TOOL BASED ON THESE REQUIREMENTS FOR EACH RISK AREA

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## COMMON TYPES OF ERRORS WHEN AUDITING

- **INPATIENT:**
  - NO ADMISSION CERTIFICATION STATEMENT
  - RECERTIFICATION STATEMENTS NOT TIMELY
  - CERTIFICATION OR RECERTIFICATION STATEMENT SIGNED AFTER DISCHARGE
  - INCORRECTLY WORDED CERTIFICATION AND/OR RECERTIFICATION STATEMENTS
  - PHYSICIAN DID NOT SIGN ADMISSION ORDERS (CONSIDERED PART OF CERTIFICATION)
  - INCORRECT FROM/THROUGH DATES - COMMONLY ADMISSION ORDER WRITTEN AFTER MIDNIGHT WHEN PATIENT ADMITTED DAY BEFORE
  - DIAGNOSES INCONSISTENT WITH PHYSICIAN DOCUMENTATION
  - NON-COVERED DIAGNOSES PER LCD

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## COMMON TYPES OF ERRORS WHEN AUDITING (CONT'D)

- **OUTPATIENT (SOP/IOP):**
  - WRONG DATE OF SERVICE - DOCUMENTATION DOES NOT MATCH DATE OF SERVICE ON CLAIM
  - INCOMPLETE OR CONFLICTING START/STOP TIMES - SUFFICIENT DURATION OF SESSION NOT ESTABLISHED
  - INSUFFICIENT DURATION OF SESSION (AT LEAST 45 MINUTES FACE-TO-FACE)
  - NO DOCUMENTATION TO SUBSTANTIATE CHARGE
  - SERVICES DOCUMENTED BUT NOT BILLED
  - SERVICES NOT ORDERED/PLANNED OR IN EXCESS OF THAT AUTHORIZED BY PHYSICIAN VIA ORDERS OR TREATMENT PLANNING
  - SERVICES DID NOT MEET REQUIRED LEVEL OF CARE TO QUALIFY FOR REIMBURSEMENT (FEWER HOURS THAN WHAT PAYER SOURCE REQUIRES)
  - INCORRECT PROCEDURE CODE UTILIZED

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## QUESTIONS



• **MICHELLE CALLOWAY, ESQ., CHC, CHPC**  
 • SENIOR OPERATIONS COUNSEL,  
 HCA CAPITAL DIVISION



• **REBEKAH STEWART, J.D., M.B.A., CHC, CHRC**  
 • CHIEF ETHICS AND COMPLIANCE OFFICER,  
 DIAMOND HEALTHCARE

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**Preventing a Whistleblower...**

Debra Maul, Qui Tam Relator *"Whistleblower"*

Barb Senters, PHR, CCEP  
 Chief Compliance & Ethics Officer  
 Ameritox

*The Ameritox Mission is to improve patient care and prevent human tragedy.*




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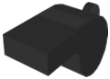
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**Whistleblowers**

- Have positive feelings about their jobs
- Have good job performance
- Believe that the company will be responsive to their complaints
- View whistle-blowing as integral to their role in the organization.



McMillan, Michael (2012, Oct). Retaliation against Whistle-Blowers: No Good Deed Goes Unpunished. [www.CFAInstitute.org](http://www.CFAInstitute.org)




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***"Whistle-blowing, is not an act of disloyalty, but the ultimate manifestation of employee loyalty to the organization ... allegiance to the organization's mission, its goals, its value statement, and its code of conduct."***

McMillan, Michael (2012, Oct). Retaliation against Whistle-Blowers: No Good Deed Goes Unpunished. [www.CFAInstitute.org](http://www.CFAInstitute.org)




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 **Whistleblower Statistics**


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**60%** Received No Response

**85%** Blew Whistle TWICE Internally

**39%** <2yrs with Company

Source: "Raising Concerns at Work: Whistleblowing Guidance for Workers and Employers in Health and Social Care"



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 **Employees Prefer to Resolve Their Concerns Internally**

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84% of whistleblowers that reported a compliance concern outside their company first reported the concern internally.

Only after the employer failed to address the concern satisfactorily did the employee report the concern to a third party outside the company.

National Business Ethics Survey 2013. www.ethics.org



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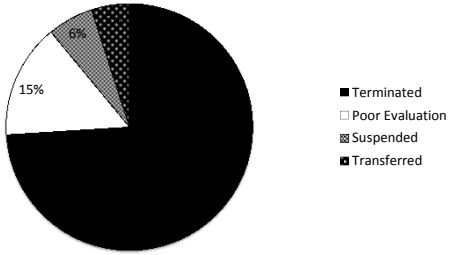
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 **Most Whistleblowers were Fired**


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15%

- Terminated
- Poor Evaluation
- ▨ Suspended
- Transferred

National Business Ethics Survey 2013. www.ethics.org



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### Whistleblower Reporting

How Incident Was Reported	Percent Utilizing Reporting Method
Supervisor	82%
Higher Management	52%
Human Resources	32%
Hotline/Help Line	16%
Ethics Officer	15%
Outside person (not governmental or regulatory authority)	13%
Legal	11%
Governmental or Regulatory Authority	9%

Overall, 20% of reporters ever chose to tell someone outside the company.

Responses total more than 100% because respondents selected all that applied.  
National Business Ethics Survey 2013. [www.ethics.org](http://www.ethics.org)

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### Themes of the story...

- Reporting Outlets
- Outside Legal Opinion
- Retaliation by Middle Manager
- Communication with the Whistleblower during Investigations
- Human Resources Issues

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### Agenda-Preventing a Whistleblower

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graph TD
    A[Effectively Address Employee Concerns] --> D((Effective Compliance Program))
    B[Compliance & Human Resources Partnership] --> D
    C[Culture & Perceptions] --> D
  
```

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### Addressing Employee Concerns

*Bottom Line: An employee's (reporter) acceptance of the outcome and continued commitment to the organization is whether or not they believe the procedure used to handle their concern was fair.*

- 1. Listen to them!** - Give them the opportunity to describe all of his or her concerns. Show that the company cares and will follow up. Ensure they know they are doing the right thing by reporting.
- 2. Don't Stonewall!** Ensure they see the process is fair...build trust.
  - ✓ Address their concerns irrespective of merit. Perceptions can be costly!
  - ✓ Change what needs changed. Timely.
  - ✓ Ensure there is no retaliation
  - ✓ Close the loop but do not share information about evidence, investigation, etc.

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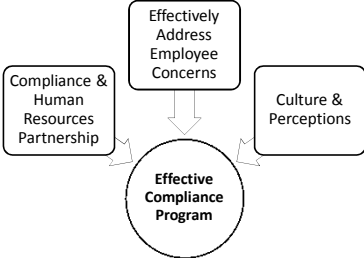
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### Preventing a Whistleblower



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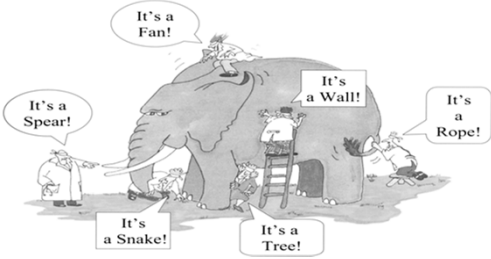
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### Perception

#### The Blind Men and the Elephant



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 **Shape Perceptions to see the big picture**

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✓ **Proactively Inform Employees of the Specific Risks and Controls**  
*Tell them about the elephant before they experience the tusks!*

Example: An employee transfers from a low producing dental office to another practice with an extremely fast paced dentist. The employee is concerned the doctor is either 1)not performing the services being billed or 2)must be performing them with sub-par quality. They didn't know about the audit plan.

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 **Shape Perceptions to see the big picture**

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- Do employees know the controls in place to address the risks that pertain to their job, department?
  - Inform them of the specific risks and how the company works to prevent & deter them.
  - Engage them as the experts on their job to enhance the Compliance Program
  - Don't keep your audits a secret



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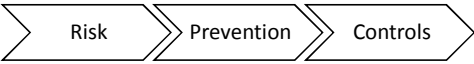
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 **Proactively Address Perceptions with your Compliance Program**

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- Approach Education as though you are training every employee to be a Compliance Officer. Explain "Why".
- Risk Assessment- Increase employee engagement by including the department in the development.





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### U.S. Sentencing Guidelines (Chapter 8)

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**§8B2.1. Effective Compliance and Ethics Program**

(a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct; and
- (2) otherwise promote an **organizational culture** that encourages ethical conduct and a commitment to compliance with the law.

 Medication Monitoring Solutions

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### What is Organizational Culture?

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A Set of shared values, written and unwritten rules that guide employee behavior.

It affects the way people and groups interact with each other, with clients, and with stakeholders. In addition, organizational culture may affect how much employees identify with an organization thus impacting performance and morale.

 Medication Monitoring Solutions

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### Organizational Culture

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What influences culture?

- **Artifacts**- Visible components of culture
  - Rituals and Ceremonies: New Hire/Annual Training, awards, Policies & Procedures
  - Symbols & Slogans-summarize intrinsic behavior.
    - Example: "No excuses, just results" or "Patients First"
- **Values** - the kind of behavior the organization wants to promote and reward vs. what behavior is actually promoted and rewarded.
- **Stories** - Narratives based on true events. Stories become company heroes. Good or bad. Employees relate to the current organization due to events that happened in the past and carries on the legacy.

 Medication Monitoring Solutions

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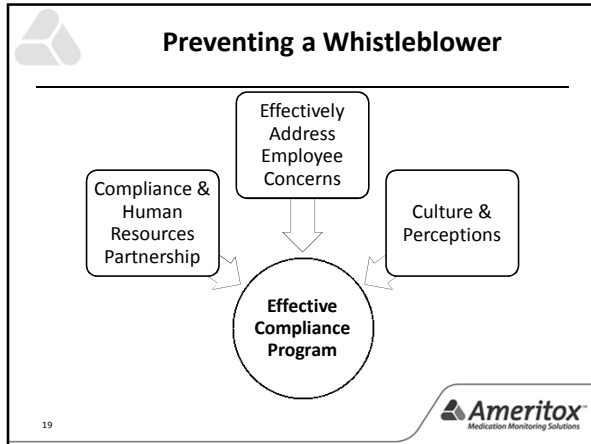
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**Compliance & HR Partnership**

**Organizational Culture Indicators You Need to Know:**

- Employee Satisfaction Surveys
- Disgruntled departments, employees, and leaders - Why?
- Exit Interviews

**Human Resources Partnership:**

- Include/Inform of Compliance Investigations
- Know HR protocols
- Inform of potential Retaliation scenarios
- New Hire Training
- Culture Strategy

BFF  
4ever

Ameritox  
Medication Monitoring Solutions

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**Summary-Preventing a Whistleblower**

- ✓ Audit the Outliers
- ✓ Address concerns irrespective of merit
- ✓ Proactively Shape Perceptions
  - ✓ Tell them about the elephant before they encounter the tusks!
- ✓ Work on the "Tone at the Middle". (Most employees report issues to their Supervisor before reporting outside the company.)
- ✓ Assess and Influence Culture
- ✓ Engage and Partner with Human Resources

Privileged & Confidential

Ameritox  
Medication Monitoring Solutions

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*The surest way to happiness is to lose yourself in  
a cause greater than yourself.*

-Unknown



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## *Compliance Today, Effectiveness Tomorrow: The Necessary Steps to Success*

HCCA's 21<sup>st</sup> Annual Compliance Institute  
Washington, DC  
March 27, 2017

Bret S. Bissey, Senior VP Compliance Services, MediTract, Inc.  
Kenneth Zeko, Senior VP, CHAN/Crowe Horwath, LLP  
Sean McKenna, Shareholder, Greenberg Traurig, LLP

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### Today's Agenda

- Enforcement Update
- CIA Trends and Impact on Compliance
- Compliance Today
- How Does Your Organization Look From The Outside?
- Compliance Leading Practices
- Conclusion

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### Enforcement Agenda

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### Enforcement Agencies

United States Department of Justice (DOJ)

- Commitment to prosecute healthcare fraud
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch
  - Healthcare fraud coordinators within 94 United States Attorneys' Offices
  - Federal Bureau of Investigation
  - Drug Enforcement Agency
  - Partnerships with private payors
- Distinct funding sources

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### Enforcement Agencies, cont'd.

Other Enforcement Agencies

- Local District Attorneys
- Offices of Inspector General
  - Federal and State
- Medicaid Fraud Control Units
  - Centers for Medicare and Medicaid Services
  - Medicaid State agencies
  - Tricare Management Authority
- Federal/State contractors
  - Commercial "Special investigative units"
- Licensing boards
- Whistleblowers

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### Enforcement Outlook in 2017

- Federal budget shortfalls
- State and federal enforcement actions increasing
- Medicare insolvent in 15 years
- State budget shortfalls
- Greater attention by U.S. Attorneys, DOJ, and OIG-HHS
- Investment and use of data analytics will continue to drive enforcement
- Increased focus on individual actors

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### Recent DOJ Activity

DOJ recovered more than \$4.7 billion in FY 2016

- Up from FY 2015 \$3.8 billion recovery
- ROI for the Health Care Fraud and Abuse Control Program \$6 returned for every \$1 expended

Continues 4-year record of recoveries over \$3 billion

Of \$4.7 billion –

- \$2.5 billion from healthcare industry, including \$330 million from hospitals
- \$2.9 billion (more than half) from cases filed by whistleblowers under FCA

Number of *qui tam* suits exceeded 700

- Up from FY 2015 600
- But way up from 1987's 30
- Whistleblowers received \$519 million

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### HHS-OIG's General Policy on Exclusion

Exclusion only apply to misconduct from the past 10 years

Early Reinstatement Process

Aggravating Factor Threshold Elevated

- Amount will have to be at least \$50,000 in several scenarios

Mitigating Factor for Exclusions

- Patient access to care significantly harmed by exclusion

Audit Obstruction Policy

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### Increased Focus on Individual Actors – Yates Memo

Sept. 9, 2015 DOJ Guidance -

*"One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing."*

Six Steps

1. Corporations must provide all relevant facts on responsible individuals to get cooperation credit
2. Investigations should focus on individuals from the inception
3. Criminal and civil attorneys handling should be in routine contact
4. Individuals should not be released from liability when resolving a matter with a corporation absent policy or extraordinary circumstances
5. DOJ attorneys should not resolve matters with a corporation without a plan to resolve individual cases, and should memorialize any declinations as to individuals in such cases
6. Civil attorneys should focus on individuals and evaluate whether to bring suit against an individual based on considerations beyond ability to pay

See <http://www.wirk.com/docs/IndividualAccountabilityforCorporateWrongdoing.pdf>

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### Parallel Proceedings

Simultaneous Civil/Criminal/Administrative investigation of same defendant(s)

- Usually jointly handled
- Can be federal and state/local or multi-district

Not every case is appropriate

- Examples of common parallel matters
  - Procurement and gov't program fraud
  - Health care fraud
  - Asset forfeiture and FLU actions
  - Environmental crimes
  - Diversion/internet pharmacies
  - SEC and antitrust investigations

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### Health Care Fraud Statute

Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347

Knowingly and willfully execute/attempt a scheme or artifice to:

- Defraud health care benefit program; or
- Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services

10-year imprisonment, restitution, and fine

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### Federal Anti-Kickback Statute

Criminal statute, 42 U.S.C. § 1320a-7b(b)

- Remuneration is anything of value
- One Purpose Test

Recommend or arrange for items/services under federal programs

- Includes non-clinicians
- State analogs may limit kickbacks in cash/private plans

Greater compliance with safe harbor generally means less risk

- Advisory Opinions address industry concerns

Forms basis for civil liability

Must be commercially reasonable

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### Stark Law

Prohibits self-referrals for federal business, 42 U.S.C. § 1395nn

- Must involve physician referral
- Designated health services
- Medicare and Medicaid only
- Ownership interest or compensation arrangement
- Generally must be commercially reasonable and fair market value
- State law may limit non-Medicare business agreements

#### Strict liability

- Must fully satisfy statutory or regulatory exception

Remedy is payment disallowance

- Exclusion and CMP liability
- May be violation of FCA

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### Civil Monetary Penalties

HHS-OIG Administrative Remedy

42 U.S.C. § 1320a-7a(a)

- Permissive exclusion and money damages for specific violations like payment or receipt of illegal kickbacks

Mirrors FCA but not governed by civil rules of procedure or evidence

- Limited discovery
- Hearsay admissible

OIG usually releases this authority in exchange for compliance obligations

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### False Claims Act (FCA)

Generally a false/fraudulent claim/statement made or caused to be made for payment to the United States, 31 U.S.C. § 3729(a)

- Includes conspiracy and "reverse" false claims provisions

Claim must be submitted "knowingly"

- Actual knowledge
- Deliberate ignorance
- Reckless disregard
- No specific intent to defraud required

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### FCA, cont'd.

#### Six-year statute of limitations

- Three years from date material facts are known or reasonably should be known by responsible official
- Not more than 10 years after the violation
- Increased penalties for violations which occurred after Nov. 2, 2015
  - Minimum per claims penalties: \$10,781 from \$5,500
  - Maximum per claim penalties: \$21,563 from \$11,000
  - Effective for penalties assessed after August 1, 2016, if the violation of law occurred after November 2, 2015
  - Excessive fine under U.S. Constitution?
- Attorney's fees and costs
- Damages not required

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### FCA Qui tam Provisions

Qui tam actions brought by private individuals ("relators" a.k.a. whistleblowers) on behalf of the Government

#### Procedure

- Relator must file a complaint, under seal, in a U.S. district court that has jurisdiction over the case
- Relator must also serve written disclosures on DOJ describing "substantially all material evidence and information the person possesses"
- DOJ has 60 days to investigate and decide whether to intervene, but extensions are liberally granted. 31 U.S.C. § 3730(b)(2).  
Trend is to limit extensions

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### Qui tam Provisions, cont'd.

After the Government fully investigates, it can:

- Intervene in the case, assuming primary responsibility for the litigation
- Decline to intervene, which allows the relator to carry on without the Government
- Move to dismiss the case (even if the relator objects)
- Seek to settle the case

Bars to qui tam suits include:

- Public disclosure (anyone could have filed this suit)
- First-to-file rule (someone already filed)
- Previous Government action (U.S. is already involved)

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### Escobar: Key Supreme Court Case

*Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016)

- Allowed implied certification BUT relied on whether material to payment
- Unanimous decision
- Implied certification can be a basis for liability under certain circumstances
- Courts continue to parse *Escobar* regarding materiality requirement

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### CIA Trends and Effect on Compliance Programs

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### Notable Requirements - 2015 CIA

- Extensive management certifications
- Focus arrangement database and process, policies, etc.
- Risk assessment and internal review process regarding arrangements and focus arrangements.
- Independent Review Organization (IRO).
  - Arrangements systems review – systems, processes, policies and procedures relating to the initiation, review, approval and tracking of arrangements.
  - Arrangements transaction review – 50 – to determine whether they complied with the focus arrangement procedures and requirements.

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### Who must certify?

President/Chief Executive Officer  
 General Counsel  
 Director, Internal Audit  
 Regional Chief Executive Officers  
 Chief Operating Officers  
 Chief Financial Officers  
 Human Resource Directors  
 Vice President, Strategic Planning  
 Senior Vice President, Communications and Marketing  
 President, Health Foundation  
 Vice President, Government and Community Relations  
 Senior Vice President, Chief Human Resource Officer  
 Senior Vice President, Chief Financial Officer  
 Senior Vice President, Chief Operations Officer  
 Vice President, Physician Services  
 Senior Vice President, Chief Information Officer  
 Vice President, Community Health Services  
 Chief Medical Officer  
 Vice President, Designated Institutional Office  
 Vice President, Corporate Compliance/Chief Compliance and Privacy Officer  
 Children's Diagnostic and Treatment Center Administrator  
 Practice Administrator  
 Accountable Care Organization Administrator

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### Certification Statement

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and xxxxx policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of xxxxx is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

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### 2014 CIA

- Appointment of service area compliance officers
- Service area compliance committees
- Must submit to OIG all documentation reviewed and actions taken related to oversight of compliance program
- Board resolution of compliance with CIA and, if cannot achieve, reasons why
- Certifications:
  - Executive leadership (9).
  - Operations leadership (15).
  - CFO; with annual report submission.
- Inpatient admission medical necessity
- Risk assessment and internal review process

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### Risk Assessment and Internal Review Process Under CIAs

Within 90 days after the Effective Date, xxxx shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements....

The risk assessment and internal review process should include: ( 1) a process for identifying and prioritizing risks, (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas, and (3) tracking results to assess the effectiveness of the remediation plans.

The risk assessment and internal review process should require compliance, legal and department leaders, at least annually, to evaluate and identify risks associated with Arrangements and develop and implement specific plans to address and mitigate the identified risks..... Term of the CIA

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### LEGAL INDEPENDENT REVIEW ORGANIZATION CIA (July 14)

- Assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations, directives, and other guidance documents related to these statutes.
- Expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review...
- Respond to all OIG inquiries in a prompt, objective, and factual manner...
- Not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the Legal IRO's engagement...
- 50 Focus Arrangements that were entered into or renewed by IHS during the Reporting Period with: (1) physicians or other health care professionals; or (2) entities owned or controlled, in whole or in part, by physicians or other health care professionals. The Legal IRO shall select its sample of Focus Arrangements for review in consultation with OIG.
- The Legal IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and xxx shall furnish such documentation and materials to the Legal IRO, prior to the Legal IRO initiating its review of the Focus Arrangements...

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### Focus Arrangements (not really new)

You need to identify which of your contracts are focus arrangements. CIAs define "focus arrangements" as:

- Between entity and actual source of healthcare business or referrals to medical center and involves, directly or indirectly, the offer, payment or provision of anything of value;
- Between entity and any physician who makes a referral to medical center for designated health services; or
- Between entity and any physician (or a physician's immediate family member) or medical practice that involves, directly or indirectly, the offer, payment or provision of anything of value in anticipation of that physician becoming an actual source of healthcare business or referrals (e.g., for purposes of recruitment).

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### June 2015 – OIG Fraud Alert Focuses on Physician Compensation Arrangements

- Targeted at physicians and directs that all compensation arrangements need to be FMV and reflect payment for bona fide services that have been provided
- If any purpose of the arrangement is to compensate a physician for past or future referrals, the potential exists AKS violation
- Could result in possible criminal, civil or administrative sanctions, including exclusion and potential draconian FCA penalties

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Who is Covered by CIA....

Be Proactive in Determining

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Effective Compliance - Today

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### What Should Your Compliance Program Look Like?

Factors to consider

- Size of the organization
  - Large organizations
  - Small organizations
- Recurrence of similar misconduct
- What are you competitors doing
- What is the government doing
- Applicable governmental regulations and industry practice

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### Three Lines of Defense

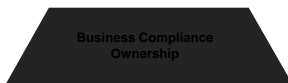
**"The Third Line"**  
Independent Compliance Oversight and Internal Audit will provide independent oversight and monitoring.



**"The Second Line"**  
Compliance will provide compliance management, framework and policies.



**"The First Line"**  
Management is accountable for identification of risks, internal controls, and compliance activities and monitoring in order to be compliant with laws and regulations.



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### What is an Effective Compliance Program?

Effective compliance programs should mitigate/eliminate regulatory/criminal risks, **foster a culture of integrity** and provide organizations with the ability to defend against allegations of fraud or abuse.

Incorporated into the OIG's various Compliance Program Guidance Documents and promulgated in the Federal Sentencing Guidelines; the Seven Elements represent the basic tenets of an effective compliance program.

1. Oversight:
  - Compliance Office & Committee
  - Oversight-boards
2. Written Standards:
  - Code of Conduct
  - Policies & Procedures
  - Event/Function specific guidance documents
3. Training:
  - Adequate training on company specific compliance policies and expectations
  - Should include all relevant employees and 3rd party agents working on behalf of the organization

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### Effective Compliance Program, cont'd.

- 4. Communication:
  - Anonymous Compliance Hotline
  - Access to supervisors and compliance personnel
  - Positive compliance tone from leadership
- 5. Risk Based Auditing & Monitoring:
  - Risk Assessment
  - Internal and 3rd party auditors
  - Business-based monitoring
- 6. Disciplinary Guidelines and Enforcement of Company Standards:
  - Clear, specific and transparent disciplinary policies
  - Consistency with consequences
  - Intentional/material vs. negligent violations
- 7. Responding to Detected Problems & Corrective Action
  - Investigations process
  - Identification of Root Cause
  - Development and corrective action/mitigation plan

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### Board Governance – Leading Practices

- Does board receive tailored education to what is occurring (internally and externally)?
- Does board understand various types of risk?
- Compliance officer can communicate with the board whenever he or she wants without hesitation?
  - Does CCO have routinely scheduled executive sessions with board?
  - Does CCO report to board?
- Does the board have any role in CCO's performance evaluation?
- Is there a formal compliance committee of the board?
- Are board members involved in the compliance program oversight?
- What is the compliance knowledge level of board?
  - Engage experts to assist in program functioning/validation of "effectiveness" of compliance program.
  - Is external assistance available when necessary?
- Does board receive updates from the organization?

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### Executive Leadership – Leading Practices

- Does leadership understand the seven elements of compliance?
- Does the CCO report to the CEO?
- How frequently does the CCO meet with the CEO?
  - Are the meetings formally scheduled?
  - Are agendas prepared?
  - Are notes taken?
  - Are minutes taken?
  - How often are these meetings canceled/rescheduled?
- Can employees give examples of leadership's commitment to compliance?
- Does CCO have an understanding of employees' perceptions of executive leadership's commitment to compliance?

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### Leading Practices, cont'd.

- Does leadership participate in operational compliance committee/matters?
- Does leadership provide outreach to employees regarding compliance
- Does leadership evaluate/consider suggestions regarding:
  - Risks
  - Value
  - Strategic Vision
  - Growth
- Does leadership kickoff annual compliance risk assessment process?
- Does leadership introduce the hotline at least annual?
- Does leadership offer frequent/comprehensive compliance training?
- Does leadership compensation include compliance metrics?

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### How Does Your Organization Look From The Outside?

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### How Does Your Organization Look From The Outside?

Consider the following:

- What are your most utilized codes?
- Who are your highest paid providers?
- Who utilizes the highest and lowest E&M codes?
- Who is responsible for denials?
- Are you performing claims reviews?
- Are you being reimbursed for non-medically necessary services?
- Are you trending findings? Are you refunding money?
- Who receives reimbursement from potential referral sources?
- Which physicians are receiving the most \$ from industry?
- Do you do business with PODs?
- Do you assess FMV when acquiring physicians?
- Do you have a documented, strategic, compliant approach to physician compensation and acquisitions?
- Have you compared physician contract amounts to accounts payable?

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**How Does Your Organization Look, cont'd.**

Ultimately...

- Do you know what your organization's compliance risk profile looks like?
- Do employees know their compliance responsibilities?
- Are they held accountable for them regardless of title?
- Are your compliance efforts satisfactory?
  - Could you attest that they are?
  - Could your board?
  - Could your executive leadership team?
  - Could operational management?
- Has the compliance program ever been assessed?

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**Compliance Leading Practices**

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**Compliance Leading Practices**

- Ensure that systems are in place to track, monitor and report time and effort
- Track nonmonetary compensation
- Conflicts of interest disclosures
- Keep documentation of negotiations
- Proactively manage complaints or concerns and ensure corrective action
- Track remuneration to and from all parties
- Track services and activity logs
- Monitor use of leased space or equipment
- Regularly audit logs and reports to substantiate payments

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### Leading Practices, cont'd.

Identify potential sources of obligations to repay

- Claims submissions
- Enrollment forms
- Contracts
- Certifications

Keep up with evolving legal standards

Receivables monitoring, auditing, disclosure

Listen and investigate when an employee, contractor, agent, or anyone tells you that there is a "problem" at the company

- Remediate promptly
- Consider self-disclosure, repayment strategies, and obligations

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### Leading Practices, cont'd.

Keep up with current enforcement trends!

The following entities are being scrutinized:

- Labs/Toxicology Labs
- Specialty Pharmacies
- Workers Comp/DOL
- Pain Management

Beware:

- Alleged Federal Carve Outs
- Uneducated sales reps willing to push the envelop for huge commissions
- Physicians' relationships with questionable entities
- Guilt by association

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### Compliance is Critical

If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place.

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**Concluding Thoughts**

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**Bret S. Bissey, MBA, FACHE, CHC, CMPE**  
Senior Vice President, Compliance Services

- Thirty years of diversified healthcare management, operations and compliance experience.
- Former SVP, chief of ethics and compliance officer at UMDNJ.
  - Credited with re-engineering the compliance program of the nation's largest free-standing public health sciences university.
  - Successfully led the compliance program to adhere to CIA with DHHS/OIG that occurred following a Deferred Prosecution Agreement.
- Chief compliance and privacy officer at Deborah Heart and Lung Center.
  - Three-year CIA, first settlement of Voluntary Disclosure Protocol.
  - Compliance program recognized by HCCA as a "Best Practice."
- Certified in HCCA and the Medical Group Management Association.
- Author of The Compliance Officer's Handbook.



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**Sean McKenna**  
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- Sean McKenna focuses his practice on healthcare enforcement and regulatory issues, representing individuals and providers under civil or administrative investigation by the Department of Justice, Offices of Inspector General, and Attorneys' General Medicaid Fraud Control Units, as well as in criminal investigations and matters involving the United States and State Attorneys General.
  - Former ten-year Assistant United States Attorney
  - Former Associate Counsel to the Inspector General
  - Former General Counsel for the U.S. Department of Health and Human Services
- Areas of Concentration
  - False Claims Act/*Qui tam*
  - Defense of criminal healthcare matters and government investigations
  - Compliance and regulatory issues
  - Healthcare litigation



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**Kenneth Zeko, JD**

Senior Vice President of Compliance and Risk Services  
CHAN/Crowe Horwath



- Ken is a licensed attorney with approximately 20 years of regulatory, compliance experience. Ken assists clients with compliance program assessments, risk assessments, investigations, coding compliance engagements, Independent Review Organization (IRO) engagements and Pre-IRO engagements.
- Ken has performed approximately 55 comprehensive compliance program assessments. He has assisted public hospitals, academic medical centers, integrated health systems, community hospitals, pediatric hospitals, medical device companies, payors, dialysis providers, physician practices and post-acute care providers.
- Ken leads a team of coding compliance professionals to perform coding compliance assessments to satisfy compliance program monitoring activities, to assist compliance programs with internal investigations and to assist counsel with attorney client privileged investigations.

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## The OIG's New Corporate Integrity Agreement Form: How Your Organization Could Benefit

Nicole Caucci, Deputy Chief, Administrative & Civil Remedies Branch, OIG, DHHS  
Steve Ortquist, Managing Director, Aegis Compliance & Ethics Center, LLP

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### Session Objectives

- ▶ Highlight key and new CIA provisions
- ▶ Discuss reasons for changes/amendments to the CIA form: What does the OIG hope to achieve?
- ▶ Discuss how substance of CIA requirements is part of effectiveness reviews for providers not under CIA
- ▶ Discuss how key and new CIA provisions might be beneficial to providers not under a CIA

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### Corporate Compliance Officer

- ▶ Corporate Compliance Officer
  - ▶ A member of senior management
  - ▶ Reporting relationships
    - ▶ To the CEO or Board
    - ▶ Not to the GC or CFO (and no responsibility to act as GC or supervise GC staff)
  - ▶ Compliance Officer duties are enumerated
    - ▶ Developing/implementing policies, procedures and practices to promote compliance
    - ▶ Reporting to the Board of Directors
    - ▶ Monitoring day-to-day compliance activities (and CIA reporting obligations)
  - ▶ Non-compliance job duties limited and do not interfere with compliance officer role

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### Compliance Committee

- ▶ Chaired by the Compliance Officer
- ▶ Includes members of senior management necessary to meet CIA requirements (e.g., billing, clinical, human resources, audit and operations)
- ▶ Meets at least quarterly
- ▶ Minutes of the Compliance Committee meetings made available to the OIG upon request (NEW)

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### Management Certifications - Certifying Employees

- ▶ I have been trained on and understand that compliance requirements and responsibilities as they relate to [DEPARTMENT], an area under my supervision.
- ▶ My job responsibilities include ensuring compliance with regard to the [DEPARTMENT] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [ORGANIZATION'S] policies.
- ▶ I have taken steps to promote such compliance.
- ▶ To the best of my knowledge, the [DEPARTMENT] of [ORGANIZATION] is in compliance with all applicable Federal health care program requirements and the obligations of the CIA.
- ▶ I understand that this certification is being provided to and relied upon by the United States.

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### Certifying Employee Process

- ▶ What policies & procedures, legal requirements, CIA requirements, etc., are core to the certification?
- ▶ Will sub-certifications be required?
- ▶ What reports and other evidence or documents that reflect the state of compliance must be reviewed?

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### Board (or Committee) Resolution

"The Board of Directors (or Board committee) has made a reasonable inquiry into the operations of [ORGANIZATION'S] Compliance Program including the performance of the Compliance Officer and Compliance Committee. Based on its inquiry and review, the Board (or Committee) has concluded that, to the best of its knowledge, [ORGANIZATION] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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### Board Oversight & Board Resolution

- ▶ Board or Board Committee Members must be independent (i.e., non-executive)
- ▶ Required to meet quarterly to review and oversee the compliance program, including (not limited to) the performance of the Compliance Officer and the Compliance Committee
- ▶ Must submit to the OIG a description of the documents and other materials reviewed, and additional steps taken, in support of the CIA required board resolution
- ▶ Retention of a Compliance Expert (some CIAs)
- ▶ Must, for each reporting period, adopt the following resolution (signed by each member of the board or board committee) . . .
  - ▶ If unable to provide the resolution, must include a written explanation of the reasons why it is unable to conclude that the compliance program is effective, and the steps it is taking to implement an effective compliance program

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### Compliance Training Plan (NEW)

- ▶ Training Plan Requirement -
  - ▶ At least annual training for all Covered Persons
    - ▶ CIA, Compliance Program, Federal health care program requirements (including AKS and Stark)
  - ▶ Board Member Training
  - ▶ Training Records

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### Risk Assessment & Internal Review Process (NEW)

- ▶ Risk Assessment Process
  - ▶ A process for identifying and prioritizing potential risks;
  - ▶ An assessment plan to evaluate and respond to potential risks, including internal auditing and monitoring of potential risk areas;
  - ▶ Corrective action plans to remediate actual non-compliance; and
  - ▶ Tracking results to assess effectiveness of corrective action.
- ▶ Connection to the IRO processes in the CIA
  - ▶ May inform scope of claims review

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### Addition of Medical Necessity to IRO Reviews

- ▶ Claims are reviewed by the IRO to determine whether the items and services were *medically necessary and appropriately documented* and whether the claim was correctly coded, submitted, and reimbursed
- ▶ IRO qualification requirements updated

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### Overpayments Provisions (NEW)

- ▶ CIAs adopt the definition of "Overpayments" from the CMS rule (but CIA overpayment provisions are applicable to overpayments from all Federal health care programs)
- ▶ CIA requires development of policies to ensure compliance with requirements of the CMS Overpayment rule
- ▶ Overpayment obligations connected to Reportable Events requirements ("Substantial Overpayments")

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### IRO Claims Review Provisions (NEW)

- ▶ Claims review may be risk based
- ▶ Overpayment obligations connected to IRO/claims review provisions
  - ▶ additional sampling/extrapolation no longer required as a result of error rates above a certain threshold
  - ▶ instead provider should evaluate its sample results in light of the CMS Overpayment Rule to determine what additional steps are required to demonstrate the exercise of due diligence (e.g., additional sampling, audits in other areas, extrapolation, etc.)

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### Annual Report Requirement: Summary of Audits by Medicare/Medicaid Program Contractors

- ▶ Must also report [ORGANIZATION'S] response/corrective action plans
- ▶ Potential source of risk identification for future IRO reviews

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### Compliance Officer AND CEO Certification

- ▶ "To the best of [his/her] knowledge, except as otherwise described in the [implementation or annual] report, [ORGANIZATION] has implemented and is in compliance with all of the requirements of the CIA; and
- ▶ "[he/she] has reviewed the [implementation or annual] report and has made reasonable inquiry regarding its contents and believes that the information in the report is accurate and truthful."

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### IAs for Practitioners and Small Entities

- ▶ Three year term
- ▶ Scaled down compliance program requirements
- ▶ More frequent audit requirements (quarterly claims review rather than annual claims review)
  - ▶ If resources are limited, focus of compliance resources should be on auditing/risk assessment

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### Questions/Discussion

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## 203 - Dealing with a Worthless Services Allegation

Julie B. Mitchell, Attorney  
Mitchell Day Law Firm, PLLC

Michael D. Peeler-Smith, RN, NHA, CHC, QCP  
Chief Compliance Officer  
Foundation Health Services, Inc.

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## Disclaimer

THIS MATERIAL IS INTENDED TO BE  
EDUCATIONAL AND DOES NOT CONSTITUTE  
LEGAL ADVICE

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## Objectives

- Understand the factors to consider in moving forward with Settlement vs. Litigation
- Know the In's and Out's of negotiating a Settlement & Quality of Care CIA
- Learn how to live life with a Quality of Care monitor

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**Worthless** – Having no real value or use

Valueless • Poor Quality • Inferior

Second Rate • Third Rate • Low-Grade

Cheap • Shoddy • Tawdry • Useless • Of No Use

Ineffective • Ineffectually Pointless • Inadequate

Deficient • Meaningless • Empty • Hollow

Trifling • Inconsequential • Lame • Pathetic

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**Recent Cases:** Federal False Claims Act  
31 U.S.C. §§ 3729-3733

- ***U.S. ex rel. Absher Mormence Meadows Nursing Center*** – 7<sup>th</sup> Circuit vacated a \$9 million dollar award finding that relators failed to establish that services rendered were worthless. The court did not invalidate the worthless services theory. The court found that in order to prevail, the relator/govt. must establish services are so deficient that they amounted to no services at all. Worth less is not worthless.

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**Continued...**

- ***U.S. ex rel. Academy Health Center v. Hyperion***  
– Ongoing
- ***Villaspring Health Care Center*** – \$350,000 settlement and independent consultant
- ***U.S. v. Houser*** – Criminal
- ***U.S. v. ARBA Group, CF Watsonville East, et al.***  
– 3.8 million and 5 year Quality Care CIA
- ***U.S. ex rel. Lovvorn v. Extencicare Health Services*** - \$38 million settlement and 5 year Quality Care CIA

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### U.S. v. Foundation Health Services

- Worthless Services
  - Alleged 90 million in damages
  - Settled prior to litigation for \$750,000
  - Ability to Pay Global Settlement
  - 3 of 9 homes targeted
  - Statistical sampling
  - 5 year Quality Care CIA with monitor

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### OIG Subpoena

Your subpoena will likely cover requests for everything from medical records to the kitchen sink- or at least you will feel that way....



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### OIG Subpoena

- › All policies & procedures, guidelines, training materials, memoranda, correspondence, emails & other documents that govern, describe or otherwise relate to operations...
- › Salaries, compensation and/or bonus systems
- › Marketing
- › Surveys mock or otherwise
- › Quality Indicators/Quality Measures
- › Complaints/Grievances
- › Satisfaction surveys

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**continued...**

- > RUG categories
- > Acquisition of Medicare or Medicaid numbers, 855s, etc.
- > Review Committees – any and all
- > Corporate overhead and structure, leases, etc.
- > Job descriptions, employee and contract employee files
- > Manuals
- > Compliance Programs and hotline reports
- > Incident/Accident reports
- > Color copies of time sheets, etc.
- > Budgets – staffing, equipment, etc.

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**Look at case early on...**

- Charting parties
- Staffing
- Surveys
- Anti - Kickback violations
- Diversion of funds
- Improper RUG coding
- Resident harm and complaints
- Therapy
- Medical Director
- Hospice

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**Contact appropriate parties**

- OIG
- DOJ
- State MFCU
- State AUSA
- Relator Counsel

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### Assess Quality of Care

- QA / Regulatory Expert
- Financial Expert
- Statistical Sampling Expert
- Cost Report Expert

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### Yates Memo: You're Fired!

- Sept. 9, 2015: Individual Accountability for Corporate Wrong Doing
- 6 key steps to pursue individual corporate wrong doing
  - Tell all the facts relating to individuals
  - Focus on the individual from beginning
  - Criminal and civil attorneys should work together
  - Do not release individuals from civil or criminal liability when resolving a matter with a corporation
  - Do not resolve corporate matter without clear plan to resolve individual case(s)
  - Look at individual regardless of ability to pay (civil)

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### Cost Analysis - Stop Litigation Early

- Cost of litigating
- Settlement
- Ability to pay



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## Litigation

- Motion to Dismiss
- Discovery
- Summary Judgment
- Trial



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## Settlement

- DOJ - \$ and Scope of Release
- OIG - CIA
- Relator - Attorney fees
  - Right to object



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## Ability to Pay

- Corporate
- Individual



**Signed under the penalty of perjury!**

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### CIA

- Must be able to live with the terms of the CIA
- Cost
- Insurance
- Monitor / IRO
- Cannot put expenses on cost report
- Policies and procedures
- Reporting

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### Quality of Care CIA

- About a dozen implemented with 5 active
- OIG website:  
<https://oig.hhs.gov/compliance/corporate-integrity-agreements/quality-of-care.asp>
  - CF Watsonville East, LLC and CF Watsonville West, LLC
  - Extendicare Health Services, Inc.
  - Foundation Health Services, Inc.
  - Parkland Health and Hospital System
  - GGNHC Holdings LLC

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### DOJ Obtains more than \$4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the Government in fiscal year ending September 30, 2016

- \$2.5 billion came from the health care industry and reflects only federal losses
- 7<sup>th</sup> consecutive year that DOJ's civil health care fraud recoveries have exceeded \$2 billion
- 19.3 billion in health care fraud since January 2009 to end of fiscal year 2016.

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**Future of Worthless Service FCA Case**

- Elder Justice Task Force
- Plaintiffs
- Whistle blowers
- Med-Mal Crisis
- Courts

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**So What Can You Expect from a Monitor?**

- A written agreement
- A five year relationship
- Routine Visits to “Monitor”
  - Routine Reporting

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**A written agreement**

- The written agreement coincides with your CIA and which outlines specific duties the Monitor must perform.

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### Routine Visits to “Monitor”

- Visits are usually quarterly and will feel much like a regular survey by your State Department of Health. A report will be generated by the Monitors and your company must address how the company will implement the monitor’s recommendations or explain why the company feels it is not appropriate to implement a recommendation.

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### Routine Reporting



- Your CIA will require an Implementation Report and Annual Reports. Additionally, you will be required to send monthly reports to your Monitor. At the discretion of the monitor, additional reporting may be required.

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### Relationships

- Work to establish a good working relationship with your monitors!
- You got ‘em- You must deal with them.
- LISTEN & LEARN!
- Try not to become defensive or adversarial
- Monitors, like surveyors, must find something to point out to validate their jobs. Accept it!
- Remain professional and leave personal feelings aside.

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## Summary

- No company is immune!
- Follow the RULES!
- Work to ensure you have a fully functioning Corporate Compliance Committee and strive in all sincerity for full compliance with regulations.
- Work to have good survey outcomes
- Work to have employee & customer satisfaction
- DOCUMENT!

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## QUESTIONS



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**Successfully Resolving a  
Multi-Year OCR  
Investigation**




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HCCA 21<sup>st</sup> Annual Compliance Institute  
March 27, 2017

Cliff Baker, Managing Partner  
Mediology Services

Karen M. Eastmond, Chief  
Compliance Officer  
CenterLight Health System

Adam Greene, Partner  
Davis Wright Tremaine LLP

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**Agenda**

- Anatomy of a Breach
- Responding to the Office for Civil Rights
- A Focus on Corrective Action

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**CenterLight at a Glance**

- Not-for-profit leader in managed long term care since 1985
- Integrated provider-payer
- Largest Program of All-inclusive Care for the Elderly (PACE) in the nation — 3,400+ members
- 5,800+ Partial Capitation MLTC Plan members (2016)
- Over 1000 I-SNP managed care members residing in skilled nursing facilities

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**Embedded in a Long-Term Care Continuum**

- Nursing homes**  
Skilled nursing, short-term rehabilitation and long-term residential care.
- Assistance at home**  
Our Licensed Home Care Services Agency (LHCSEA) provides assistance with activities of daily living.
- Skilled nursing at home**  
Our Certified Home Health Agency (CHHA) to help regain function following injury or surgery.
- Music therapy**  
Groundbreaking techniques that harness the power of music to heal and recover physical and cognitive function.
- Independent housing**  
Four housing facilities in the Bronx, staffed by CenterLight professionals and subsidized by New York City and New York State funding programs.

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**Setting the Scene...**

- Temp hired to process new member enrollments
- Temp downloads and emails files containing PHI to his personal email account
- Email with PHI was not identified by security controls
- Compliance Office receives a report of potentially suspicious activity
- Investigation initiated and incident identified

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**What Happened Next?**

1. Conducted breach risk assessment to assess situation and to stem further disclosure
2. Complete an Incident Report
3. Determine if incident is a breach
4. Gather documentation
5. Mobilize incident response team

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**Who Did We Involve?**

- Department Involved and Temp agency
- Customer Service/Finance/IT/Human Resources
- Healthcare IT Consultant
- HIPAA Counsel
- Credit Monitoring Services
- Corporate Communications / PR Team
- Board of Directors

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**Notification Process**

1. Drafted and notified impacted members
2. Placed ad in local paper
3. Notified OCR, CMS, if applicable and State Attorney General (depending on State law requirements)
4. Trained customer service, develop FAQ
5. Contacted Business Associate (Temp vendor) involved

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**Be Prepared to Wait...**

- Gather documentation to support your case
  - Training materials
  - Privacy & Security policies and procedures
  - Disciplinary action policies
- Further assess risks - consider whether you have adequate resources to do risk assessment or hire consultant with expertise in HIPAA Privacy & Security
- Consult with HIPAA counsel

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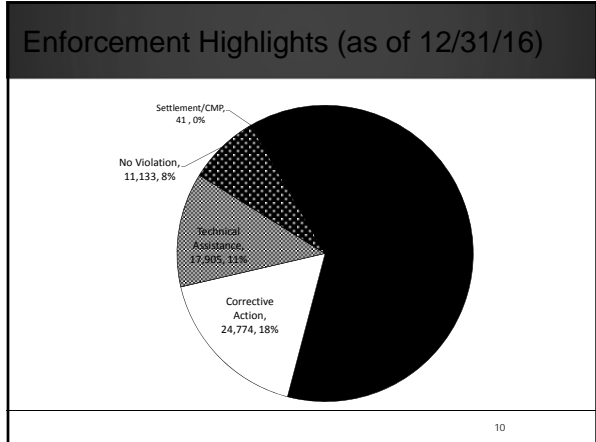
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Potential Violation	Description	# of Years	Potential CMP
§ 164.502(a)	Disclosure	1	\$1.5M
§ 164.502(b)	Minimum Necessary	6	\$1.5M
§ 164.530(c)	Safeguards	6	\$9M
§ 164.530(f)	Mitigation	1	\$1.5M
§ 164.308(a)(1)(ii)(A)	Risk Analysis	6	\$9M
§ 164.308(a)(1)(ii)(B)	Risk Management	6	\$9M
§ 164.308(a)(1)(ii)(D)	Information System Activity Review	6	\$9M
§ 164.308(a)(6)(ii)	Security Incident	6	\$9M
§ 164.310(a)(1)	Facility Access Controls	6	\$9M
§ 164.312(a)(2)(iv)	Encryption (at rest)	6	\$9M
§ 164.312(b)	Audit Controls	6	\$9M
§ 164.312(d)	Authentication	6	\$9M
§ 164.312(e)(1)	Transmission Security	6	\$9M
<b>Total</b>			<b>\$94.5M</b>

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- ### What OCR Is Focused On
- Corrective Action
  - Risk Analysis
  - Risk Management
  - Policies and Procedures
  - Training
  - Sanctions
- 12

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### How to Respond to OCR

- Collaborative rather than adversarial
- Transparent rather than obscuring
- Recognize gaps and explain future corrective action

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### Drafting a Response

- Don't merely respond to specific requests; provide a complete picture
- Highlight a culture of compliance
- Professional and gracious tone
- Include relevant supporting documentation as attachments
- Consider Bates stamping attachments

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### Corrective Action Plan

If you don't provide a solution a solution will be provided for you that you may not like

- Corrective Action Plan Characteristics
  - Identified Risk
  - Risk level (e.g., High, Med, Low)
  - Remediation Steps
  - Owner
  - Timeframe
  - Status and progress



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### Corrective Action Plan - Governance

- Executive accountability
- Project management
- Roles and responsibilities
- Regular status updates and progress reporting

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### Corrective Action Plan - Scope

- Policy updates
- Process documentation
- People
  - Skillsets
  - Contract resources
  - Consulting
- Technology Solutions
  - Patch management
  - Two factor authentication
  - Monitoring solution



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### Corrective Action Plan – Key Considerations

- Don't set yourself up to fail:
  - Timing (i.e., start and end dates)
  - Level of effort (i.e., FTE effort to get the work done)
  - Investment (i.e., budget)
  - Skillsets
  - Dependencies
  - At first focus on quick wins



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### Corrective Action – Challenges

- Accommodating for all exceptions
- Fixes that have dependencies on various teams
  - Secure configuration
  - Patch management
- Fixes that require technical components
  - Strong authentication
  - Logging and monitoring
- Fixes that require significant process improvements
  - Access reviews
  - Vendor assessments

"Better a diamond with  
a flaw than a pebble  
without."  
— Confucius

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### Final thoughts

- The corrective action plan should not become the security strategy
- The security strategy should encompass the corrective action plan
- Continue to update risk assessments and adjust priorities accordingly
- Fully leverage the moment to increase management's attention and support

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### Questions?



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Contact Information




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202.973.4213

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## Cleaning Up the Low Hanging Fruit to Protect Your Physician Practices

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VALLEY VIEW HOSPITAL  
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NANCY C. KENNEDY, RHIT, CPC, CHC, CHPC  
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WICHITA, KS

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## Objectives

2

- Learn about the “low hanging fruit” in most physician practices that can open the door to potential fraud and abuse.
- This session will provide overviews of high risk areas for physician practices and how to determine your risks.
  - Incident-To
    - Non-Physician Provider Students / Medical Students
  - 99211
  - Anticoagulation Clinics
  - Locum Tenens
  - Supervision of Diagnostic Testing
- Learn the steps to take to effectively minimize the risks to your organization and physicians through simple and effective education, auditing and refunding processes.

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## Billing “Incident To” Physician’s Professional Services

3

- Allows certain services performed in the physician’s office/clinic by someone other than the physician to be
  - Billed under the physician’s provider number
  - Paid at 100% of the physician fee schedule
- The “Services” provided by the physician’s auxiliary staff and Non-Physician Practitioner (“NPP”) must meet certain criteria and rules established by Medicare.
  - Not all Insurance Payers (e.g. Commercial & Medicaid) use the same rules or allow Incident-To billing.

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**"Incident To" Definition**

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**Incident to a physician's professional services means that the services are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness.**

*Source: Medicare Benefit Policy Manual (Internet Only Manual) Chapter 15, Section 60.1 – Incident To Physician's Professional Services (Rev. 1, 10-01-03) B3-2050.1*

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**"Incident To" Definition**

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**To be covered incident to the services of a physician or other practitioner, services and supplies must be:**

- o An integral, although incidental, part of the physician's professional services
  - The **initial service** must be done by the physician.
    - o The NPP and/or Auxiliary staff may only complete and document the ROS and PFSH. The physician must complete the Chief Complaint, History of Present Illness, Examination, Assessment, and Plan of Care.
  - A **plan of care** must be **established by physician and followed**.
    - o New problems and changes to the treatment plan – the physician must see the patient first and modify the plan of care before the NPP can provide follow-up care and bill "Incident To"
  - There must be **subsequent services** by the physician of a **frequency that reflects the physician's continuing active participation** in and management of the course of treatment.

*Source: Medicare Internet Only Manual Chapter 15, Section 60 - Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service*

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**" Incident To" Definition, Continued**

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- o **Furnished by the physician or by auxiliary personnel under the physician's direct supervision.**
  - **Auxiliary personnel**
    - o Any individual who is acting under the supervision of a physician, regardless of whether the individual is an **employee, leased employee, or independent contractor** of the physician, or the legal entity that employs or contracts with the physician.
      - W2 or 1099 Nurses, Technicians, Therapists, Aides
    - o Under the control of the physician
    - o Must **represent an expense** to the physician, group practice, or legal entity.

*Source: Medicare Internet Only Manual Chapter 15, Section 60 - Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service*

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Involvement of Other Persons in "Incident To"

7

- **Residents/Fellows** may not supervise "incident to".
- **Students (Medical & Non-Physician Provider)** services can not be billed "Incident To"
  - Students are not paid W2 or 1099 "employees"
    - Exception - stipends paid to students by the practice.

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Documentation to Support "Incident To"

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- **Documentation**
  - Must clearly document who performed the "Incident To" service and
  - The physician's presence in the office suite during the service/procedure with a note by the NPP and/or Auxiliary staff

*Dr. Jones was immediately available and provided direct supervision in the office during the patient's visit today. Vicki Dwyer, APRN/CNS*

- AND the signature of the physician providing direct supervision.

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99211 - Definition

9

"Office or other outpatient visits for the evaluation and management of an established patient, that may not require the presence of a physician.

Usually, the presenting problem(s) are minimal.

Typically, 5 minutes are spent performing or supervising these services."

*Source: American Medical Association cpt® Standard*

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**Billing 99211**

⑩

- Requires a face-to-face patient encounter.
- May be performed by ancillary staff and billed as if the physician personally performed the services.
  - Must meet Incident-to requirements.
- Must be REASONABLE & NECESSARY
- The documentation of each patient encounter:
  - Must have reason for the encounter and elements of evaluation and management
    - ✦ Historical information and/or physical data
    - ✦ Medical decision-making, provision of patient education, etc.

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**Documenting a 99211**

⑪

- The documentation of each patient encounter:
  - Services performed by ancillary staff and billed incident-to the physician should demonstrate the “link” between the non-physician service and the precedent physician service.
  - Must contain the date of the service, legible identity and credentials of both the individual who provided the service and the supervising physician.

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**99211 Billing**

⑫

- 99211 should NOT be used to bill:
  - Solely for the writing of prescriptions (new or refill) when no other E/M is necessary or performed
  - Routine blood pressure checks that have no impact on patient's care.
  - When drawing blood for laboratory analysis or when performing other diagnostic tests, whether or not a claim for the venipuncture or other diagnostic study test is submitted separately.
  - Routinely when administering medications, whether or not an injection (or infusion) code is submitted on the claim separately.
  - For performing diagnostic or therapeutic procedures (especially when the procedure is otherwise usually not covered/not reimbursed or payment is bundled with payment for another service), whether or not the procedure code is submitted on the claim separately.
  - Phone calls to patients.

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**99211 in the Anticoagulation (Coumadin) Clinic**

13

- **Appropriate Use of 99211 in addition to the laboratory blood draws for warfarin management:**
  - If it's determined the patient's medication needs adjustment, the INR is not therapeutic, or if the patient has symptoms that need to be addressed.
    - Assessing and documenting the patient in-person for signs and symptoms of bleeding or adverse effects to anticoagulant therapy.
    - Assessing the patient for changes in health status that may account for fluctuations in lab results.
    - A new anticoagulant patient where education is required regarding dietary modifications, medicine restrictions, etc.
    - A new caregiver accompanies the patient so education is needed to ensure compliance
  - Documentation of the services provided by the physician or nurse, discussion of symptoms, side effects, patient observations etc. are considered supportive of the 99211 service.

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**99211 "Dos" for Anticoagulation Management**

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- Documenting the patient's indication for anticoagulant therapy, current dose, protime and INR results
- Assessing the patient in-person for signs and symptoms of bleeding/adverse effects to anticoagulant therapy
- Assessing the patient for changes in health status that may impact or account for fluctuations in lab results (for example, new or changed medications that may cause a drug interaction with the anticoagulant therapy)
- Providing medically necessary education as needed based on the patient's individual circumstances
- Documenting the identity of the ancillary staff performing this service "incident to" the supervising physician
- Documenting the identity of the billing physician who was notified of results, gave orders, and provided direct supervision

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**99211 "Don'ts" for Anticoagulation**

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- **Billing for 99211**
  - when the in-person encounter with the patient was only for the diagnostic test
  - for telephone care, i.e. instructions on changing dose, assessment, and/or education
  - when the only documentation would be vital signs, the patient's current and future dose of anticoagulant, and when lab work is to be repeated
  - when direct physician supervision is not met or is not by the physician treating the patient's medical problem requiring anticoagulant therapy (i.e. as seen in some "Coumadin® clinic" scenarios)
  - based on the delivery of repetitive education that does not serve the medical needs of the individual patient

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### 99211 in the Anticoagulation (Coumadin) Clinic

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- **Do Not Bill** a 99211 in the Anticoagulation Clinic when The **INR** is **within the therapeutic range**, and
  - The documentation does not support a need for adjustment of warfarin dosage, or
  - The documentation does not support that the patient is symptomatic, or
  - The documentation does not support the presence of a new medical co-morbidity or dietary change.
  - When the purpose of the visit is for refilling the current prescription
  - When lab work must be repeated.
  - When **direct supervision** is not met or is not met by the physician treating the patient's medical problems requiring anticoagulant therapy.

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### Locum Tenens Definition

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- A physician who serves temporarily as a substitute (or a "place-holder") for a regular physician is absent most commonly due to illness, pregnancy, vacation, or continuing medical education, but occasionally for a physician who has left a physician group or an employer.
  - The substitute physician generally has no practice of their own and moves from area to area as needed to provide these temporary services.
  - The regular physician generally pays the substitute physician a fixed amount per diem, with the substitute physician having the status of an independent contractor rather than of an employee.

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### Use of Modifier Q6 for "Locum Tenens"

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- **Regular Physician** is the physician that is normally scheduled to see a patient and may include specialists but not Non-Physician Providers.
- **Q6** is a billing modifier added to the claim for services furnished by a locum tenens physician. When this modifier is added to the CPT code, Medicare pays the regular physician (under the regular physician's NPI) for services provided by a Locum Tenens.

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Medicare Rules for Locum Tenens

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• Medicare Payment Procedure:

- A patient's regular physician may submit the claim, and (if assignment is accepted) receive the Part B payment, for covered visit services (including emergency visits and related services) of a locum tenens physician who is not an employee of the regular physician and whose services for patients of the regular physician are not restricted to the regular physician's offices, if:
  - ✦ The **regular physician is unavailable to provide the visit services**;
  - ✦ The Medicare beneficiary has arranged or seeks to receive the visit services from the regular physician;
  - ✦ The **regular physician pays the locum tenens** for his/her services on a per diem or similar fee-for-time basis;

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Medicare Rules for Locum Tenens

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• Medicare Payment Procedure:

- ✦ The substitute physician does not provide the visit services to Medicare patients **over a continuous period of longer than 60 days\*** subject to the exception for military personnel; and
- ✦ The **regular physician identifies the services as substitute physician services meeting the requirements of this section by entering HCPCS code modifier Q6** (service furnished by a locum tenens physician) after the procedure code.
- ✦ When Form CMS-1500 is next revised, provision will be made to identify the substitute physician by entering his/her unique physician identification number (UPIN) or NPI when required to the carrier upon request.

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Medicare Rules for Locum Tenens

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• Medicare Payment Procedure:

- Physicians who are members of a group but who bill in their own names are generally treated as independent physicians for purposes of applying the Locum Tenens requirements for payment for locum tenens physician services.
  - ✦ Compensation paid by the group to the locum tenens physician is considered paid by the regular physician for purposes of those requirements.
  - ✦ The term "regular physician" includes a physician who has left the group and for whom the group has hired the locum tenens physician as a replacement.

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### Definition of a "Continuous Period"

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- **Begins** with the first day on which the covering physician (Locum Tenens) performs the covered visit services to Medicare Part B patients of the regular physician, and **ends** with the last day the covering physician (Locum Tenens) performs services to these patients before the regular physician returns to work.
- This **period continues without interruption** on days on which no covered visit services are provided to patients on behalf of the regular physician or furnished on days which no covered visit services are provided by the covering physician on behalf of the regular physician.

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### Example of 60-day Continuous Period

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- The regular physician goes on vacation on June 30, 2016 and returns to work on September 4, 2016. A substitute physician (Locum Tenens) provides services to Medicare patients of the regular physician on July 2, 2017, and at various times thereafter, including September 2, 2017. The **continuous period** of covered visit services begins on **July 2 and runs through September 2, a period of 63 days**
  - The regular physician may bill and receive payment for services the substitute physician provided on his/her behalf from July 2 through August 30.
  - Since the **September 2 services occur after 60 days, the regular physician is not entitled to bill and receive payment for them.** The substitute physician must bill for these services in his or her own name.

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### What if the Regular Physician will be Absent More than 60 Days?

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- At the end of the 60 continuous days the regular physician can:
  - Contract with a **different** substitute physician.
  - **Return to work for 1 day** then renew the contract with the existing substitute physician.
  - **Hire** the substitute physician as an independent contractor, credential them and bill under their own NPI.

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Locum Tenens Questions

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- Can a Locum Tenens substitute for more than one physician at a time in our group?

Per CMS, locum tenens physician is the substitute for a physician who is absent. Once entered into, the locum tenens physician **should not substitute for a different absent physician**. It is the expectation that the locum tenens will see only those patients that requested the regular physician for which the locum is substituting. This would **include a new patient**

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Locum Tenens Questions

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- Does locum tenens apply to a deceased provider?
- **No**, Medicare only permits payment for services furnished prior to a physician's death. When a physician becomes deceased, his/her billing number, NPI and enrollment are deactivated and cannot be used after the date the physician passes away, therefore, a locum tenens arrangement would not be permitted for a deceased provider.

10.12.2015

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Locum Tenens Questions

27

- Can we hire a Locum Tenens to build or supplement staffing?

**No**, per Medicare, a **locum tenens** physician is **meant only for the temporary absence of a regular physician** or when a regular physician has left a group practice.

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### NPP Supervision of Diagnostic Testing

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- Nurse Practitioners, Clinical Nurse Specializes, and Physician Assistants may not function as “supervisory physicians”, however they may perform diagnostic tests under their own statutory benefits and state requirements for physician supervision.
- “Section 410.32(b) of the Code of Federal Regulations requires that, with certain exceptions, **diagnostic tests** covered under §1861(s)(3) of the Social Security Act and **payable under the physician fee schedule have to be performed under the supervision of an individual meeting the definition of a “physician”**.”

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### NPP Supervision of Diagnostic Testing

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- Pub 100-02 Medicare Benefit Policy, Section 40.4 – Definition of Physician/Practitioner:
  - For purposes of this provision, the term “**physician**” is limited to doctors of medicine; doctors of osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; and doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the State in which such function or action is performed; no other physicians may opt out.
  - Also, for purposes of this provision, the term “**practitioner**” means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements: Physician assistant; Nurse practitioner; Clinical nurse specialist; Certified registered nurse anesthetist; Certified nurse midwife; Clinical psychologist; Clinical social worker; *Registered dietitian; or Nutrition Professional*

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### NPP Supervision of Diagnostic Testing

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- This policy applies to technical components (TCs) (including TCs billed globally with the professional component (PC) of the procedure) and other diagnostic procedures, which do not have relative value units reflecting physician work. These supervision requirements do not apply to diagnostic tests furnished in hospitals.
- Documentation maintained by the billing provider must be able to demonstrate that the required physician supervision is furnished.
  - Services that are not performed under the appropriate supervision are not considered reasonable and necessary and, therefore, are not covered under Medicare.

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### NPP Supervision of Diagnostic Testing

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- **Limited License Practitioners**
  - Nurse practitioners, clinical nurse specialist, and physician assistants are **not defined as physicians**. Therefore, they **may not function as supervising physicians under the diagnostic tests benefit**.
  - However, when performing diagnostic tests, they are not required to meet the physician supervision requirements defined here.
  - Instead, they may perform diagnostic tests pursuant to State scope of practice laws and under the applicable State requirements for physician supervision or collaboration.
- **'Incident To' Benefits**
  - Because the diagnostic tests benefit set forth in §1861(s)(3) of the Act is separate and distinct from the incident to benefit set forth in §1861(s)(2) of the Act, **diagnostic tests need not meet the incident to requirements**.

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### Identifying the Low Hanging Fruit

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- **Conduct investigatory audits**
  - Pull all 99211, Incident-To, Locum Tenens, etc. billed over a designated month period.
    - Appears there could be a problem
      - Root Cause Analysis
      - Education & Training
      - System Issues
  - Follow the 60-day Overpayment rule to Quantify and Refund.
    - Identify
    - Quantify
    - Refund
- Conduct Follow-up Audits

21<sup>st</sup> Annual compliance Institute, National Harbor, MD      Session 205 Monday, 03.27.2017

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### Cleaning Up the Low Hanging Fruit to Protect Your Physician Practices

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EXAMPLES  
AND  
DISCUSSION

# QUESTIONS?

21<sup>st</sup> Annual compliance Institute, National Harbor, MD      Session 205 Monday, 03.27.2017

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# Thank You!

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21<sup>st</sup> Annual compliance Institute, National Harbor, MD

Session 205 Monday, 03.27.2017

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## "Random" is Not Necessarily "Valid": Managing and Defending Against Statistics in Audits and FCA Claims

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**Key model predicts big election win for Clinton**

**FOX NEWS POLL: Clinton leads Trump by 10 points, both seen as flawed presidential candidates**

by Heather Long @heatherlong  
November 1, 2016 9:32 AM ET

**MOODY'S MODEL PREDICTS BIG ELECTION WIN FOR CLINTON**

U.S. Presidential Popular Vote		2016 Presidential Elector (113 seats)	
Candidate	Percentage	Electors	Percentage
Dem.	51.1%	286	47%
Rep.	48.9%	233	53%

**HILLARY CLINTON WILL WIN ELECTION BY A LANDSLIDE ACCORDING TO MOODY'S HIGHLY RELIABLE ELECTION MODEL**

PATRICIA RAMIREZ

**WRGB.com**  
**DECISION 2016**  
WARREN & GRIFFIN  
YOUR LOCAL LAWYERS

**PARKER HUDSON  
RAINER & DOBBS**

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Excerpt from DOJ brief filed in Florida, in 2013

"The applicability of inferential statistics have [sic] long been recognized by the courts." In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019-20 (5th Cir. 1997). Indeed, as even the public is well aware during election cycles, surveys of a small number of voters can predict the electoral winner. See United States v. Ukwu, 546 Fed. Appx. 305, 308 (4th Cir. 2013) ("[I]n many elections, a sample of 1,000 Americans can show, with enough certainty to satisfy the preponderance of the evidence standard, what is likely to happen in an election involving over 100 million voters.") (upholding the use of statistical sampling to prove amount of loss in tax fraud case)."

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Statistics in Audits  
*Trends*

- “Routine” Government Audits  
**DEFAULT** to statistical extrapolation
- Use of Statistics in False Claims Act Cases
  - Errors show “reckless disregard” or intent

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Statistics in Audits  
*Inferential Statistics*

- Definition -
- **Sample** items
  - To determine **what the population** might look like
  - Example: Pull 20 coins **at random** from the “box”
    - All coins sampled are quarters
  - What do you know about the population based on those quarters?

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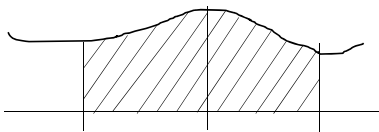
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Statistics in Audits

Why does representativeness matter?



Median Coverage

**Normal** distribution ... of sampled items?

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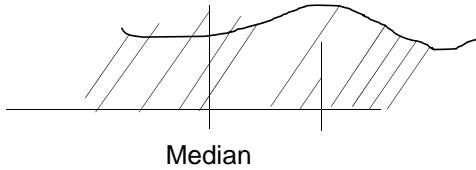
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## Statistics in Audits

Why does representativeness matter?



Skewed distribution? **BIAS?**

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## Statistics In Audits *Precision and Error Rates*

- Precision
  - Coefficient of Variation
  - Reliability
  - Can the 90% Confidence Interval "correct" for very imprecise data?
    - **NO**

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## Statistics in Audits *Inferential Statistics*

Wisdom in conducting a "probe" audit

- Why?
- To be sure have a good understanding of the population and study design
- We don't always know how many quarters versus nickels are in the box!

**UNFORTUNATELY, the government often ignores this**

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OIG Audits  
*Hospital Compliance Reviews*

We identified **multiple strata**, to be more **precise**  
***Strata of DRG Codes?***

Range: Underpayments to Overpayments  
From underpaid 20K to overpaid 150k

How Precise?

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Government Audits  
*Reviews*

We identified **multiple strata**, to be more **precise**  
***Strata of CPT codes?***

More likely to be precise? How variable are payments?

Claim **lines** sampled?

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OIG Audits  
*Hospital Compliance Reviews*

**OIG Auditors:**  
We identified **multiple strata**, to be more **precise**

What is the sampling unit?  
A **claim per OIG** .....

A **beneficiary's** claim is really a **CLUSTER** of Claims which is less precise

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Audits  
*CMS Standards in PIM*

**Medicare Program Integrity Manual – Chapter 8**  
Describes “step by step” instructions  
- Including need to maintain records  
CAVEAT- Government auditors ignore **VALIDITY** requirement, state that if it’s random, it is VALID  
Government argument: If “miss” a step, ok, as long as outcome reasonable

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OIG Audits  
*Hospital Compliance Reviews*

**OIG Auditors:**  
“We pulled a sample of claims for January 1, 2012 to December 31, 2014 and extrapolate medical necessity denials across the population ...”

**Your Answer:** \_\_\_\_\_

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OIG Audits  
*Hospital Compliance Reviews*

- **What happened October 1, 2013 for medical necessity?**  
THE RULES FOR MEDICAL NECESSITY CHANGED!
- The law said NO claims could be reviewed for MN until after “probe and educate”
- **OIG ANSWER:** We’ll pull charts for patients up until October 1, 2013 and sample, extrapolate across universe

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OIG Audits  
*Hospital Compliance Reviews*

- **OIG ANSWER:** We'll pull charts for patients up until October 1, 2013 and sample, extrapolate across universe
- **WRONG:** If you extrapolate "across" that date, you are making medical necessity denials, right?  
–But legally, you cannot make medical necessity denials unless completed probe and educate!

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Applicable Standards

- Case Law: Caring Homes Personal Home Services, Inc. v. Burwell. (10<sup>th</sup> Cir.) (Decided May 31, 2016)

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Statistics in Audits  
*Government Audit*

- What is error rate?  
    1 out of 20?  
    \$5 out of \$10,000

Government threshold 5% in Settlements!

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Statistics in Audits  
*Government Audit*

- Corporate Integrity Agreements from HHS-OIG= 5%
- CMS Medicare Managed Care Manual, Chapter 7, § 120.2, 5
  - CMS requires accurate data
  - **If plan submits 5% or greater duplicates (errors), not accurate**

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HHS OIG Integrity Agreements

**What is the purpose of a Discovery Sample for a CIA Claims Review?**

The purpose of conducting a Discovery Sample as part of the Claims Review is to determine the net financial error rate of the sample that is selected. **If the net financial error rate equals or exceeds 5%, the results of the Discovery Sample are used to determine the Full Sample size.**

The Full Sample size is based on an estimate of the variability of the overpayment amount in the population from which the sample was drawn. The results of the Discovery Sample allow the reviewer to estimate how many sample units need to be reviewed in order to estimate the overpayment in the population within certain confidence and precision levels (e.g., generally, a 90% confidence and 25% precision level).

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Standards in Audits  
*Error Rate*

PRRB Cases

- Providence Medical Center (1999)
  - Sampled bad debts
  - JUDGMENTAL sampling
  - Lack of Documentation for sampling method
  - 4% error rate
- St. Francis Hospital (2000)
  - 15% audit threshold error rate without basis to extrapolate

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Statistics in Audits  
*Government Audit*

Medicare Modernization Act

- **NO** statistical extrapolation unless SUSTAINED/HIGH ERROR RATE
- What if no "sustained" error rate?
- Unsuccessful legal challenges

TALK TO YOUR LEGISLATORS!

Should not have ANY SVRS – recall ZPIC audits/ letters?

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Statistics in Audits  
*Government Audit*

Even IF you win on appeal, remember to

**DOCUMENT Why NOT RETAINING AN OVERPAYMENT!**

The new CMS Overpayment Rule is independent of appeal wins!

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Statistics in Audits



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False Claims Act  
*Statistical Sampling*

- ***U.S. ex rel. Martin v. Life Care Centers of America*** (Sept. 2014)
- Statistics to “prove” intent? Damages?
- **The “Problem”:**
  - Life Care operates over 200 SNFs; billed 68% of its Medicare rehabilitation stays using the Ultra High category (national average of 35%)
  - 54,000 patients admitted assigned to Ultra High level rehabilitation; over 154,000 submitted claims

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False Claims Act  
*Statistical Sampling*

- ***U.S. ex rel. Martin v. Life Care Centers of America*** (Sept. 2014)
- Statistics to “prove” intent? Damages?
- **The Problem: Is there really a Problem?**
  - Could Life Care operate SNFs located adjacent to rehab hospitals? Have patients needing more rehab?
  - Each patient individually considered? Is it false claim?
  - What about reversal rate when auditors “denials” appealed?

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False Claims Act  
*Use of Statistical Sampling*

- U.S. ex rel. Michaels and Whitesides v. Agape*** (Dec. 2012)
- Rock Hill Division of District of South Carolina
  - Statistical Problem (per the Court) – each claim asserted involved question of medical necessity for hospice services to SNF resident
  - By Order of 6/25/15, certified to Fourth Circuit – the issue of whether the Relator can use statistical sampling to prove both liability and damages
  - Oral argument held 10/26/16

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Agape Fourth Circuit Brief Highlights

**Relator's FCA claims cannot be proved by statistical sampling.**

- Statistical evidence is poorly adapted to proving the falsity and knowledge elements of FCA liability generally, and it is particularly ill-suited for use in a case that, like this one, involves an exercise of clinical judgments – whether a patient is terminal-that is highly individualized, context-specific, and uncertain.
- While "clinical medical judgments are not automatically excluded from liability" under the FCA, courts agree that "FCA liability must be based on an objectively verifiable fact." *United States ex rel. Landis v. Hospice Care of Kansas, LLC*, 2010 WL 5067614, at \*4(D. Kan. Dec. 7, 2010)

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Agape Fourth Circuit Brief Highlights

The factors relevant to a patient's eligibility for hospice care are multifaceted, complex, and highly individualized. Indeed, the applicable regulations explicitly forbid the use of "check boxes or standard language used for all patients" in hospice-eligibility certifications. 42 C.F.R. §418.22(b)(3)(iv).

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Agape Fourth Circuit Brief Highlights

**Courts have consistently rejected attempts to use statistical sampling to prove liability in fraud cases.**

- Relators seek to rely on aggregate data – as opposed to direct proof – to establish that Agape patients were falsely certified to be eligible for hospice care. Although Relators and the Government repeatedly insist that courts routinely accept statistical evidence to prove liability, a review of relevant decisions makes clear that this is not so. To the contrary, courts have consistently rebuffed attempts to use extrapolated data to prove liability in fraud cases.

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Agape Fourth Circuit Brief Highlights

**Statistical Sampling cannot be used to prove scienter in an FCA case.**

- It simply is not possible to prove the *knowing* submission of false claims through aggregate proof. “Welding different [statistical] inferences together cannot substitute for direct proof[.]” *Hockett*, 498 F. Supp. 2d at 66. The Relators must, for each claim, adduce evidence of falsity and scienter – and aggregate data cannot prove the falsity or scienter of an individual claim.

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SavaSeniorCare Amicus Brief Highlights

**The Reasonable Exercise of Professional Judgment Is Essential**

- The entire Medicare program depends on the reasonable exercise of professional judgment focused on the unique, individual needs of each Medicare beneficiary.

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SavaSeniorCare Amicus Brief Highlights

**The FCA Does Not Authorize Trial by Formula, Which the Supreme Court Has Rejected Under Analogous Circumstances**

- As this Court has explained, the “conduct alleged [in an FCA case] must represent an objective falsehood.” *United State ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4<sup>th</sup> Cir. 2008).
  - In this case, Relators lament that “[d]ue to the sheer volume of [payment] claims at issue, trying this case would be cost-prohibitive and would result in a trial of monumental proportions spanning over a year... .” Relators’ Br. at 10 (internal quotation marks omitted). However, it is Relators who made the voluntary decision to seek the maximum bounty possible by alleging that Agape submitted thousands of false payment claims involving thousands of Medicare beneficiaries and dozens of health-care facilities about which Relators have no personal knowledge.

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SavaSeniorCare Amicus Brief Highlights

**The Court Should Reject the Adverse-Consequences Arguments Made by Relators and the Government**

- Relators suggest that unless this Court condones the use of statistical sampling and extrapolation to establish liability and damages in FCA cases based on medical necessity, fraud will go unpunished and undeterred.
- The concerns expressed by the Government do not outweigh a defendant's fundamental right to insist that relators and the Government present proof as to each element of each FCA cause of action seeking relief that is essentially punitive in nature.

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American Healthcare Association Amicus Brief Highlights

**Allowing Sampling to Prove FCA Liability Would Impermissibly Shift and Distort the Burden of Proof the Statute Imposes on Qui Tam Relators and the Government**

- The focus of the burden is on the specific false claims alleged because they are the "sine qua non" of an FCA violation. *Sanderson v. HCA – The Healthcare Co.*, 447 F.3d 873, 878 (6<sup>th</sup> Cir. 2006)(citation omitted). Thus, relators must prove, "at an individualized transactional level," that actual claims were submitted.
  - Falsity requires proof of "an objective falsehood" a "difference of opinion" or statements "about which reasonable minds may differ cannot be false."
- If sampling could be used to prove FCA liability for a mass of unspecified claims in cases like this one, that would shift the burden of proof to defendants to have to *disprove* the elements of FCA liability for each unspecified claim.

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American Healthcare Association Amicus Brief Highlights

**Allowing Sampling to Prove FCA Liability Would Magnify the Threat to Health Care Providers of the Statute's Draconian Penalties and the Enormous Pressure to Settle Meritless Claims.**

- If Relators are permitted to use their suggested "Trial by Formula" approach to proving FCA liability – an approach relators and the government are invoking with increasing frequency against health care providers nationwide – that will amplify, by many orders of magnitude, the serious threat of massive FCA liability and additional adverse consequences that those providers already face.
- Allowing the use of sampling to prove FCA liability – and the exponential multiplying of damages and penalties it entails – will only intensify providers' already substantial incentives "to settle otherwise unmeritorious suits to avoid rising financial ruin."

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## QUESTIONS?

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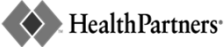
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# Implementing Drug Diversion Risk Rounds

Sara Schroeckenthaler, JD  
Program Manager, HealthPartners  
Tracy E. Tracy, JD CHC

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## Who We Are

- ▶ HealthPartners is a Minnesota-based integrated health care organization founded in 1957
- ▶ Provides health care services and health plan administration
- ▶ Employs more than 23,000

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In 2015: 2 million people had a substance abuse disorder involving pain relievers

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In 2015: 20,000 overdose deaths

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- ▶ Between 10-15% of healthcare workers are addicted to opioids
- ▶ In an organization with 23,000 employees, potentially 2300 health care workers could have an opioid substance abuse problem.

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Emory University Hospital

Xanax and pain medications like hydrocodone diverted from pharmacy by pharmacy technicians

Georgia Board of Pharmacy Order: pharmacy license on probation for 3 years and hospital fined \$200,000

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**\$2.3 Million**

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### Highlights from the DEA Corrective Action Plan

1. Drug Diversion Compliance Officer
2. Drug Diversion team
3. Review ADM settings
4. Pandora surveillance
5. Enhanced reporting
6. Quarterly trend analysis by drug diversion team
7. Targeted staff training
8. Standardized diversion investigation process
9. Enhanced monitoring and auditing

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### What's the Role of Compliance?

- ▶ Bridge the gap
- ▶ Manage risk
- ▶ Structure - 7 Elements
- ▶ Convene the right players

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**Foundation for Risk Rounds**

- ▶ Senior leadership support
- ▶ Urgent issues addressed

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**Stakeholders**

- ▶ Pharmacy
- ▶ Nursing
- ▶ Senior Leadership Team

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**Objectives**

- ▶ Assess the current state of medication security
- ▶ Identify opportunities

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Diversion Risk Round Assessment Tool

This section for locations with controlled substances only. *Not applicable to locations without controlled substances.*

Measure #4 (only applicable to controlled substance)	Yes	No
Controlled substances processes		

**Look & Ask:**

Show me how you keep controlled substances secured? Where are they stored?  
Comments: \_\_\_\_\_

How are CSs tracked? That is, how do you know what has been received, dispensed, how much and by whom? **Review the CS log.**  
Comments: \_\_\_\_\_

Tell me about your process for handling discrepancies.  
Comments: \_\_\_\_\_

Tell me about how you would handle a suspected diversion?  
Comments: \_\_\_\_\_

Tell me how the "override function" on Pyxis is used in your department (if applicable).  
Comments: \_\_\_\_\_

**Scoring: Using observations and discussion from Measures 1-4, score each measure using the scoring system below:**

Measure #1 score \_\_\_\_\_

Measure #2 score \_\_\_\_\_

Measure #3 score \_\_\_\_\_

Measure #4 score \_\_\_\_\_

TOTAL SCORE: \_\_\_\_\_

**0: No controls, no policy or staff unaware of policy and/or controls**

**1: Policies and/or controls in place, but not always followed**

**2: Policies/control in place and followed**

HealthPartners 4

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### Implementation

- ▶ Identify site leaders
- ▶ Surveyor training
- ▶ Communication plan
- ▶ Announced surveys
- ▶ Action plans

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### Survey Team

- ▶ Pharmacy
- ▶ Compliance
- ▶ Quality
- ▶ Nursing
- ▶ Safety and Security
- ▶ Employee Health
- ▶ Patient Safety

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**What did we learn?**

- Enhanced surveyor training
- Site prioritization
- Unannounced vs. Announced
- Monthly touch points with pharmacy and nursing

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**Questions?**

Contact information

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Sara.M.Schroeckenthaler@healthpartners.com

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Dedicated experts to support your practice goals.



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## Sampling 101

Presented by:  
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 Director of Analytics and Business Intelligence  
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 800.635.4040

**DOCTORS  
 MANAGEMENT**  
 Leave the business of medicine to us

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### Why Sample?

- Because it is often impossible to collect 100% of the data on 100% of the population (or universe)
  - This is called a census
- It is an efficient and inexpensive way to infer the statistics of a sample to the universe (or sample frame).

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### For Government Audits

- If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are “not statistically valid” cannot legitimately be made. In other words, a probability sample and its results are always “valid.”

[CMS Pub.100-08 Chapter 3 Section 10.2]

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### For Self-Disclosure

- If the financial review was based upon a sample, the review report must also include the Sampling Plan that was followed. At a minimum, this includes:
  - Sampling unit
  - Sampling Frame
  - Sample Size
  - Source of Random Numbers
  - Method of Selecting Sampling Units
  - Sample Design
  - Missing Sample Items and Other Evidence
  - Estimation Methodology

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### The Sampling Process

1. Define the population of interest
2. Create a sampling frame
3. Determine the sampling method
4. Calculate the sample size
5. Sample the data
6. Analyze the results
7. Infer to the population of interest

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### Definitions

- Universe or Population
  - A collection of units being studied. Units can be beneficiaries, claims, claim lines, procedures, drugs, tests, etc.
- Sampling Unit
  - A *sampling unit* is any of the designated elements that constitute the population of interest
- Sample Frame
  - A *sample frame* is a collection of units from which a sample will be drawn. The data should be homogenous and share similar characteristics
- Sample
  - a finite part of a statistical population whose properties are studied to gain information about the whole

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## Definitions

- Parameter
  - Considers the characteristics of the population
- Statistic
  - A numerical value, such as standard deviation or mean, that characterizes the sample from which it was derived
- EPSeM
  - Equal Probability of Selection Method
  - the application of a sampling technique that results in the population elements having equal probabilities of being included in the sample.

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## What Size Sample?

- Large enough to minimize sampling error and not so small that it no longer fairly represents the population in question
- Too large a sample can cost more money and consume more resources without added benefits
- Too small a sample creates too much error and renders the results useless

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## Ideally . . .

- The sample is representative of the qualities of the population
  - The sample has the same characteristics as the population
- It is of sufficient size to satisfy the assumptions of the statistical techniques used in our analysis
- *NOTE: For self-disclosure, the sample size must be at least 100 claims (or other sampling units)*

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## Sample Size Rules of Thumb

- Any probability sample will have some inaccuracy, or sample error
- The larger the sample, the smaller the error (not always a good thing)
- The more homogenous the variables, the smaller the error (always a good thing)
- Sample size determination is a fairly complex undertaking

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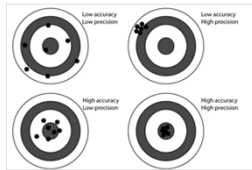
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## Precision vs. Accuracy

- Accuracy measures how close the statistic is to the true value
- Precision measures how close the variables are to one another
- Accuracy is easier to fix; just move the model
- Precision is harder to fix as it indicates instability




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## Why Random Sampling?

- It eliminates bias in selecting units
- It enables us to infer (extrapolate) the results to a larger population based on what is learned from sample results
- It allows us to estimate sampling error, which is critical for extrapolation
- Randomness *does not* guarantee representativeness, particularly if the population is biased

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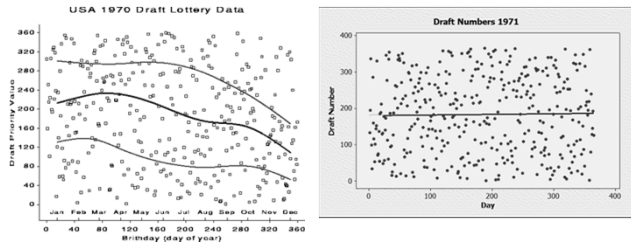


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### Nonrandom Risk: The 1970 Draft Lottery




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### Random Sampling Methods

1. Simple Random sample
  - Every unit has an equal (non-zero) chance of being selected
    - Selecting claims to study payer behavior
2. Stratified sample
  - Breaking the universe into homogenous sampling frames from which a homogenous sample is drawn
    - Procedure type (E&M v. Surgical)
    - Beneficiary type (age, sex, etc.)
    - Diagnosis
    - Paid amounts

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### Random Sampling Methods

3. Cluster sampling
  - Organizes the units into similar subsets
  - Two stage
    - i.e., random sample of beneficiaries and then random sample of claims for each
  - Multi-stage
    - i.e., random sample of beneficiaries from which we draw a random sample of claims from which we draw a random sample of claim lines

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## Cluster Sampling




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## How Do I Randomize?

- You can use a software program
  - RAT-STATS, MiniTab, Excel, SQL, etc.
- You can systematize the sample
  - Every  $n^{\text{th}}$  unit, such as every 10<sup>th</sup> or 25<sup>th</sup> or 50<sup>th</sup> unit
- You can sort by some variable (such as claim ID or claim code) that is not otherwise ordered

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## How about Statistically Valid?

- There is a difference between a sample being random and it being statistically valid
- Random just means that every unit had an equal chance of being selected
- Statistically valid has to do with the representativeness of the sample

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## Stratified Sampling

- When the population can be described by a number of different characteristic groups, the frame can be organized into separate "strata"
- Each stratum can then sampled as an independent sub-population, subject to SRS
- Most often, the strata are sampled proportionate to the population
- If done properly, it reduces variability and increases precision

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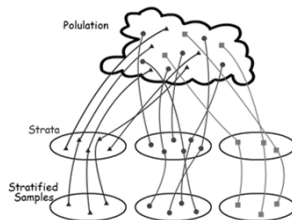


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## Stratified Sample Example




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## Types of Stratified Samples

- Proportionate
  - The sample for each stratum **has the same distribution proportion** as the universe
- Disproportionate
  - The sample has a **different percent distribution** than the population

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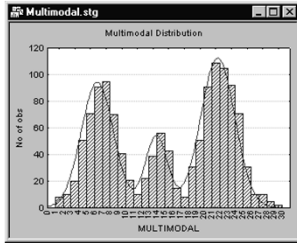


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### Example of Multimodal Distribution



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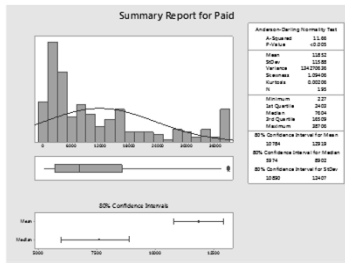
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### Pre-Stratification



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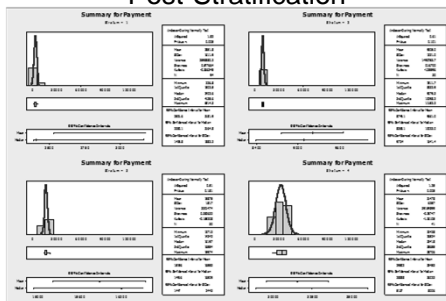
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### Post-Stratification



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### Certainty Stratum

- The statistical reason for selecting a certainty stratum is to capture and isolate the largest unit values so that their extremely large values do not influence sampling variability
- This is a great way to deal with outliers
- Certainty strata are *not* part of the extrapolation calculation but rather the face value is added on to the total

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### Sampling Bias

- A sampling method is called **biased** if it *systematically* favors some outcomes over others.
- Any event that causes one or more variables within a population to have a different chance of selection
- This can lead to over or under representation of a group of variables
- Bias isn't always bad

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### Examples of Sampling Bias

- Telephone surveys
  - Often exclude cell phone numbers
  - 40% of households do not have land lines
- Voluntary response sample
  - Some people enjoy surveys while others do not
  - Think about a jury pool
- Seasonal selection issues
  - Taking a sample in Florida in January or June
- Self reporting
  - Weight and height for BMI statistics

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### Types of Appraisal Methods

- Variable Appraisal
  - To measure a quantitative characteristic such as the dollar amount per claim, line or beneficiary
  - Continuous variable
- Attribute Appraisal
  - to determine the number of items that meet a given set of criteria, such as the proportion of lines with improper modifier usage
  - Proportion or ratio (like a percentage of error)

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### Sample Error

- Sample error is an estimate of the potential error (or precision) the results have in relation to the population (or universe)
- Most often, sample error is measured by confidence intervals

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### What is a Confidence Interval (CI)?

- The purpose of a confidence interval is to validate a point estimate; it tells us how far off our estimate is likely to be
- A confidence interval specifies a range of values within which the unknown population parameter may lie
  - Normal CI values are 90, 95%, 99% and 99.9%
- The width of the interval gives us some idea as to how uncertain we are about an estimate
  - A very wide interval may indicate that more data should be collected before anything very definite can be inferred from the data

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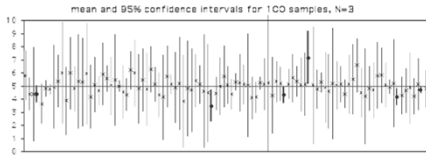
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### Confidence Interval Example



Note that in only six of the 100, the mean was not within the range of the upper and lower bound. Ideally, this should have been five, but it's pretty close!

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### Calculating Sample Error

- For a variable appraisal, sample error is calculated as the standard deviation divided by the square root of the sample size
- For an attribute appraisal, sample error is calculated as the square root of the proportion times 1- proportion, all divided by the sample size

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### Example of Sample Error (SE)

- A sample of average charges for 99213 was taken from 50 practices in a given area
- Mean = \$82.40 and STDev = \$15.55
  - Assume normal distribution
  - 68.26% of values between \$66.85 and \$97.95
- SE = Stdev/sqrt(N), or 15.55/sqrt(50), or
- 15.55/7.07 = 2.2
- The standard error for our estimate of the mean of \$82.40 is \$2.20
- Our precision is around 2.6% (pretty good!)

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### What is Margin of Error?

- The Margin of error is a range of error that is based on the confidence interval we select.
- The higher the CI, the larger the scores and the wider the margin of error
  - 99% = 2.576
  - 95% = 1.96
  - 90% = 1.645
  - 80% = 1.28

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### Calculating the Margin of Error

- The margin of error is a standard score times the standard error
  - Score values depend on how wide or narrow you want the margin of error to be
  - The higher the value, the higher the margin of error
- Sample of 50, 95% margin of error
  - Mean = 82.40, stdev = 15.55, SE = 2.20
  - Margin of error = score times SE
    - $\frac{1}{2}$  Interval =  $1.96 * 2.20 = 4.31$

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### Calculating the Confidence Interval

- Using our average charge example:
  - Mean = 82.40, stdev = 15.55, SE = 2.20, ME = 4.42
  - CI = 82.40 +/- 4.42, or
  - 95% CI = \$77.98 to \$86.82
- If I were to take 100 samples, in 95 of them the actual point estimate would be somewhere between \$77.98 and \$86.82

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### Why is this Important?

- In an audit situation, we want to be able to estimate precision
  - OIG states that precision should be no worse than 25% using a 90% confidence interval
- In an extrapolation, we want to use sample error to our advantage
  - Most commonly, the extrapolation uses a point estimate minus the ½ interval of a 90% confidence interval

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### Creating a Sample for Review

- It is not necessary (and often ill-advised) to create a statistically valid random sample (SVRS) for an internal review
  - Obligates you to extrapolate the overpayments
- Use nonprobability sampling

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### Nonprobability Sampling



- Convenience samples
  - Selecting units that are easy and accessible
  - i.e., the last five encounters
- Quota sampling
  - A specific quota is established and you choose any unit you want until the quota is met
- Purposive sampling
  - This involves choosing the units for the sample that you think are most appropriate
- Prospective audit
  - Select the next  $n$  units prior to submitting the claim

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For More Information

- Frank D Cohen
- [www.frankcohengroup.com](http://www.frankcohengroup.com)
- [fcohen@drsmgmt.com](mailto:fcohen@drsmgmt.com)
- 727.442.9117

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Yeah, but what's in it for me?

Making training and communications  
Impactful, Relevant, and **Fun!**

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### Covered Entities and Business Associates under HIPAA

- The HIPAA Rules apply to **covered entities and business associates**.
- Individuals, organizations, and agencies that meet the definition of a **covered entity** under HIPAA must comply with the Rules' requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. If a covered entity engages a **business associate** to help it carry out its health care activities and functions, the covered entity must have a written business associate contract or other arrangement with the business associate that establishes specifically what the business associate has been engaged to do and requires the business associate to comply with the Rules' requirements to protect the privacy and security of protected health information. In addition to these contractual obligations, business associates are directly liable for compliance with certain provisions of the HIPAA Rules.
- If an entity does not meet the definition of a covered entity or business associate, it does not have to comply with the HIPAA Rules. See definitions of "business associate" and "covered entity" at 45 CFR 160.103.

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### Calin Elardi

Compliance Project Manager; Sound Physicians

- Highly skilled compliance expert
- CHC, CHPC, CCEP and CCEP-I certified
- Compliance Project Manager for Sound Physicians
- Second year, Executive MBA at University of Nevada Las Vegas Lee Business School

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## Kristy Grant-Hart

Spark's London-based Founder and CEO

*"An accomplished compliance professional and true expert in her field."* – Risk Universe Magazine

- Author
- Speaker
- Former Chief Compliance Officer
- Lawyer

- Consultant
- Professor



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Avoid

BORING!

Not Impactful

**NOT FUN!**

Repetitive

Lengthy

EASY

TOO

Repetitive

**Too Legalistic**

Repetitive

**NOT RELEVANT**

Not Specific

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# IMPACTFUL

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**G** **GENERATIONAL INSIGHTS**  
by Cam Marston

Baby Boomers      Gen-X      Millennials




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Baby Boomers

- Will call meeting to “get everyone on the same page”
- Highly value “Face Time”


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Generation X

- Can be overly direct- to the point of seeming to abandon common courtesy
- Avoid sugar coating
- Think that the things that boomers call meetings about could be handled in a brief email.

**OOPS!**  
**DID I JUST**  
**ROLL MY EYES**  
**OUT LOUD?**

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### Millennials

- Often seen as disengaged
- Always looking at their phones
- Can be perceived as rude
- Enjoy the “social aspect” of the workplace



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## RELEVANT

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What's my return on investment?



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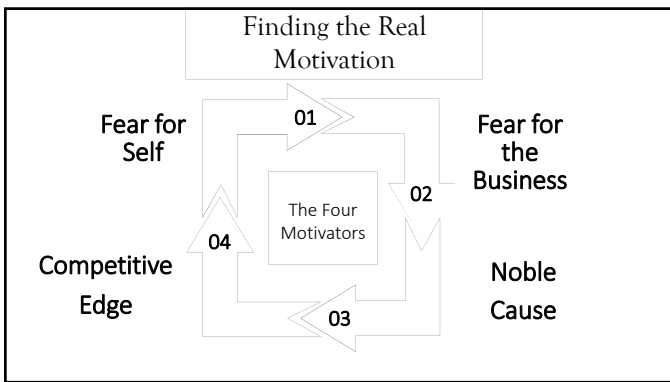
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Story Telling -  
It's how people learn



- Engages imagination
- Creates anticipation
- Physical response

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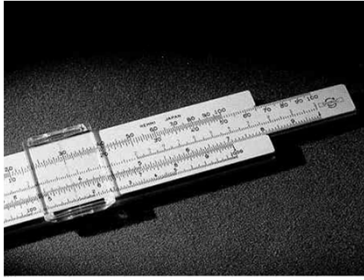
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Slide Rules



- Pictures
- Key Messages
- Background
- Font

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Top Three Tips

- Tailor to the Risk Profile
- Sell the benefits, not the features
- Respond to objections before they are voiced



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**FUN!**

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Fun!

- Short burst training
- Multiple-format options



How do you like to learn?

- \* Just the facts ma'am
- \* Videos and graphics make it come to life
- \* I'm feeling competitive
- \* Real-life scenarios please

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Fun!



- Interactive
- Gamification

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Fun!



- Competition – both with self and in teams in the group
- Colorful, fast-paced

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Fun!

- In-person where possible
- Specific to the individual's learning needs:
  - Evaluation
  - Opt-out training




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### Covered Entities and Business Associates under HIPAA

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### We're a Covered Entity



Business Associates



In Writing




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# Thank you!

Let's Stay In Touch!

### Kristy Grant-Hart

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✉️ [KristyGH@SparkCompliance.com](mailto:KristyGH@SparkCompliance.com)

🌐 [www.SparkCompliance.com](http://www.SparkCompliance.com)

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### Calin Elardi

🐦 Twitter: @CalinElardi

📞 Phone: 615-828-4606

✉️ [calinelardi@gmail.com](mailto:calinelardi@gmail.com)

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**hccs**  
A HealthStream Company

**HCCA Compliance Institute**

**Conflicts of Interest and Big Data:  
 What Can We Learn from Large Databases of Provider Disclosures?**

**Part I – Evaluating COI at the Macro Level**

**March 27, 2017**

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**Agenda**

- Introductions
- Understanding Conflicts of Interest
- What is “Big Data”?
- Big Data Meets Conflicts of Interest: The “Open Payments” Database
- Other sources of Big Data useful for the analysis of Conflicts of Interest
- How Big Data analysis is providing a trove of data for Journalists
- Use of Big Data at the Macro level
  - National and Regional Data Analysis



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**My Background**

- 40 Years in Health Care
- MBA in Healthcare Management
- Medical Practice Manager
- Practice Plan Director at Temple, UCLA
- Consultant
- Co-Founder of HCCS
- VP HCCS/HealthStream





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### Understanding Conflicts of Interest



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### Who is at Risk?

- Any organization that regularly acquires pharmaceuticals or medical devices
- Any organization that employs or provides a practice location for physicians
- Any organization conducting research funded by the federal government
- Any non-profit organization

hccs

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### What is at Risk?

- The Financial Health of your Institution
  - Research funding
  - Purchasing decisions
- Your Tax Exempt Status
  - Failure to accurately complete and file the IRS Form 990
- Your Reputation
  - Hospital conflicts of interest become big local news stories



hccs

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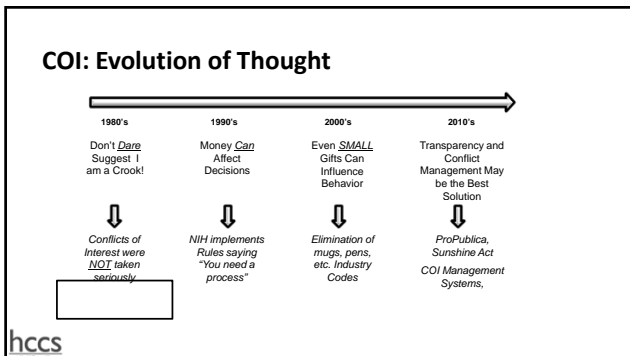
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### What is Big Data?

“Data of a very large size, typically to the extent that its manipulation and management present significant logistical challenges.”

-Oxford English Dictionary

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### What is Big Data?

“An all-encompassing term for any collection of data sets so large and complex that it becomes difficult to process using on-hand data management tools or traditional data processing applications.”

- Wikipedia

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**What is Big Data?**

“The ability of society to harness information in novel ways to produce useful insights or goods and services of significant value”

- Viktor Mayer-Schönberger and Kenneth Cukier

“Big Data, A Revolution that will Transform How We Live, Work and Think”




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**Big Data Meets Conflicts of Interests**

Implications of the “Sunshine” Database

- The CMS “Open Payments” Database was first published on September 30, 2014 and each June 30<sup>th</sup> since then
- Any payment over \$10.00 from the pharma or medical device industry to any Physician will become public information!




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**2015 Data from the “Sunshine” Database**

The Facts About Open Payments Data




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**Other Sources of Available Data**

In addition to the CMS Open Payments Database:

- National Provider ID Database
- Medicare Part D Prescriber Database
- Social Media: e.g. Google Search and Twitter!




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**Cleaning and Matching the Data**

- CMS was prohibited from including the NPI in the Open Payments database BUT...  
....they included names and addresses
- The NPI database included names and addresses allowing a 93% match
- Numerous iterations with state and other licensing agencies brought us to 97% match




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**Use of the Data for Analysis**

Pretty Maps!

General Payments by Zip Code

(Source: CMS Open Payments)




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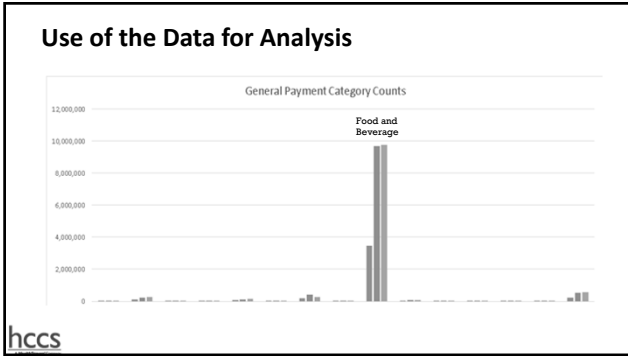
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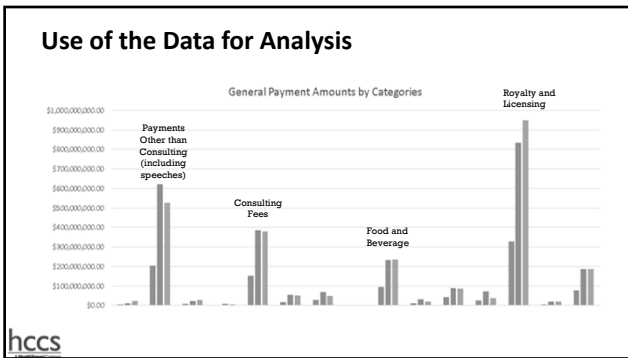
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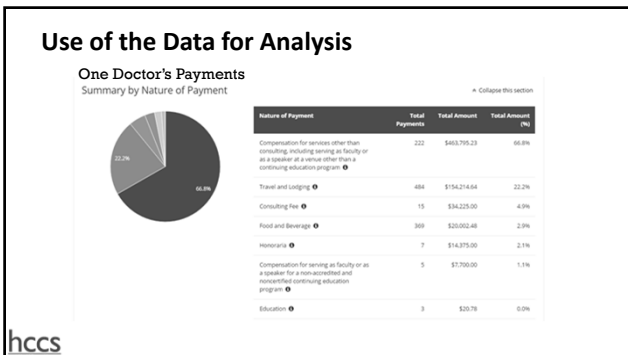
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**Use of the Data for Analysis**

**Matching Industry Payments to Medicare Prescribing Patterns: An Analysis**

Ryann Grochowski Jones and Charles Ornstein  
ProPublica March 2016




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**Use of the Data for Analysis**

Top five drugs prescribed, and the \$ spent to promote them:

- Blood thinner Xarelto (\$28.4 million),
- Rheumatoid arthritis drug Humira (\$24.9 million)
- Diabetes drug Invokana (\$20.9 million),
- Hepatitis C drug Viekira (\$19.2 million),
- Blood thinner Eliquis (\$18.8 million),




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**Use of the Data for Analysis**

Table 1: Rate of doctors who received payments, by specialty

	Total doctors with >1,000 claim count	Subset who received an industry payment	Percent who received a payment
Family Medicine	65,651	46,753	71.2%
Internal Medicine	51,607	36,329	70.4%
Cardiology	13,817	12,308	89.1%
Psychiatry	11,052	8,650	78.3%
Ophthalmology	8,196	7,117	86.8%




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**Use of the Data for Analysis**

Table 8: Mean brand-name prescribing rate, meals v. other payments only v. no payments

	Mean brand-name prescribing rate		
	No payments	Meals only	Other types of payments
Family Medicine	18.7%	19.8%	20.8%
Internal Medicine	19.8%	21.3%	22.8%
Cardiovascular Disease	19.2%	20.8%	22.2%
Psychiatry	13.6%	14.9%	15.8%
Ophthalmology	46.4%	56.0%	59.3%




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**Use of the Data for Analysis**

**Top Medicare Prescribers Rake In Speaking Fees From Drugmakers**

Charles Ornstein, Tracy Weber and Jennifer LaFleur  
ProPublica June 2013




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**Use of the Data for Analysis**

- Nine of the top 10 prescribers of the Alzheimer's drug Exelon received money from Novartis, the drug's maker
- Eight of the top 10 for Johnson & Johnson painkiller Nucynta were paid speakers...
- As were six of the top 10 for Pfizer's antidepressant Pristiq.

Charles Ornstein, Tracy Weber and Jennifer LaFleur  
ProPublica




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**Use of the Data for Analysis**

January 17, 2017

**Financial Conflicts of Interest Among Hematologist-Oncologists on Twitter**

Derrick L. Tao, BS; Aaron Boothby, BS; Joel McLouth, BS; Vinay Prasad, MD, MPH  
 Author Affiliations  
*JAMA Intern Med.* Published online January 17, 2017.  
 doi:10.1001/jamainternmed.2016.8467




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**Use of the Data for Analysis**

A preliminary analysis of tweets by these doctors has shown that “a sizable percentage are tweeting about drugs that they have specific ties to”

- Vinay Prasad, assistant professor of medicine at Oregon Health & Science University




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**Use of the Data for Analysis: Closer to Home**

Once you match NPI data to Open Payments Data you can run Hospital Level Reports

<b>Report: 06 - Payment Summary</b>	
Client:	Health System
Run Date/Time:	2/1/2017 7:25:52 PM ET
Version Date:	11/25/2015
Users With NPIs	5,708
Users Who Could Have Incorrect NPIs	1
Recorded in COI-SMART	
Matched To Open Payments	2,911
Physical Profile Count	2,907
Total Open Payments 2014 Amount	\$21,125,423.27
General Payments Count	2,717
Total General Payments Amount	\$9,714,274.24
Owner Payments Count	14
Total Ownership Payments Amount	\$1,312,301.31
Total Ownership Value	\$1,440,528.07
Research Payments Count	22
Total Research Payments Amount	\$769,330.81
Associated Research Funding Count	146
Total Associated Research Funding Amount	\$7,888,988.84




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**Use of the Data for Analysis: Closer to Home**

Allowing you to identify trends, such as significant increases in industry payments year over year

Category	Count 2013	Count 2014	Count 2015	Amount 2013	Amount 2014	Amount 2015
General	1,038	2,497	2,263	\$903,782	\$1,644,339	\$3,828,504
Research	9	17	86	\$21,416	\$20,741	\$176,179
Ownership Associated Research	1	0	0	\$0.01	\$0.00	\$0.00
Totals	1,354	3,700	3,389	\$1,081,855	\$4,238,689	\$6,037,624




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**HCCA Compliance Institute**  
Conflicts of Interest and Big Data: What Can We Learn from Large Databases of Provider Disclosures?

Part II – Evaluating COI at Your Institution

March 27, 2017




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**Topics**

- Background
- Reviewing Conflict of Interest Disclosures
- Using Data to Identify Highest Risk Disclosures
- Open Payments Analysis
- Results & Future Actions




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### About Carolinas HealthCare System



- One of Most Comprehensive Public, Not-for-Profit Systems in Nation
- More than 7,600 Licensed Beds at 900 Care Locations
  - Includes Physician Practices, Outpatient Surgical Centers, Hospitals, Freestanding Emergency Departments, Urgent Care, Behavioral Health, Rehabilitation Centers, Nursing Homes, Home Health Agencies, Hospice and Palliative Care
- Almost 12 million Patient Interactions Annually
- Employs Nearly 60,000 People



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### Who Needs to Disclose



- Any Position with Responsibilities for a Material Segment of the Operation, Management or Oversight of Carolinas HealthCare System
  - Physicians
  - Mid-Level Providers
  - Director Level and Above
- More than 5300 Teammates Received Questionnaire
  - 2500 Physicians



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### My Background

- 25 Years in Health Care
  - 6+ Years with Carolinas HealthCare System
  - 18 Years with Revenue Cycle Consulting Company
- Application Development
  - Hospital & Physician Contract Management
  - Budgeting & Cost Accounting
  - Work Plan Management



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### Analytical Tools

- Microsoft SQL Server
- Microsoft Access

One  Carolina HealthCare System

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### Create COI Database

- Created SQL Server Database to Store and Track 5000+ Respondents
- Automated Weekly Process to Upload Files



One  Carolina HealthCare System

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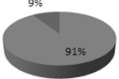
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### Key Performance Indicators

- Response Rates
- Disclosures

#### Questionnaire Disclosure Rate



Category	Percentage
Without Disclosure	9%
With Disclosure	91%

One  Carolina HealthCare System

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### Review Process



- Establish Guidelines for Identification of Potential Conflicts
- Initial Reviews by Corporate Compliance
- Escalate Potential Conflicts to Conflict Of Interest Oversight Council
- Create Management Plans (if applicable)
- Administrative Follow-Up




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### Analysis to Create Review Guidelines



- North & South Carolina Regional Analysis
- Consulting Services & Speaker Engagements

	Total	CHS	CHS Percent
Providers	2655	124	4.6%
Payments	\$44.7 MM	\$3.2 MM	5.9%
Mean	\$10,218	\$13,433	
Median	\$6,000	\$9,056	
Max	\$736,950	\$221,571	
Greater Than \$200K	24	2	8.3%
Greater Than \$100K	124	9	7.3%
Greater Than \$50K	269	18	6.7%




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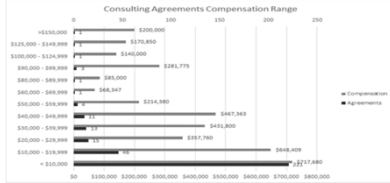
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### Analysis to Create Review Guidelines



- Understanding Compensation for Consulting Services & Speaking Engagements




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### Analysis to Create Review Guidelines

- Commitments of Time for Consulting Services & Speaking Engagements




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### Open Payments Analysis



- Integrate Open Payments Data
  - Use NPI to Match Carolinas HealthCare System's Physicians with Open Payments Data
  - Match and Compare Self-Disclosures using Drug and Medical Device Manufacturers
  - Non-Disclosures & Under-Reported Differentials Greater than \$5,000
- E-Mails to Physicians
  - Link to Open Payments Site




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### Data Transformation for Oversight Council Review

- Convert Answers for Each Question (Multiple Rows) in Report to Single Row for Ease of Review




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### Results & Future Actions



- Questionnaire Revisions
  - Open Payment Data Manufacturers Listed in Questionnaire to Improve Exact Matches
  - Coordinate Responses to Open Payments Categories
    - Consulting Fees, Speaking Engagements, Royalty or License, Education, Honoraria, Charitable Contribution, Travel & Lodging, Food & Beverage
- Policy Revisions
- Standard Operating Procedures



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### Question and Answer

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# Audit Log Demands During Litigation: Response Conundrums from a Compliance Perspective

Carey Cothran, MJ, CHC, CHRC  
Executive Director, Corporate  
Compliance & Audit  
WellStar Health System

Emily Reilly, JD, CHC, CHPS  
Regulatory Corporate  
Compliance Administrator  
WellStar Health System

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## Prologue

### ACME Health System: December 2012

- **Patient:** Sixteen year old boy who suffered hemorrhagic stroke is undergoing repair of the malformed vein mass. During embolization of the malformed vein mass a tragic medical error occurred.
- **Prognosis:** Lifetime paralysis, aphasia, memory loss, impaired cognitive function.
- **Litigation:** Electronic health record (EHR) and accompanying audit logs requested during discovery.
- **The physician:** Found guilty of medical malpractice due to a failure to calibrate equipment.
- **Evidence:** The electronic health record (EHR) audit logs indicate a failure to calibrate equipment before the procedure.

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## Introduction

The increasing use of electronic health records (EHR) means an increased ability to electronically track activities that occur within a specific medical record.

### Unintended Consequences of EHRs

- Medical malpractice attorneys are being encouraged to use audit logs to obtain evidence for use in medical malpractice litigation. (1)
- The Office of the Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) are encouraging the use of audit logs for identifying fraudulent coding and billing. (2)

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## Audit Logs: Inherent Problems

The use of audit logs to prosecute healthcare organizations or providers for malpractice or fraudulent coding/billing practices is fraught with inherent problems.

**Inherent Problems**

- Consistency
- Integrity
- Interpretation
- Retention requirements
- Burdensome

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## Definitions

Understanding the audit log conundrum facing healthcare providers begins with understanding the definitions and technical differences between metadata, audit logs or audit trails, and access logs and reports.

- **Metadata:** Metadata is the computer generated and stored "data about other data."
  - Where it was collected, who created it, when it was created, etc.
- **Audit logs/audit trails:** Audit logs/audit trails are a type of metadata that provide documentation of sequential activity within a software application including when the data was created, accessed, revised, etc. (3)
- **Access logs/reports:** An application user access log can be used to create a report of all users who have accessed a specific patient's medical record within an EHR.(4)

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## Potential Uses: Investigations and Litigation

When analyzed properly and within appropriate context, audit logs can provide a useful tool for the investigation and prevention of different types of theft and fraud.(5)

- Theft of patient data
- Inappropriate access (privacy violations)
- Fraudulent billing practices
  - Copy/paste
  - Auto-populate

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Compliance Conundrums:  
Integrity

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EHRs and Audit Log Integrity Issues

- **Author Identification:** multiple providers can add documentation to the same progress note without allowing or requiring each provider to sign their entry, making it "impossible to verify the actual service provider or the amount of work performed by each provider."(6)
- **Automated Change of Note Author:** automatic author change to the current user of the note, deleting any reference to the original author.
- **Automated Date Assignment:** some systems automatically date an entry while others allow users to change the documentation entry date to the treatment date or the date of service, which may misrepresent the sequence of treatment events.

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EHRs and Audit Log Integrity Issues

- **Amendments:** allows providers to amend a record without requiring a date entry or notation that this is a change from the original entry.
- **Disabled Audit Logs:** 2013 OIG survey where nearly half (44 percent) of the hospitals that participated in the survey reported they can disable and/or delete their audit logs.(7)
- **FDA:** "...Health information technology software is a medical device... [but] to date, FDA has largely refrained from enforcing our regulatory requirements." EHRs remain "experimental" according to the FDA.(8)

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**Compliance Conundrums:  
Disparate Regulations**

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**Disparate Regulations for  
Audit Requirements**

- **HIPAA Security Rule:** Requires "audit controls" by implementing "hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information."
  - o Does not specify how this should be accomplished, or who should examine the data. Different employee functions may recognize different problems: IT may recognize hacking, but miss fraudulent billing issues or clinical data integrity issues.

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**Disparate Regulations for  
Audit Requirements**

- **Meaningful Use:** Audit log content requirement for Meaningful Use certification set by referencing the American Society for Testing and Materials (ASTM)
  - o Required: date, time, patient ID, user ID, type of action (addition, deletion, change, queries, print copy)
  - o Optional: device used for access, identification of the patient data accessed, source of access, reason for access.
  - o Only if you "elect" to participate in Meaningful Use!
- **Federal Rules of Evidence**
  - o Standard for validating business records: "evidence describing a process or system and showing that it produces an accurate result."
  - o "A record of an act, event, condition, opinion, diagnosis [is admissible] if ... (E) neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness."

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### Disparate Regulations for Retention

- **HIPAA Security Rule:** 6 year retention requirement is for documentation created pursuant to the rule (i.e., incident reports, policies, sanctions, etc.)
- **HITECH:** Accounting of Disclosures requirement vs. access report
  - o Accounting of Disclosures – 6 years
  - o Access Report – disclosures through an EHR – 3 years
- **Meaningful Use:**
  - o Audit log retention requirement – 6 years
  - o But, participation in Meaningful Use is voluntary

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### Disparate Regulations for Retention

- **False Claims Act:** OIG "noted that auditors use the logs to authenticate medical records supporting claims made to Federal Health Care programs" and indicated "an effective audit of claims based on EHRs requires the use of the audit log."
  - o 6-10 years statute of limitations
  - o Treat audit logs like part of the medical record?
  - o Also consider state law retention requirements
- **OIG and CMS:** recommend retaining audit logs as long as required to retain clinical records to prove medical necessity/accuracy of coding and billing

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### Compliance Conundrum: Case Law

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### Case Law

**Peterson v. Matlock**

- o Plaintiff sought to compel production of HER records in "native readable format" or by "searchable headings."
- o Records were produced in PDF format and organized in chronological order, which were difficult to "navigate and interpret," according to Plaintiff.
- o Plaintiff claimed that the records produced were not in the format that the provider views when providing treatment and that the record is missing "the functionality, searchable data points, and metadata which are part of the electronic medical record and are available to a provider."
- o Plaintiff had an expectation that the audit logs would be produced as a matter of course based on the request for the EMR alone.
- o Defendants explained that their particular HER provides details about what a user did while logged on, but does not have the details indicating which individual user actually was logged on.
- o Court ruled that Defendants must produce ERH and audit logs, but not in the format requested by Plaintiff.(9)

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### Case Law

**Hall v. Flannery:**

- o Plaintiff alleged receiving two "different" medical records related to care, believing that the medical records had been improperly altered by the Defendant.
- o Defendant argued that audit logs for access to the medical record after the treatment period had ended were not discoverable and may be protected by peer review or subject to work product privilege.
- o Court required that Defendant produce the audit logs.
- o Court indicated the audit trail is just one aspect of a patient's medical record "that is generated in the ordinary course of the hospital's business."
- o Arguably, this opinion could stand for the proposition that a request for the "entire medical record," now includes audit logs.(10)

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### Case Law

**Vargas v. Lee:**

- o Plaintiff's request for audit logs as part of medical record is denied.
- o Court found that Plaintiff had "not distinguished the audit trail's utility from that of its corresponding EMR" and "a party does not have the right to uncontrolled and unfettered disclosure."
- o The audit trail may be pertinent if the authenticity of documentation was in question but, details about the patient's treatment were already available in the medical records previously produced.
- o That the audit trail may contain information on the "timing and substance of plaintiff's care," is not sufficient to compel production. (11)

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### Case Law

**Green v. Penn. Hosp.**

- o Allegation that certain reports had been altered or deleted from the application used by the hospital.
- o An "informatics expert" testified that she "had never before worked with the particular system used by the Hospital as a nurse, had never analyzed or worked with it before in her capacity as an informatics consulting expert, and had never before seen the audit logs generated by [the hospital]."
- o The expert stated, "I can't give you specifically what was altered, nor by whom... I can only look at what the audit trail shows as people having documented and then trying to track it back to the medical record and not being able to find entries that support that notation on the audit log."
- o The Court recognized that these statements did not fall within the domain of expert testimony, and precluded it from the case. (12)

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### Case Law

**United States ex rel. Sheldon v. Kettering Health Network**

- o Audit logs not requested, but of interest for those familiar with Meaningful Use.
- o Qui tam case where relator alleged False Claim Act violation based on a HIPAA Privacy/Security violation.
- o Plaintiff alleged that because her PHI was able to be inappropriately accessed and re-disclosed by an employee, the covered entity did not conduct their HIPAA risk assessment in accordance with HITECH standards, but accepted Meaningful Use incentive payments anyway.
- o Court dismissed allegations, finding that "attestation of compliance [with the HITECH Act] is not rendered false by virtue of individual breaches." (13)

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## Compliance Conundrum: Burdens to Healthcare Providers

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### Burden to Healthcare Providers

- **Costly data storage**
  - From EPIC, EHR Vendor to the OCR HIT Policy Committee: access logs are quite large and storing them often "takes up more than 50% of an organization's reporting database capabilities."
- **Expanded definition of medical record**
  - See Hall v. Flannery: In their opinion, the court cited Allen v Crowell-Collier Pub Co. stating that "the words 'material and necessary' are to 'be interpreted liberally to require disclosure, upon request, of any facts bearing on the controversy which will assist in preparation for trial by sharpening the issues and reducing delay and prolixity'; indicating that the "test is one of usefulness and reason."

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### Burden to Healthcare Providers

- **Rapid technology advancement**
  - To meet OIG and CMS guidelines for storing audit logs, as if they were the clinical record results in "saving large amounts of data that quite likely will be inaccessible and/or unusable in a few years" due to rapid advances in technology.
- **Multiple EHR applications:**
  - Hospitals and health systems often use multiple EHR systems requiring the maintenance and expertise of audit logs for each application.
- **Qualified informatics experts:**
  - Very expensive to hire individuals or entities with the expertise to retrieve and accurately interpret audit log data.

It seems intuitive to think that the ability to store, search and retrieve huge amounts of data would serve as a great resource savings in time, effort, and money, but unfortunately when it comes to the discovery of EHR audit logs, it is exactly opposite.(14)

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### Epilogue

In the Prologue, a physician is found guilty of malpractice based on timestamps from the EHR audit logs...but what if:

- There had been a system patch or a version upgrade?
- The software linking the equipment to the EHR had undergone a recent upgrade which then threw off the synchronization of the audit logs systems to the clinical systems?

It would appear from the audit logs that the physician failed to perform a mandatory system check that resulted in an unfavorable patient outcome.

An excellent physician would have been held accountable and suffered terrible consequences based on data that was neither reliable nor trustworthy.

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### Conclusion

- EHRs were not be designed with discovery and litigation in mind, but were designed for the flow of digital patient data to encourage integrated delivery of treatment to improve the health and reduce costs.
- Audit logs can be misinterpreted when viewed outside of the context of their intended environment.
- Healthcare organizations face increased risks for medical malpractice in addition to "increased scrutiny, investigation, and even prosecution by the very government that promoted the switch to EHRs in the first place."

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### Take-Aways

- Determine the risk to your organization by reviewing relevant retention laws and create policy for retaining audit logs.
- Make a plan for dealing with requests for audit logs pursuant to subpoena.
- Retain and/or train your own experts who can accurately interpret audit logs for your EHRs, and be familiar with exactly what your audit logs can and cannot tell you.

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### References

1. Jennifer Keel. *Follow the Audit Trail*. Trial 29-33 (May 2014); Mark R. Bower, Nurse S. Jackson & Jerry I. Meyers. *Another Trip Down the Audit Trail*. AAJ Prof'l Negligence Newsletter (Fall 2011).
2. Centers for Medicare and Medicaid. *Documentation Integrity in Electronic Health Records*. June 2016. [2] <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ehr-docintegrity-factsheet.pdf>. Ret. Sept. 17, 2016
3. Lee, Patricia A. *New Jersey Law Review*. Page 2. September 7, 2015. <http://www.conellilley.com/sites/default/files/files/20150907/2015%20Handling%20EHR%20Suite%20Audit%20Trails%20and%20Self-Audits.pdf>. Retrieved Oct. 1, 2016. Sanford PPT presentation. NIST website. [http://csrc.nist.gov/news\\_events/hipaa\\_june2012/day1/day1-3\\_cmatson\\_establishing-access-auditing.pdf](http://csrc.nist.gov/news_events/hipaa_june2012/day1/day1-3_cmatson_establishing-access-auditing.pdf). Ret. Oct. 23, 2014.
4. Epic letter to the OCR. Sept. 2013. [https://www.healthit.gov/FACAS/sites/faca/files/0930\\_EpicHITPCAO2Testimony.pdf](https://www.healthit.gov/FACAS/sites/faca/files/0930_EpicHITPCAO2Testimony.pdf). Ret. October 23, 2016.
5. Centers for Medicare and Medicaid. *Program Integrity Issues in Electronic Health Records: An Overview*. Page 6. <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ehr-provider-booklet-overview.pdf>. Ret. Oct. 1, 2016.
6. CMS Detecting and Investigating Unauthorized Access to Electronic Health Records— A Case Study. p.7. <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ehr-casestudy-booklet.pdf>. Ret. Oct. 1, 2016.
7. ELECTRONIC DISCOVERY AND DIGITAL EVIDENCE: ARTICLE: ELECTRONIC HEALTH RECORDS SYSTEMS: TESTING THE LIMITS OF DIGITAL RECORDS' RELIABILITY AND TRUST. 12 Ave Maria L. Rev. 257, pp.261, 262. Ret. Oct. 2016  
U.S. Department of Health and Human Services. Office of the Inspector General. (December 2013). *Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology* (pp. 15-16; Appendix A). <http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf>. Ret. Oct. 1, 2016.

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## References

8. Miller, Clay, Weisbrod, Les. ELECTRONIC RECORDS AND AUDIT TRAILS. [https://www.millerweisbrod.com/docs/max/Electronic\\_Records\\_and\\_Audit\\_Trails.pdf](https://www.millerweisbrod.com/docs/max/Electronic_Records_and_Audit_Trails.pdf) Ret. Sept. 25, 2016.
9. *Peterson v. Mallock*, 2014 U.S. Dist. LEXIS 152994 \*, 2014 WL 5475236 (D.N.J. Oct. 29, 2014) p.7.
10. *Hall v. Flannery*, 2015 U.S. Dist. LEXIS 57454 \*, 2015 WL 2008345 (S.D. Ill. May 1, 2015) p.11.
11. *Vargas v. Lee*, 2015 N.Y. Misc. LEXIS 2176, 2015 NY Slip Op 31048(U) (N.Y. Sup. Ct. June 5, 2015) p.1.
12. *Green v. Pa. Hosp.*, 2013 Phila. Ct. Com. Pl. LEXIS 108, 30 Pa. D. & C.3th 245, 2013 WL 8596359 (Pa. C.P. 2013) p.7.
13. Byrne, Terence K., The Federal Rules Of Civil Procedure, Electronic Health Records, And The Challenge Of Electronic Discovery, Cleveland State University, *Journal of Law and Health*, p.379, 2015, <http://engagedscholarship.csuohio.edu/cgi/viewcontent.cgi?article=1465&context=jlh> Ret. Oct. 1, 2016
14. Brouillard, Chad P., Esq., "EHR Audit Trails Might Reveal More Than You Think: Hall v. Flannery, a Sign of the Times", *Inside Medical Liability*, 2015, <http://www.migma-akc.com/wp-content/uploads/2015/10/IML-3Q-2015-pp-18-20.pdf> Ret. Nov. 26, 2016
15. Szerejko, Joseph D. *NOTE: Reading Between the Lines of Electronic Health Records: The Health Information Technology for Economic and Clinical Health Act and Its Implications for Health Care Fraud and Information Security*, 47 *Conn. L. Rev.* 1103 p. 1152

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**COMPLIANCE CHALLENGES IN THE  
YATES MEMO ERA**

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HCCA'S 21<sup>ST</sup> ANNUAL COMPLIANCE  
INSTITUTE, March 27, 2017

Gina Simms, Esq.  
George Breen, Esq.  
Tarra DeShields, AUSA – District of Maryland

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**SESSION OVERVIEW**

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The Yates Memo and its Legal Implications in Corporate Investigations.

Enforcement Trends – The Impact on You.

Practical Tips to Manage Risks.

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**Background on  
the Players: Federal and State**

- Federal Entities/Individuals:
  - U.S. Department of Justice (USAOs)
  - U.S. Department of HHS, Office of Inspector General
  - Law Enforcement: FBI, HHS-OIG, IRS-CI, OPM-OIG, and other federal government agencies' OIGs
  - CMS: Recovery Audit Contractors (RACs) and ZPICs (Zone Program Integrity Contractors (ZPICs))
  - U.S. Department of Justice- Compliance Counsel
- State Entities:
  - Medicaid Fraud Control Unit (MFCUs)

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## THE YATES MEMO – WHAT IS IT?

- First issued on September 9, 2015.
- Referred to informally as the Yates Memo because it is a policy pronouncement made by the then-Deputy Attorney General Sally Quillian Yates.
- Constitutes new guidelines for Department of Justice attorneys' handling corporate investigations and prosecutions.
- Traditionally, a corporation's cooperation with the federal government's investigation may be factored into how to resolve the case. U.S. Attorney's Manual, § 9-28.700.
- Corporations act through individuals and so investigating the conduct of individuals is the logical means of learning the facts and extent of corporate misconduct and individual misdeeds.
- The Yates Memo sets forth the Department's commitment to seeking individual accountability for corporate wrongdoing.

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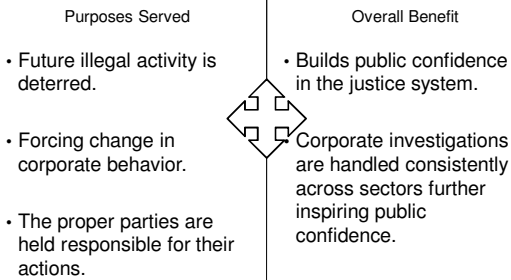
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## WHY THE INTEREST IN INDIVIDUAL ACCOUNTABILITY?



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## YATES MEMO GUIDANCE

The Six Key Points to Understand

- Eligibility for cooperation credit means that corporations must provide the DOJ all relevant facts about individuals involved in corporate misconduct;
- Focus on individuals from start of criminal and civil investigation;
- Criminal and Civil DOJ attorneys will be in routine communication with each other;
- No corporate resolution should provide protection from criminal or civil liability for any individuals;
- Corporate cases should not be resolved without a clear plan to resolve related individual cases; and
- Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based upon factors beyond the ability to pay money to the Government.

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### PRACTICAL IMPACT OF THE YATES MEMO -- WHAT'S CHANGED?

- The most important changes are:
  - Corporations will no longer receive partial credit for their cooperation in investigations;
  - Corporations must provide "all relevant facts relating to individual culpability" to be eligible for cooperation credit;
  - DOJ attorneys will no longer agree to any settlement or corporate resolution that dismisses charges or provides immunity for individual C-suite officers or employees; and
  - Civil attorneys will likely pursue civil remedies against individual wrongdoers even if the person lacks the ability to pay a civil monetary judgment. *See also* 6/9/16, Memorandum of Acting Associate Attorney General Bill Baer, "Cooperation in Civil Investigations."

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### KEY CHANGE -- COOPERATION CLAUSES

Where They Appear –

- Criminal plea agreements;
- Civil settlement agreements;
- Deferred prosecution agreements; and
- Non-prosecution agreements.

What They Require –

- Fully cooperate with investigations relating to the settlement allegations, including investigations into individuals and entities not released from liability in the settlement;
- Make former directors, officers, and employees available for interviews and testimony; and
- Produce non-privileged documents concerning the conduct covered in the settlement.

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### YATES MEMO IMPACT

The Acclarent Case – An Example of How Yates Operates:

- Acclarent was a California maker of devices used in sinus surgeries.
- Device FDA approved for use as a spacer used with saline to maintain sinus openings post-surgery.
- Acclarent engaged in off-label promotion of device for an unapproved use.
- Corporate investigation resulted in the CEO and Vice President of Sales being criminally charged and convicted of 10 counts of introducing misbranded and adulterated medical devices into interstate commerce and also securities fraud upon proof that the off-label promotion was intended to increase the company's sales to heighten its attractiveness to potential buyers. The company was bought by Johnson & Johnson.
- Acclarent paid a civil False Claims Act settlement to the United States in the sum of \$18 million dollars.

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**False Claims Act—31 U.S.C. §3729 et. seq.**

Prohibits

- Filing, or *causing* to be filed ...
- "False or fraudulent" claims

•Knowing

- Requires actual knowledge of falsity, or deliberate ignorance or reckless disregard of truth or falsity.

•Intent

- "Intent to defraud" not required
- Filing claims with "reckless disregard" of their truth or falsity is sufficient

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**False Claims Act—31 U.S.C. § 3729 et. seq.**

- Liability
  - 3X Damages
  - Was \$5,500 to \$11,000 *per claim*; As of 8/1/16, \$10,781.40-\$21,562.80 *per claim*)
  - *Potential exclusion consequences*
- Can include false statements in support of a claim.
- Materiality of claim is an issue
- Anti-kickback Statute as a predicate for FCA liability
- 60 days to return "known" overpayment- Reverse False Claims Act liability

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**False Claims Act—31 U.S.C. §§ 3729 et. seq.**

- Whistleblower Provisions
  - Non-Retaliation Policy
  - Relief from Retaliatory Actions:
    - Reinstatement
    - Two times the amount of back pay
    - Interest on back pay
    - Compensation for any special damages

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### Civil False Claims Act Cases

- Corporations and Individuals Can Be Liable
- Examples of Fraudulent Conduct
  - Kickbacks/Inducements
  - Medically Unnecessary Services
  - Billing for Services not Rendered
  - Upcoding

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### Recent False Claims Act Cases

- United States ex. rel. Oughatiyan v. IPC The Hospitalists, Inc. et. al- \$60 million settlement (Feb. 2017)(“upcoding”) – IPC encouraged physicians to bill Medicare, FEHB, Medicaid for a higher level of service than provided
- United States ex. rel. Marc D. Baker v. Walgreens- \$50 million settlement (Jan. 2017) (inducements/kickbacks)- FCA and AKS violations-gov’t beneficiaries received discounts/monetary incentives under “prescription savings club” to induce them to patronize Walgreens pharmacies.
- United States ex. rel. Daniel v. Vibra Healthcare, LLC- \$32.7 million settlement (Sept. 2016) (medically unnecessary services)- patients admitted to long-term care hospitals and in-patient rehab who did not need hospital-level care.
- United States ex. rel. Drakeford v. Tuomey Healthcare Systems- \$72.4 million judgment after jury trial (Oct. 2015) (STARK –physician compensation arrangements-referrals by doctors with improper financial arrangements)→ **Ralph J. Cox, III** (Sept. 2016) –**former Tuomey CEO- and Board Member** \$1 million settlement agreement & 4 years’ exclusion from federal programs - ignored “red flags” raised by attorney regarding contracts.

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### Sample of Applicable Federal Criminal Statutes

- Anti-Kickback Statute- 42 U.S.C. § 1320a-7b
- Health Care Fraud- 18 U.S.C. § 1347
- Wire Fraud- 18 U.S.C. § 1343
- False Statements- 18 U.S.C. §1035
- False Claims- 18 U.S.C. §287
- Conspiracy, 18 U.S.C. §371
- Money Laundering- 18 U.S.C. §§ 1956-1957
- Forfeiture Allegations

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## Criminal False Claims and False Statements

### Examples of Fraudulent Conduct

- Kickbacks
- Billing for services not rendered
- Up-coding
- Medically unnecessary services
- Obstruction of Justice

### Corporations and Individuals Can Be Liable

- U.S. Sentencing Guidelines
  - Fines- Corporations
  - Jail Time or Probation
  - Restitution

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## Recent Criminal Cases

- [United States v. Michael Babich, et. al.](#) (Dec. 2016) (RICO conspiracy, Mail Fraud, Wire Fraud)- former **Insys Therapeutics, Inc.** CEO and executive managers charged with paying bribes and kickbacks to pain management physicians to prescribe drugs to patients who did not have cancer.
- [United States v. Alan Beauchamp et. al.](#) (Nov. 2016) (conspiracy to violate the Anti-Kickback Statute, Travel Act)- Forrest Park Medical Center (FPMC), a physician owned surgical hospital- President, Board Members and other executives charged with bribing physicians for referring Tricare and other patients to FPMC
- [United States v. Tenet Healthcare Corporation](#) (Sept. 2016)(conspiracy to violate the AKS)- Tenet and two of its subsidiaries agreed to pay \$513 million to resolve criminal charges and civil claims related to paying bribes for referrals.
- [United States v. Olympus Corporation of the Americas](#) (March 2016)-\$623.2 million to resolve criminal and civil charges related to scheme to pay kickbacks to doctors and hospitals in exchange for purchasing equipment.
- [United States v. Warner Chilcott](#) (Oct. 2015)(health care fraud)- \$22.9 million fine-related to the submission of false prior authorization requests for osteoporosis drugs. Simultaneous \$91.5 million FCA settlement for AKS violations. Several individuals also charged with criminal conduct

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## OIG Exclusion Authority

### Exclusion

- Mandatory exclusion bases include convictions of various crimes related to provision of services under Medicare/Medicaid or healthcare fraud.
- Permissive exclusion bases include:
  - Conviction of certain misdemeanors and other crimes.
  - Administrative determination that individual or entity has committed an act that is subject to civil money penalties or criminal penalties (including anti-kickback statute) under Medicare authorities.

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**OIG Exclusion Authority**

- §1128 and 1156 of the Social Security Act.
- Effect of Exclusion:
  - No Federal health care program payment may be made for items or services:
    - Furnished by an excluded individual.
    - Directed or prescribed by an excluded individual, where person furnishing the item or service knew or had reason to know of the exclusion.

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**OIG Exclusion Authority**

- Excluded individual also subject to Civil Monetary Penalty of \$10,000 for each violation, plus potential treble damages.
- 20 statutory bases for exclusion.
  - 4 bases for mandatory exclusion.
  - 16 bases for permissive exclusion.

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**OIG Exclusion Authority**

**OIG Mandatory Exclusion**

- § 1128 (a) of the Social Security Act.
- 5 year minimum term.
- Resulting from:
  - Felony convictions relate to health care fraud or controlled substances.
  - Felony or misdemeanor convictions for program related crimes or patient neglect or abuse.

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**OIG Exclusion Authority**

**OIG Permissive Exclusion**

- § 1128(b) of the Social Security Act

**Select Bases:**

- Engaging in fraud, kickbacks or other prohibited activities.
- Performance of unnecessary or substandard services.
- License revocation/suspension.
- Conviction relating to obstruction of investigation.
- Entities controlled by a sanctioned individual.

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**OIG Exclusion Authority**

- § 1128 (b)(15) permits exclusion of the following individuals within a “sanctioned entity” based on the entity’s conviction of certain offenses or exclusion:

- Owners – if they know or should have known of the wrongful conduct leading to the sanction.
- Officers and Managing Employees – based solely on their position with the sanctioned entity, regardless of their knowledge.

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**OIG Exclusion Authority**

**OIG Guidance for Implementing Permissive Exclusion**

**The OIG may consider:**

- Circumstances of Misconduct.
- Conduct during Government’s Investigation
- Significant Ameliorative efforts
- History of Compliance

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### Expansion of Exclusion Authority January, 2017

- 10 year SOL for Affirmative exclusion actions.
  - §1128(b)(7) (fraud, kickbacks or other illegal activities).
- Exclusion for conviction of offense related to interference with or obstruction of an audit.
- Exclusion for failure to provide payment information when requested by federal healthcare programs.
- Exclusion for false statement, omission or misrepresentation of material fact in applications to enroll as provider or supplier.

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### Civil Monetary Penalties Actions

- Affirmative fraud litigation.
- Standard = knows or should know
  - Actual knowledge
  - Deliberate indifference
  - Reckless disregard
- 6 year S.O.L.
- Generally spin off, or companion to pending FCA case.

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### Exclusion In Action

- Roben Brookham 1/17
- Convicted, unlicensed dentist
  - \$1 million fine
  - 50 year exclusion
- Labib Riach, M.D. 11/16
- \$5.25 million FCA settlement
  - 20 year exclusion
- Susan Toy 9/16
- Billing company owner
  - \$100K CMO
  - 5 year exclusion

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**Enforcement Trends:  
Where Can You Look to Find Them?**

- DOJ and HHS-OIG Settlements, CIAs & Press Releases
- OIG's Yearly Work Plans
- OIG's Semi-Annual and Annual Reports
- HHS-OIG Fraud Alerts

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**HYPOTHETICAL**

- Employee Hypothetical:
  - Employee is a sales person at a pharmaceutical company that seeks to become the market leader.
  - Employee is given an expense account for use in conducting business and given directives from upper management on how best to deploy this tool to increase sales. Bonuses are given at year's end for the most sales of the company's product.
  - Employee hosts dinners, reimburses travel, gives cash, medical supplies, equipment and speaker's fees for bogus speaking engagements and case studies to physicians and clinics to induce the use of the company's product.

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**Yates Memo  
Impact**

HYPOTHETICAL  
CONTINUED

The Employee's  
Conduct

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

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**HYPOTHETICAL- COMPANY UNDER CIA**

- Company is subject to a Corporate Integrity Agreement ("CIA").
- In connection with obligations imposed by the CIA, Company Senior Vice President was obligated to certify that during the time period of the CIA, Company was in compliance with terms of participation in Medicare and Medicaid and the terms of the CIA.
- You have discovered that during the time period of the CIA, Company provided loans to another health care provider.
- You have also discovered that during the time period of the CIA, the healthcare provider would refer patients to Company.
- You have additionally learned that during this same time, the Company and healthcare provider entered into contractual relationship for provider to provide services to Company.

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Yates Memo Impact  
Hypothetical Continued:  
COMPANY UNDER CIA

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

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**HYPOTHETICAL- BILLING COMPANY**

- ABC Billing Company ("ABC") is a national provider of billing services for physicians, hospitals and other health care providers
- Your entity, Honest Quality Care Health System (HQCHS) hired ABC to submit claims to Medicare, Medicaid and FEHB insurers for services performed by emergency room physicians at one of its hospitals, Loving Care Hospital (LCH), which is located in Louisiana
- ABC receives medical records and other information related to the services rendered in the emergency room of LCH.
- You are a compliance officer at HQCHS. You receive an anonymous call from someone who claims to be a former ABC coder. He tells you that he has seen ABC coders submit claims forms to Medicare, Medicaid and FEHB insurers that reflect higher E/M services than LCH's ER doctors performed. He also tells you that he has seen some ABC coding supervisors tells staff to add charges to the E/M claims for minor services that were not performed by ER physicians, but, rather, by LCH nursing staff.
- You are so busy that you do not have time to act on this immediately. You don't even bother to try to get the caller's name or phone number. You do, however, make a note to ask your audit department to look into this further.
- 10 days after the call, you receive subpoenas from HHS-OIG and the MFCU in Louisiana demanding documents related to services provided by your ER physicians for the past 7 years.

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Yates Memo  
Impact  
HYPOTHETICAL  
(CONTD)  
Third Party Vendor-  
Billing Company

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

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Summary Slide: "Take aways" from Recent Government Enforcement Activity

- Substantial Government Expenditures re: Fraud and Abuse/Coordinated Efforts
  - "Takedowns"- Criminal Cases (HEAT)
- Increase in Qui Tam Actions
  - Aggressive Application of Laws
  - Review as Criminal Actions
- Increase in AKS Investigations
- Administrative Resolutions: Exclusion and CMPs
- Personal Liability Claims
  - Yates Memorandum
- Blurring Between Mistakes/Overpayments v. False Claims

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Practice Tips: How Do You Respond to Allegations of Wrongdoing?

- Consideration of legal issues:
  - Analyze applicability of civil or criminal statutes/regulations
- What is your first step regarding complaint received?
- Develop an Investigation/Incident Response strategy
  - How quickly must you act? False Claims Act: 60-day overpayment issues?
- Conduct an internal investigation
  1. Document Preservation Hold: consult with experienced legal counsel
  2. Draft an Investigations Plan- Timeline
    - Document/data collection (e-docs, v/m, texts)- who are the relevant custodians?
    - Who will assist you with the investigation?
    - Analyzing data- who are the relevant players to assist you?
    - Interviewing witnesses- "buddy system"
  3. Expert witness/consultants
  4. To whom do you report your findings?

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**Practice Tips: What Should You Be Doing in a “Yates Memo World?”**

- Make sure that all managers and leadership are aware of:
  - Yates Memorandum;
  - recent case examples;
  - DOJ’s Compliance Counsel;
  - DOJ’s Criminal Fraud Section’s “Evaluation of Corporate Compliance Program” Document (February 8, 2017);
  - and the U.S. Sentencing Guidelines Manual: §8B2.1
- Root Cause Analysis Required
- “Notice/Knowledge” Assessment
- Remedial Measures

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**Practice Tips: What Should You Be Doing in a “Yates Memo World?”**

- How effective is your current compliance program?
  - How robust is your documentation of how well compliance works
  - How promptly do you investigate complaints and do you document CAPs
  - Questionnaire re: what the employees know about your compliance policies
- Risk Assessment:
  - Arrangements with physicians
  - Practices of sales/marketing employees
- Specific Compliance Training
  - AKS, STARK, FCA, Health Care Fraud, Conspiracy, Obstruction of Justice and Witness Tampering
- Social Media Policies

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**Practice Tips: What Should You Be Doing in a “Yates Memo World?”**

- Third Party Vendor Relationships
- Auditing
- Independent Entity conducts Compliance Assessments
- Periodic Meetings with Business Leaders/Service Lines

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## 302 The Blame Game: Accountability in Healthcare Compliance

Rick Kam  
President and Co-Founder  
ID Experts



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## Learning Objectives

- Blame Game: Covered Entity versus Business Associates
- What a business associate agreement should include
- What to do to be prepared before a data breach
- Responding to a data breach

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## What Not Covered?

- Not providing legal advice
- Cyber security best practices
- Compliance with HIPAA Security/Privacy rules
- Other

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## What is a Data Breach?

Data Breach is a "Legal" Construct

All breaches start as incidents, but not all incidents end up as breaches

"Incident" = attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI/PII

"Breach" = acquisition, access, use, or disclosure of PHI/PII [that poses a significant risk of financial, reputational, or other harm]\*

\*The definition of "data breach" varies across specific legislation and rules. In US states, many include a "harm threshold"

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## Complex Web of Breach Laws

Organizations that hold regulated data must comply with data breach notification laws.



- Data Breach Notification Laws:**
- 47 state laws
  - 3 U.S. territories
  - HIPAA Final Breach Notification Rule
  - Gramm-Leach-Bliley Act (GLBA)

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## Healthcare is a Prominent Target

Industries Affected by Data Breaches:



● Healthcare	26.9%
● Education	16.8%
● Government	15.9%
● Retail	12.5%
● Financial	9.2%
● Service	3.5%
● Banking	2.8%
● Technology	2.6%
● Insurance	1.6%
● Media	1.4%
● Others	6.8%

Source: TrendMicro, Follow the Data: Analyzing Breaches by Industry, 2015



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## Why Target Health Data?

Why hackers are targeting health data:

- **Value.** Health data on the black market is more valuable than other kinds of personal and financial data
- **Vulnerability.** Organizations with health data, including third parties, have less mature security postures compared with financial firms
- **Scale.** With an APT, there is the ability to acquire massive amounts of data



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## The Costs Are Still Rising...

Average organizational cost of a data breach: \$7.01 Million

- Up 130% in 2 years

The cost per record can vary based on root cause of breach:

- Malicious or criminal attack = \$236
- System glitch = \$213
- Human error = \$197

\*IBM/Ponemon Institute, 2016 Cost of Data Breach Study

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## Blame Game

Protecting PHI not improving...



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### Third Parties Increase Risks

- 41% of healthcare data breaches were caused by third-party snafus
- Third parties are often negligent in the handling of sensitive data, lacking resources, technology, and processes
- Legal responsibility lies with the covered entity




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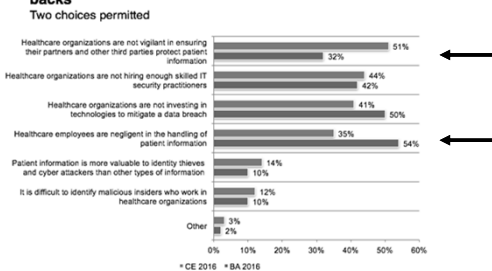
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### Reasons why healthcare and business associates believe they have a target on their backs




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### What a BAA Includes?

A Written contract that defines responsibilities between CE and BA that helps mitigate BA risk

1. Permitted and required uses of PHI
2. Not further disclose PHI
3. Implement appropriate safeguards for PHI
4. Report breach of PHI
5. Provisions to increase collaboration on pre-breach readiness

<https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>

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### Mitigating Financial Risk: Cyber Insurance

- What does your policy cover?
  - First party losses and costs?
  - Third party costs?
  - Remediation costs?
  - Fines and penalties?
  - Risk management services?
- What is the retroactive date?
- What does your policy allow you to choose?
  - Selection of outside counsel?
  - Selection of breach responders?
- Do the limits of liability match your exposure?




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### Strategies for Mitigating Operational Risk

- Conduct inventory of all hardware and software
- Use current version of operating systems
- Automate security patching
- Enable intrusion detection & prevention systems
- Segment network
- Control access based on need to know
- Require complex passwords & use multi-factor authentication
- Eliminate unnecessary data and processes
- Protect data
- Monitor endpoints
- Conduct due diligence on all third party service providers
- Conduct joint risk assessments
- Conduct vulnerability testing and audit
- Develop incident response plan & test the plan
- Conduct employee training on network security awareness
- Common risk assessment methodology




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### Future Predictions

- IoT will provide basis for attacks on attached devices of all kinds
- Ransomware will continue to be successful in targeting healthcare
- Medical device and wearable hacks will surface soon
- Growth in cybercrime-as-a-service make attacks viable for less sophisticated actors




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## Questions?

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# Making the Most of a CIA

Laura Ellis, Senior Counsel, Office of Inspector General  
Donna Thiel, Chief Compliance Officer, ProviderTrust

HCCA Compliance Institute  
March 27, 2017

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## Today's Objectives

- Discuss what to do even before the CIA is finalized
- Discuss how to get past the "This isn't fair" phase
- Discuss how to make the most of the expertise of the OIG, the IRO, Quality Monitor, Compliance Expert.
- Discuss tips on implementing a CIA



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## Role of the Compliance Officer



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### Role of the Compliance Officer

- **OIG Perspective**
  - Should be involved in all facets of negotiations and implementations
  - Primary contact with the OIG during CIA period
  - An experienced Compliance Officer is a great asset.

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### Role of the Compliance Officer

- **Provider Perspective**
  - Must be involved in all facets of negotiations and implementation
  - Face of the Company
  - Voice of Compliance (outward facing and behind the scenes)
  - Biggest compliance cheerleader

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**Settlement is Imminent,  
Now what?**

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**Settlement and CIA are imminent, now what?**

- **OIG Perspective:**
  - Negotiations take up to a year – use this time to prep
  - Review other CIAs
  - Evaluate current Compliance Program
  - Evaluate current CCO
    - If a change is necessary; do it before the CIA is signed
  - CCO needs to be part of the CIA negotiations

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**Settlement and CIA are imminent, now what?**

- **Provider Perspective:**
  - CCO needs to be a part of all negotiations
  - Review other CIAs and your current CIA drafts
  - Create a basic plan from the draft CIA requirements
  - Complete a mini-gap assessment comparing CIA requirements and current Compliance Program
  - Begin discussing implementation strategies
  - Begin discussing resource needs (People and costs)

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**Relationships and Attitude Matter**

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**Relationships and Attitude Matter**

- OIG Perspective:
  - OIG "contact" is transferred from Negotiator to Monitor
  - Get to know your OIG Attorney ASAP
  - Set-up a call or meeting to discuss expectations
  - Good First Impressions Count – Attitude

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**Relationships and Attitude Matter**

- Provider Perspective:
  - Feeling frustrated
  - Feeling overwhelmed

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**Relationships and Attitude Matter**

- Provider Perspective:
  - Critical to success of CIA implementation
  - Primary source for CIA clarification
  - Relationship will build
  - Always listen and follow up

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**Tips for Getting the Most From Your CIA**

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**Tips for Getting the Most From Your CIA**

- Start Early
  - Plan
    - Requirements
    - Teams
    - Project Plan
- Calendar – When Will Reports Be Due?
- Initial Risk Assessment

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**Tips for Getting the Most From Your CIA**

- Buy-In From Organization
  - Leadership
  - Board
- Communicate
- Purpose of CIA – Improve Compliance Program

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**Tips for Getting the Most From Your CIA**

- Use Your Compliance Committee
  - Who Will Be On It?
  - Make It An Active Resource
  - Eyes and Ears
  - Involve in Every Aspect of Risk Assessment
  - Use to Make Case that Compliance Adds Value

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**Monitors, IROs, OIG – Resources?**

- OIG Perspective:
  - OIG – Resource for CIA Terms
  - IRO, Expert, Quality Monitor
    - Choose wisely if you select
    - You're paying for them – so make the most of them
    - Get them to help you with your biggest risks

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**Monitors, IROs, OIG – Resources?**

- Provider Perspective:
  - Yes, Yes, Yes
  - Compliance Experts
  - Industry Experts
  - Expensive, why not get the most out of the money you are spending?

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**CIA survival tips**

- OIG Perspective:
  - CIA: Tool or Burden?
  - Communicate with OIG Contact
  - Be Transparent with OIG Contact
  - Plan Long Term From the Start
  - What is the End Goal?

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**CIA survival tips**

- Provider Perspective:
  - Don't waste too much time feeling sorry for yourself
  - Leverage every resource
  - Listen, listen, listen,
  - Learn, learn, learn
  - Grow, grow, grow

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**Five Years Later...**

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**Was It A Success?**

- OIG Perspective:
  - Do You See Lasting Change?
  - Did You Get Most Out of CIA?
  - Do You Know Where Your Compliance Program Goes Next?
  - Is Your Leadership With You?

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**CIA is completed, now what?**

- Provider Perspective:
  - Celebrate the strides you have made
  - Continue with your improved culture
  - Continue use of new or improved compliance tools
  - Celebrate

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**Benefits of having a CIA?**

- Provider Perspective:
  - Expert resources you may not have had access to previously
  - Possibly new department resources
  - Compliance may become a higher priority to the organization

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## QUESTIONS



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## Contact Information

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**Managing the  
Business Associate Relationship:  
From Onboarding to Breaches**

March 27, 2016

HCCA's 21<sup>st</sup> Annual Compliance Institute  
National Harbor, MD

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**Today's Agenda**

- **Onboarding:** Health care providers and payers have a duty to ensure that the vendors in which they entrust PHI will protect it and use it appropriately—we will discuss business associate onboarding strategies, pitfalls and best practices
- **Ensuring Compliance:** Ensuring ongoing compliance with HIPAA and other privacy laws by your business associates is challenging—we will discuss monitoring your business associates, auditing rights and handling disputes
- **Handling Breaches:** Business associates are a leading cause of breaches for health care providers and payers—we will discuss how to best prepare your organization upfront should a breach occur and special considerations for handling a business associate breach

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**Key Concepts**

- Vendor Screening
- Business Associate/Vendor Questionnaire
- Developing and Using the Questionnaires
- Reviewing the Questionnaires
- I Like This Vendor, But...
- Contracting with a Business Associate
- Auditing Your Business Associate
- Dealing with a Breach Caused by Your Business Associate

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## Our Philosophy

*“The Best Offense is a Good Defense”*



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## Onboarding

- Increased risks and potential liability for the acts or omissions of a business associate call for a more comprehensive approach to selecting and contracting with business associates
- Risks include:
  - Vicarious liability
  - Government enforcement actions
  - Negligence suits
  - Reputational harm
  - Breaches



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## Instructive Enforcement Actions

- Advocate Health Care
  - \$5.55 million settlement
  - Largest to-date settlement against a single entity
  - Breaches affected the PHI of approximately 4 million individuals
- Investigation revealed Advocate failed to:
  - Conduct an accurate and thorough risk assessment
  - Implement policies and procedures and facility access controls to limit physical access to the electronic information systems
  - Obtain satisfactory assurances in the form of a written business associate contract that its business associate would appropriately safeguard all PHI in its possession
  - Reasonably safeguard an unencrypted laptop when left in an unlocked vehicle overnight

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### Instructive Enforcement Actions

- Catholic Health Care Services (CHCS)
  - Theft of a CHCS mobile device (iPhone) compromised the protected health information (PHI) of 412 patient records
  - CHCS provided information management services to 6 skilled care facilities
  - \$650,000 settlement and a corrective action plan
  - CHCS had no policies addressing the removal of mobile devices containing PHI from its facility
  - No security incident policy; no risk analysis or risk management plan
  - 1<sup>st</sup> time OCR settled with a Business Associate

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### Vendor Screening

- 
- Due Diligence by a Covered Entity
  - Vet Before Signing a BAA
  - It's Your Organization's PHI
  - No Guarantees

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### Vendor/BA Security Questionnaires

- Trending in the healthcare sector
- Covered entities should use, and a BA should be prepared to answer these types of questionnaires
- Consider covered entity's leverage

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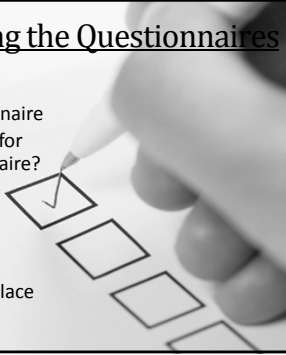
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### Developing and Using the Questionnaires

- Who Should Develop?
- Timelines to Use Questionnaire
- What Should be the Basis for Developing the Questionnaire?
- Need to Ask What Safeguards in Place
- Touch on Critical Areas of Maintaining PHI
- Policy and Procedures in place
- Training Capabilities



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### Instructions for Responding

- Please respond to each question
- Any questions not answered will be considered a "No" response
- If explanation is required, please submit an attachment to this questionnaire and indicate the question number for the response
- For any "No" responses, the Covered Entity may allow the Business Associate/Vendor/Subcontractor additional time to meet compliance requirements
- This questionnaire should not be considered a replacement for a Business Associate Agreement

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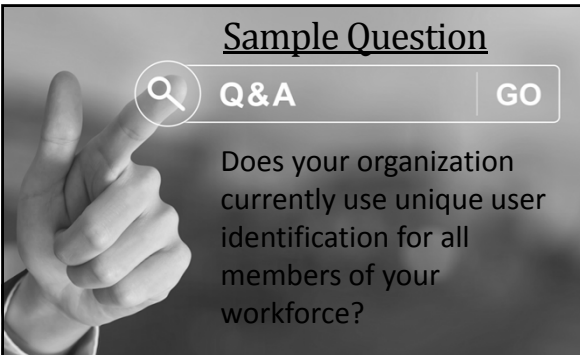
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### Sample Question

Does your organization currently use unique user identification for all members of your workforce?

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**Sample Question**

 **Q&A** **GO**

Does your organization have workstation use policies and procedures?

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**Sample Question**

 **Q&A** **GO**

Does your organization's contingency plan address disaster recovery and back up?

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**Reviewing the Questionnaires**

- Who Should Review
- All Positive Responses – Trust but Verify
- Dealing with Negative Responses
- Remediation Time
- Resubmit and Review
- A Final Determination to Move Forward with a BAA
- Document Management

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### I Like This Vendor, But...

- The Responses Were too Negative
- Sole Source, Specialty Vendor
- Don't Compromise
- Ability to Make it Right
- Time Factor



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### Deciding to Contract

- Congratulations!!! You have met the business associate of your dreams – compliant, proactive, great advisers and a culture dedicated to patient privacy and data security
- Now you need to seal the deal with a Business Associate Agreement
- **Remember:** Don't limit yourself to HIPAA when drafting and negotiating BAAs

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### Business Associate Agreements

- A best practice is to have only one business associate agreement between one covered entity and one business associate to govern all agreements and relationships between the parties
- Develop your own form business associate agreement
  - Worth the exercise to determine what you want in the agreement and what your risk profile is
  - Try to start with your own form and negotiate from there
- When negotiating a business associate agreement, your goal should be to protect your organization – not to argue/win on every point
  - In other words, **stay focused and don't over-lawyer**
  - Recognize your bargaining power and market position and be realistic in what you can achieve
- Address state law or other federal laws in the BAA

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## Auditing Your Business Associate

- Basis for the Audit – BAA
- What Can You Ask to Audit or Review?
- Confidentiality Issues
- Warning Signs
- Call to Action

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## A Breach

• Every relationship has it's ups and downs, though few can be as challenging to handle as a data breach. To prepare for the inevitable event, we will address the following:

- What your BAA should say
- Managing the business associate
- Investigation
- Delegation
- Post-Breach Activities



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## Your BAA

- Your CEO's first question: "What does the BAA say?"
- Let's hope it adequately addresses the following:
  - Breach notification
  - Breach mitigation
  - Cooperation
  - Indemnification/Reimbursement
  - Insurance



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## Managing the Business Associate

- Not all business associates have the same resources to handle a breach. To ensure you are protected, consider the following:
  - Understand scope of breach – how many covered entities are affected? Did the breach occur at the business associate or another downstream entity?
  - Understand proposed response plan – who is advising the business associate? Who is reviewing the breached PHI, systems or equipment? What is the business associate’s timetable?

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## Investigation

- Investigating a breach at a business associate is often challenging because you lack the facts, access to relevant parties or the breach may be at a downstream entity with which you have no relationship
- Despite these challenges, consider the following:
  - Request periodic touch point calls
  - Request a single point of contact for breach-related questions (likely their outside counsel)
  - Ask to see the data
  - Request the risk assessment
- Track costs incurred

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## Delegation

- The business associate informs your CEO that it will accept “delegation” of breach-related notifications. Should you accept?
- Understand the specific delegation proposal – when will notices be submitted? Who will draft them? Will the covered entity have review/approval rights? Who will select media outlets?
- If you agree to delegation, get the entire plan in writing. Specify what the BA will handle and what you will handle. Delegation may be partial
- Ask: does it make sense for the covered entity to retain some obligations, such as substitute notice?
- Consider remedies for business associate failure to adhere to delegation plan or comply with legal obligations

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## Post-Breach Activities

- Address costs of the breach
  - Look to your contract's or your BAA's indemnification and breach reimbursement clauses
  - Arrange for a business courtesy payment
    - Note: be aware of waivers/releases
- Remediation plan
  - What will the business associate do to reduce the likelihood of a reoccurrence?
  - Is there an opportunity to restructure your relationship to minimize risk? Consider return or destruction of unnecessary PHI, periodic destruction schedules, re-imagining data security, de-identification/masking options

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## Post-Breach Activities

- A break-up?
  - If the outcome of the breach is an ending of the relationship, look to the BAA and underlying contract for protections
  - The documents should address at least the following issues:
    - Did the breach of data constitute a breach of the contract or BAA?
    - Do you have access to your data during the transition?
    - Who elects return or destruction of PHI? Who pays for it?
    - Timeline for return or destruction? Methods?
    - Certification of destruction?

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## A Note on HIPAA & Cloud Computing

- CSPs generally offer online access to shared computing resources with varying levels of functionality depending on the users' requirements, ranging from mere data storage to complete software solutions (e.g., an electronic medical record system), platforms to simplify the ability of application developers to create new products, and entire computing infrastructure for software programmers to deploy and test programs

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### A Note on HIPAA & Cloud Computing

- When a Business Associate subcontracts with a CSP to create, receive, maintain, or transmit PHI on its behalf, the CSP subcontractor itself is a business associate
- This is true even if the CSP processes or stores only encrypted PHI and lacks an encryption key for the data
- Lacking an encryption key does not exempt a CSP from business associate status and obligations under the HIPAA Rules

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### Questions?

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# Split Shared/Consulting Services...to Split Share or Consult is the Question

HCCA Compliance Institute 2017  
National Harbor, MD

March 27, 2017

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## Disclaimer

The views and opinions expressed during this presentation are those solely of the presenters and not those of any company or entity with which they may be associated.

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## Objectives

- Discuss split shared and consulting E/M clinical case scenarios
- Review an audit plan
- Split/Shared or consulting services for providers in same specialty



*Learning Objectives*

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## Consult & Split Shared



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## Effective January 1, 2010

- Medicare no longer recognizes consultation codes regardless of what other third party payers recognize.
- New modifier: AI – "Principal Physician of Record" - used with inpatient hospital admission codes and initial nursing facility visit code.



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## Consult: Hospital vs. Office

### Hospital

- Admission code (99221-99223)
- **Cannot** bill consult codes for Medicare patients

### Office

- New patient codes (99201-99205)
- Established patient codes (99212-99215)
- **Cannot** bill consult codes for Medicare patients



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## Keep In Mind

- **New Patient**

- o No professional services received from a physician or physician group practice
  - E/M Services
  - Face-to-Face (i.e., surgical procedure)
- o No visits from any provider in same physician specialty
- o Physicians in the **same specialty and subspecialty**. For Medicare E/M services, the same specialty is determined by the physician's or practitioner's primary specialty enrollment in Medicare.
- o Within previous three (3) years

- **Established Patient**

- o Professional services received from physician/NPP
- o Physician of same specialty within group practice
- o Within previous three (3) years

- **Setting of Service**

- o Office or other outpatient setting
- o Hospital Inpatient
- o Emergency Department (ED)
- o Nursing Facility




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## Physician Specialty Codes

01	General Practice	36	Nuclear Medicine
02	General Surgery	37	Pediatric Medicine
03	Allergy/Immunology	38	Geriatric Medicine
04	Otolaryngology	39	Neurology
05	Anesthesiology	40	Hand Surgery
06	Cardiology	41	Ophthalmology
07	Dermatology	42	Infectious Disease
08	Family Practice	43	Endocrinology
09	Interventional Pain Management	44	Podiatry
10	Gastroenterology	45	Rheumatology
11	Neuro Medicine	72	Pain Management
12	Orthopedic Manipulative Medicine	73	Peripheral Vascular Disease
13	Neurology	77	Vascular Surgery
14	Neurosurgery	79	Cardiac Surgery
16	Obstetrics/Gynecology	79	Addiction Medicine
17	Hospice and Palliative Care	82	Critical Care (Intensivists)
18	Ophthalmology	82	Thrombology
19	Oral Surgery (Dentists only)	82	Hematology/Oncology
20	Orthopedic Surgery	84	Preventive Medicine
21	Cardiac Electrophysiology	85	Maxillofacial Surgery
22	Pathology	86	Neuropsychiatry
23	Sports Medicine	88	Likewise Provider
24	Plastic and Reconstructive Surgery	88	Medical Oncology
25	Physical Medicine and Rehabilitation	91	Surgical Oncology

\*List is not all inclusive

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## Office Split/Shared

- Split/Shared evaluation management (E/M) encounter between a physician and a non-physician practitioner
  - o Nurse practitioner (NP), physician assistant (PA), clinical nurse specialist (CNS) and certified nurse midwife (CNM)
- Service is considered to have been performed "incident to" if the requirements for "incident to" are met and the patient is an established patient.
- If "incident to" requirements are **not** met - bill under the NPP's UPIN/PIN and payment of 85% will be made.
- Incident-to billing is not allowed for new patient visits.

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## “Incident To”

- Services must be part of patient’s normal course of treatment.
- Physician **personally performed an initial service** and remains **actively involved** in the course of treatment.
- Document the essential requirements for incident to service in patients’ records
- Direct supervision is required.
  - Physician doesn’t have to be physically present in the room.
  - Physician must be in the office suite readily available to render assistance, if necessary.

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## Hospital Split/Shared

- Medically necessary encounter with a patient where the physician and a qualified non-physician practitioner (NPP) each personally perform a substantive portion of an E/M visit, face-to-face with the same patient on the same date of service.
  - A substantive portion of an E/M visit involves all or some portion of the history, physical exam or medical decision making key components of an E/M service.
  - The physician and NPP both must be in the same group practice or employed by the same employer.
- Applies only to selected E/M visits and settings
  - Hospital inpatient, hospital outpatient, hospital observation, emergency department, hospital discharge, office and non-facility clinic visits, and prolonged visits associated with these E/M visit codes.
- Does not apply to critical care services or procedures
- Bill under either the physician’s or the NPP’s UPIN/PIN number

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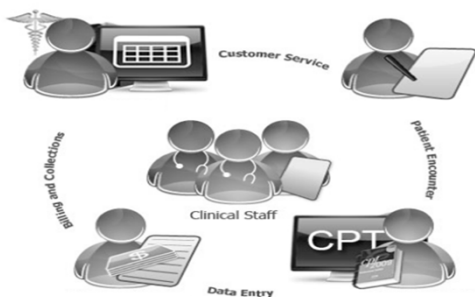
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## Understanding the Revenue Pitfalls




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# Office Visit Scenario 1

## Referral for Subspecialty

- Dr. A is primary specialty Cardiology only.
- Dr. B is primary specialty Cardiology and subspecialty Electrophysiology.
- Both doctors are in same group practice

If Dr. A refers patient to Dr. B for subspecialty of Electrophysiology, can Dr. B bill a new patient visit?

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# Office Visit Scenario 2

## Subspecialty Refers to Primary Specialty

- Dr. Wiseguy and Dr. GetItRight are both orthopedic primary specialists in the same group practice.
- Only Dr. Wiseguy has a subspecialty in sports medicine.

Can Dr. Wiseguy, who treated the patient initially for sports medicine services, refer this patient to Dr. GetItRight for surgery?

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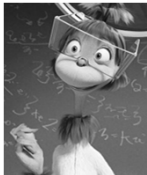
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# Office Visit Scenario 3

## Second Opinion Referral

Dr. Suzie treats a patient but the physician would like for the patient to receive a second opinion from Dr. Q-Tip, who is a partner in the same group practice.

Can Dr. Q-Tip bill for a new patient visit?



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### Office Split/Shared Scenario 1

- Mr. McGee, physician assistant (PA), is seeing an established patient in the office.
- Dr. How steps into examining room with the PA to perform part of exam and review plan with patient.

Is this a split/shared visit?

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### Office Split Shared Scenario 2

- Ms. Betty, certified nurse practitioner, is seeing an established patient in office located on first floor.
- Ms. Betty calls the physician to ask him/her to review the patient's progress note for collaboration. The physician documents additional orders and plan of care.

Is this a split/shared visit?

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### Hospital Split/Shared

Ms. Betty evaluates a 70-year-old patient admitted for chronic obstructive bronchitis and progressing shortness of breath. Ms. Betty documents the service and provides the attending physician with an update on the patient's status. The following day, the physician makes rounds and concurs with the patient's current plan of care.

Can the physician bill for split/shared visit in a hospital setting?

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## Hospital Split/Shared Scenario 2

Ms. Cox, a hospital employed certified nurse practitioner, treats a patient on the telemetry unit in the morning. Dr. Jeffery, an independent physician, rounds the unit later that afternoon and evaluates the same patient assigned to Ms. Cox.

How does Ms. Cox and Dr. Jeffery bill for treating the same patient on the same day?

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## Hospital Consult Scenario

Mr. Jones was admitted to an inpatient unit to receive psychiatric treatment as the primary diagnosis. The patient also requires treatment for his/her diabetes management. The psychiatrist is not able to treat the diabetes. Therefore, psychiatrist consults with an internal medicine provider. The internal medicine provider evaluates and treats Mr. Jones for diabetes as an inpatient.

How should the internal medicine provider bill for the diabetes management services?

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## Audit Plan

- Identify risks
- Assign qualified auditors to complete tasks
- Review external audit reports
- Design audit tool/process to prevent inappropriate claim submissions or billing errors
- Review claim denials and appeals
- Ongoing education/training
- Data mining
  - o Trends
  - o High utilization of certain CPT codes
- Communicate audit results and corrective action plans to senior management, physician leadership and others

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### References

- <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf>
- <http://www.cms.gov/manuals/downloads/clm104c26.pdf>
- [http://www.wpsmedicare.com/j5macpartb/departments/enrollment/specialty\\_codes.shtml](http://www.wpsmedicare.com/j5macpartb/departments/enrollment/specialty_codes.shtml)
- Medicare Claims Processing Manual – Chapter 12 Physicians in Group Practice (Rev. 1, 10-01-03)
- <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r178cp.pdf>
- <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf>

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## Example Audit Plan

Split Shared Visits		
Description	Timing	Responsible Party
Each quarter, randomly select and audit five (5) Medicare/Medicaid patient accounts from the previous quarter with E/M codes for Split/Shared visits.	Quarterly	Compliance Department or assigned designee
<ol style="list-style-type: none"> <li>1. Review patient's medical record to validate Split/Shared billing accuracy:               <ol style="list-style-type: none"> <li>a. Medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service.</li> <li>b. Verify, a substantive portion of an E/M visit involves all or some portion of the history, exam or medical decision making key components of an E/M service.</li> <li>c. Split Shared (POS 21 or 22) occurred in hospital outpatient clinic/office and Other Outpatient Visits (99201-99205). Hospital clinic office is the same as provider based status.</li> </ol> </li> <li>2. Verify that the physician and the qualified NPP must be in the same group practice or be employed by the same employer.</li> <li>3. Relationship to Incident-To must meet the following in a provider office setting (POS 11).               <ol style="list-style-type: none"> <li>a. Incident-to regulations do not apply to New Patients, Only Established Patients</li> <li>b. use codes 99211-99215 for an established patient with an established plan of treatment</li> <li>c. The service or supplies are an integral, although incidental, part of the physician's or practitioner's professional services</li> <li>d. The services or supplies are of a type that are commonly furnished in a physician's office or clinic</li> </ol> </li> </ol>	Quarterly	Compliance Department or assigned designee

## Example Audit Plan

<ul style="list-style-type: none"> <li>e. The services or supplies are furnished under the physician's/practitioner's direct supervision</li> <li>f. The services or supplies are furnished by an individual, who qualifies as an employee of the physician, NPP or professional association or group that furnishes the services or supplies</li> <li>g. The service is part of the patient's normal course of treatment, during which a physician personally performs an initial service and remains actively involved in the course of treatment</li> </ul>		
<p>Split/shared E/M visit rule applies only to selected E/M visits such as these in the hospital settings</p> <ul style="list-style-type: none"> <li>1. Hospital admissions (99221-99223)</li> <li>2. Follow-up visits (99231-99233)</li> <li>3. Discharge management (99238-99239)</li> <li>4. Observation care (99217-99220, 99234-99236)</li> <li>5. emergency department visits (99281-99285)</li> <li>6. prolonged care (99354-99357)</li> <li>7. hospital outpatient departments (provider-based visits) (99201-99215)</li> </ul>	Quarterly	Compliance Department or assigned designee
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<p>Split/shared visits do not apply to consultations (99241-99255), critical care services (99291-99292) or procedures</p>	Quarterly	Compliance Department or assigned designee

\*POS = Place of Service

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\*POS = Place of Service

## Physician Specialty Codes

01	General Practice		36	Nuclear Medicine
02	General Surgery		37	Pediatric Medicine
03	Allergy/Immunology		38	Geriatric Medicine
04	Otolaryngology		39	Nephrology
05	Anesthesiology		40	Hand Surgery
06	Cardiology		41	Optometry
07	Dermatology		44	Infectious Disease
08	Family Practice		46	Endocrinology
09	Interventional Pain Management		48	Podiatry
10	Gastroenterology		66	Rheumatology
11	Internal Medicine		72	Pain Management
12	Osteopathic Manipulative Medicine		76	Peripheral Vascular Disease
13	Neurology		77	Vascular Surgery
14	Neurosurgery		78	Cardiac Surgery
16	Obstetrics/Gynecology		79	Addiction Medicine
17	Hospice and Pallative Care		81	Critical Care (Intensivists)
18	Ophthalmology		82	Hematology
19	Oral Surgery (dentists only)		83	Hematology/Oncology
20	Orthopedic Surgery		84	Preventive Medicine
21	Cardiac Electrophysiology		85	Maxillofacial Surgery
22	Pathology		86	Neuropsychiatry
23	Sports Medicine		88	Unknown Provider
24	Plastic and Reconstructive Surgery		90	Medical Oncology
25	Physical Medicine and Rehabilitation		91	Surgical Oncology

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**HCCA COMPLIANCE INSTITUTE**  
**Advice of Counsel and Good Faith**  
**Reliance: Best Practices in a Risky**  
**Environment (Session 306)**

**James G. Sheehan**  
 Chief, Charities Bureau, Office of New York  
 Attorney General Eric Schneiderman  
**Kevin McAnaney**, *Attorney, Law Office of*  
*Kevin G. McAnaney*

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## Overview

1. Basics of Advice of Counsel Reliance and Defense
2. Why Compliance Officers Should Understand Advice of Counsel
3. Issues Related to Advice of Counsel Defense
4. A Case Study of the Advice of Counsel Defense Used in Tuomey and the Impact on Enforcement Decisions

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## What is the Advice of Counsel Defense?

- Advice of counsel is a legal defense to allegations of intentional illegal conduct
- Basically, it says a person or entity did not intentionally violate the law because they sought advice from counsel prior to acting and acted on that advice
- Advice of counsel only is a defense where the intent of the party is an element of the offense
  - Proof of violation requires proof of a level of intent
  - Not Stark violations: strict liability (overpayment)
  - Not miscoding: strict liability (simple overpayment)
  - But False Claims Act requires "knowing" conduct (can be reckless disregard")
  - AntiKickback Act requires "knowing and willful" violation

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WHY IT MATTERS-INDIVIDUAL RISKS  
FOR COMPLIANCE OFFICERS

- (DOJ) "Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals."
- " (DOJ) Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay."

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Why Advice of Counsel Matters  
To Compliance Officers

Compliance Officer Interactions  
with Counsel

- Routine Day to Day Interactions
- Answering Legal Questions/Interpreting the Law
- Development of Compliance Policies
- Assistance with Complex Matters

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ADVICE OF COUNSEL-COMPLIANCE  
OFFICERS' RISKS

- Second hand receipt of underlying facts(passed through others)
- Second hand receipt of advice (we ran this past the lawyers)
- Uncertain facts
- Uncertain opinion-not in writing
- Individual employee could not disclose the privileged information necessary to raise an advice-of-counsel defense because the corporation owns the privilege. US v. Wells Fargo Bank, NA, 132 F. Supp. 3d 558 (SDNY 2015)
- What documents will exist after the fact to show your good faith

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## Why Advice of Counsel Matters To Compliance Officers

Handling of Post Advice Communications

- Verbal Communications
- Written Communications
- Policies
- Board Communications

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## Why Advice of Counsel Matters To Compliance Officers

- Increasing cases against compliance officers (SEC and FINRA)
- Susan L. Martin "Compliance Officers: More Jobs, More Responsibility, More Liability" 29 Notre Dame Journal of Law, Ethics, & Public Policy (2015)
- Deborah A. DeMott, *The Crucial but (Potentially) Precarious Position of the Chief Compliance Officer*, 8 Brook. J. Corp. Fin. & Com. L. (2013).

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## When it works . . .

- "After an extensive investigation,. . . This office has determined that the parties involved cannot be appropriately prosecuted, given their reliance on the advice of counsel. . . This conclusion is not an endorsement of the conduct at issue; indeed, the transactions appear contrary to the intent and spirit of the laws. . . "
- March 16, 2017 NY District Attorney letter declining prosecution of New York Mayor DeBlasio.

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## Elements of Advice of Counsel Defense

1. Counsel is aware of all relevant facts( complete disclosure by client)
2. Counsel is consulted as to legality of conduct before the action taken
3. Counsel's advice is clear (that conduct was legal)
4. Counsel's advice is relied upon in good faith and followed  
*Markowski v. SEC, 34 F.3d 99, 105 (2nd Cir.1994)*
5. IMPORTANT QUESTION: Can the defendant rely upon advice given to another party to transaction? (common interest doctrine-sharing communications that facilitate compliance)
6. IMPORTANT QUESTION: Can an individual defendant rely upon advice given to the entity that employs them?

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## Advice of Counsel: Pluses and Minuses

- Benefits
  - o If successful, it may be a complete defense
  - o The ultimate issue of whether a defendant relied in good faith on **advice of counsel** and therefore did not act willfully is a question of fact to be resolved by the jury. "Whether the defendant fully disclosed the relevant facts, failed to disclose all relevant facts, or concealed information from his advisor, and relied in good faith on his advisor are matters for the jury—and not the court—to determine, under proper instruction." *United States v. Kofwitz, 614 F.3d 1241, 1272 (11th Cir.)*, opinion withdrawn and reissued in relevant part, 627 F.3d 1383 (11th Cir.2010).
  - o No bad intent, no violation
  - o But may still be overpayment
- Downsides
  - o It rarely works
  - o Party must waive attorney privilege for all related communications with any attorney
  - o Can make things much worse depending on communications
  - o What will the attorney say?

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## Why Advice of Counsel Rarely Works at Trial

- Conflicting advice from counsel
  - o Opinion shopping
- Advice given after the fact
- Counsel not given all relevant information
- Advice from counsel is equivocal
- Advice not strictly followed

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## Risk of Advice of Counsel Defense may be effective pre-indictment tactic

- Subject of investigation not required to commit to use of defense (prevents discovery of communications)
- Reluctance of DOJ attorneys to subpoena, depose attorneys-US Attorney's Manual **9-13.410 - Guidelines for Issuing Subpoenas to Attorneys for Information Relating to the Representation of Clients**
- requires prior authorization for the subpoena, by the AAG of the Criminal Division, even in civil cases.
- DOJ must show that "All reasonable attempts to obtain the information from alternative sources shall have proved to be unsuccessful."

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## Advice of Counsel Waives Attorney Client Privilege

- Attorney client privilege
  - A/C privilege protects communications between counsel and the client entity with respect to legal advice, including investigations.
  - Privilege extends to communications with in house counsel as well as outside counsel so long as the communications address legal matters
- Assertion of the advice of counsel defense by the holder of the privilege waives the attorney client privilege for all legal communications on the subject matter

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## WAIVER OF PRIVILEGE BY PUTTING ISSUE IN CASE- Columbus

- "Columbus Regional intends to offer evidence at trial that it believed its conduct was lawful. Columbus Regional does not assert an "advice of counsel" defense, and it does not intend to rely on communication with its attorneys in support of its defense."
- CMS 855 Claim form represents compliance with Anti-Kickback and Stark-Columbus put in affirmative defense of belief its conduct was lawful in answer.
- when a defendant affirmatively asserts a good faith belief that its conduct was lawful, it injects the issue of its knowledge of the law into the case and thereby waives the attorney-client privilege. *Barker v. COLUMBUS REGIONAL HEALTHCARE SYSTEM*( MD Georgia August 29,2014) citing *Cox v. Administrator U.S. Steel & Carnegie*, 17 F.3d 1386 (11th Cir. 1994).

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### WAIVER OF PRIVILEGE BY SUBJECT MATTER DISCLOSURE

- The voluntary disclosure by a client of a privileged communication waives the privilege as to other such communications relating to the same subject matter made prior to and after the occurrence of the waiver. In Re Application of Chevron Corporation 650 F. 3d 276 (3d Cir. 2011)(dictum) ("presence of strangers" in meeting means no privilege attaches, therefore no waiver)

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### WAIVER OF PRIVILEGE BY SELECTIVE WAIVER

- Health care-In Re Columbia/HCA Billing Practices Litigation 293 F. 3d 289 (6<sup>th</sup> Cir. 2002) waiver to one is waiver to all-focus on the communication purpose of the privilege

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### HOLDER'S BURDEN IN ASSERTING ATTORNEY CLIENT PRIVILEGE

- "To determine if a particular **communication** is confidential and protected by the attorney-client privilege, the holder must prove the communication was (1) intended to remain confidential and (2) under the circumstances was reasonably expected and understood to be confidential." Bogle v. McClure, 332 F.3d 1347, 1358 (11th Cir. 2003).
- See generally In U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, Case No: 6:09-cv-1002, 2012 U.S. Dist. LEXIS 158944 (M.D. Fla. Nov. 6, 2012) for detailed discussion of necessary showings

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## The Kellogg Test (DC Circuit)

- Was obtaining or providing legal advice a **primary** purpose of the communication, meaning one of the significant purposes of the communication? In re Kellogg Brown & Root, Inc., 756 F.3d 754(DC Cir. June 27, 2014)
- Compare: "**the predominant purpose** of the communication is to render or solicit legal advice." In re County of Erie, 473 F.3d 413, 420 (2d Cir. 2007)
- Some Third Circuit cases use phrase "**the primary purpose**"

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## WAIVER OF PRIVILEGE BY INTERNAL DISCLOSURE

- Law firm retains public relations firm to act as consultant on communications relating to its representation. PR firm participates in meetings with client and attorneys.
- Disclosure of client communications to PR firm, or attendance by PR firm at attorney client meetings "waives the privilege" Calvin Klein Trademark Trust v. Wachner 198 F.R.D. 53(SDNY 2000) (the possibility that the communications to the PR firm may have been helpful in formulating legal strategy and assisting counsel assessing probable public reaction "is neither here nor there.")

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## NOT ALL COMMUNICATIONS ARE PRIVILEGED

- 1) Is this a communication by a client to an attorney for "the purpose of obtaining or providing legal assistance to the client." (attorney-client) In re Grand Jury Subpoena, 223 F.3d 213, 219 (3d Cir.2000)
- 2) Is this a document or tangible thing prepared by or for an attorney in **anticipation of litigation** or for trial? (work product)
- 3) Has the protection already been waived by disclosure? (in depositions, proffers, by a public report, or to the other side in a transaction)
- 4) Can a client make a selective waiver of the protection in order to assert or present an advice of counsel defense, or allow others to do so?
- 5) Did the client "intend to commit a crime or fraud" at the time the attorney was consulted? and did the client use the attorney-client communication or work product in furtherance of the fraud?
- 6) Who has the authority to waive the privilege to assert the defense?

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## WAIVER OF PRIVILEGE BY DISCLOSURE?

- GM issues extensive Valukas Report concerning its investigation into the ignition switch defect and internal follow up
- Communications by employees protected: "the fact that certain information in [otherwise protected] documents might ultimately be disclosed does not . . . create the factual inference that the communications were not intended to be confidential at the time they were made."
- Report disclosure does not open up other work product: "A voluntary disclosure in a federal proceeding or to a federal office or agency . . . generally results in a waiver only of the communication or information disclosed." Fed. R. Evid. 502, Committee Notes
- IN RE GENERAL MOTORS LLC IGNITION SWITCH LITIGATION( SD New York January 15, 2015)

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## MANDATORY REPORTING OF CONDITIONS AFFECTING RIGHT TO PAYMENT

- required to be disclosed to a government entity or private party Model Rule of Professional Conduct 1.6
- CMS Form 855 and 855a certification
- ACA 6402 report refund explain overpayment within 60 days
- Section 111 reporting of primary insurance by primary insurer
- CONDITIONS OF PARTICIPATION-855
- STARK VIOLATIONS
- HOSPITAL READMISSION

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## ADVICE OF COUNSEL ISSUES FOR PRIVILEGE AND DISCLOSURE

- You will (probably) want to preserve the privilege until the organization decides that advice of counsel disclosure is in its best interest
- But-you may decide to create documents outside of the privileged context so that they can be used to support an advice of counsel argument without waiving the privilege generally
- EXAMPLE: Stark analysis of transactions

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## Not Reliance on Advice of Counsel, but Evidence of Good Faith?

- -believed materials reviewed and approved by lawyers and other professionals
- Defense to "knowingly and willfully" in Anti-Kickback statute?
- "pure heart/empty head" good faith
- "Scienter ... is a subjective inquiry. It turns on the defendant's actual state of mind." Thus, "although we may consider the objective unreasonableness of the defendant's conduct to raise an inference of scienter, the ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity."
- SEC v. Platforms Wireless Intern. Corp., 617 F. 3d 1072, 1093 (9<sup>th</sup> Cir. 2010)

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## Other Lessons Learned

- Assume there is no Advice of Counsel Defense
- Evaluate Attorney Advice Carefully
- Think Independently

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Physician Arrangements

Conducting the Audit & Ensuring a Resolution

Juliette Stancil, J.D., LL.M., CHC - Regional Compliance Officer, Presence Health

Anne Brummell - Regional Compliance Officer, Presence Health

2017 HCCA Compliance Institute  
National Harbor, MD | March 27, 2017

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Physician Arrangements

### Road Map

- Why spend valuable resources auditing Physician Arrangements?
- What data to gather in developing the question sets.
- Conduct a mock audit of a Medical Directorship.
- Define and interpret audit findings.
- How to report results to management and legal effectively.
- Distinguish roles of compliance officer and legal counsel during corrective action.



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Physician Arrangements

"Failure to structure physician contracts to comply with Stark and Anti-Kickback Statutes can easily result in seven-digit fines and repayments. Such violations can also adversely affect the status of tax-exempt entities. If you have not done so recently, **now is time to audit your physician contracts** to ensure compliance."  
-Hawley Troxell, posted in [Health Law](#) 1992

### Just the Facts...

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Physician Arrangements



1. Why spend valuable resources auditing Physician Arrangements?

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Physician Arrangements

### Why? It's the Law

- **Physician Self-Referral Law ("Stark")**
  - Physician may not refer patients nor bill Medicare unless arrangement fits within a regulatory safe harbor.
- **Anti Kickback Statute**
  - A criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals
- **False Claims Act**
  - It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.

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Physician Arrangements

### Why? Save Yourself from Trouble

- **Anti Kickback Statute Penalties**
- **Stark Penalties**
- **False Claims Act Penalties**
- **Mitigating Provider Liability**
  - Refund overpayments
  - Whistleblowers
- **The Regulatory Climate**
  - Increases in Government Enforcement
  - Allegation that Compensation is not Fair Market Value, not Commercially Reasonable, and that Compensation Takes into Account Referrals

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Physician Arrangements



...Get your posse together.

**P**lan  
**O**ccurrence  
**S**cope of Payments  
**S**ample Size  
**E**ndorsement

First Things First!

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Physician Arrangements

**P**lan **O**ccurrence **S**cope **S**ample **E**ndorsement

- o Create Formalized Plan
  - o Who is accountable?
  - o Use SMART Goals
- o Decide How Often?
  - o Monthly, Quarterly, Semi-annually, it's your choice!
  - o Have a routine in which there is an even flow
- o Layout Scope of Payments
- o Determine your Sample Size and Method
- o Get backing from Legal, AP, Governing Body



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Physician Arrangements

### Types of Physician Agreements

<ul style="list-style-type: none"><li>o Call Coverage</li><li>o Chairperson</li><li>o <b>Medical Director</b></li><li>o Employment</li><li>o Leases</li><li>o Honorariums</li></ul>	<ul style="list-style-type: none"><li>o Teaching</li><li>o Income Guarantees</li><li>o Subsidy/Stipends</li><li>o Clinical Services</li><li>o Management &amp; Billing</li></ul>
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Physician Arrangements



1. Gathering the data and developing the question sets

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Physician Arrangements

### Gathering Data

- o Physician Contract List w/in-house Responsibilities
- o Actual Contract
  - o schedule describing service
- o Detailed List of Physician Payments
  - o Date paid
  - o Amount paid and or requested
  - o Services rendered
- o Company Crosswalk Chart
- o Physician Call/Time Sheets or Attestations
  - o Physicians signature
  - o Approver's signature
- o List of Fair Market Values
  - o company's appropriate productivity-based compensation formula or benchmark surveys

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Physician Arrangements

### Question Sets

Does the agreement comply with the averages for services performed by other MDs of the same specialty for the Hospital?

Does the agreement specify the amount of Physician compensation?	Is there a properly signed agreement specifying services?	Does the agreement replace the pre-existing agreement?
Does the compensation structure measure the volume or value of the physician's referrals?	Does the agreement incorporate or otherwise reference other agreement between hospital and physician?	
Is there evidence of FMV determination?	Did the appropriate authorizing parties sign?	Is the term of the agreement for at least 1 year?

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Physician Arrangements

## Contract Database/Spreadsheet



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Physician Arrangements



## 2. Setting up Regulatory Matters to match Audit Questions

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Physician Arrangements

## Medical Directorship

<p><b>Stark Law Requirement</b></p> <ul style="list-style-type: none"><li>Arrangement is set out in writing, is signed by the parties, and specifies the services covered.</li></ul>	<p><b>Audit Question</b></p> <ul style="list-style-type: none"><li>Is there a properly signed agreement specifying the services to be performed?</li></ul>
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Physician Arrangements

### Scope of Services

<b>Stark Law Requirement</b> <ul style="list-style-type: none"><li>• The arrangement covers all of the services to be furnished by the physician to the entity.</li></ul>	<b>Audit Question</b> <ul style="list-style-type: none"><li>• Does the agreement incorporate or otherwise reference other agreements between Hospital and Physician?</li></ul>
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Physician Arrangements

### Reasonable & Necessary Test

<b>Stark Law Requirement</b> <ul style="list-style-type: none"><li>• The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.</li></ul>	<b>Audit Question</b> <ul style="list-style-type: none"><li>• Does the agreement comply with the averages for services performed by other <i>Medical Directors</i> of the same specialty for the Hospital?</li></ul>
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Physician Arrangements

### Time Frame

<b>Stark Law Requirement</b> <ul style="list-style-type: none"><li>• The duration of each agreement is at least 1 year.</li><li>• If terminated within the first year, was another agreement entered into?</li></ul>	<b>Audit Question</b> <ul style="list-style-type: none"><li>• Is the term of the agreement for at least 1 year?</li><li>• Does this agreement replace a pre-existing agreement?</li></ul>
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Physician Arrangements

## 3-Prong Compensation Test

**Stark Law Requirement**

The compensation to be paid over the term of each arrangement:

- o is set in advance;
- o does not exceed FMV; and
- o does not take into account the volume or value of any referrals or other business generated between the parties.

**Audit Question**

- o Does the agreement specify the amount of Physician compensation?
- o Is there evidence of FMV determination?
- o Does the compensation structure measure the volume or value of the Physician's referrals?

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Physician Arrangements



**AUDIT**

Can you spot all of the issues in this mock arrangement?

## 3. Conducting the Mock Audit

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Physician Arrangements

## The Payment

- o A check of your AP system populates this timesheet and corresponding payment data



Payment Date: 11/15/16  
 Payee: Bob Smart, MD      Address: 3456 Merryville Lane  
 GI Unit      10010      Anytown, USA 10001  
 Memo: Behavioral Health Oct 16      Amount: \$1237.50

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Physician Arrangements

## Properly Executed Agreement

- Is there a properly signed agreement specifying the services to be performed?

**INDEPENDENT CONTRACTOR  
PROFESSIONAL MEDICAL SERVICES AGREEMENT**

**EXECUTION IN WITNESS WHEREOF** the parties have executed this Agreement effective as of the date the last party to this Agreement executes it, being the Effective Date:

**SMALL TOWN HOSPITAL**  
By: [Signature]  
Name: John J. [unclear]  
Title: CEO  
Date: 2/23/2017

**MEDICAL DIRECTOR**  
By: [Signature]  
Name: Bob [unclear]  
Title: Medical Director of Obstetrics and Gynecology Services  
Date: \_\_\_\_\_

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Physician Arrangements

## Other Business Relationships

- Does the agreement incorporate or otherwise reference other agreements between Hospital and Physician?

**Other Business Relations.** Any prior-existing agreements between Physician and Hospital are listed herein in Exhibit C to this Agreement. Such agreements are hereby incorporated by reference into this Agreement between Hospital and Physician.

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Physician Arrangements

## Commercial Reasonableness & Business Justification

- Does the agreement fall within the medium of services performed by other Medical Directors of the same specialty for the Hospital?

Physician's invoiced time for services performed under this Agreement shall not exceed 15 hours monthly.

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Physician Arrangements

## Duration

- Is the term of the agreement for at least 1 year?

9. **Term.** This Agreement shall begin on August 1st, 2016 and will continue until terminated as provided in this Agreement.

10. **Termination and Non-Compete.** Written notice of intention to terminate this Agreement must be served upon the Hospital at least one (1) month prior to termination date. Upon termination of this Agreement, Physician will not practice in Hospital's Primary Service Area or a Medical District for a period of ~~at least two years~~

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Physician Arrangements


## Pre-existing Agreement

- Does this agreement replace a pre-existing agreement?

Does the current agreement:

- Replace another one within the first year (for the same or similar services)?
- Overlap with an agreement currently in effect?
- Specifically mention that it replaces another agreement?

You may have to do some digging! Check your central contract repository.



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Physician Arrangements

## Compensation

- Does the agreement specify the amount of Physician compensation?
- Does the compensation structure measure the volume or value of the Physician's referrals?

2. **Compensation for Services Rendered.** Hospital will compensate Physician on hourly rate of \$225.00 for services rendered under this Agreement. Physician's hourly rate has been determined the fair market value for services rendered under this Agreement by professionals in the Physician's Specialty. Physician shall complete a Hospital approved timesheet monthly for services performed using the timesheet included herein as Exhibit A and submit it for payment and processing not later than the 15<sup>th</sup> day of the month following services.

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Physician Arrangements

## Fair Market Value Analysis

- o Is there evidence of FMV determination?



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Physician Arrangements

## Organization Specific

- o Did the appropriate authorizing parties sign the agreement?
- o Is the agreement currently effective?

What are your organizations priorities about physician contracts?

These would make great audit questions!

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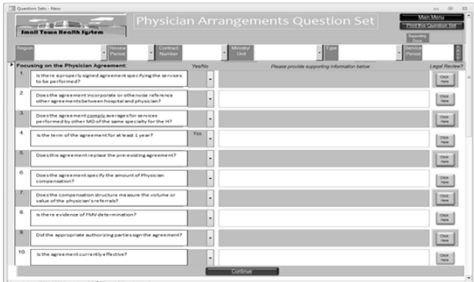
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Physician Arrangements

## Documenting Findings



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Physician Arrangements



4. Reporting results to management and legal effectively

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Physician Arrangements

### The Value of Knowing Your Leaders to Ensure a Resolution

- Results from these audits can be humbling for many in leadership.
- Present your findings in the way your leader will best perceive the information as an opportunity, rather than an attack.
- Use graphs and be prepared to show cause of why the audit & its questions were structured that way.

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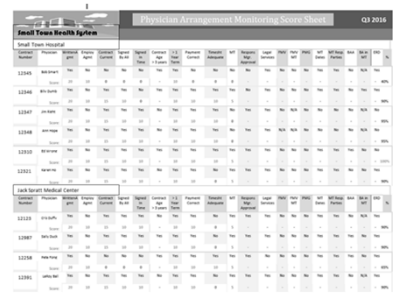
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Physician Arrangements

### Score Sheet



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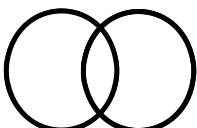
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Physician Arrangements



5. Distinguishing roles of compliance officer and legal counsel during corrective action

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Physician Arrangements

### Compliance Officer & Legal Counsel Relations 101

- The lines between legal counsel and compliance officer can often be blurred without a thorough and formal understanding of the job duties of each.
- Be cautious and refrain from offering legal advice related to the functionality of the agreement.
- Regardless of reporting relationship, don't underestimate the importance of having the support of your General Counsel.
- Legal Counsel should prioritize these efforts based on the governments scrutiny of this area of enforcement.

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Physician Arrangements

### Questions & Discussion



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Physician Arrangements

### Contact Info

- Juliette Stancil, Regional Compliance Officer
  - [juliette.stancil@presencehealth.org](mailto:juliette.stancil@presencehealth.org)
  - Office: 773.990.3992
- Anne Brummell, Regional Compliance Officer
  - [anne.brummell@presencehealth.org](mailto:anne.brummell@presencehealth.org)
  - Office: 773.665.3268

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**Auditing Compliance for Clinical Documentation and Coding: Collaboration is Key**

**AUDIENCE PARTICIPATION NOTE:  
PLEASE SEAT YOURSELVES WITH COLLEAGUES FROM YOUR ORGANIZATION.**

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**Auditing Compliance for Clinical Documentation and Coding: Collaboration is Key**

DEBBIE MORGAN, CHC, CPC  
COMPLIANCE OFFICER  
JUSTIN WHEELER, MD  
VICE PRESIDENT OF CLINICAL SERVICES

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**Today's Objectives**

- Learn how an effective partnership between Compliance, Coding and Clinical leadership can lead to an effective internal auditing and education program.
- Hear how an Auditing Compliance Committee and a Clinical Documentation Improvement Committee work together to identify trends and develop effective provider education that increases provider engagement and improves accuracy rates.
- Leave this session with a template for creating an effective internal auditing program that engages providers, EHR trainers, coders and compliance and results in clinical documentation improvements.



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### Purpose and Focus of Auditing Compliance Plan for Clinical Documentation Improvement

Plan designed to meet three objectives:

1. **Assure patient safety**
  - 24 hour documentation completion expectation
  - Complete and accurate documentation in the EHR to support patient safety
2. **Comply with CMS documentation guidelines/requirements**
  - Accurate clinical documentation compared to codes submitted for payment
3. **Assure success in future reimbursement models**
  - Quality payments will rely heavily on data obtained from CPT and ICD coding.




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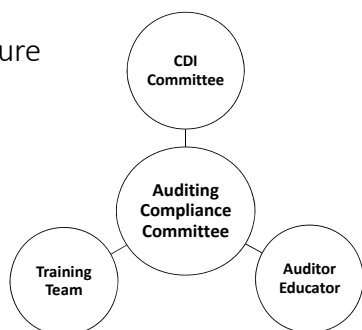
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### Collaborative Structure

- Assure patient safety
- Comply with CMS documentation guidelines & requirements
- Assure success in future reimbursement models




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#### Clinical Documentation Compliance Committee

**Function/Scope:** Provide Plan Oversight to assure compliance. Trend Analysis, Reporting, Removal of barriers to Success

**Members:** VP, Clinical Services, Compliance Officer, Auditor/Educator and Coding Leadership

Auditor/Educator	CDI Committee	Training Team
<p><b>Function/Scope:</b> Perform documentation audits and education to providers and coders. Identify and provide data trends to Compliance Committee.</p>	<p><b>Function/Scope:</b> Identify topics for CDI trainings. Topics based upon trends from audits. Provider input solicited for topic selection. <b>Members:</b> VP, Clinical Services, Providers, EHR Trainers, Auditor/Educator and Coding Manager</p>	<p><b>Function/Scope:</b> Prepare and deliver monthly trainings to providers during clinician meetings at each site. Trainings are based upon trend data and directed via the CDI Committee. <b>Members:</b> EHR Trainer, Auditor/Educator, Coding Manager, Clinical Content Experts</p>




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### Program Evolution Timeline

2011/2012	2013	2014	2015	2016
<ul style="list-style-type: none"> <li>Auditor Hired</li> <li>Baseline Audit</li> <li>Quarterly Audits w/limited feedback to providers</li> <li>Siloed efforts within Finance team</li> <li>Recognized necessary to translate CDI efforts to the EHR</li> </ul>	<ul style="list-style-type: none"> <li>Awareness that collaboration is necessary across other departments</li> <li>Vision to establish coders at each clinic</li> <li>Revenue Cycle Director hired</li> <li>Change in Organization and Clinical Leadership (new collaborative partnerships possible)</li> </ul>	<ul style="list-style-type: none"> <li>Auditing Plan and committee structure implemented</li> <li>Providers sign attestations/New Provider Orientation</li> <li>Accuracy goals set at 95% (OIG)</li> <li>Clinic-based coders</li> <li>Intermittent auditing due to staffing and org challenges</li> </ul>	<ul style="list-style-type: none"> <li>Added external audits from Nat'l firm to fill gaps from internal staffing challenges</li> <li>CDI education monthly</li> <li>Coder inexperience a gap</li> <li>Nat'l firm evaluated coding dept. structure, plan to improve</li> </ul>	<ul style="list-style-type: none"> <li>Updated Plan</li> <li>Goal – Continuous Improvement</li> <li>Added CO and Rev Cycle Leadership weekly meetings</li> <li>New Auditor hired, brought consistency</li> <li>External Audit shows change</li> </ul>




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### Impact of Collaboration

	Previous	Current
Culture	<ul style="list-style-type: none"> <li>Auditing in a Silo</li> <li>Providers experienced as punitive</li> <li>No shared language</li> </ul>	<ul style="list-style-type: none"> <li>Partnership between Clinical Leadership, Auditing, Coding, &amp; Compliance</li> </ul>
Activities	<ul style="list-style-type: none"> <li>Quarterly Audits</li> <li>Education limited to corrective action</li> </ul>	<ul style="list-style-type: none"> <li>Quarterly audits</li> <li>Focused Audits</li> <li>External Audits</li> <li>Quarterly CDI Trainings</li> <li>New Provider Onboarding Process</li> <li>Focused Education</li> </ul>




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### Program Impact: what the data shows

- Cohort of 25 Providers continuously employed since 2011
  - 15% absolute improvement in E&M accuracy
- Outside Audit 2015 vs 2016 Comparison
  - Total of 57 providers
  - 19% absolute improvement in E&M accuracy




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## Collaboration & Engagement Pearls

- Why is this important work
  - Quality
  - Risk
  - Safety
  - Payment Reform
- How to best engage partners:
  - Clinicians
  - EHR support team
  - Coders, auditors, educators
  - Executive Team (to support the costs related to program)
  - Operational Support at Sites
- No one can do it alone




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## Learning from Experience

- Successful program cannot be an isolated effort
- Culture change takes time
- Clinical Leadership and Sponsorship is necessary
- Continual need to monitor the work (provider and coding staff turnover, new regulations, changing payment models, build and rebuild trust)
- Data is important but data alone won't drive change
- Clinical documentation is multi-disciplinary effort/process/culture
- In the age of EHR's, providers benefit from learning:
  - The Why
  - The How
  - Not just the What




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## Activity

Build Your "Collaboration Template":

1. Who are the important partners to collaborate with at your entity? Map the roles you can realistically structure for your program. (5 minutes)
2. What barriers do you anticipate with this structure or what barriers do you currently encounter? (5 minutes)
3. Group will share experiences and ideas to overcome the barriers. (10 minutes)




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Q&A



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Speaker:  
Frank Ruelak  
Facility Compliance  
Professional,  
SIFM/C/DR

Session 309 Risk: **A Fundamental 4-Letter Word for Compliance Professionals**

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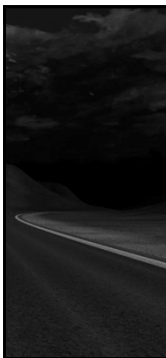
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**Break down risk into its fundamental components to better align mitigation activities or strategies**

Compare and contrast qualitative and quantitative approaches to assessing risk

How other program elements (auditing and monitoring) provide information on risk management

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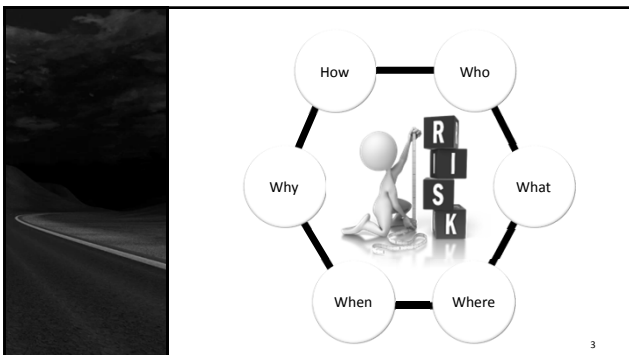
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How Who

Why What

When Where

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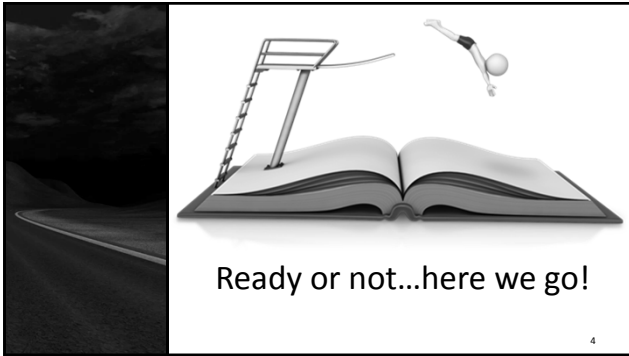
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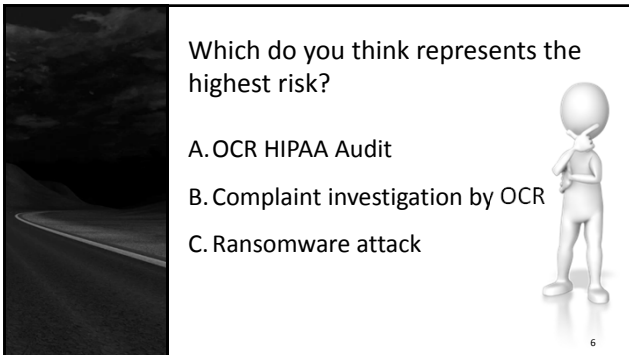
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Let's set some context and give people a chance to find another session.



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Who is from an organization where HIPAA applies?

- A. Healthcare Provider
- B. Health Plan
- C. Clearinghouse
- D. Business Associate\*

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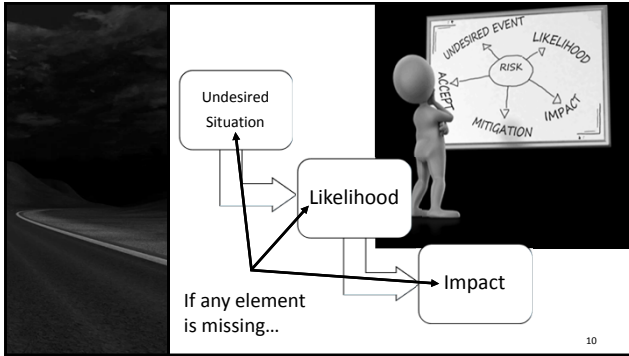
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Undesired Situation

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“Something” we  
would prefer not  
happen.

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**Undesirable Situation**

What is the risk of losing your money in Las Vegas?



What is the risk of hitting a jackpot in Las Vegas???

Wait a minute...  this isn't undesirable?

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**Undesirable Situation**

What is the risk of losing your money in Las Vegas?



Hey buddy...what's  
this????

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**Undesirable Situation**  
What is the risk of winning a jackpot in Las Vegas?



That's more like it!

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**Undesirable Situation**  
What is the risk of winning a jackpot in Las Vegas?



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Aria Resort, Las Vegas, NV April 15-18, 2018



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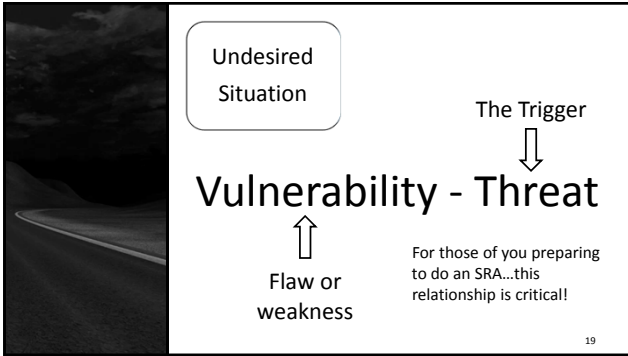
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Undesired Situation

The Trigger

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**Vulnerability - Threat**

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Flaw or weakness

For those of you preparing to do an SRA...this relationship is critical!

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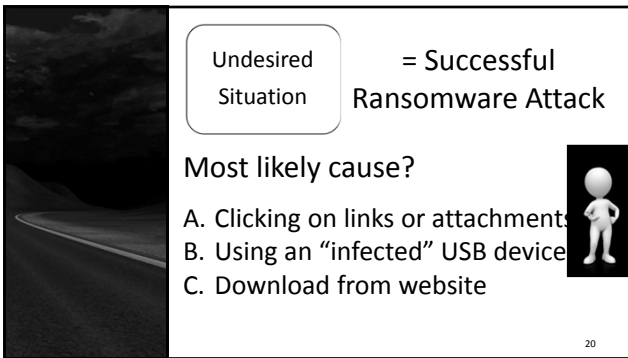
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Undesired Situation = Successful Ransomware Attack

Most likely cause?

- A. Clicking on links or attachments
- B. Using an "infected" USB device
- C. Download from website



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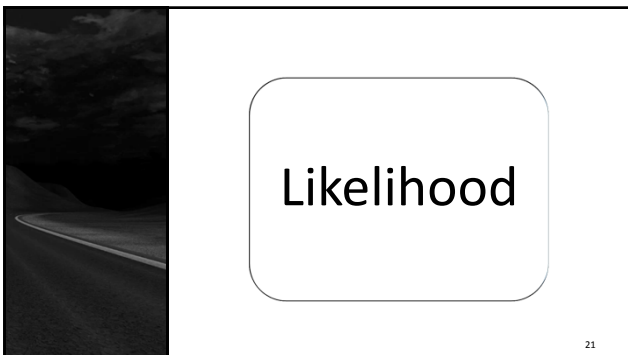
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Likelihood

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Will "something" happen?

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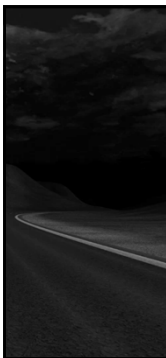
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Likelihood



Top synonyms:  
 - Possibility  
 - Probability  
 - Chance

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Likelihood

Chance that what  will happen?

A. Low  
 B. Medium  
 C. High

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Impact

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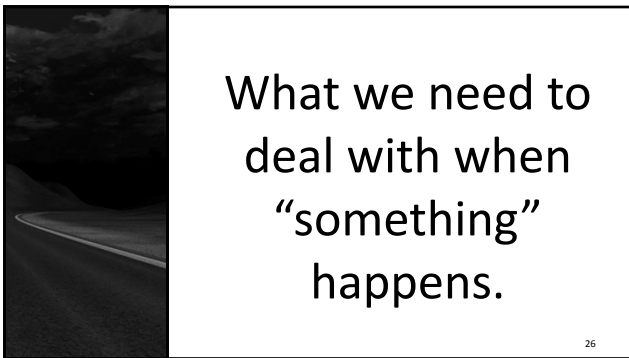
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What we need to deal with when "something" happens.

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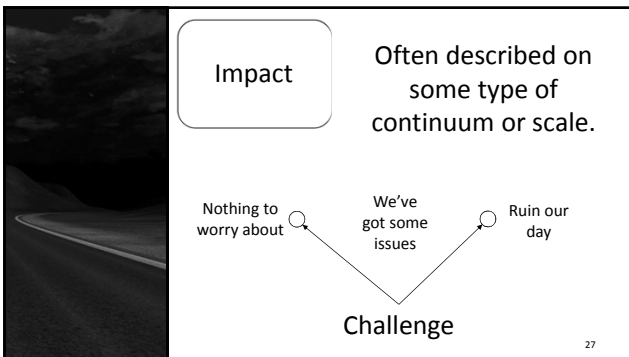
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Impact

Often described on some type of continuum or scale.

Nothing to worry about

We've got some issues

Ruin our day

Challenge

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Fundamental Relationships



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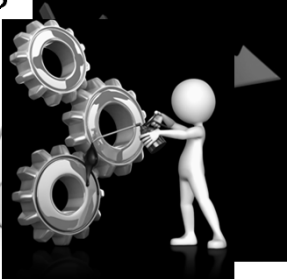
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Choices

- ~~What is it?~~



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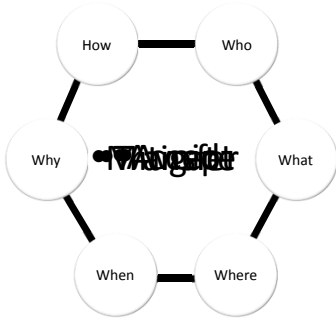
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Qualitative  
vs  
Quantitative

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Quality  
vs  
Quantity

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Quality (rating)  
vs  
Quantity (value)

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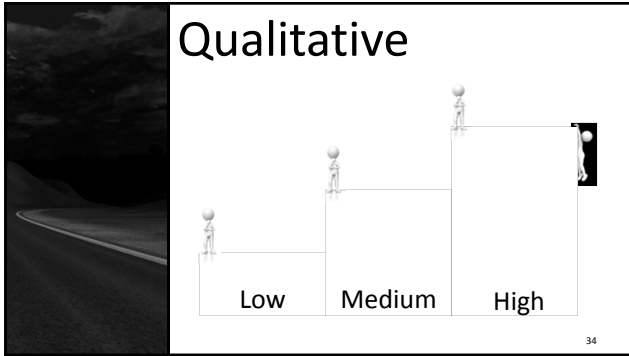
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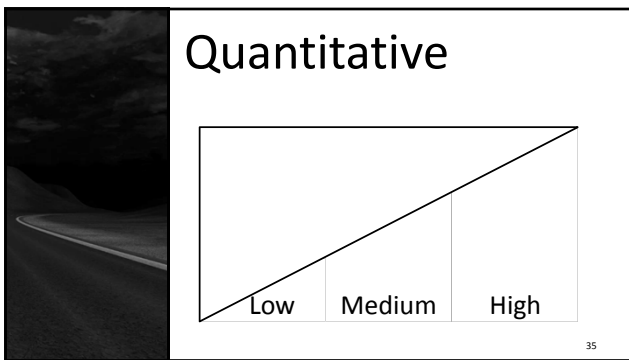
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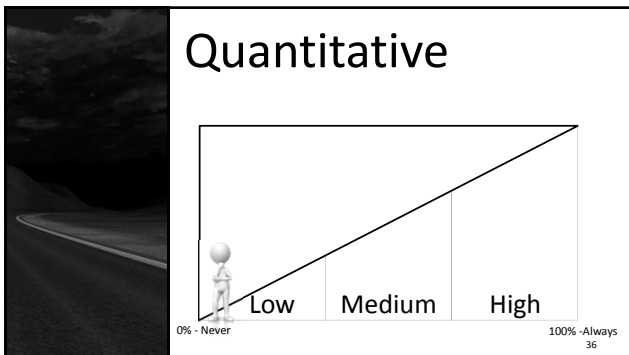
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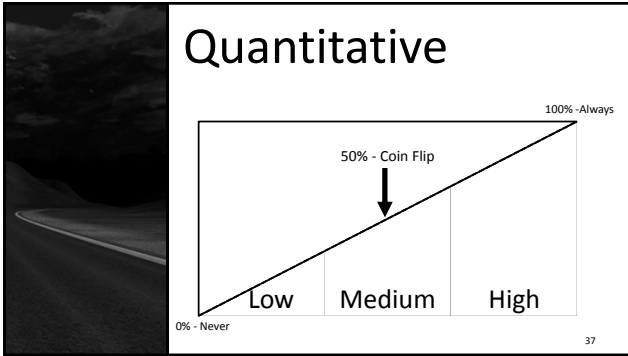
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## Auditng & Monitoring

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### Auditing & Monitoring

Where would you rate overall effectiveness of the A&M element?

- A. High (1<sup>st</sup>, 2<sup>nd</sup>)
- B. Medium (3<sup>rd</sup>, 4<sup>th</sup>, 5<sup>th</sup>)
- C. Low (6<sup>th</sup>, 7<sup>th</sup>)

39

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### Auditing & Monitoring

How many samples do you need for a probe audit as described by CMS?

- A. 20
- B. 30
- C. 40

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### Auditing & Monitoring

Reasons to audit:

- Required by regulations
- Required by P&P
- By choice\*

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### Auditing & Monitoring

Reasons to audit:

- Required by regulations
- Required by P&P
- By choice\*

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## Auditing & Monitoring

Reasons people audit (or not):

- FEAR
  - Familiar
  - Experience
  - Assess Let's see how we can apply this to the Compliance Program...
  - Results

43

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## Written Policies and Procedures

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## Designation of a Compliance Officer and a Compliance Committee

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Conducting Effective Training and Education

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Developing Effective Lines of Communication

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Enforcing Standards Through Well-Publicized Disciplinary Guidelines

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## Auditing and Monitoring

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## Responding to Detected Offenses and Developing Corrective Action Initiatives

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## Written Policies and Procedures

- Tangible – “get your hands on them”
- Binomial state
- Possible e-strateg
- Meaningful
  - Regulations
  - Organization
  - Processes
  - Assistance



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**Written Policies and Procedures**

- Standards of Conduct
- Risk Areas (18 call outs)
- Claims Development and Submission Process
- Medical Necessity – Reasonable Services
- Anti-Kickback and Self Referral
- Bad Debt
- Credit Balances
- Retention of Records
- Compliance as an Element of Performance

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**Written Policies and Procedures**

- Standards of Conduct
- Risk Areas (18 call outs)
- Claims Development and Submission Process
- Medical Necessity – Reasonable Services
- Anti-Kickback and Self Referral
- Bad Debt
- Credit Balances
- Retention of Records
- Compliance as an Element of Performance

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**Risk Areas**

- Billing for items or services not actually rendered;
- Providing medically unnecessary services;
- Upcoding;
- “DRG creep;”
- Outpatient services rendered in connection with inpatient stays;



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**Risk Areas**

- Teaching physician and resident requirements for teaching hospitals;
- Duplicate billing;
- False cost reports;
- Unbundling;
- Billing for discharge in lieu of transfer;



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**Risk Areas**

- Patients' freedom of choice;
- Credit balances—failure to refund;
- Hospital incentives that violate the anti-kickback statute or other similar Federal or State statute or regulation;
- Joint ventures;



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**Risk Areas**

- Stark physician self-referral law;
- Knowing failure to provide covered services or necessary care to members of a health maintenance organization; and
- Patient dumping.
- Financial arrangements between hospitals and hospital-based physicians;



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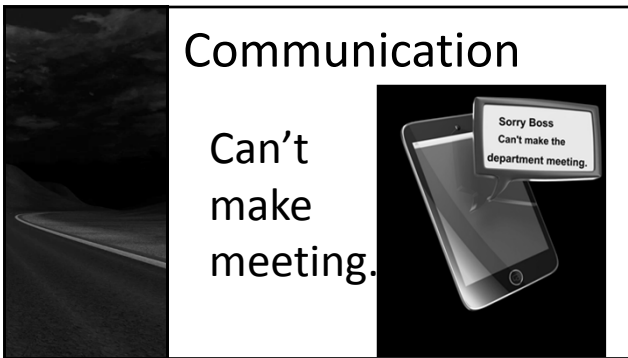
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## Communication

Can't make meeting.



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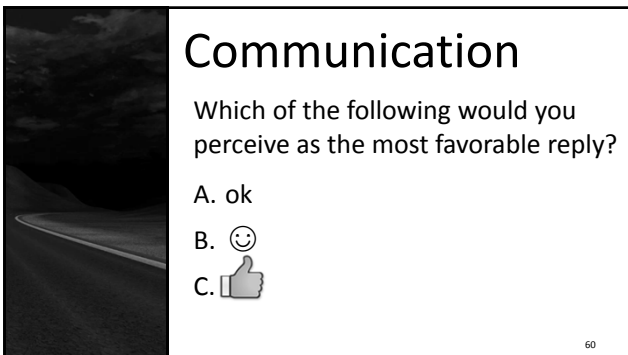
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## Communication

Which of the following would you perceive as the most favorable reply?

- A. ok
- B. 😊
- C. 👍

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**Mitigation**  
Let's talk about safeguards.

61

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**Mitigation**  
Let's talk about safeguards.  
Administrative Safeguard

Example:  
Policy and Procedure

62

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**Mitigation**  
Let's talk about safeguards.  
Administrative Safeguard  
Technical Safeguard

Example:  
Login and Password

63

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## Mitigation

Let's talk about safeguards.

- Administrative Safeguard
- Technical Safeguard
- Physical Safeguard

Example:  
Doors and Locks

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## Mitigation

Let's talk about safeguards.

- Administrative Safeguard
- Technical Safeguard
- Physical Safeguard

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## Mitigation

Apply resources where most effective.

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## Mitigation

Apply resources where most effective.

High Risk → Mitigation → High Risk

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## Mitigation

Apply resources where most effective.

High Risk → Mitigation → High Risk  
High Risk → Mitigation → Medium Risk

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## Mitigation

Apply resources where most effective.

High Risk → Mitigation → High Risk  
High Risk → Mitigation → Medium Risk  
High Risk → Mitigation → Low Risk

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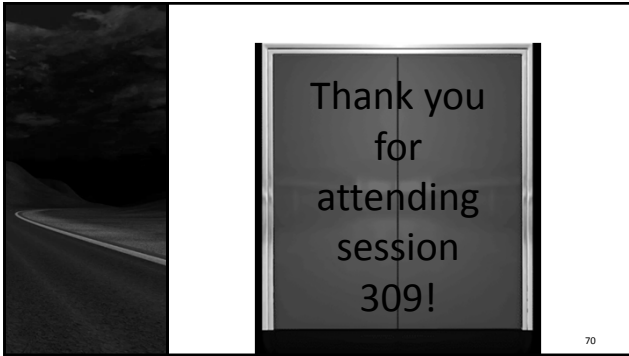
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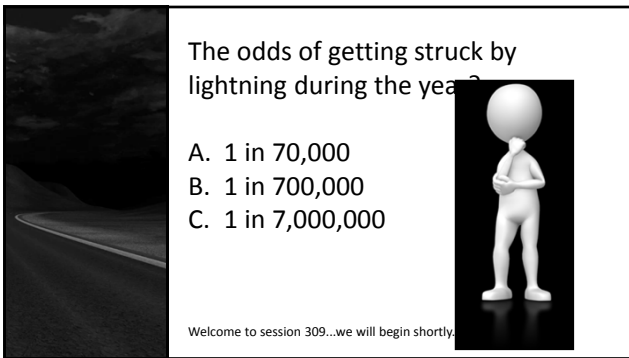
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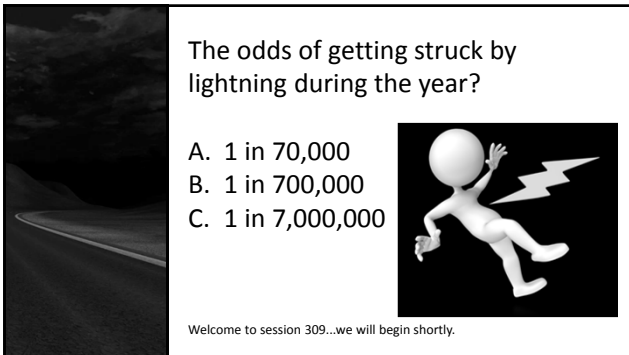
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The odds of getting attacked by a shark worldwide?

- A. 1 in 5,000,000
- B. 1 in 10,000,000
- C. 1 in 15,000,000



Welcome to session 309...we will begin shortly.

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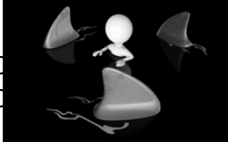
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The odds of getting attacked by a shark worldwide?

- A. 1 in 5,000,000
- B. 1 in 10,000,000
- C. 1 in 15,000,000



Welcome to session 309...we will begin shortly.

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The odds of being killed in an elevator?

- A. 1 in 10,000,000
- B. 1 in 20,000,000
- C. 1 in 30,000,000



Welcome to session 309...we will begin shortly.

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The odds of being killed in an elevator?

- A. 1 in 10,000,000
- B. 1 in 20,000,000
- C. 1 in 30,000,000



Welcome to session 309...we will begin shortly.

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The odds of winning the Powerball lottery?

- A. 1 in 100,000,000
- B. 1 in 200,000,000
- C. 1 in 300,000,000



Welcome to session 309...we will begin shortly.

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The odds of winning the Powerball lottery?

- A. 1 in 100,000,000
- B. 1 in 200,000,000
- C. 1 in 300,000,000



Welcome to session 309...we will begin shortly.

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The odds of an average golfer making a hole in one?

- A. 1 in 9,000
- B. 1 in 12,000
- C. 1 in 15,000



Welcome to session 309...we will begin shortly.

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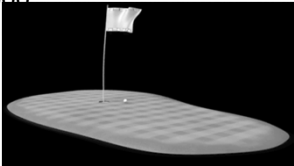
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The odds of an average golfer making a hole in one?

- A. 1 in 9,000
- B. 1 in 12,000
- C. 1 in 15,000



Welcome to session 309...we will begin shortly.

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The odds of getting blackjack?

- A. 5%
- B. 10%
- C. 25%



Welcome to session 309...we will begin shortly.

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The odds of getting blackjack?

- A. 5%
- B. 10%
- C. 25%



Welcome to sessio

The image shows a stack of casino chips in the background. In the foreground, two playing cards are visible: the Ace of Clubs (A♣) and the Jack of Spades (J♠).

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The odds of flipping a nickel and it landing on it edge?

- A. 0.16%
- B. 0.016%
- C. 0.0016%



Welcome to session 309...we will begin shortly.

The image shows a white 3D-rendered figure of a person with a large spherical head, standing with arms crossed.

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The odds of flipping a nickel and it landing on it edge?

- A. 0.16%
- B. 0.016% (1 in 6,000)
- C. 0.0016%



Welcome to session 309...we will begin shortly.

The image shows a close-up of a US nickel coin, featuring the profile of Thomas Jefferson.

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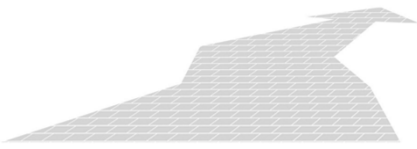
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**YOU DON'T NEED TO BE A WIZARD TO SOLVE TODAY'S COMPLIANCE CHALLENGES**

**Simione**  
HEALTHCARE CONSULTANTS

Seven Steps To Ensure Your Compliance Program "Follows The Yellow Brick Road"



John R. Hamilton III, Vice President of Compliance, Kindred Healthcare, Inc.  
Karen Bommeije, Senior Manager Compliance  
Simione Healthcare Consultants

*The way is in sight-*

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**Objectives**

**Simione**  
HEALTHCARE CONSULTANTS

- The Seven (or 8) Elements of an Effective Compliance Program
- Practical Importance of an Effective Compliance Program (e.g., avoidance and/or management of CIAs & Risk Mitigation)
- Evaluation of Compliance Program Effectiveness
- Key Elements of a Risk Assessment



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**Seven (or 8) Elements of an Effective Compliance Program**

**Simione**  
HEALTHCARE CONSULTANTS

- 1. Implementing written policies, procedures and standards of conduct.
- 2. Designating a compliance officer and compliance committee.
- 3. Conducting effective training and education.
- 4. Developing effective lines of communication.
- 5. Conducting internal monitoring and auditing.
- 6. Enforcing standards through well-publicized disciplinary guidelines.
- 7. Responding promptly to detected offenses and undertaking corrective action.

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**The Magical 8<sup>th</sup> Element** **Simione**  
HEALTHCARE CONSULTANTS

- **Define Roles and Responsibilities, Assign Oversight for Compliance, and Conduct an Assessment of the Program's Effectiveness.**



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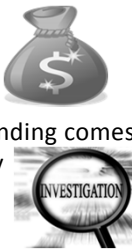
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**Importance of Compliance in Today's Environment** **Simione**  
HEALTHCARE CONSULTANTS

- The rise in beneficiaries equates to dramatic increase in spending
- Along with the increase in spending comes increased government scrutiny



5 *The way is in sight™*

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**Importance of Compliance in Today's Environment** **Simione**  
HEALTHCARE CONSULTANTS

- Justice Department recovered over \$4.7 Billion from FCA Cases in FY 2016
- Increase in Qui Tam suits & recoveries FY 2016 – 702 suits = \$2.9 Billion
- Spotlight on C-Suite in healthcare fraud investigations

6 *The way is in sight™*

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**Importance of Compliance in Today's Environment** **Simione**  
HEALTHCARE CONSULTANTS

- Justice Department adds new official as Compliance Counsel - chief role to determine effectiveness of Compliance Programs
- Data Mining
- OIG Work Plan
  - Identified vulnerabilities in payment, compliance, oversight, and quality of care concerns
  - Compliance with Medicare requirements



7 *The way is in sight™*

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**Implementing Written Policies, Procedures, & Standards of Conduct** **Simione**  
HEALTHCARE CONSULTANTS

- Develop compliance-related policies & procedures based on areas of risk and, importantly, related to:
  - Auditing & Monitoring
  - Compliance Record Retention
  - Self-disclosure
  - Regular Sanction Checks
  - Specific risk areas:
    - Conflict of interest
    - Billing
    - Third party relationships



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**Implementing Written Policies, Procedures, & Standards of Conduct** **Simione**  
HEALTHCARE CONSULTANTS

- Code of Conduct - confirmation of organization's support of compliance conduct & includes:
  - Compliance expectations for all employees
  - Reflect Culture, Tone at the Top & Values of Organization – enterprise wide
  - Ensure consistency with company policies and procedures
  - Education provided specifically to the Code
  - Summarize specific compliance guidelines
  - Clear understanding of universal enforcement and disciplinary actions for non-compliance



9 *The way is in sight™*

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**Establishing Compliance Oversight** 

- Compliance Officer & Compliance Committee
  - Oversight & monitoring implementation & ongoing operation of the compliance program
  - Regular reporting to Governing Body/Board of Directors, CEO, & Compliance Committee
  - Periodic revisions of program as appropriate
  - Develop, coordinate & participate in compliance training
  - Ensure independent contractors & 3<sup>rd</sup> parties aware of agency compliance program requirements



10 *The way is in sight™*

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**Establishing Compliance Oversight** 

- Compliance Officer & Compliance Committee
  - Ensure appropriate background and exclusion checks to avoid use of excluded individuals & contractors
  - Assist with auditing & monitoring activities
  - Independent investigation and action on matters related to compliance
  - Identification & prioritization of risk
  - Review & assess compliance policies & procedures



11 *The way is in sight™*

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**Establishing Compliance Oversight** 

- Compliance Officer & Compliance Committee
  - Assist with development of standards of conduct & policies & procedures
  - Conduct annual review of Compliance Plan
  - Determine strategy to promote compliance
  - Develop system to solicit, evaluate, and respond to complaints and problems



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**Training & Education** **Simione**  
HEALTHCARE COMPLIANCE

- General Compliance Education to Include:
  - Elements of the Compliance Program
  - Organization's Code of Conduct
  - Reporting System
  - Individual accountability for reporting suspected non-compliance
  - Non-retaliation policy
  - Who is the Compliance Officer
  - Explanation for fraud, waste, and abuse
  - Ethics
  - Privacy

Knowledge is power 

*The way is in sight*

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**Training & Education** **Simione**  
HEALTHCARE COMPLIANCE

- Specific Focused Training for High Risk Areas and Specialized Personnel to Include:
  - Actions outside scope of practice
  - Government & Private payer reimbursement principles
  - Third party relationships
  - Identification of Privacy breach
  - Stark/Anti-Kickback Laws
  - Submission of claims which do not meet payer requirements for reimbursement
  - Conflicts of Interest
  - Documentation to support services

Knowledge is power 

*The way is in sight*

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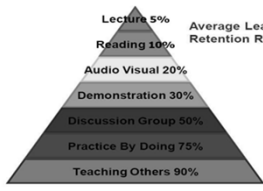
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**Training & Education** **Simione**  
HEALTHCARE COMPLIANCE

- Training Adult Learners and Keeping Training "Fresh":
  - Principles of Adult Learners
  - Use of different methods
  - Train the Trainer exercises

**Average Learning Retention Rates**



Method	Retention Rate
Lecture	5%
Reading	10%
Audio Visual	20%
Demonstration	30%
Discussion Group	50%
Practice By Doing	75%
Teaching Others	90%

Knowledge is power 

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Source: National Training Laboratories, Bethel, Maine

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**Monitoring & Auditing** **Simione**  
HEALTHCARE COMPLIANCE

- Step One – Conduct a Risk Assessment:
  - Documentation, Coding, & Billing Reviews
  - OIG work Plan
  - OIG Fraud Alerts
  - Internal Audits
    - QAPI
    - Compliance
  - External audits
    - Commercial Payer
    - Medicaid
    - Consultant
  - State Survey
  - Accreditation Survey



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**Monitoring & Auditing** **Simione**  
HEALTHCARE COMPLIANCE

- Next – Analyze Risk Assessment:
  - Identify key Priorities
  - Identify key Risks
  - Analyze & prioritize risks to guide auditing & monitoring
  - Collaborate to assess organization’s risk tolerance
  - Develop realistic audit plan to address high risk areas



17 *The way is in sight-*

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**Monitoring & Auditing** **Simione**  
HEALTHCARE COMPLIANCE

- Auditing:
  - Objective and Independent
  - Concurrent – “real time” to identify & address potential problems as they arise
    - Example-pre-billing audit – if problems identified, able to immediately implement corrections, education and prevention
  - Retrospective – baseline assessment or “snapshot” of a period of time in the past
    - Easier to collect information; however, if problems identified, difficult to know how far back to audit and may require billing adjustments or paybacks and/or possible self disclosure



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**Monitoring & Auditing** **Simione**  
HEALTHCARE COMPLIANCE

- Monitoring:
  - On-site visits
  - Interviews – management, operations, coding, claim submission
  - Questionnaires
  - Peer reviews
  - Documentation reviews
  - Trend analysis
  - Exit interviews
  - Hotline issues & trends



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**Reporting & Investigating** **Simione**  
HEALTHCARE COMPLIANCE

- Importance of communication in the Compliance process with open lines of communication between the Compliance Officer/Personnel
- Open Door Policy
- Hot/Help Line
- No retaliation or retribution
- Confidentiality & Anonymity
- Specially trained staff
- Complaints logged & tracked
- Thorough investigation
- Responsiveness & feedback to caller



20 *The way is in sight-*

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**Enforcement & Discipline** **Simione**  
HEALTHCARE COMPLIANCE

- Enforce the Standards of Conduct and Policies/Procedures by being Fair, Equitable, & Consistent
  - Discipline administered for non-compliant behavior
  - Employees have an obligation to report suspected non-compliance
  - Disciplinary procedures
  - Clear responsibility for actions
  - Fair & consistent discipline



21 *The way is in sight-*

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**Response & Prevention** **Simione**  
REALIZABLE CONSULTANTS

- Thorough Investigation & Documentation to include:
  - Description of potential misconduct & how reported
  - Description of investigative process
  - List of relevant documents reviewed
  - List of employees interviewed

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**Response & Prevention** **Simione**  
REALIZABLE CONSULTANTS

- Thorough Investigation & Documentation to include:
  - Employee interview questions & notes
  - Changes to policies/procedures, if appropriate
  - Documentation of disciplinary action, if appropriate
  - Investigative final report – allegation substantiated or not

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**CORPORATE INTEGRITY AGREEMENTS** **Simione**  
REALIZABLE CONSULTANTS

*The way is in sight™*

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**WHAT DO THESE AGENCIES HAVE IN COMMON?** **Simione**  
HEALTHCARE CONSULTANTS

- Compassionate Care Hospice of New York
- Family Care Visiting Nurse
- St. Joseph Hospice
- Hospice of the Comforter
- Friendship Home Health
- Three Rivers Hospice
- Hernando Pasco Hospice
- Amedisys

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** **Simione**  
HEALTHCARE CONSULTANTS

Agency X has and shall continue to maintain the aforementioned Compliance Program. X shall continue to participate in and comply with its Compliance Program which shall, at a minimum, include the following elements:

→ *Compliance Officer and Committee*

*Compliance Officer:* Agency X has and shall maintain an employee in the position of Compliance Officer for term of this CIA. The Compliance Officer shall be a member of senior management of Agency X shall report directly to the Chief Executive Officer of Agency X, and shall not be or be subordinate to the General Counsel or Chief Financial Officer of Agency X or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Agency X.

26 *The way is in sight™*

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** **Simione**  
HEALTHCARE CONSULTANTS

- Compliance Officer shall be responsible for, without limitation:
  - developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements
  - *Compliance Committee.* Within 90 days after the Effective Date, X shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations).

27 *The way is in sight™*

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** 

The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (shall assist in the analysis of risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

28 *The way is in sight™*

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** 

- The Governing Body shall, at a minimum, be responsible for the following:
  - meeting at least quarterly to review and oversee the Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
  - for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Governing Body summarizing its review and oversight of compliance with Federal health care program requirements and the obligations of this CIA.

29 *The way is in sight™*

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** 

- ✓ *Code of Ethics.* X has and shall maintain for the term of the CIA a Code of Ethics to which X is subject.
- ✓ ...X shall make the performance of job responsibilities in a manner consistent with the Code of Ethics an element in evaluating the performance of all employees.
- ✓ *Policies and Procedures.* X represents that it has developed and implemented written Policies and Procedures regarding the operation of its Compliance Program.
- ✓ Throughout the term of this CIA, X shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** 

- ✓ *Training Plan.* X represents that it has developed, and shall maintain, a written plan (Training Plan) that outlines the steps X will take to ensure that: (a) all Covered Persons receive adequate training regarding X CIA requirements and Compliance Program, including the Code of Ethics
- ✓ *Risk Assessment and Internal Review Process*

X has and shall maintain a centralized annual risk assessment and internal review process to identify and address risks associated with) the submission of hospice claims for items and services furnished to Medicare program beneficiaries

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**COMPLIANCE PLAN ELEMENTS IN CORPORATE INTEGRITY AGREEMENTS** 

- Mission and Core Values are supported by everyone
- Top Leadership develops a compliance plan that is based on current regulations and identified risks
- Leadership expectation is that ALL Managers understand how compliance affects their area of responsibility
- Resource allocation
- Clear lines of communication
- Accountability

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**COMPLIANCE PROGRAM TIPS** 

- No One Size Will Fit All
- Needs to Evolve and Change Based on Industry Changes and Trends
- Needs to Evolve and Change Based on Provider Changes and Identified Trends
- Consider a Compliance Program Risk Assessment and/or External Compliance Probe Audit to Validate Effectiveness of Compliance Program

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**QUESTIONS** **Simione**  
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**HCCA 21<sup>st</sup> Annual Compliance Institute  
March 26-29, 2017**

**Overlapping Surgery Developments**

**Alana B. Sullivan  
Erlanger Health System**

**Sara Kay Wheeler  
King & Spalding LLP**

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**Agenda**

- Overview of Overlapping Surgeries
- Discussion of Key Authority
  - Teaching Setting
  - Non-Teaching Setting
- Recent Spotlight on Overlapping Surgeries
- Enforcement Developments
- Practical Strategies for Providers
- Questions?

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**Basic Overview of Overlapping Surgeries**

- Overlapping surgeries generally occur when two surgical procedures under one attending surgeon overlap in part

Procedure 1

Procedure 2

- Overlapping surgeries may occur in multiple settings:
  - Teaching hospitals (often with the assistance of residents)
  - Non-teaching hospitals (often with help from other surgical assistants)
- Over the past 1.5 years, we have seen a significant surge of attention surrounding these issues

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### Numerous Considerations and Stakeholders




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### Overview of Authority

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### Brief Overview of Medicare Rules for Teaching Surgeries

- Medicare billing rules for teaching surgical services permit certain parts of two surgical procedures, under the supervision of one attending surgeon, to overlap in certain circumstances.
  - The teaching surgeon must *personally document* in the medical record that he/she was physically present during the *key/critical portion(s) of both procedures*
  - The teaching surgeon has discretion to define the key/critical portion(s)
  - When the key/critical portion of one procedure is over, the teaching surgeon may move to a second procedure. The teaching surgeon must designate another qualified surgeon to be *immediately available* for the first procedure, should the need arise

See 42 C.F.R. § 415.172; Medicare Claims Processing Manual, Ch. 12

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**Brief Overview of Medicare Rules for Teaching Surgeries**

- Medicare does not pay for instances where the key/critical portions of both procedures overlap
  - The American College of Surgeons calls this scenario “concurrent” surgery
- Three overlapping teaching surgical procedures are not billable to Medicare

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**Brief Overview of Authority for All Overlapping Surgeries, Including Non-Teaching Procedures**

- No Medicare payment rules for *non-teaching* overlapping surgeries
- Medicare Conditions of Participation call for providers to deliver surgical services in accordance with acceptable standards of practice (See 42 C.F.R. § 482.51)
  - Consider guidelines from industry groups, such as the American College of Surgeons
- Consider State Law
- Consider State Medical Board requirements
- Consider Joint Commission and other accreditation requirements

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**Recent Spotlight On Overlapping Surgeries**

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## American College of Surgeons Guidance



**AHA, AAMC Urge Hospitals to Review Updated American College of Surgeons Statements on Principles and Make Any Needed Changes to Hospital Policies**

May 11, 2016

The American College of Surgeons (ACS) recently released *Statements on Principles on the responsibility of the primary surgeon during surgery*. Several news reports have raised questions about the primary surgeon, including: *Publicly scrutiny of the best surgery was fully available?* Their intent, led to: *A surgeon's best if he or she first only performs that make an intervention during the course of a surgery and the appropriate actions that need to be taken to inform the patient and ensure continued safe care.*

In the guidance, ACS states:

The primary attending surgeon is personally responsible for the patient's welfare throughout the operation. In general, the patient's primary attending surgeon should be in the operating room or be immediately available for the entire surgical procedure. There are minimum exceptions with good patient care that are valid exceptions. However, when the primary attending surgeon is not present or immediately available, another attending surgeon should be assigned as being immediately available.

The American Hospital Association (AHA) and Association of American Medical Colleges (AAMC) encourage all hospitals to undertake a review of their policies and procedures and make appropriate changes to make them consistent with the updated ACS Statements on Principles.

**What You Can Do**

The goal of hospitals and physicians is safe, high-quality and efficient patient care. In response to new technology, increased demand for quality, better operating surgical techniques, and the growth and aging of the population, U.S. hospitals have

- On April 12, 2016, the ACS revised their Statement on Principles, which addresses the inter-operative responsibility of surgeons
- The ACS Principles are similar, but not identical to, the Medicare billing rules
- ACS Principles emphasize patient informed consent and communication
- In light of the updated ACS Statements on Principles, the AHA has *urged hospitals to review their policies and procedures*

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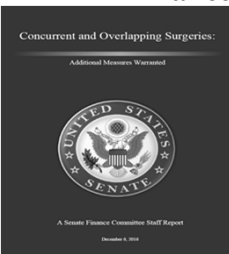
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## December 2016 Senate Finance Committee Report



**Concurrent and Overlapping Surgeries: Additional Members Warned**

UNITED STATES SENATE

A Senate Finance Committee Staff Report

December 6, 2016

The Senate Finance Committee released a report on concurrent and overlapping surgeries on December 6, 2016, highlighting areas of **Congressional concern**, including:

- Hospital policies, or lack thereof
- Hospital policy training and enforcement
- Practice of "concurrent" surgeries where key/critical portions of two procedures overlap
- Patient safety
- Patient informed consent
- Improper payments and billing concerns
- Lack of Medicare payment regulations in non-teaching context
- Lack of government enforcement

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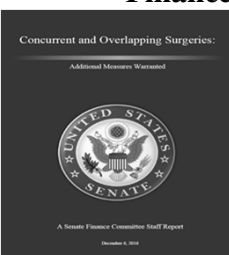
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## December 2016 Senate Finance Committee Report



**Concurrent and Overlapping Surgeries: Additional Members Warned**

UNITED STATES SENATE

A Senate Finance Committee Staff Report

December 6, 2016

Senate Finance Committee staff recommendations regarding improper payments:

- The HHS OIG should review the controls in place to ensure that hospitals and physicians are *appropriately billing for physician services provided by teaching physicians*
- CMS should review the agency's billing requirements for services performed by teaching physicians to determine if those *requirements should be established for other surgical facilities and scenarios*

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### Patient Safety Data

- Recent research regarding overlapping surgeries supports safety of practices
  - *Outcomes of Concurrent Operations: Results from the American College of Surgeons' National Surgical Quality Improvement Program:* Concurrent operations at ACS NSQIP hospitals were not associated with increased risk for poor outcomes when compared to non-concurrent operations. (Annals of Surgery, submitted 2017)
  - *Safety of Overlapping Surgery at a High-volume Referral Center:* Findings from administrative and clinical registries support the safety of overlapping surgical procedures at this center (Annals of Surgery)

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### Enforcement Developments

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### Recent and Significant Qui Tam Enforcement Activity

- January 2017: Vanderbilt close to finalizing settlement to resolve False Claims Act suit brought by **three physicians** who allege the University's medical center billed Medicare as if physicians were present for the key/critical portions of procedures when only residents were present
- August 2016: A *qui tam* lawsuit **filed by a former medical resident** filed against an Advocate Health Care teaching hospital is unsealed
  - Allegations include that surgeons improperly used (and billed for) assistants at surgery (including PAs) when qualified residents were available to assist

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### Recent and Significant *Qui Tam* Enforcement Activity

- **July 27, 2016:** DOJ announces a **\$2.5 million** settlement with the University of Pittsburgh Medical Center and related organizations to resolve False Claims Act allegations in connection with a *qui tam* lawsuit
  - Complaint alleged neurosurgeons submitted claims for surgical procedures performed by other surgeons or practitioners, *when the neurosurgeons did not participate in the surgeries to the degree necessary to bill for the claims*
  - One of the whistleblowers was a neurosurgeon
- **January 2014:** **Individual surgeons** settled with whistleblowers (one whistleblower was an orthopedic surgeon) in a case against Rush University Medical Center
  - Allegations include that surgeons improperly billed for overlapping surgeries that did not meet Medicare rules

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### Practical Strategies for Providers

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### Potential Provider Efforts: General Considerations

- Increased focus on teaching surgeries and overlapping procedures has raised tough questions
- Important to make sure right stakeholders are at the table
- Requires individualized analysis specific to each institution
  - Teaching institutions vs. non-teaching institutions
  - Consider employed versus non-employed physicians
  - Certain rules contain discretion and ambiguity
  - Continuum of approaches and risk
  - Certain institutions elect to enact rules that are more restrictive than the regulations

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### Potential Provider Efforts: Retrospective Considerations

#### Retrospective Efforts

- Potential retrospective claims/billing review
  - Consider 60 Day Overpayment Rule implications
- Diligence regarding historical practices and understanding of the rules
  - May require interviews, OR suite observation, etc.
  - Review policies regarding teaching and/or overlapping surgeries

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### Potential Provider Efforts: Prospective Considerations

#### Prospective Efforts

- Revise teaching surgery and/or overlapping surgery policies
- Refine training and education
- Refine documentation: consider paper order sets and electronic health systems refinements
- Develop prospective claims/billing audit plan
- Review and update patient informed consent processes and forms
- Review of patient safety considerations
- Prepare for media and patient questions
- Prepare for increased government enforcement, audits, etc.
- Continue to follow industry developments and research regarding overlapping surgeries

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### Questions & Discussion



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### Contact Information

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Health Care Compliance Association  
2017 Annual Healthcare Enforcement Compliance Institute

### Down the Rabbit Hole: Compliance Investigations, Corrective Action Planning, and Self-Disclosure

**Anne Sullivan Daly**, RN, JD, CCEP, CHC, Corporate Compliance Officer, Ann & Robert Lurie Children's Hospital of Chicago  
**Tony Maida**, Partner, McDermott Will & Emery, LLP

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### Agenda

- Explore best practices and the roles of Legal, Compliance and outside counsel in conducting internal compliance reviews, corrective action planning, and disclosure decision-making
- Review the analysis for determining whether an overpayment has been received and compliance with the 60 Day Overpayment Rule
- Discuss the benefits and risks of self-disclosure and strategic considerations in deciding where to disclose

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### Compliance and Legal As Team

- Compliance and Legal should function as a team
  - Jointly make decisions on risk management
  - Both have interest in compliance
  - For some issues, the organization should make decision to conduct investigation under privilege sooner rather than later



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### Overpayment or Potential Fraud Liability?

- Legal Questions
  - Applicable coverage and payment statutes and regulations
  - Manual provisions
  - 60 Day Overpayment Rule
- Factual Questions
  - Who, what, when, where, why
  - Internal investigation/review process
- Optics Considerations
  - Comfort level of explaining the decision to the government or other external stakeholder (e.g. potential buyer) in the future

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### Legal Question: Is There an Overpayment

- Primacy of legal authority
  - Statute
  - Regulation
  - Sub-regulatory guidance
    - National Coverage Decisions
    - Local Coverage Decisions
    - CMS Preambles
    - CMS Manuals
    - Contractor Guidance
  - Appeal experience
- Binding requirement or Guidance?
  - Clear or ambiguous?
  - Condition of Payment or Participation?
  - Legal standard or audit standard?

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### Conduct Legal Research Early On to Set Framework for Investigation

**What Are Company's Legal Obligations?**

**Ethics = Voluntary**

**Legal Obligations = Mandatory**

**Gray areas – manuals, policy statements, sub-regulatory guidance**



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### Gathering Facts

- Who should direct the investigation
  - Counsel
    - Inside or outside
  - Compliance
  - HR
  - Other
- Who should "conduct" the investigative steps
  - Counsel
  - Auditors
  - Compliance staff
  - HR staff
  - Managers
  - Outside consultants
- What are the investigative steps?
  - Start with preserving and gathering documents
    - Allows you to ask better questions in interviews
    - Gives you important background
    - You may want to ask witnesses about particular documents
  - Audits as a starting point?
    - Can establish whether there is a problem

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### Gather Facts: Documents

- Documents drive government and internal investigations
- Fact chronology – create a timeline
- Organize documents in witness folders
- Get the org chart and job descriptions (official and "real")
- Make a process chart
- Issue-specific
  - Space issue = get the lease, floor plan, rental log, and tour



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### Gathering Facts: Interviews

- Goals
  - Gather information
  - Assess interviewee's credibility
    - Demeanor
    - Logic and consistency of witness' statement in the context of other information
    - Corroboration
  - Limit unnecessary disclosures
  - Maintain credibility of your investigation
  - Keep people open to talking to you – building trust will get to the truth



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### General Interview Guidelines

- The ideal is to conduct interviews in person with two interviewers
- Try not to draw attention to the person being interviewed
- No group interviews
- Take notes, do not tape
- Be conversational, personable, and serious
- Focus on listening, not talking
- Don't put words in the person's mouth
- In general, don't discuss one person's interview with another person
- Don't be opinionated or judgmental
- You can remind employee that refusal to cooperate in an internal investigation may lead to discipline if the person is being evasive or uncooperative

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### General Interview Guidelines

- Start by giving an initial introduction
- Corporate Miranda or "Upjohn Warning" – if interview done by counsel
  - Company counsel only represents and advises company, not any individuals
  - Company controls attorney-client privilege, witness must maintain confidentiality
  - Company may disclose interview
- Ask open-ended questions
  - What happened? When? Where? Who did it?
- Follow up with specific questions
  - Who said what? In what order? How long was the conversation? Did he or she say anything else? What did the other person say in response?
- Focus on how the interviewee knows what he or she is telling you

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### Privileges and Investigations

- Typically, there is no privilege for routine compliance materials
  - Attorney-client and attorney work-product privileges usually do not apply if cannot meet threshold requirements
  - Self-evaluative privilege not widely recognized
- Types of materials potentially subject to disclosures (unless privileged)
  - Audits (preliminary, draft, etc.)
  - E-mails
  - Compliance committee meeting agendas and reports
  - Compliance reports to board
  - Any other materials

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Privileges (cont.)

- Attorney-Client Privilege
  - Protects communications between attorney and client for purpose of seeking legal advice
    - Protects direct communications with in-house or outside legal counsel for legal (not business) advice
    - Attorney can retain agents to assist
      - Auditors
      - Investigators
      - Consultants
      - Communications between agents and client; or between agent and attorney can be covered by privilege
      - But must be for the purpose of providing legal advice

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Overpayment Statute: ACA, *Section 6402(a)*; SSA *Section 1128J(d)*; 42 U.S.C. § 1320a-7k(d)

- **In general.** If a person has received an overpayment, the person shall –
  - report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  - notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- **What is an “Overpayment?”**
  - The term “overpayment” means any funds that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after applicable reconciliation, is not entitled under such subchapter.

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Overpayments and False Claims

- **Deadline for reporting and returning overpayments.** The later of –
  - the date which is 60 days after the date on which the overpayment was identified; or
  - the date any corresponding cost report is due, if applicable
- **Enforcement:** If an overpayment is retained past the deadline, it may constitute an “obligation” under the False Claims Act.
  - False Claims Act: imposes liability for “knowingly concealing or knowingly and improperly avoiding or decreasing an obligation” to pay the United States. (31 USC 3729(a)(1)(G))
  - ACA also created new CMPL action for a penalty of up to \$10,000 per item or service and three times the amount claimed and exclusion for “Any person . . . that **knows** of an **overpayment** . . . and does not report and return the overpayment in accordance with [section 6402].”

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### Final Rule, 81 FR 7954 (February 12, 2016)

- Regulatory provisions interpreting the Overpayment Statute (42 C.F.R. 401.301-5)
  - Lookback period
    - 6 years from the date the overpayment was identified
  - How to report and return
    - Use the "most appropriate mechanism" based on the "nature of the overpayment"
  - Meaning of identified
    - When a provider or supplier "has determined, or should have determined through the exercise of reasonable diligence, that [it] **received an overpayment and quantified the amount** of the overpayment"
    - "Should have determined" means the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment

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### When does the 60 day clock start?

- CMS said providers have time to conduct the "reasonable diligence" before the 60 day clock starts to run
  - After receiving "credible information" the provider needs to undertake reasonable diligence
  - CMS articulated a 6 month "benchmark" for conducting reasonable diligence, except in "extraordinary circumstances" such as Stark issues, natural disasters, or states of emergency
  - The 60 day clock starts to run when either:
    - When the reasonable diligence is completed, or
    - On the day the credible information was received and the provider failed to conduct reasonable diligence (and an overpayment in fact was received)

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### Hypo Two Midnight

- Shady Pines Hospital GC, Dorothy Zbornak, calls in a panic. Shady Pines is in the last year of its inpatient admission CIA and the IRO says that they believe the Discovery Sample error rate exceeds 5%, which triggers a Full Sample.
- The IRO, Sophia Petrillo, identified 15 out of 50 claims in the Discovery Sample as not qualifying for inpatient payment because the patient was stable at the time the inpatient admission order was written, and therefore, the physician could not have reasonably expected the patient to require inpatient hospital services for two-midnights following the time the inpatient order was written.
  - For these patients, they were in outpatient status for some portion of their hospital stay.
  - Appropriate care was provided and at some point in time prior to discharge, the physician wrote an inpatient admission order.

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### Hypo Home Health

- The St. Olaf Medical System in Minnesota is a large, integrated health system that owns a home health agency. Rose Nylund, the GC, calls in a panic – she just received an email from an employee that was fired last week for insubordination that says the agency is committing blatant Medicare fraud.
- The former employee, Blanche Devereaux, says that the agency frequently bills illegally for home health services:
  - With insufficient medical documentation
  - The certifying physician does not conduct a face-to-face evaluation of the patient and the face-to-face evaluation is not done before services begin
  - Before it has received a signed certification from the physician
  - That have defective recertification forms that fail to meet Medicare requirements

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### Options: Deciding Where to Disclose

- If you decide there is an overpayment or potential liability, where to report and return:
  - Contractor Refund
  - CMS SRDP
  - OIG SDP
  - State Medicaid agencies
  - DOJ




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### Self-Disclosure Options

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"> <li>• Simple process/ minimizes legal fees</li> <li>• No reduction in amount</li> <li>• No release of any kind</li> <li>• Six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Track record suggests likelihood of reasonable settlement</li> <li>• Stark only</li> <li>• 1877(g)(1) release</li> <li>• <i>De facto</i> six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Benchmark 1.5 multiplier</li> <li>• Release of CML and exclusion</li> <li>• Potentially reduce FCA exposure</li> <li>• Updated guidelines</li> <li>• Six-year SOL</li> </ul>	<ul style="list-style-type: none"> <li>• Release of State authorities only</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• SOL varies</li> </ul>	<ul style="list-style-type: none"> <li>• Broadest release</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• Six-year SOL</li> </ul>

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**Outcomes: Disclosure Pros and Cons**

<b>Pros</b>	<b>Cons</b>
<ul style="list-style-type: none"><li>▪ Legal duty if received overpayment</li><li>▪ Start from positive place<ul style="list-style-type: none"><li>– Good corporate citizen</li><li>– Effective compliance program</li></ul></li><li>▪ Can be prepared</li><li>▪ Less disruptive</li><li>▪ Lower multiplier more likely</li><li>▪ Presume no CIA/exclusion</li><li>▪ Closure</li><li>▪ Less reputational effect possible</li></ul>	<ul style="list-style-type: none"><li>▪ Some pathways are less predictable than others</li><li>▪ Payment usually necessary</li><li>▪ Not place to get agency's opinion</li><li>▪ Can be long process</li><li>▪ Referrals among agencies possible</li><li>▪ Follow on actions by private insurance or states</li><li>▪ Some publicity still happens</li></ul>

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**Thank you!**

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## Congratulations on that New Acquisition! *Compliance Lessons Learned the Hard Way*

Donald A. Sinko,  
Chief Integrity Officer

Vicki R. Bokar,  
Sr. Director Corporate Compliance  
Cleveland Clinic

March 27, 2017

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## Announced Hospital Mergers & Acquisitions, 1998-2015



Source: Irving Levin Associates, Inc. (2016). The Health Care Services Acquisition Report, Twenty-Second Edition.

<sup>(1)</sup> In 2004, the privatization of Select Medical Corp., an operator of long-term and acute-care hospitals, and divestiture of hospitals by Tenet Healthcare Corporation helped to increase the number of hospitals affected.

<sup>(2)</sup> In 2006, the privatization of Hospital Corporation of America, Inc. affected 175 acute-care hospitals. The acquisition was the largest health care transaction ever announced.

<sup>(3)</sup> In 2013, consolidation of several investor-owned systems resulted in a large number of hospitals involved in acquisition activity. Chart 2.10 in 2009 and earlier years' Chartbooks.

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## Agenda

- Overview of Cleveland Clinic Health System and Compliance structure
- Compliance reporting lines and its relevance to acquisitions
- How Compliance can add value in the due diligence process
- Recommendations for a compliance-focused due diligence

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### Disclaimers

- We are not lawyers!
- We don't have all the answers
- We will share what we've learned through experience
- We will ask you to share your experience

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### Cleveland Clinic Health System



- 7.1M Outpatient Visits
- 161,664 Acute Admissions
- 3,584 Physicians & Scientists
- 51,487 Employed Caregivers
- 28.5M sq. ft. Facility Space
- 10 Regional Hospitals
- 150+ Northern Ohio Outpatient Locations
- Staff physicians are salaried; on one year contracts

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### National & International Locations



- Canada – Executive Health, Sports Health and Rehabilitation
- Nevada – Lou Ruvo Center for Brain Health, Glickman Urological & Kidney Institute
- Florida – Integrated Medical Campus in Weston; Outpatient Locations in West Palm Beach
- Abu Dhabi - Partnership with Mubadala Development Co.
- London – In Progress

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### Cleveland Clinic Health System

- Chief Integrity Officer serves as the Clinic's Compliance Officer
- Positioned in the C-suite
- Collaborative, but independent relationship with Chief Legal Officer, Chief Financial Officer
- Oversees Compliance & Internal Audit

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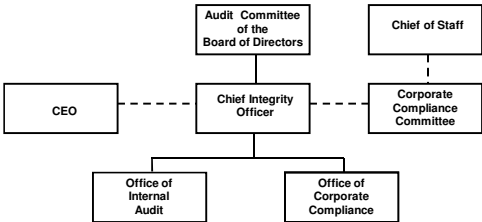
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### Chief Integrity Officer Reporting Lines



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### Reporting Lines Are Relevant to New Acquisitions

- Due diligence process is typically led by attorneys
- In some entities, the Compliance Officer reports to the Legal Officer
- The Legal Officer, Compliance Officer and Privacy Official may be one and the same person
- What difference does it make?

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### Complimentary but Different Roles

- **Legal Department**
  - Zealously defend & protect the entity's interests
  - Assists in defining & establishing standards
  - Give sound legal advice
  - Generates documentation that is protected from disclosure
- **Compliance Department**
  - Zealously prevents, detects & remedies misconduct
  - Supports a culture of accountability and integrity
  - Advises "Do the Right Thing"
  - Generates documentation that may be disclosed
  - Independent

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### The Whole Truth (Compliance)



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### The Truth (Legal)



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**Assumption Traps**

- Compliance should not assume that the legal team will evaluate all compliance topics & documents during due diligence
- The legal team should not assume they know all compliance topics & documents to evaluate during due diligence

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**Why Compliance & Audit Need to be Part of Due Diligence**

- Assess internal controls and their effectiveness
- Evaluate effectiveness of the target entity's compliance program
- Identify potential barriers that could delay integration
- Determine compliance with HIPAA Privacy & Security Rules
- Prioritize post-acquisition plans

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**What Can Go Wrong?**

- 60 Day Rule
- Successor liability
- Incompatibility of billing and other systems
- Preparedness for unannounced surveys and audits in the immediate post-acquisition phase

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**Compliance Due Diligence**

- **Compliance Officer to Compliance Officer interview**
- **Documents to review:**
  - Code of Conduct
  - Compliance hotline data & trends (incl. no. anonymous reports)
  - Compliance Committee composition, minutes, agendas
  - Deficit Reduction Act (Employee Handbook, False Claims Act materials)

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**Compliance Due Diligence**

- **Documents to review (cont'd)**
  - Training completion rates (FWA, Privacy, Security Awareness)
  - Government audits, reviews and investigations (OIG, FDA, OCR)
  - Results of coding audits
  - PEPPER reports
  - Summary of overpayments that have been returned (and timeliness of repayment)

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**Compliance Due Diligence**

- **Documents to review (cont'd)**
  - Exclusion screening
  - Enforcement of disciplinary policies (for all position levels)
  - Policies and procedures
    - Claims
    - Privacy & security
    - Teaching & supervision
  - Security risk analysis and risk management
  - Business Associate Agreements

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### Compliance Due Diligence

- Documents to review (cont'd)
  - Documentation of IRB or Privacy Board waivers, Data Use Agreements
  - Breach reports to HHS
  - Breach risk assessments
  - Medical record requests & turn-around times
  - ACO compliance program documentation
  - Process & procedures for claims
  - Procedures for supervision

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### Integration Priorities

- Code of Conduct
- Promote compliance Help Lines/Hotlines
- Any impending regulatory deadlines
- Coding/billing reviews
- Remediate any issues

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### Integration Priorities (cont'd)

- Compliance Committee & related documentation
- Coding compliance
- Risk Assessment (general compliance & HIPAA)
- Re-evaluate covered entity status (including affiliated entities, OHCAs etc.)

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### Start Early

- Consult with Legal at Letter of Intent (LOI) stage or earlier
- Provide LOI "wish list" (document review, access to people/info)
- Share concerns; seek advice
- Ask about successor liability

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### Questions?

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**Cleveland Clinic**

Every life deserves world class care

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## Mitigating Hot Button Risk Areas in Home Health & Hospice

Kathryn Krenz, RN, CPC, CHC, CHPC, Brookdale Senior Living  
 Kimberly Hrehor, MHA, RHIA, CHC, TMF Health Quality Institute

HCCA Compliance Institute  
 March 27, 2017

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## Agenda

- What are the risk areas?
- How can you learn/prepare?
- Resources and tools
- Next steps

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## Home Health/Hospice Risk Areas



Who defines risk areas, and how are they looking at them?

- CMS
- Office of Inspector General
- Medicare contractors
- Others: MedPAC, CERT, law enforcement

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### HH/Hospice Improper Payments

- Comprehensive Error Rate Testing (CERT)
- Available at CMS.HHS.gov/CERT
- 2016 HH: 42.0%, \$7.65B projected (down from 59%, \$10B projected)
- 2016 Non-hospital based Hospice: 14.6%, \$2.13B projected (up from 10.7%, \$1.4B)
- 2016 Hospital-based Hospice: 31.0%, \$390M projected (up from 18.9, \$250M)

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### Home Health Risk Areas

- Pre-claim review demonstration
- Probe & educate
- Conditions of participation
- Quality
- Medical necessity
- Certification/recertification
- OASIS assessments
- Code changes

What's HOT?

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### Hospice Risk Areas

- Notices of election, of termination/revocation
- Election
- Quality
- Length of stay
- Levels of care
- Live discharges
- Place of care/site of service
- Services provided last days of life

HOT BUTTON

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## Future Risk Areas?

- Quality measures
- Outcomes
- Patient surveys
- Physician involvement
- Safety



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## What's a Provider to Do?



- OIG Work Plan
- CMS listserv
- Contractor websites and listservs
  - Local coverage determinations
  - Denial codes
- CERT annual report

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## Comparative Data

- PEPPER
- Public Use File (PUF) data
- Quality reports
- HH Compare



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Program for Evaluating Payment Patterns Electronic Report

- Available for Home Health Agencies, Hospices
- Summarizes Medicare claims data for areas at risk for improper Medicare payments
- Cannot identify improper payments.....
- How to use it?

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### Risk Areas Included in PEPPER

- Home Health:
  - Average Case Mix
  - Average Number of Episodes
  - Episodes w/ 5 or 6 Visits
  - NonLUPA Payments
  - High Therapy Utilization Episodes
  - Outlier Payments

- Hospice:
  - Live Discharges
  - Live Discharges Revocations
  - Live Discharges LOS 61-179
  - Long Length of Stay (>180 days)
  - CHC in ALF
  - RHC in ALF
  - RHC in NF
  - RHC in SNF
  - Single Diagnosis Coded
  - No GIP or CHC
  - Long GIP Stays

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Home Health Agency PEPPER [Visit PEPPERresources.on](#)

Compare Targets Report, Four Quarters Ending Q4 CY 2015

002271, Provider D02271

Target	Description	Target Count/ Amount	Percent/ Rate	Home Health Agency National %ile	Home Health Agency Jurisdict. %ile	Home Health Agency State %ile	Sum of Payments
Average Case Mix	Proportion of the sum of case mix weight for all episodes paid to the HHA during the report period, excluding LUPAs and PEPs, to the count of episodes paid to the HHA during the report period, excluding LUPAs and PEPs.	639	1.22	86.6	95.6	92.0	Not Calculated
Average Number of Episodes	Proportion of the count of episodes paid to the HHA during the report period, to the count of unique beneficiaries served by the HHA during the report period.	569	1.56	38.2	63.2	80.0	\$1,852,613
Episodes with 5 or 6 Visits	Proportion of the count of episodes with 5 or 6 visits paid to the HHA during the report period, to the count of episodes paid to the HHA during the report period.	23	4.1%	14.1	7.2	4.3	\$39,765
Non-LUPA Payments	Proportion of the count of episodes paid to the HHA that did not have a LUPA payment during the report period, to the count of episodes paid to the HHA during the report period.	532	95.2%	60.9	78.8	88.0	\$1,843,013
High Therapy Utilization Episodes	Proportion of the count of episodes with 20+ therapy visits paid to the HHA during the report period (first digit of HHRG equal to 51) to the count of episodes paid to the HHA during the report period.	82	14.7%	81.5	91.8	89.5	\$464,824
Outlier Payments	Proportion of the dollar amount of outlier payments for episodes paid to the HHA.	\$8,011	0.4%	16.2	11.4		Not Calculated

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## Audit Tools

- Palmetto Home Health Medical Review Audit Form
  - [http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Home\\_Health\\_Medical\\_Record\\_Audit\\_Form.pdf/\\$File/Home\\_Health\\_Medical\\_Record\\_Audit\\_Form.pdf](http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Home_Health_Medical_Record_Audit_Form.pdf/$File/Home_Health_Medical_Record_Audit_Form.pdf)

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## Audit Tools, cont.

- Palmetto Hospice Documentation Audit Tool
  - [http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Hospice\\_Documentation\\_Audit\\_Tool.pdf/\\$File/Hospice\\_Documentation\\_Audit\\_Tool.pdf](http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Hospice_Documentation_Audit_Tool.pdf/$File/Hospice_Documentation_Audit_Tool.pdf)
- Palmetto Hospice GIP Audit Tool
  - [http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Hospice\\_GIP\\_Audit\\_Tool.pdf/\\$File/Hospice\\_GIP\\_Audit\\_Tool.pdf](http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Hospice_GIP_Audit_Tool.pdf/$File/Hospice_GIP_Audit_Tool.pdf)

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## Audit Tools, cont.



- NGS
  - ADR Checklist
  - Mock Chart Checklist Suggestions
- CGS
  - Medical Review ADR Process
  - HH and Hospice
- Other job aids

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### Customizing Your Audit Tools

- Usual documentation reviews – focus on physician face-to-face, certifications, medical necessity
- Outcomes – does documentation support outcomes?
- Denials/Probe and Educate – analyze what you may need to audit

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### Customizing Your Audit Tools, cont.

- Use your data to develop further tools – PEPPER, PUF
- HH recerts and hospitalizations
- Quality ratings
- Individualize based on your agency’s risk assessment

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### Internal Steps/Actions

- Audit/Monitor medical record documentation
- Review your claims data
  - Payments, denials
  - Know your regional idiosyncrasies
- Know your agency’s risk



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### Internal Steps/Actions, cont.

- Training
  - Internal comprehensive/Ongoing
  - Take advantage of what's out there
  - Questions re: policy/regulations/billing?
    - Contact your MAC
- Be ready for change
  - Follow regulatory talk/trends/final rule

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### Responding to Auditors



- Be aware of your data/auditing/monitoring results
- Be prepared for “when,” not “if”
- Know your strengths, weaknesses
- Have subject-matter experts ready
- Educate all staff members

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### Conclusion

- Strive for excellence
- Stay alert for changing risk areas
- Be ready for unexpected hazards



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**Mobile Health (mHealth)  
Applications in a Health Care  
Environment**

Brandon Goulter, Facility Compliance Professional  
Steven Baruch, Senior Compliance Director



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**Agenda**

- Overview of Mobile Health Applications & The State of Mobile Health
- Mobile Health Applications Related to Patient-Centric Care
- Legal and Privacy Implications
  - Health Insurance Portability and Accountability Act (HIPAA)
  - Federal Food, Drug, and Cosmetic Act (FD&C)
  - Federal Trade Commission Act (FTC)
  - FTC's Health Breach Notification Rule.
- HIPAA and the Liability for Clinical Providers



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**Reflection**

“The internet of things connects our devices to help us improve our healthy lifestyles; and big data may help researchers improve health outcomes for our nation. At the same time, these important tools also create risks to the privacy and security of our health information”

- Jocelyn Samuels, Director of the HHS Office for Civil Rights  
(October 13, 2016)



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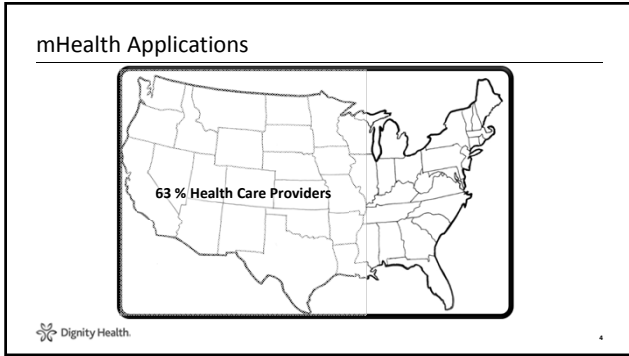
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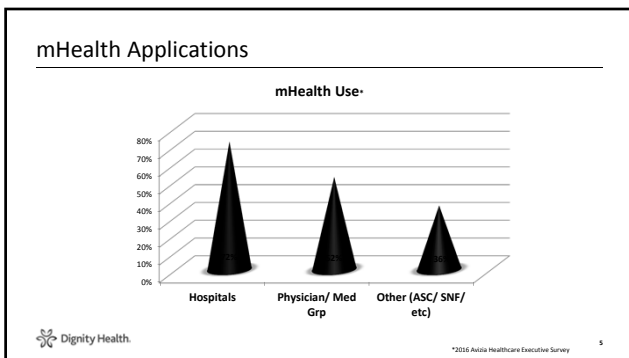
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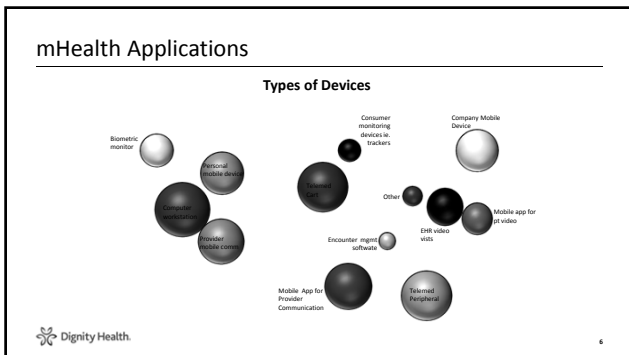
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### mHealth Applications

The largest anticipated future growth of mHealth...



Patient video visits, including mobile apps

Dignity Health.

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### Mobile Health Applications

- Affordable Care Act
  - Made access to health information more important
  - Value over Volume
- Meaningfully Using Data to treat
  - Chronic Diseases (e.g. Diabetes)
  - Remote monitoring of data (e.g. electrocardiogram or fetal monitoring)
- Enables the physician to work with the patient to make better and more informed decisions



Dignity Health.

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### Examples

- Telehealth & Communication:
  - Encrypted Messaging (OnePass/Consult Accelerator, Signal, WhatsApp)
  - Video Conferencing/Consulting (WebEx)
- Medical Device:
  - Concussion Monitoring (BrainCheck),
  - Patient Fetal/EXG Monitoring (Airstrip),
  - Glucose Monitoring / Insulin Dosing
- Patient Management
  - Electronic Preventive Services Selector (AHRQ)
- Personal Health
  - Fitbit
  - Microsoft HealthVault (PHR)



Dignity Health.

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### Pro's and Con's of mHealth Technology

- Patients & Providers Have access to data they wouldn't ordinarily have
- Patients have access to specialists they wouldn't ordinarily have
- Timely access to emergency care
- Physicians are able to diagnosis, provide guidance, assist with preparing a patient for transfer, and assist in lowering the rates of unnecessary care.
- Encourage healthy behavior
- Lack of ability to bill for "virtual visits"
- Data Security / Data Privacy
- Complicated regulations
- Lack of Regulation (e.g. Apps that should be regulated, aren't)
- Long and complicated privacy policies or terms and conditions.
- No SMS Texting or Texting Orders

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### Regulatory Environment

- Office for Civil Rights (OCR):
  - Health Insurance Portability and Accountability Act (HIPAA)
- Food and Drug Administration (FDA)
  - Federal Food, Drug, and Cosmetic Act (FD&C)
- Federal Trade Commission (FTC)
  - Federal Trade Commission Act
  - FTC's Health Breach Notification Rule
- State Specific Laws
  - E.g. California includes the Confidentiality of Medical Information Act (CMIA)




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### mHealth Device / mHealth App (Application)

A mHealth App is any application that can be run on a mobile platform with or without wireless (internet) connectivity. This includes any application that is running as a software as a service (e.g. hosted on a server and is customized to run on a portable or mobile device).

***The intended use of the device, not the hardware, is what will inevitably define which regulation will be used when assessing compliance or liability.***

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### Where does your mHealth device fall?

- Determine which laws apply. Multiple Laws?
  - Health Information Present? FTC / HIPAA
  - Prescription Needed? FTC/ HIPAA / FD&C (FDA)
  - Medical Device? HIPAA / FDA
    - Minimal Risk? FTC / FDA (Not enforced)
  - Mobile Medical App? FTC / FDA / HIPAA
- Are you seeing a trend? Lets dive into each law.




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### Health Insurance Portability & Accountability Act (HIPAA)

- HIPAA's focus is on provider data; when HIPAA does not apply:
  - Patients can collect data on themselves for their own purposes
  - Patients may voluntarily collect data and give to covered entity.
  - Healthcare providers may receive data in any fashion the patient chooses
- Any solution deployed by a covered entity requires a HIPAA risk assessment be performed
- Litmus Test: App Developer must be creating, receiving, maintaining or transmitting protected health information (PHI) on behalf of a covered entity or business associate.

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### Health Insurance Portability & Accountability Act (HIPAA)

- Health information is protected by the HIPAA rules when it is individually identifiable and created, received, maintained, or transmitted by a covered entity (or a business associate on the covered entity's behalf) in its role as a covered entity.
- mHealth application developers are business associates if:
  - They are directly contracting with the healthcare organization;
  - The device or software allows a patient to enter PHI;
  - The information transfers directly into the patient's EHR for the purposes of medical decision making and planning.




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### Use of Secure Texting in Healthcare Settings

- SMS text messaging is prohibited!
- Healthcare organizations should create a policy governing the use of "texting"
- *Texting Orders is Prohibited!*  
(Per The Joint Commission, December 2016)
- Use "Secure Texting" solutions
  - Encrypted Transport
  - Auditing
  - EHR Integration




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### Federal Food, Drug, and Cosmetic Act (FD&C Act)

- The Food and Drug Administration (FDA) enforces the FD&C Act
- The FD&C Act regulates the safety and effectiveness of medical devices, including certain mobile medical apps.
- Scope is limited to those devices that pose a greater risk.
  - Class I, II, III – Lowest to highest in terms of regulatory controls
  - Current Regulations indicate that most mobile devices fall into Class I or II
  - Premarket notifications are often required on Class II under the submission type of 510k.

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### Medical Device Companies

- Subject to the jurisdiction of the FDA
- May be a health care provider if it furnishes, bills, or is paid for "health care" in the normal course of business.
- Business Associate agreements are **not** required for treatment related disclosures.
- When is a Business Associate Agreement Needed?

*Navigating regulations regarding medical devices can be complicated, consider guidance from counsel*

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### Trust Gained / Trust Lost?

- Internet Connected Children's Toys: Privacy Concern?
  - FTC complaint filed Dec. 6
  - Did not obtain consent to disclose children's recordings to Nuance Communications, Inc. who is using the data for voice recognition products.
- Pokémon Go!
  - Full control over your Google Account and no notice to consumers.



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### Federal Trade Commission (FTC) Act

- Companies must not mislead consumers!
  - Consider all statements to consumers that when taken together don't create deceptive or misleading impressions.
  - Don't promise to keep information confidential when, in fact, you will ask customers later to authorize the disclosure of the same information.
  - Eliminate contradictions from Privacy Statements, Terms and Conditions, or Terms of Use.
- Bottom Line: If you say you will or will not do something, make sure that what is written is happening.

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### FTC's Health Breach Notification Rule

- Apply only when you've experienced a breach of PHR-identifiable health information.
  - Personal Health Records (Mobile & Non-Mobile)
  - Businesses that deal in Medical Information but are not covered by HIPAA.
- Triggers for Notification
  - Unsecured/Unauthorized acquisition
- Notification to:
  - Each affected person who is a citizen or resident of the United States; the Federal Trade Commission; and in some cases, the media.

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### Enforcement & Liability

- Catholic Health Care Services (\$650,000)
  - Failure of a Business Associate to secure PHI stored on a mobile device (Unencrypted iPhone without password protection)
  - Individuals impacted: 412
  - Lack of Enterprise-Wide Risk Assessment
- Children’s Medical Center of Dallas (\$3.2 Million)
  - Unencrypted/Non-password protected BlackBerry & Laptop
  - Individuals impacted: 3,800 & 2,462 respectively.
  - Failure to implement risk management plans, deploy encryption, implement access controls, and inventory devices.




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### Enforcement & Liability

- Biosense Technologies (2013) – uCheck (Urinalysis)
  - FDA Required Biosense to seek 510(k) clearance of its mobile medical app or convince the FDA that such clearance is not needed.
  - Smartphone App: Not Cleared, Strips: Cleared
  - Currently no longer available in the United States – India Only.
- Carrot Neurotechnology (2015) – Ultimeyes (Improve Vision)
  - “Scientifically shown to improve vision” through the use of a mobile interactive game.
  - \$150,000 settlement with the FTC and an agreement to stop making deceptive claims related to improving patient vision using an App.
  - Any future advertising would require verbose and competent scientific evidence.

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### Legal and Privacy Implications: Takeaways



- Ensure you are doing what you state you are doing with the data.
- Ensure you have a Business Associate Agreement for provider sponsored devices.
- If the Mobile Application is a Medical Device, ensure it is FDA cleared or approved.
- If the Mobile Application is a Medical Device, ensure you know whether the representative from the company is acting as a Covered Entity or a Business Associate.

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### Legal and Privacy Implications: Takeaways



Perform risk assessments on all devices that store PHI that are being used to store or transmit data on behalf of your organization.

Ensure your leadership teams and employees are aware that device manufacturers should be cleared by Compliance, Privacy and Security prior to their use (and who to call!)

Lack of follow-through may cost the organization time, money, and a corrective action plan!

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### Tools & Resources

- Federal Trade Commission: Mobile Health Apps Interactive Tool (<https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool>)
- FDA Cleared Mobile Apps (<http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm>)
- FDA Guidance Document on Mobile Medical Apps (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>)
- DHHS / OCR Website for App developers (<http://hipaasportal.hhs.gov/>)
- DHHS / OCR Website: Health Information Privacy (<http://www.hhs.gov/hipaa/for-professionals/faq/>)
- Podcasts (iTunes, etc.): Help Me With HIPAA, Security Now, This Week in Law, Unfair & Unbalanced (SCCE).

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Questions?



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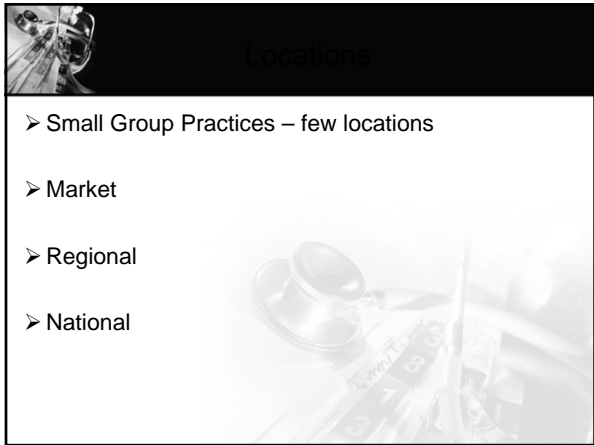
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- Small Group Practices – few locations
- Market
- Regional
- National

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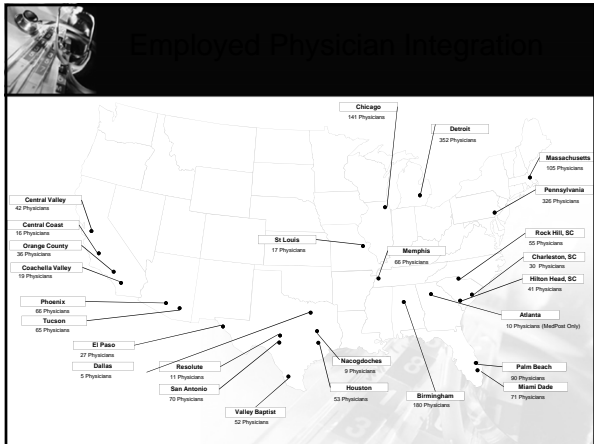
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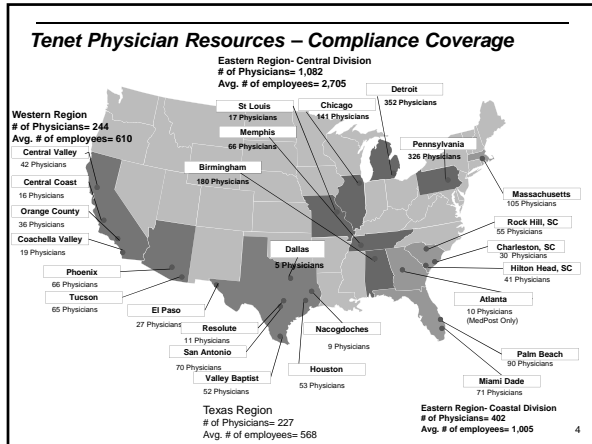
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- How to Effectively Communicate Across Practices
- Training Methods for Practices
- Initiatives For Physician Practices

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- Can be difficult due to makeup of organization
  - In Person
  - Remotely
- Difficulty in getting message to physicians

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➤ Methods of Communication

- Cascade down the message
- Videos
  - ❖ New Hire Training
  - ❖ Annual Refresher Training
  - ❖ Specialized/Targeted
- Web-ex sessions
- Monthly re-occurring calls
  - ❖ Bi-Weekly Operations Call
  - ❖ Monthly Practice Managers Calls
    - ✓ Meeting recorded
    - ✓ Minutes taken

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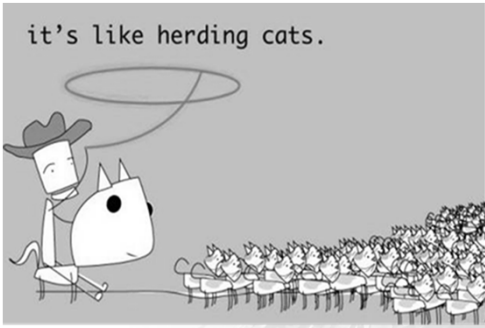
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it's like herding cats.



A cartoon illustration showing a cowboy on the left, holding a lasso that is looped around a single white cat. In the background, a large group of many small cats are gathered together, representing a difficult task to manage.

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➤ Three major ways to accomplish:

- Live
- Computer course with test
- Video



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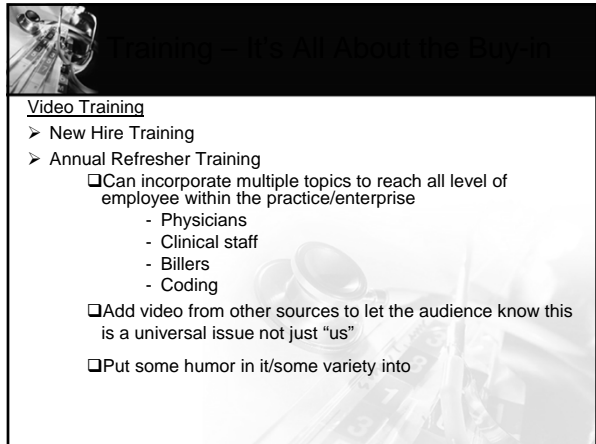
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**Video Training**

- New Hire Training
- Annual Refresher Training
  - ❑ Can incorporate multiple topics to reach all level of employee within the practice/enterprise
    - Physicians
    - Clinical staff
    - Billers
    - Coding
  - ❑ Add video from other sources to let the audience know this is a universal issue not just "us"
  - ❑ Put some humor in it/some variety into

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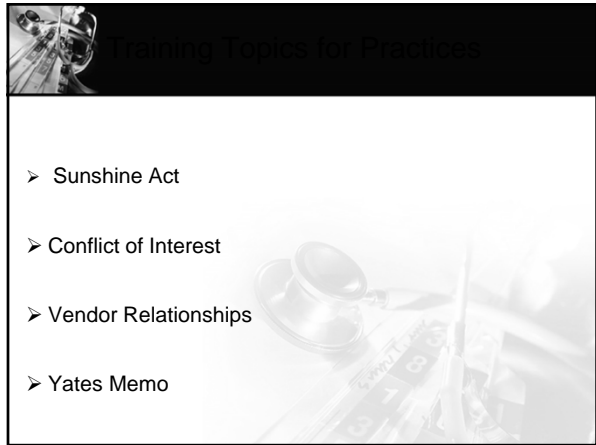
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- Sunshine Act
- Conflict of Interest
- Vendor Relationships
- Yates Memo

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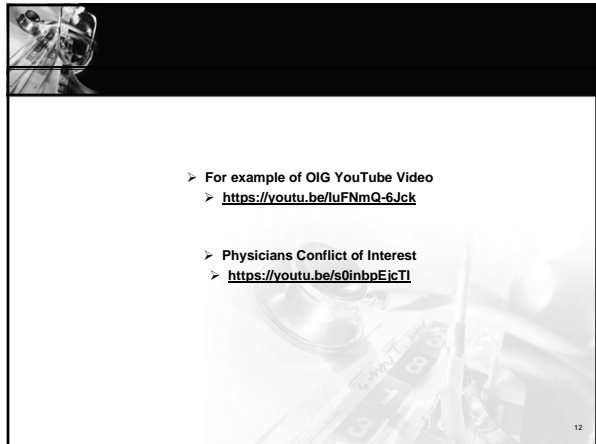
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- For example of OIG YouTube Video
  - <https://youtu.be/luFNmQ-6Jck>
  - Physicians Conflict of Interest
    - <https://youtu.be/s0inbpEicTI>

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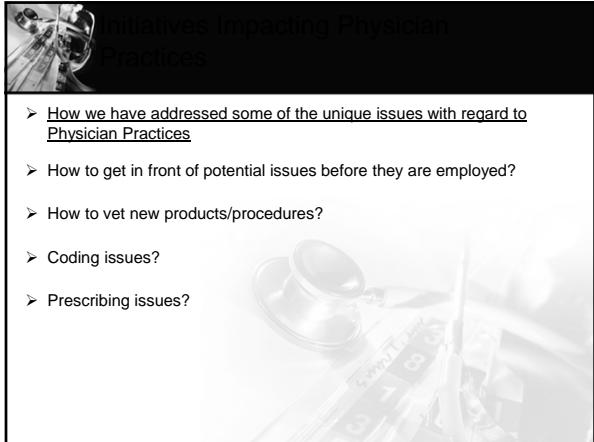
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- How we have addressed some of the unique issues with regard to Physician Practices
- How to get in front of potential issues before they are employed?
- How to vet new products/procedures?
- Coding issues?
- Prescribing issues?

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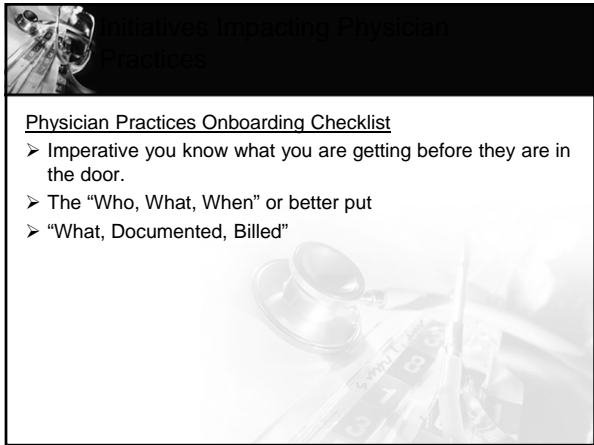
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**Physician Practices Onboarding Checklist**

- Imperative you know what you are getting before they are in the door.
- The "Who, What, When" or better put
- "What, Documented, Billed"

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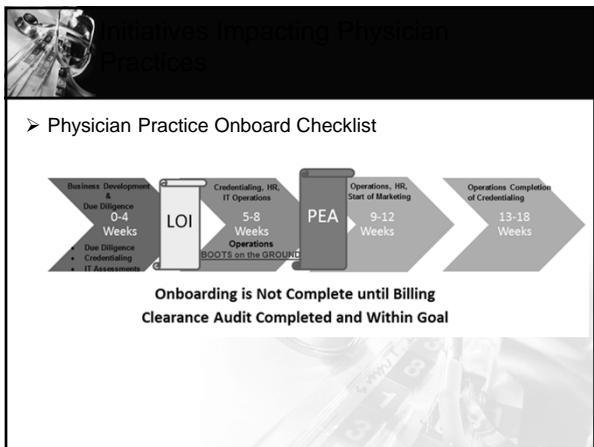
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➤ **Physician Practice Onboard Checklist**



**Onboarding is Not Complete until Billing Clearance Audit Completed and Within Goal**

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**Alternative Lines of Business**

- Alternative Line of Business means any items and/or products that may not fit into traditional lines of service for the primary or specialty care practice.
- Examples –
- Supplements
- Cosmetic procedures and services
- Oncology infusion

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**Alternative Lines of Business**

- Getting in front of it before they are hired
- Latest/greatest trend - colleague is doing it

**Alternative Lines of Business Policy/Job Aid**

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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">1070</td> <td style="width: 40%;">Tent Physician Revenues Policies and Procedures</td> <td style="width: 10%; text-align: center;">No.</td> <td style="width: 30%; text-align: center;">EPR.QM.107.00</td> </tr> <tr> <td></td> <td>Title:</td> <td style="text-align: center;">Page:</td> <td style="text-align: center;">2 of 2</td> </tr> <tr> <td></td> <td>Effective Date:</td> <td style="text-align: center;">Revised:</td> <td style="text-align: center;">07/2015</td> </tr> <tr> <td></td> <td>Author:</td> <td style="text-align: center;">Revised:</td> <td style="text-align: center;">Veronica Harsh</td> </tr> </table> <p><b>ALTERNATIVE LINES OF BUSINESS REVIEW PROCESS</b></p> <p>I. SCOPE:</p> <p>This policy applies to all physician practices owned or operated by Tenet Healthcare Corporation's consolidated subsidiaries (each, a "Tenet Physician Practice").</p> <p>II. PURPOSE:</p> <p>The purpose of this policy is to ensure that the Physician Practice adheres to practice, accepted standards of practice for the specialties of the practices of the Physician Practice. Further, it sets the expectations that in providing professional and medical services, the Physician Practice adheres to industry best practices and standards of care.</p> <p>III. DEFINITIONS:</p> <p>"Alternative Lines of Business" means any items and/or products that may not fit into traditional lines of service for the practice or specialty care practice, and that are included but not limited to the list of services attached to the Job Aid for this Policy.</p> <p>IV. POLICY:</p> <p>The Physician Practice must obtain the approval of the Vice President Physician Practice Management or designate the name of an approved line of business (subject to approval) under the existing job aid process in place. Approval must be obtained before proceeding with any expansion of services.</p> <p>V. PROCEDURE:</p> <p>A. Job Aid</p> <p>The Physician Practice will follow the procedural steps required to obtain prior approval for the new and alternative lines of business as outlined in the job aid and listed in the reference section of this policy.</p> <p>B. Standard</p> <p>Each Tenet Region will establish, and the Physician Management Executive Committee must approve performance standards for the policy. The policy job aid will include the standards.</p> <p>C. Responsible Parties</p> <p>The Physician Practice Manager or designee is responsible for ensuring that all activities, and the implementation of the policy. If the Physician Practice Manager identifies non-compliance with the policy, the Physician Practice Manager or designee will immediately report the non-compliance to the Physician Practice Director or designee.</p>	1070	Tent Physician Revenues Policies and Procedures	No.	EPR.QM.107.00		Title:	Page:	2 of 2		Effective Date:	Revised:	07/2015		Author:	Revised:	Veronica Harsh	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">1070</td> <td style="width: 40%;">Tent Physician Revenues Policies and Procedures</td> <td style="width: 10%; text-align: center;">No.</td> <td style="width: 30%; text-align: center;">EPR.QM.107.00</td> </tr> <tr> <td></td> <td>Title:</td> <td style="text-align: center;">Page:</td> <td style="text-align: center;">2 of 2</td> </tr> <tr> <td></td> <td>Effective Date:</td> <td style="text-align: center;">Revised:</td> <td style="text-align: center;">07/2015</td> </tr> <tr> <td></td> <td>Author:</td> <td style="text-align: center;">Revised:</td> <td style="text-align: center;">Veronica Harsh</td> </tr> </table> <p><b>ALTERNATIVE LINES OF BUSINESS REVIEW PROCESS</b></p> <p>D. Auditing and Monitoring</p> <p>The Market Operations Director or designee will audit adherence to this policy by monitoring the services being provided by the Physician Practice and ensuring that data in the Job Aid for this policy have been approved. Periodic Clinical and Quality Management will monitor the provision of services by specialty as part of normal quality review cycles and alert the Market Operations Director or designee and the Physician Practice Compliance Officer to any coding results that may warrant review against this policy and job aid.</p> <p>E. Enforcement</p> <p>All employees whose responsibilities are affected by this policy are expected to be familiar with the best practices and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate performance management processes as applicable, policies and procedures, up to and including termination. The performance management unit will monitor notification of compensation, including any award or discretionary compensation awards, as allowed by applicable law.</p> <p>VI. REFERENCES:</p> <p>Related Policies:</p> <p>Job Aid</p> <p>IA.TPR.QM.107.00 Alternative Lines of Business Job Aid</p>	1070	Tent Physician Revenues Policies and Procedures	No.	EPR.QM.107.00		Title:	Page:	2 of 2		Effective Date:	Revised:	07/2015		Author:	Revised:	Veronica Harsh
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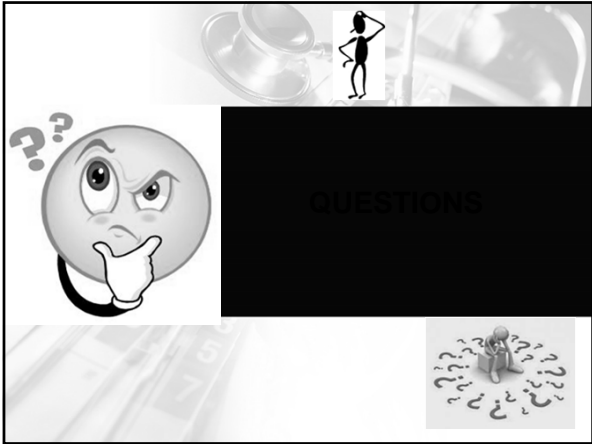
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QUESTIONS

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# Federal Administrative Sanctions: Exclusion and Civil Monetary Penalties

2017 HCCA Compliance Institute

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Lauren Marziani, OIG  
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## Introduction: Exclusion and Civil Monetary Penalties

- OIG Exclusion
  - Overview of authorities
  - Differences between exclusion and CMS revocation authority
- OIG Civil Monetary Penalties
  - OIG priority areas
  - Overview of authorities
  - Recent case results

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## OIG Organization

- Office of Audit Services (OAS)
- Office of Evaluation and Inspections (OEI)
- Office of Investigations (OI)
- Office of Counsel to the Inspector General (OCIG)
- Office of Management & Policy (OMP)



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### What is Exclusion?

- Protects Federal health care programs from untrustworthy providers
- No Federal health care program payment may be made for items or services:
  - Furnished by an excluded individual or entity
  - Directed or prescribed by an excluded individual, where the person furnishing the item or service knew or had reason to know of the exclusion
- Exclusion applies to direct providers (e.g., doctors, hospitals) and indirect providers (e.g., drug manufacturers, device manufacturers)
- Special Advisory Bulletin on the Effect of Exclusion




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### Mandatory Exclusions – § 1128(a) of the SSA

- Based on convictions for:
  - Medicare/Medicaid Fraud
  - Patient Abuse/Neglect
  - Felony Health Care Fraud
  - Felony Relating to Controlled Substances
- Conviction is broadly defined in § 1128(i) of the SSA
- Minimum 5 year exclusion term
  - Aggravating and mitigating circumstances

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### Permissive Exclusions — § 1128(b) of the SSA

- 16 bases, most are derivative and include:
  - Misdemeanor health care (non-Medicare/Medicaid) fraud conviction;
  - Obstruction of investigation/audit;
  - Misdemeanor controlled substances conviction;
  - License revocation or suspension;
  - Individuals controlling a sanctioned entity;
  - Entities controlled by a sanctioned individual.
- Term of exclusion varies based on grounds for permissive exclusion
  - Adjustments to term based on aggravating and mitigating factors

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### Affirmative Permissive Exclusions

- Fraud/Kickbacks – §1128(b)(7)
- Failure to meet professionally recognized standards of care – §1128(b)(6)(B)
- Failure to provide medically necessary services meeting professionally recognized standards of care – § 1156
- Knowing false statements or misrepresentations on enrollment applications – §1128(b)(16)
- Failure to grant immediate access - § 1128(b)(12)

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### 1128(b)(7) Criteria – Exercise of OIG Discretion

- 62 Fed. Reg. 67392 (Dec. 24, 1997), superseded and replaced by new policy published April 18, 2016:  
<https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>



- Four broad categories of factors:
  - Nature and circumstances of conduct, conduct during the Government's investigation, significant ameliorative efforts, and history of compliance

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### Procedure for Exclusions – 42 C.F.R. Part 1001

- Derivative exclusions (mandatory and permissive):
  - Notice of Intent to Exclude (opportunity to respond)
  - Notice of Exclusion (goes into effect 20 days from letter)
  - any appeal of exclusion (basis and/or length) is before HHS Departmental Appeals Board Administrative Law Judge (<https://dab.efile.hhs.gov/>)
- "Affirmative" exclusions:
  - OIG notifies individual/entity of proposed exclusion and length via letter
  - Generally\* goes into effect AFTER hearing before ALJ (or 60 days from letter if provider doesn't appeal to ALJ)

\* (b)(6)(B) exclusions go into effect before hearing, but opportunity to meet with OIG before exclusion imposed

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### Waiver of Exclusion

- OIG has the authority to waive an individual's or entity's exclusion as a provider from Federal health care programs
- A waiver may be requested only by **the administrator of a Federal or State health program**
- Waivers are available only for those excluded providers who are the sole community physician or the sole source of essential specialized services in a community
- Excluded individuals or entities may not request a waiver from the OIG

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### Reinstatement

- Reinstatement into the Federal health care programs is not automatic at the end of the exclusion period
- Individuals must apply to OIG for reinstatement
- OIG has discretion to grant or deny reinstatement petition
- No judicial review of OIG's decision to deny petition
- "Billing while excluded" is a common reason for denial

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### Screening for Excluded Persons

- Best practices
  - Screen at hiring with employee/contractor certification
  - Screen monthly
- OIG List of Excluded Individuals and Entities (LEIE)
  - <http://exclusions.oig.hhs.gov>
  - Updated monthly

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CMS Revocation Rules

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Topics for Discussion

- Medicare Enrollment: Requirement to Maintain Accurate and Complete Data
- Mechanisms for Verifying Compliance with Enrollment Rules
- Increasing CMS Scrutiny – Medicare Sanctions
- Revocation Case Law Trends
- What can you do to prevent such actions?

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Medicare Enrollment

- Increasing efforts to combat fraud, waste and abuse through the enrollment rules and CMS sanctions
- Enrollment application is considered essential part of the agency's ongoing effort to combat fraud and abuse
- False or misleading information, or a simple omission, can lead to deactivation or revocation of Medicare billing privileges

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### Complete and Accurate Data Required

- 42 C.F.R. § 424.510(d) requires all providers and suppliers to:
  - (1) Submit a complete enrollment application and supporting documentation which
  - (2)(i) includes complete, accurate, and truthful responses to all information requested.
  - (3) The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier. The signature attests that the information is accurate.

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### Medicare Enrollment – Updating Data

- 42 C.F.R. § 424.516(e) requires reporting of:
- Changes in Ownership or Control, or changes in authorized official(s) or delegated official(s) to be reported no later than 30 days after the effective date
  - Any revocation or suspension of a federal or state license must be reported by no later than 30 days after the effective date.
  - All other changes to enrollment within 90 days

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### Medicare Enrollment – Updating Data

- 42 C.F.R. § 424.502 Final Adverse Action means:
  - A Medicare-imposed revocation of any Medicare billing privileges;
  - Suspension or revocation of a license to provide health care by any State licensing authority;
  - Revocation or suspension by an accreditation organization;
  - A conviction of certain Federal or State felony offenses within the last 10 years preceding enrollment, revalidation, or reenrollment; or
  - An exclusion or debarment from participation in a Federal or State health care program.

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### Medicare Enrollment – Updating Data

- 42 C.F.R. § 424.530(a)(3) Final Adverse Action includes certain federal or state felony convictions:
  - Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
  - Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.
  - Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.
  - Any felonies that would result in mandatory exclusion under section 1128(a) of the Act.

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### Consequences for Non-Compliance

- When licensure or database issues are identified:
  - If attempting to enroll, under 42 C.F.R. § 424.530(a)(i) CMS may deny the enrollment if provider or supplier is determined to not be in compliance with the enrollment requirements in this subpart P or in the enrollment application.
  - If already enrolled, under 42 C.F.R. § 424.535(a)(i) CMS may revoke a currently enrolled provider's or supplier's Medicare billing privileges and any corresponding provider or supplier agreement.

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### Sanctions for Failing to Comply

- Deactivation -- temporary suspension of billing privileges without termination of the provider or supplier agreement. 42 C.F.R. § 424.540
- Revocation -- automatic termination of the provider or supplier agreement. 42 C.F.R. § 424.535
  - Generally, effective 30 days following notice unless based on final adverse action or non-operational location, then effective as of the date of the adverse action or finding location to be non-operational.
  - Reportable event to Medicaid and other federal payers (mandated cross-termination), and other third party payers.

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### CMS Sanctions -- Billing Privilege Revocation

#### Bar to Re-Enrollment

- Bar itself is not discretionary.
- Generally, length of bar is discretionary and is to be based on severity of the basis for revocation.
- Exceptions:
  - Failure to report final adverse action: 1-year bar if already enrolled, 3-years if new enrollee.
  - Failed site visit: 2-year bar.
  - Submitting claims after license suspension or felony conviction or falsification of information: 3-year bar.
- Must reapply as a new provider/supplier

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### CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535
  - (1) Not in compliance with the enrollment regulations or the applicable enrollment application requirements;
  - (2) Provider, any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel is excluded, debarred or otherwise not eligible to participate in federal health care programs;
  - (3) Felonies by provider, supplier or any owner within 10 years of enrollment or revalidation that CMS determines to be detrimental to best interests of programs and beneficiaries;

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### CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
  - (4) False or misleading information on the enrollment application
  - (5) Based on an on-site review or other reliable evidence, CMS determines that the provider is no longer “Operational” or otherwise fails to satisfy any Medicare enrollment requirement.
  - (6) Failure to pay the application fee or obtain an approved hardship exception to pay the fee.
  - (7) Misuse of billing number: The provider or supplier knowingly sells to or allows another individual or entity to use its billing number.

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### CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
  - (8) Abuse of billing privileges which includes either of the following:
    - Submission of claim for services that could not have been furnished to a specific individual on the date of service, such as when the beneficiary is deceased, a supervising physician or beneficiary is not in the state or the equipment necessary for testing is not present.
    - CMS determines that the provider has a “pattern or practice” of submitting claims that do not comply with Medicare’s claims completion rules.

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### CMS Sanctions – Billing Privilege Revocation

- *Pattern or Practice* 42 C.F.R. § 424.535(a)(8)(ii)
  - Provides a basis when “CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.
  - Factors that CMS is to consider include:
    - Percent of submitted claims that were denied,
    - Reason(s) for the claim denials,
    - History of a final adverse action and, if so, the nature of any such action,
    - Length of time over which the pattern occurred, and
    - How long the provider or supplier was enrolled.
  - However, when finalizing the rule, CMS commented that as little as 3 claims could be pattern or practice.

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### CMS Sanctions -- Billing Privilege Revocation

- Bases for Revocation – 42 C.F.R. § 424.535:
  - (9) For physicians, non-physician practitioners and their organizations, failure to report change of ownership or control, or revocation or suspension of Federal or State license within 30 days; All other changes to enrollment data within 90 days;
  - (10) Failure to document or provide CMS access to documentation;
  - (11) For home health agencies, if HHA cannot provide supporting documentation verifying that the HHA meets the initial reserve operating funds requirement within 30 days of request; and
  - (12) Mandated cross-termination if terminated or revoked by a state Medicaid agency.

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### CMS Sanctions – Billing Privilege Revocation

- Appeals process:
  - Request for Reconsideration filed within 60 days of the notice of the revocation
  - CMS or its contractor, or the provider or supplier dissatisfied with the Reconsideration Determination may request an ALJ Hearing within 60 days from receipt of the Reconsideration Decision
  - CMS or its contractor, or the provider or supplier dissatisfied with the ALJ Hearing Decision may request Board review by DAB within 60 days from receipt of the ALJ's decision.
  - Provider or supplier dissatisfied with the DAB Decision may seek judicial review in District Court by filing a civil action within 60 days from receipt of the DAB's Decision

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### Increased Scrutiny: GAO & OIG Reports

- GAO Report, "MEDICARE Program: Additional Actions Needed to Improve Eligibility Verification of Providers and Suppliers," GAO-15-448 (June 2015)
- OIG Report, "Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results (April 2016)"

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### Revocation – No Longer Operational

- *AR Testing Corp. v. CMS*, HHS DAB, Docket No. A-15-69 (Mar. 10, 2016)
  - CMS MAC performed unannounced inspection of IDTF practice location identified in Medicare enrollment application. Unable to locate supplier in facility or signage.
  - Surveyor left message for owner; owner returned message that day and stated moved location.
  - MAC revoked billing privileges and terminated provider agreement on ground that IDTF was "no longer operational."

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### Revocation – No Longer Operational

- *AR Testing Corp. v. CMS* (cont'd)
  - Petitioner unsuccessfully argued it was operational because its mobile-unit and off-site locations were in compliance.
  - CMS guidance states IDTF performance standards, including accessibility requirement, apply to home location (e.g., maintenance of patient records, primary business phone). Petitioner's home location was not staffed and open to beneficiaries, and signage at location provided no clear guidance as to how services could be accessed.
  - ALJ upheld revocation

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### Revocation - Adverse Final Action

- *Brown and Obeng v. CMS*, HHS DAB, Docket Nos. C-10-443 and C-10-481 (Jun. 9, 2010).
  - DC DOH summarily suspended Petitioners' licenses to practice medicine effective 4/17/09.
  - Petitioners entered into settlement agreements and license suspensions were lifted effective 5/6/09.
  - MAC revoked billing privileges with a one-year bar to reenrollment under 42 C.F.R. § 424.535(a)(9).

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### Revocation - Adverse Final Action

- *Brown and Obeng v. CMS* (Cont.)
  - Petitioners unsuccessfully argued that suspension did not need to be reported since the licenses were reinstated within the 30-day reporting period.
  - Petitioners incorrectly interpreted the regulation as requiring reporting within 30 days, only if the adverse event continues, or will continue, beyond 30 days.

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### Revocation – Failed Site Visit

- *Healthy Point Medical Care, PC v. CMS*, HHS DAB, Docket No. C-15-1614 (Sept. 29, 2015).
  - 9/23/14 site verification visit to practice location -- no longer operational.
  - Revocation under 42 C.F.R. § 424.516(d)(1)(iii) for failure to report a change in practice location within 30 days, with required two-year reenrollment bar for failed site visit.
  - Practice submitted a Corrective Action Plan enclosing CMS 855B to delete practice location effective 7/1/14 and affidavit from office manager accepting responsibility for reporting failure.
  - CMS prevailed on summary judgment motion.

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### Revocation – Ordering and Referring

- *George M. Young, M.D. v. CMS*, HHS DAB, Docket No. C-15-3553 (Mar. 1, 2016).
  - 1/6/15 letter requesting medical records (orders, progress notes, patient information sheets) for 14 Medicare beneficiaries for whom ordered DME.
  - Physician unable to produce records since facility where he was employed, which had possession of the records, could not locate records.
  - Revocation under 42 C.F.R. § 424.535(a)(10), with one-year reenrollment bar, for failure to provide access to documentation.
  - Revocation upheld.

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### OIG’s Civil Monetary Penalties Law

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### What is the Civil Monetary Penalties Law?

- Administrative fraud remedy (42 U.S.C. § 1320a-7a)
  - new regulations 81 Fed. Reg. 88,334 (Dec. 7, 2016)
  - Assessment (ex. 3x amount claimed) + penalties (ex. \$50k/act) + exclusion
  - Penalties updated annually for inflation, 45 CFR Part 102
- Alternative or companion case to a criminal or civil health care fraud action
  - Physicians, owners, or executives
- Burden of Proof: preponderance of the evidence (same as civil)
- Statute of Limitations: 6 years (same as civil)
- Intent: generally “knows or should know”
  - Actual knowledge, deliberate ignorance or reckless disregard

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### How does OIG use the CMPL?

- Enforcement actions on many different grounds, including:
  - False or fraudulent claims
  - AKS and beneficiary inducement
  - Arranging or contracting with excluded person
  - Ownership, control or management while excluded
  - Ordering or prescribing while excluded
  - Knowing false statement on application, bid or contract to participate or enroll
  - Knowing retention of overpayment
  - Provision of untimely or false information by a drug manufacturer with rebate agreement
- Self-Disclosure Protocol

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### How does the CMPL fit in the government’s enforcement toolbox?

- Specialized areas of enforcement
  - Beneficiary inducement
  - Billing, ordering, prescribing while excluded
  - Knowing retention of an overpayment
  - Failure to properly report required drug pricing information
- Opportunity to complement criminal or civil cases
- Cases where exclusion is important remedy

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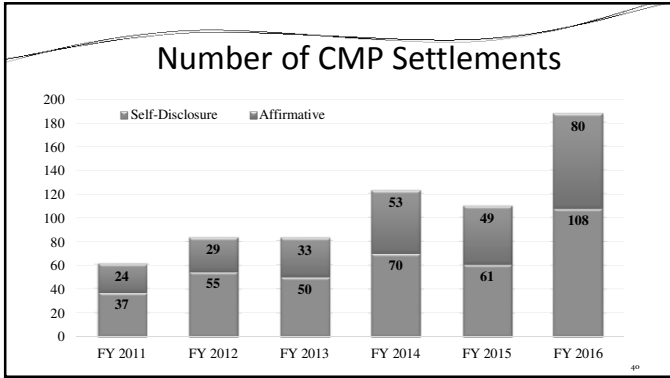
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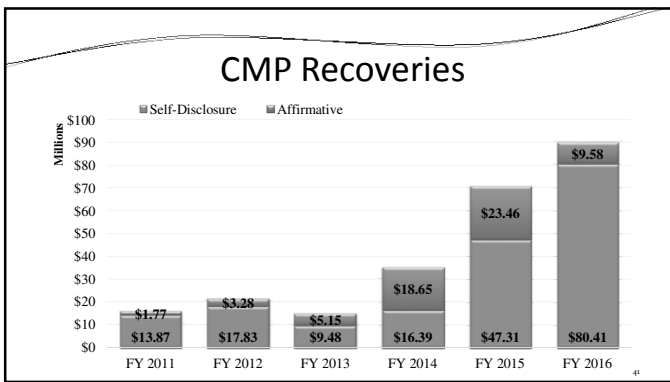
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### Fraud by Excluded Individuals

**Roben Brookhim**

- Conduct:** Brookhim, an unlicensed dentist, was excluded in 2000; he subsequently owned and controlled a NJ dental practice using the identity of a licensed dentist to submit claims (even after the licensed dentist died).
- Result:** \$1.1 million CMPL and 50-year exclusion




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### Kickback Cases *Orange Community MRI*

- Criminal spin-off
- Conduct: Referring physicians received cash kickbacks for referrals; amount of remuneration per referral was based on the procedure ordered
- Result: Settlements with Dr. Sharif for \$52,280; Dr. Shah for \$104,950; Dr. Collin for \$111,415



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### Kickback Cases *OneStep Diagnostic, Inc.*

- Civil FCA spin-off
- Conduct: Physicians received remuneration from OneStep Diagnostic, Inc. in the form of Medical Directorship agreements.
- Result: Settlements with 8 physicians for a total of \$735k



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### Kickback Cases *Jack Baker Fairmont Diagnostic Center and Open MRI, Inc.*

- Civil FCA spin-off
- Conduct: Referring physicians received kickbacks in the form of medical directorship fees and office staff arrangements
- Result: Settlements with 11 physicians for a total of \$1.4 million and one exclusion



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## Fraud Alert to Physicians



Fraud Alert: Physician Compensation Arrangements  
May Result in Significant Liability

June 9, 2015

OIG alerted physicians that compensation arrangements may violate the Anti-Kickback Statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business.

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## Services Not Rendered or Supervised

*Dr. Labib Riachi*



- **Conduct:** Dr. Riachi failed to personally perform or supervise pelvic floor therapy services, physical therapy services, and other services provided by unqualified and unlicensed individuals.
- **Result:** 20 year exclusion (previous \$5.25m FCA settlement)

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## Services Not Rendered or Supervised

*Mississippi PT Doctors*

- **Criminal spin-off**
- **Conduct:** Physicians failed to personally render or directly supervise physical therapy services billed under their provider numbers
- **Result:** Settlements with nine physicians for a total of \$630,375



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## Fraud Alert to Physicians



### OIG ALERT

OIG alerted physicians that if they reassign their right to bill the Medicare program and receive Medicare payments by executing the CMS-855R application, they may be liable for false claims submitted by entities to which they reassigned their Medicare benefits.

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## Exclusions

- **Phillip Minga:** owner of DME company excluded for 10 years after billing for diabetes supplies that were not delivered, were the result of telemarketing rules violations, or were tainted by kickbacks.
- **Alexander Khavash:** chiropractor excluded for 40 years after submitting claims for chiropractic services that were not provided as claimed and were not medically necessary.
- **Eugene Fox:** podiatrist excluded for 30 years after he billed for podiatric services that were not rendered or were rendered by unqualified personnel.
- **Michael Esposito:** physician excluded for 5 years after forging another physician's signature on prescriptions for himself and another person.

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## Drug Pricing Cases

- **Office of Evaluations and Inspections referral**
- **Conduct:** Pharmaceutical companies failed to submit accurate drug pricing information to CMS, which uses the information to determine payment amounts for drugs reimbursed by Medicaid
- **Results:** \$17.8 million in settlements with 8 companies, including \$12.64 million settlement with Sandoz

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### Sub-standard Quality of Care *Dr. Bobby Merkle*

- Quality Improvement Organization (QIO) referral
- Conduct: Violated obligations to provide services to 5 Medicare beneficiaries through practices that violated professionally recognized standards of care.
- Results: 3 year exclusion under 42 USC § 1320c-5

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### Data Mining - *Ambulance Cases*

Conduct: Emergency ambulance transportations to inappropriate destinations such as skilled nursing facilities or residences.

Result: Over \$3.4 million under the CMPL.



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### Data Mining – *Molecular Pathology Procedures*

Conduct: Billing for physician interpretation and report on molecular pathology procedure where no consultation request had been made, no written report had been written, or exercise of medical judgment by a consulting physician was not required.

Result: Over \$650k under the CMPL.



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**OIG Compliance Resources**  
<http://oig.hhs.gov/compliance/>



OFFICE OF INSPECTOR GENERAL  
**Special Fraud Alert**  
RENTAL OF SPACE BY PHYSICIAN OFFICES BY PERSONS OR ENTERED TO WHICH PHYSICIANS REFER

**HHS-OIG Compliance Training**  
oig.hhs.gov

**GUIDANCE for Health Care Boards**

**A Roadmap for New Physicians**  
Avoiding Medicare and Medicaid Fraud and Abuse

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**QUESTIONS?**



time for questions

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### Premise

- Risk assessments explain why there may/may not be flexibility.
- Knowing how risk assessments are made in research can help avoid compliance issues.

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### The importance of research risks

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### What is risk assessment in research?

- Determining whether a study is minimal or greater than minimal
  - **Minimal Risk:**
    - **HHS Definition from 45 CFR 46.102**
    - *Minimal Risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

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### Risk Assessment

- Is normally done for the entire study but can also be done:
  - For a component of the study.
    - For example:
      - Modification of written consent for one population in the study
      - Minors (child) determination
      - Revision and whether it can be reviewed expedited

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### Risk Assessment for Devices

- This is a different risk assessment for investigational devices that are not considered EXEMPT from the investigational device exemption (IDE) requirement.
- This is different from the risk rating given to an overall study.

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### Devices and Risk

- A device is deemed non-significant risk but the overall study is still deemed greater than minimal risk.
  - Non-significant risk for a device means that an IDE is not needed.
  - Significant risk for a device means an IDE is needed.
- Overall study risk ≠ Device Classification

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Why is risk assessment important?

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Risk Assessment is determining:

- the overall risk of a study.
- the risk of a change to a study.
- a device risk classification that is different from an overall study risk determination.

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What are research risks?

- ▶ **Physical** - drug toxicities, exposure to radiation, research injuries
- ▶ **Psychological** - emotional distress, anxiety in making choice
- ▶ **Social** - one's reputation, social standing, retaliation
- ▶ **Legal** - risk of criminal or civil liability
- ▶ **Economic** - impact on employment, insurance, research costs

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**How research risks affect approval, IRB review, consent, and indemnifications**

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**The level of risk assigned a research protocol affects:**

- Mode of review
  - Expedited vs Full Board
- Need for additional approvals
  - IRB alone or DHHS secretary needed
- Types of protections/additional protections
  - Certificate of Confidentiality
  - Data Safety Monitoring
- Frequency of review
  - Annual or more frequent
- Consent requirements
  - Written, modification, waiver
- Indemnification language negotiations
  - Needed?
- Etc.

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**Assessing risk**

- Is required in 45 CFR 46 and 21 CFR 50
- Is listed in the criteria for review

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<b>Criteria for approval 45CFR 46.111 and 21 CFR 56.111</b>
Risks to subjects are minimized
Risks to subjects are reasonable in relation to anticipated benefits
Selection of subjects is equitable and additional protections for vulnerable populations
Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
Informed consent will be appropriately documented.
When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

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<b>Mode of Review: Expedited Review</b>
The regulations allow for an expedited review (45 CFR 46.110 and 21 CFR 56.110):
(b) An IRB may use the expedited review procedure to review either or both of the following:
(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

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18
<b>Examples of Minor Changes</b>
<ul style="list-style-type: none"> <li>• Changing most research team members</li> <li>• Adding a recruitment method such as a flyer</li> <li>• Adding a funding source</li> <li>• Adding a performance site</li> </ul>

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### Expedited and Exempt Categories

- Both HHS and FDA define certain categories of research that may be reviewed using an “expedited reviewer” system.
- Research that falls exactly within the boundaries of these categories is considered *minimal risk*.

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### What does “Exempt” Mean?

- Currently it is considered human subjects research.
  - It must be reviewed by an IRB or IRB designated reviewer.
- The study is “exempt” from the federal regulations but not pertinent ethical codes.
- Once approved, it does not have to be renewed annually however:
  - Any modifications must be submitted to and approved by the IRB.
  - Any events that increase risks to participants must be reported to the IRB along with any other reportable events.

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### Exempt categories cannot be applied to:

- Research with prisoners
- Deception studies

45 CFR 46.101(b) and 21 CFR 56.104

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If a study does not meet Expedited or Exempt Category criteria.....

**It has to go to a full board to review...more than one reviewer.**

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**Full Board Reviews**

- Investigational drugs, devices, biologics, supplements
- Investigational uses of FDA approved drugs and devices, biologics and supplements
- Radiation-emitting products such as X-Ray and PET
- Gene Therapy
- Any new study that does not fit exactly into one or more of the HHS Exempt or Expedited Categories

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**Certificate of Confidentiality**

- Issued by the National Institutes of Health (NIH) or the Food Drug Administration (FDA)
- Protects identifiable research information from forced disclosure (subpoena).
  - Allows refusal to access research records or disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- Protects information that if disclosed could damage financial standing, employability, insurability, or reputation.
- May help achieve research objectives and promote participation in studies
- May be requested by the funding source

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**Are there times when a Certificate of Confidentiality is ineffective?**

1. The information is already in the medical record.
2. No sensitive information is being collected.
3. When disclosure is mandated by state or federal law.  
Examples include: suspected child abuse, threat of harm to self or others, reportable communicable diseases, FDA or DHHS audit or program evaluation.
4. the participant discloses the information to his/her insurance company, primary care provider or other clinician, or any other voluntary disclosure, etc.
5. Data maintained outside the U.S.

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**All human subjects research needs some type of monitoring**

- NIH now requires a Data Safety and Monitoring plan for all studies with human subjects
- FDA requires collection of safety and effectiveness data
- Monitoring should be commensurate with risks, nature, size and complexity of the trial

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**Frequency of Review**

- Studies deemed “exempt” do not undergo annual review.
- Studies deemed “minimal risk” must renew every 365 days.
- Studies deemed “greater than minimal” must renew no less than 365 days but may be put on a 3 or 6 month renewal due to risks.

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### Consent Requirements

- Minimal risk studies that are FDA funded could qualify for a Waiver of Written Consent.
- Minimal risk studies that are not funded or HHS funded may qualify for a Waiver of Consent, Waiver of Written Consent, or Waiver of one of the eight elements of Consent.

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### Risk Classifications for Minors

- 46.404; 50.51: Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.  
– **One parent signature**
- 46.405; 50.52: The research risk is greater than minimal and it presents the prospect of direct benefit to the participant.  
– **One parent signature**
- 46.406; 50.53: Minor increment over minimal risk: The research is greater than minimal with no direct benefit to the minors but is it likely to yield generalizable knowledge about the subject's disorder or condition.  
– **Two parent signature**
- 46.407; 50.54: The research uses minors that do not have the disease being studied and is greater than minimal risk.  
– **Two parent signature**

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### Indemnification Language

- Injury language is required in greater than minimal risk studies.
- Often this language is negotiated at the time of the contract.
  - Language is often vague in nature.

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**What risks are considered?**

- 45 CFR 46.111 (a)(2): In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
- Harms are distinguished from discomforts
  - Severe allergic reaction vs. body image issues
  - Renal failure vs requiring a SS# for payment

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What does this mean?	What does this NOT mean?
Known risks are considered –Listed in the investigator's brochure, consent, recent literature, etc.	If this study is conducted, then in 5 – 10 years public policy will be changed to reflect the findings of the study.
Foreseeable risks are considered –When looking at the list of risks, there is a likelihood that a given risk could occur during the study	If this study is approved, then all other studies like this one will have to be approved.

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**How risk can be minimized using preliminary risk assessments**

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**Determine appropriate Oversight**

- Ensure Patient Safety
  - Standard or investigational procedures
  - Proper oversight by PI
  - Trained, qualified research team members with needed experience, expertise, licensure
  - Proper consent procedures
  - Privacy provisions
- Ensure Data Validity and Integrity
  - Confidentiality and security measures

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**Corrective and Preventative Action (CAPA) involves:**

- Improvements to an organizations processes
- Elimination of causes of non-conformities or undesirable situations
- Part of Good Manufacturing Practices (GMP), it focuses on root causes of identified risks or problems to prevent recurrence or occurrence, in the first place.
  - Principles can be applied to research in general

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**Corrective action or minimizing risks can be done in response to:**

- Complaints
- Protocol non-conformance
- Issues identified in an external or internal audit of the study.
- Adverse event trends
- On-going monitoring (data safety monitoring) of the study
- Findings in progress reports, statistical analysis

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How can you make a preliminary risk assessment?

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1. Know the published exempt and expedited categories.
  - If your study fits into one or more categories exactly, it will probably be minimal risk.
2. Know the types of interventions that get sent to full board.
  - These are most often given a greater than minimal risk rating.
3. Know the risks
  - Of the study; the severity of the risks; the probability of the risks

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Magnitude of Risks vs. Risk Probability Example

		PROBABILITY		
		RARE (<2%)	LESS LIKELY	LIKELY (>30%)
MAGNITUDE	MILD	Minimal	Minimal	Minimal
	MODERATE	Minimal	Reviewer's Discretion	Greater than Minimal
	SEVERE	Reviewer's Discretion	Greater than Minimal	Greater than Minimal

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4. Know your population

- Adults: minimal vs greater than minimal risk
- Minors: 4 risk classifications
  - Healthy?
    - 46.404 or 21 CFR 50.51
    - 46.407 or 21 CFR 50.54
  - Condition under study?
    - 46.405 or 21 CFR 50.52
    - 46.406 or 21 CFR 50.53

5. What has been done in the study to minimize risks?

- Do these minimize the risks enough to change the risk rating?

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What risk rating would you assign?

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**Example 1**

- Subjects will be randomized to one of two surgical procedures. Both procedures are considered standard clinical care for the subjects condition.
- Subjects are 18 – 45 years old, diagnosed with the condition requiring treatment, no complicating factors
- Procedure will be the same standard care, but follow-up visits will be more frequent and in depth than standard care.
- PI will be qualified to perform both surgical procedures. Subjects will be monitored closely and medical care will be given as needed.
- Randomization is to one of two surgical procedures.

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**Example 1 Classification**

- Greater than minimal risk
  - Randomization to two surgical procedures where the physician discretion has been eliminated.
- How were risks reduced?
  - Standard care procedures
  - Close monitoring
  - Medical care given as needed
  - More frequent follow-up visits
  - More in-depth follow-up visits
  - Surgeon qualified to conduct both procedures.
- But, this is still greater than minimal risk.

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**Example 2**

- A study proposes to use a FDA approved device off-label.
- All other procedures are standard but being done solely for the research.
- The PI and study team are properly trained and qualified.
- Written consent will be obtained.

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**Example 2 Classification**

- “Off-label” means “investigational” in research terms.
  - This makes the study automatically greater than minimal risk.
- Standard procedures being done for research will need to be included in the consent form as they now become research procedures.
  - Risks of these procedures will also need to be included in the consent document.
- Risks are reduced by consent, qualified personnel, and use of standardly accepted procedures.

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Can anything happen to change a study's risk rating?

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**Unanticipated problem involving risks to participants or others:**

- a. Are unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; and
- b. Are related or possibly related to participation in the research; and
- c. Suggest that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
  - Lost laptop
  - Study coordinator quits
  - Participant does not show up for his/her scheduled visit

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**THANK YOU!**

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314-747-6861

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ADDITIONAL REFERENCES

- Office of Human Research Protection’s Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
- Food and Drug Administration’s Guidance on Adverse Event Reporting to IRBs-Improving Human Subject Protection

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APPENDIX 1:  
 Criteria for approval  
 45CFR 46.111 and 21 CFR 56.111

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- 51
- **Criteria for approval 45CFR 46.111 and 21 CFR 56.111:**
    - Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
    - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

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**• Criteria for approval 45CFR 46.111 and 21 CFR 56.111:**

- Selection of subjects is equitable.
  - IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
  - When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners or pregnant women, additional safeguards have been included in the study to protect the rights and welfare of these participants.

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**• Criteria for approval 45CFR 46.111 and 21 CFR 56.111:**

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- Informed consent will be appropriately documented.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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APPENDIX 2:  
Brief Description of  
Expedited Categories

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**Expedited Categories**

- **CATEGORY 1**  
FDA approved Drugs and/or Devices used for their FDA approved indication
- **CATEGORY 2**  
Blood Samples. No more than 50 ml in a 8 week period with no more than 2 sticks per week for children.
- **CATEGORY 3**  
Prospective collection of biological specimens for research purposes by noninvasive means.

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**Expedited Categories**

**CATEGORY 4**  
Routine Noninvasive Procedures. Does not include any radiation exposure, e.g. DEXA, X-ray, PET

**CATEGORY 5**  
Data Collected; clinical or for another research study. Can keep all the identifiers needed for the study

**CATEGORY 6**  
Voice, Video, Digital, Image Recordings

**CATEGORY 7**  
Group or Behavior Characteristics like interviews, surveys, focus groups

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**Expedited Categories**  
**renewals deemed minimal risk by a full board**

- **CATEGORY 8 Previously Approved Research**  
a.) where (i) permanently closed to enrollment of new subjects; (ii) all subjects have completed all research- related interventions; and (iii) the research remains active only for long-term follow-up of subjects b.) where no subjects have been enrolled and no additional risks have been identified c.) where the remaining research activities are limited to data analysis.
- **Category 9 Previously Approved Research not using an IND or IDE**  
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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**APPENDIX 3:  
Brief Description of  
Exempt Categories**

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**Only FDA Exempt Category**

- Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

21 CFR 56.104    45 CFR 46.101(b)

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**HHS Exempt Categories**

1. Research conducted in established or commonly accepted educational settings...
2. Research involving use of educational tests, survey procedures, interview procedures, or observation of public behavior

45 CFR 46.101(b)

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**HHS Exempt Categories**

3. Research not approvable under #2 but is conducted with elected or appointed public officials or candidates for public office or federal statue requires that confidentiality of Private identifiable information will be maintained.

45 CFR 46.101(b)

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**HHS Exempt Categories**

4. Research involving the collection of existing data, documents, records, pathological specimens, or diagnostic specimens if sources are publically available or if information is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to subjects.

45 CFR 46.101(b)

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**HHS Exempt Categories**

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads

45 CFR 46.101(b)

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**APPENDIX 4:  
OPTIONS FOR  
DATA SAFETY MONITORING**

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**Data and Safety Monitoring**

- Can be defined as a planned, ongoing process of reviewing data collected in a clinical trial
  - Includes adverse event reporting
  - Other safety information
  - Changes to the protocol, consent, investigator's brochure, device pamphlet
  - Recent literature

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**What types of individuals should you select to Monitor Data and Safety?**

- Clinical expert in the field under study
- Methodological expertise (biostatistician)
- Clinical trial expertise /DMC experience

And for DSMBs you will also want:

- A non-scientist member
- Should have no conflict of interest
- Ideally, should not be affiliated with the study

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**Options include:**

- PI and IRB**  
-to review unanticipated problems, AEs, SAEs and other study events
- Independent Safety Monitor**  
-independent MD/expert/safety officer reviews unanticipated problems, AEs, and other study events and makes recommendations
- Independent Monitoring Committee**  
-small group of independent investigators and biostatisticians review data and make recommendations
- DSMB**  
-independent committee reviews interim safety and efficacy data and makes recommendations about continuation, modification or termination of the study

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**What might be recommended?**

- Continue study plan as designed
- Study continuation with major or minor changes
- Temporary suspension until some uncertainty is resolved
- Early termination of the study  
*-(i.e.) patients receiving the investigational treatment are found to be at higher risk of death than those in the control arm -or-  
-Interim analysis shows that the investigational product is of no benefit -or-  
-Unexpected, unacceptable side effects*

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**Dynamic Board Reports**  
*What do they really want to know?*

Cindy Matson, BS, CHC, CHPC  
*Sr. Executive Director, Compliance, Sanford Health*  
Ruth Krueger, MS, RRT, CHC  
*Compliance Program Administrator, Sanford Health*

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**Objectives**

- **Board expectations**
- **Key metrics**
- **Program risk and growth needs**

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**Board Structure**

- **Governance and Reporting**
  - 1 Board of Trustees - Quarterly
    - Audit and Compliance Committee - Annual
  - Operating Boards - Annually
  - Advisory Boards
  - Ad Hoc

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### Why is this topic important?

- Board report can make or break trust in compliance
- Tell the story to get the “a-ha” moment
- Crucial to know your audience
- Conversation must be world-class, to the point, effective, impactful and leave each board member informed.

Source: *Ethisphere WMEC*

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### OIG Fiduciary Duties of Board

#### Duty of Care

- (1) a corporate information and reporting system exists
- (2) the reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course.

*Synopsis of Rule of Law.* Directors are potentially liable for a breach of duty to exercise appropriate attention if they knew or should have known that employees were violating the law, declined to make a good faith effort to prevent the violation, and the lack of action was the proximate cause of damages.

Source: *OIG & ALA Resource for Healthcare Boards*  
Case Study: *Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996)

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### Questions Boards Should Ask

- Is the scope and adequacy of the compliance program aligned to the size and complexity of the organization?
- Does the scope and adequacy of the compliance program align with well recognized programs at similar companies (benchmarking)?
- What has changed in the regulatory landscape that could affect the scope and adequacy of our compliance program?
- Is our compliance program appropriately resourced to achieve a level of scope and adequacy we expect?
- Do we need a compliance expert to advise the Board?

Source: *Practical Guidance for Healthcare Boards*

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### Where to Focus Your Energy

In addition to program scope, benchmarks, risks, & resources;

- Paint a picture and tell your story
- Share insights and your perspective on key issues
- Lively, robust discussion of key metrics
- Demonstrate the depth of your knowledge and compliance program

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### What to Report?

- Internal and external investigations
- Serious issues raised in internal and external audits
- Hotline call activity
- All allegations of material fraud or senior management misconduct
- Code of conduct and/or expense reimbursement policy exceptions
- Significant regulatory changes
- Enforcement events relevant to the organization's business

Source: *Navigant – What's a Board to Do?*

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### Benchmarks - What Boards Want

- Highlighted risks up front
- Highlighted trends/changes with standardized reports
- Management insights
- Concise executive summary
- Lead time to review key summary
- Fewer acronyms and industry jargon
- Better scrutinized to remove irrelevant information
- Less formalized with more spontaneous discussion

Source: *PwC 2015 Annual Corporate Director Survey*

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### Ask Your Board What They Want

- Tailored to culture of org
- In line with organization's strategic objectives
- What are they aware of and have concerns about?
- Open investigations/settlements
  - ✓ What is the right level of detail?

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### OIG/Daniel Levinson Guidance

- "Board involvement and commitment is critical for a successful compliance program – top down approach."
- "The best boards are active, questioning, even skeptical"
- "Boards should receive **candid, timely, and comprehensive information on how organization's compliance program is operating.**"
- "Boards shouldn't make assumptions, or view their job narrowly, or shy away from tough questions."

Source: Inspector General Discusses the Importance of Health Care Compliance

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### Educate Your Board

- Give them context
- Their role in organization
  - ✓ *Principles of Good Governance and Ethical Practice*
- Broad understanding of Compliance Program
- Risks your organization faces
- Enforcement Environment

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*Design Your Report*

*Step 1*

- Size
- Scope
- Detail



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*Design your report*

*Step 2*

- Consistent
- Strategic
- Concise
- Structure
- ✓ Standardized format
- Role/responsibility
- Touch on all elements



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*Ideas for Content*

- Compliance Metrics
  - ✓ External & Internal audit findings
  - ✓ Financials by Market - paybacks
  - ✓ Hotline & Reported Concerns data - trended & benchmarked
  - ✓ Work Plan
- Open investigations
- Effectiveness initiatives
- Scrutiny by Federal/State payers
- Challenges and successes of your program

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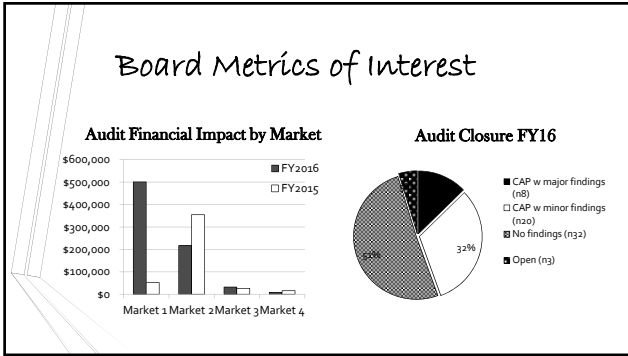
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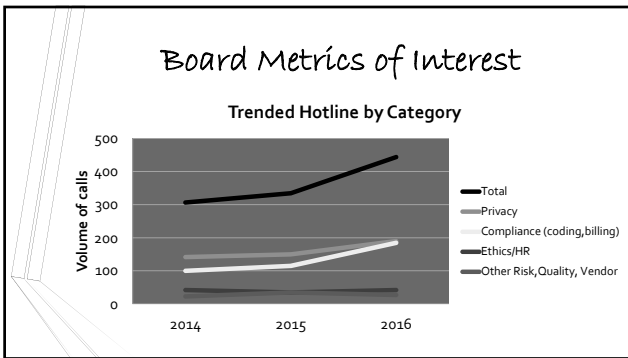
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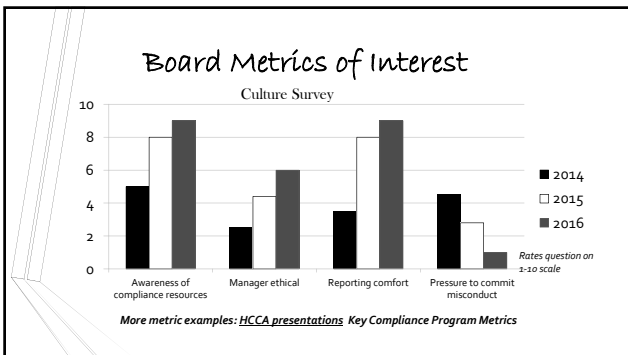
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### Board Report Examples



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### Things to Consider

OIG also recommends that the Board consider conducting regular “executive sessions” (i.e. excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to foster more open communication, and conduct these sessions on a routine basis – not only when issues arise.

Source: [Practical Guidance for Healthcare Boards](#)

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### Tips for success

- Show, don't tell
- Request a 1 on 1 with committee chair to preview report and proposed handouts for feedback
- Use plain English and avoid industry jargon and acronyms
- Don't read your report

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More Tips

- Keep it simple and to the point
  - ✓ fewer words, more punch
- Decide well before what the key takeaways are and highlight them
- Allow time for discussion
- Provide clear answers to questions – if unable, promise to research and get back with answer.

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What are your challenges/successes with board reports?



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Thank you for attending!

[Cindy.Matson@sanfordhealth.org](mailto:Cindy.Matson@sanfordhealth.org)

[Ruth.Krueger@sanfordhealth.org](mailto:Ruth.Krueger@sanfordhealth.org)

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## QUARTERLY COMPLIANCE SUMMARY

### Hotline Statistics

Total calls:  
Number anonymous:  
Number substantiated:  
Numbers with disciplinary action:

### Compliance Audits

Audit description:  
Internal or external:  
Findings:  
Corrective action taken:

Audit description:  
Internal or external:  
Findings:  
Corrective action taken:

### External Audits or Investigations

Issue description:  
Status:  
Agency involved:  
Findings:  
Repayments, settlements or fines:

### Education & Training Provided

Topic:  
Audience:  
Number attending:

Topic:  
Audience:  
Number attending:

### Compliance Initiatives

Project:  
Goal:  
Progress & expected completion date:  
Barriers:

### Regulatory & Enforcement Update

Description:  
Agency:  
Internal assessment:  
Activity needed:

## COMPLIANCE QUARTELY REPORT

Educational Focus: Employee reporting of concerns (this is an example topic)

### Discussion Questions

- Why do we want employees to report concerns?
- How do we assure they are comfortable in doing so?
- What are the ways our employees have to report?
- How does our organization compare to national reporting benchmarks?
- Why might our reporting numbers be higher/lower?
- Should we be doing anything different?

Regulatory & Enforcement Focus

May have multiple topics. Use a recent OIG settlement/report to convey information on a risk area. Apply it to your organization. How do you measure up? Do you have minor or significant risk? What controls are in place or what steps are you taking to assess those controls?

Audit Focus

May have multiple topics, include internal compliance audits as well as external sources such as MAC, RAC, SMRC, OIG, etc. Summarize risk area, reason for audit, findings and any corrective action that has occurred. Discuss controls that have been put in place to prevent future occurrences.

Program Metrics

Include graphs or tables of key metrics for quarter. Consider rotating metric by quarter or providing ad hoc metrics related to initiatives or investigations.

Program Focus

What project(s) are you currently working on and why is it important? Discuss objectives, accomplishments and barriers to the project and how you will measure success.

## ANNUAL BOARD REPORT

### **Program Overview**

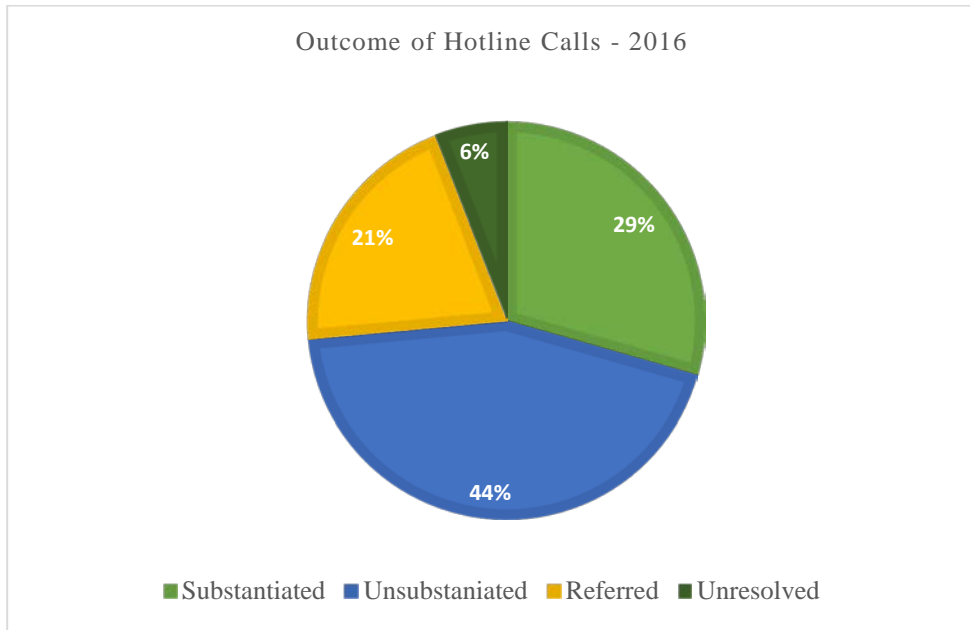
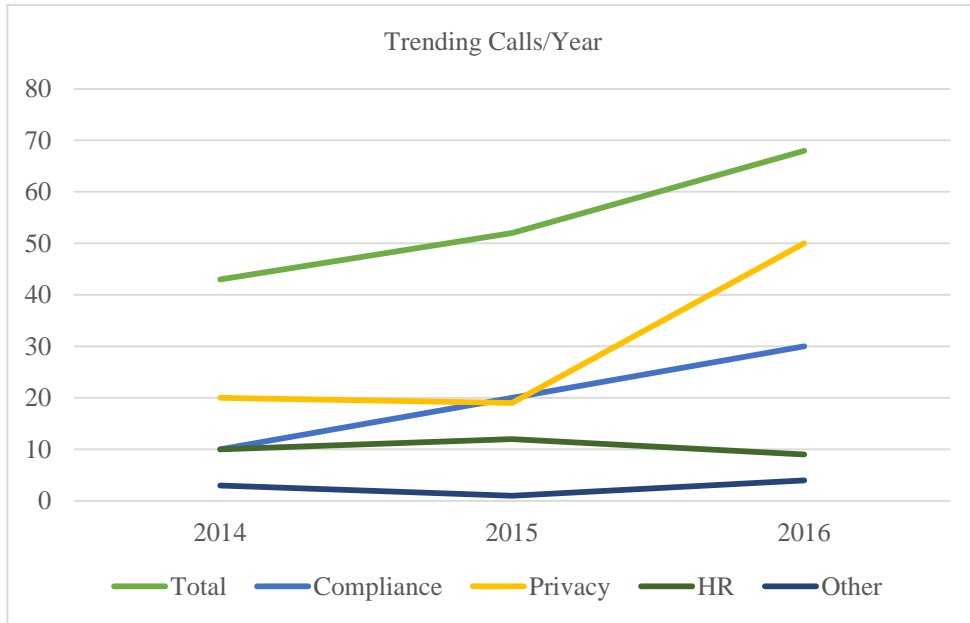
*Describe key components of program, strategic plans for program development and major milestones met. Also potentially discuss strengths, weaknesses and threats to the program.*

### **Compliance Developments & Emerging Risk Areas**

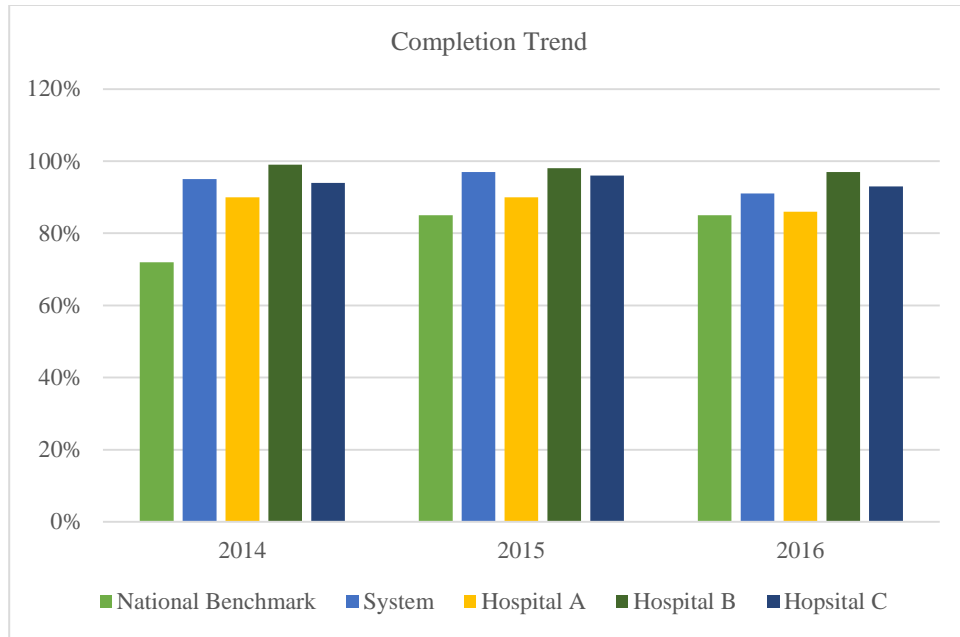
*Provide updates on developments regarding new and existing regulatory changes, risk areas as well significant investigations and enforcement activity within the industry.*



## Compliance Hotline Activity



## Compliance Training



## QUARTERLY COMPLIANCE SUMMARY

### Hotline Statistics

Total calls:  
Number anonymous:  
Number substantiated:  
Numbers with disciplinary action:

### Compliance Audits

Audit description:  
Internal or external:  
Findings:  
Corrective action taken:

Audit description:  
Internal or external:  
Findings:  
Corrective action taken:

### External Audits or Investigations

Issue description:  
Status:  
Agency involved:  
Findings:  
Repayments, settlements or fines:

### Education & Training Provided

Topic:  
Audience:  
Number attending:

Topic:  
Audience:  
Number attending:

### Compliance Initiatives

Project:  
Goal:  
Progress & expected completion date:  
Barriers:

### Regulatory & Enforcement Update

Description:  
Agency:  
Internal assessment:  
Activity needed:



### 409 - How to Get More LinkedIn Views Than Roy:

Practical Tips for Improving Your LinkedIn Profile & Getting Employers to Seek You Out



Brenda Manning, JD, CHC, CHPC  
Privacy & Regulatory Affairs Director  
University of Minnesota Physicians  
[bmanning10@umphysicians.umn.edu](mailto:bmanning10@umphysicians.umn.edu)  
[www.linkedin.com/in/brendamanning](http://www.linkedin.com/in/brendamanning)

HCCA 21<sup>st</sup> Annual Compliance Institute  
Gaylord National in National Harbor, MD  
March 26 – 29, 2017

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### The Secret to Surviving a Job Search

- Determination
- Flexibility
- Resilience
- Gratitude



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### Today's Presentation

Discuss Tips For:

- Creating a Strong First Impression
  - With your LinkedIn Profile
  - Resume
- Job Application Strategies
- Having a Winning Interview Experience

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What is



- Not just a "Job Site"
- Social media marketing
- 400 million+ users, about ¼ of them active
  - In over 200 countries & territories
  - Founded in Dec 2002
  - Acquired by Microsoft in June 2016
  - Considered the 14<sup>th</sup> most popular website in the world

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### Being Successful on LinkedIn

- Depends on goal
- Want a new job? Be active!
  - Be mindful of your posts
- Creating profile & doing nothing will accomplish little
- Rewards users / activity
- Secret algorithm
  - All-star profile status
  - 500+ connections
  - Participation




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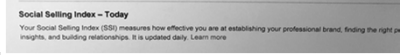
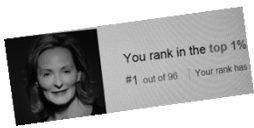
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### Vanity Metrics

- Pretty Meaningless
- Premium member only metrics
- *Quality vs. Quantity*
- SSI




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### Top Ways to Get a Job

- *Recruiters*
  - Accounts for about 10% of the market
  - You can't hire
  - Work for companies, not applicants
- *Networking*
  - About 70% of hiring occurs in this fashion ←
  - It really is about who you know!
- *Online Applications / Job Boards*
  - About 20% of the job market

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### Create a Brand

- Convey a consistent brand / message professionally
  - Your photo, name, tag lines etc... should be consistent across platforms
  - LinkedIn, Twitter, HCCA, work intranet
  - Get ideas by looking at profiles of like professionals
  - Hire consultant




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### Professional Name

- Use name on resume
- Insert nickname in the middle if necessary
  - James "Jim" Johnson
- No fake names, or First name last initials
  - James B.
- Credentials after your last name if add value
  - James "Jim" Johnson, JD, CHC
  - James Johnson, JD (attorneys typically don't use this credential – use your discretion)

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### Happy Professional Photo

Ghost 



- Headshot should be happy, 😊 smiling, forward facing, preferably color
- Business / business casual attire
- Lighter, non-distracting background
- Professional photos are great
  - Save \$\$ with cell-phone photo, edit with apps such as Perfect 365

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### Create a Branded Background Photo

- Access by editing your profile, selecting “edit background photo”
- Customize using Youzign or Canva
- Tip: <http://linkedinriches.com/profile/> John Nemo free LI how to videos




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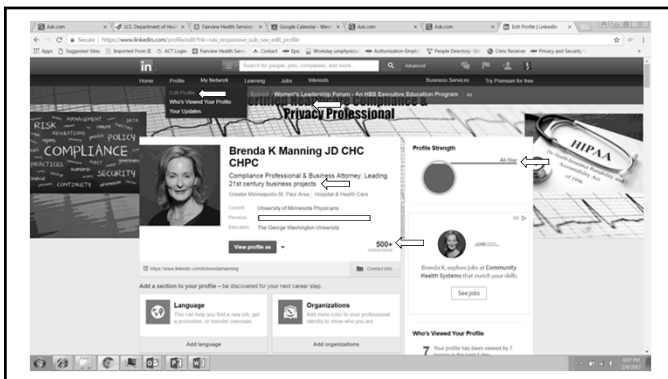
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### Branded Headline

- Defaults to your current Job Title
- Should reflect your brand → who you are as a professional
  - 120 characters, first 68 characters show on mobile app
  - Consider emoji's / vary with capitals
  - Choose something that will set you apart when you are on a recruiter list or being viewed by others

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### Sample Headlines

Great:  
 Independent Contractor Specializing in Social Security Filings for Local Attorneys & Advocacy for Disabled Individuals  
 Compliance Officer | Attorney | Health Law | E-Health | Privacy & Information Security | Fraud & Abuse | Reimbursement  
 HITRUST Expert, Risk Management, HIPAA, OCR Audit, Compliance, CyberRisk, IT/IS Strategy, Management Consulting

Avoid:  
 Director, Regulatory Affairs at XYZ Healthcare  
 Unemployed  
 Seeking New Opportunitites (note the typo!!!)  
 Attorney  
 Privacy & Compliance Professional

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### Summarize Who You Are

- 2,000 characters, first 62 characters show on mobile app
- LI is NOT your resume
- Use this section to tell a little about yourself
  - What you do, why someone should hire you
  - Consider using a video
  - Ageism: don't lead with "25 years experience"
  - Keywords / Core Competencies
  - "seeking new opportunities"
  - Highlight achievements

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**WHO I AM**  
 I am a solutions-based, multi-disciplined, counsel poised to work cross-functionally to deliver legal insight and business analysis in areas centered on healthcare compliance & privacy, with a strong focus on business improvement initiatives, strategic planning, and excellent implementation proficiencies. I would describe myself as a high energy, down to earth, glass is half full type person who thoroughly enjoys helping others and is everything but the stereotypical stuffy lawyer.

**MY PHILOSOPHY**  
 I believe in approaching compliance from a solution oriented perspective, working with people within the organization to help them accomplish the goals of the business while operating within the confines of the law. I believe when compliance is approached in a positive fashion, you are more likely to have employees come to you with issues, embrace compliance and achieve overall better results for the organization.

**WHAT I DO**  
 I am a forward-thinking professional who implements governance and public affairs policies by interpreting new regulations and laws while liaising with management, recommending strategies and leading teams.

**HIGHLIGHTS:**  
 High-energy attorney, board certified in healthcare compliance and healthcare privacy with 16 years of compliance experience and proven track record of being approachable leader with business insight.  
 Proven team player able to support other attorneys and business professionals in cross-functional settings  
 Clearly communicate ideas and thoughts so that all engaged parties are capable of understanding and implementing a plan of action

**MY CORE SKILLS**  
 Compliance & Privacy Law | HIPAA & HITECH | Information Security | Risk Management | Creative Thinking | FDCA | Business Intelligence | Business Process Innovation | Negotiation & Contract Review | Transactional Legal Skills | Internal & External Reporting | Communication Skills

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**Highlight Relevant Experience**

- Work History
- Use "key words"
  - Including in your job title if necessary
  - Descriptors can be added to your title with this line: |
    - Example: Privacy Manager | Risk Management | Compliance
- Put dates, limit this to about 10 years (case by case)
- Not your job description
- List accomplishments / achievements




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**Associate Attorney | Social Security | Medicaid | Patient Advocate**

September 1998 – December 2016 (18 years 4 months) | Waukegan, IL

Advocate for uninsured hospital patients at administrative Medicaid hearings on behalf of client hospitals seeking reimbursement for this Circuit Court and appellate level practice; extensive experience writing briefs and conducting oral arguments.

**SPECIFIC ACCOMPLISHMENTS:**

**PROJECT MANAGEMENT:** 11 years managing firm's Social Security Disability program, including representing a select group of hospital patients from our client hospitals and program project management

**CROSS-FUNCTIONAL LEADERSHIP:** Manage all Medicaid litigation, working in as many as 12 states and managing appeal staff in multiple locations

**RESEARCH:** Assist managing attorney in wide variety of legal research and complex civil litigation matters both State and Federal and miscellaneous business matters

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### Relevant Education & Certifications

- List your education & certifications
- Do not list dates or GPA's unless you just graduated & had a 4.0

#### Education

The George Washington University  
 Graduate Certificate, Healthcare Corporate Compliance  
 Graduate level healthcare corporate compliance program with a focus on federal healthcare programs, Anti-kickback Law, Stark Law, EMTALA, False Claims Act, Corporate Responsibility, HIPAA, 501(c)(3) Tax Exemption and Anti-Trust




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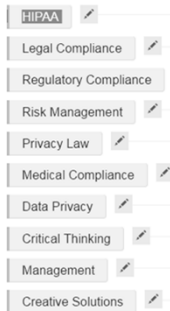
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### Skills & Endorsements

- Add up to 50 skills
- Rank them in order of importance
- Endorse others for their skills & they will return the favor




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### Create a Winning Network

- 500+ = "magic number"
- Personalize invites
- Start with family, friends, former classmates & coworkers
  - Don't limit to your industry
  - Join groups
  - Comment on articles
  - Connections will naturally follow




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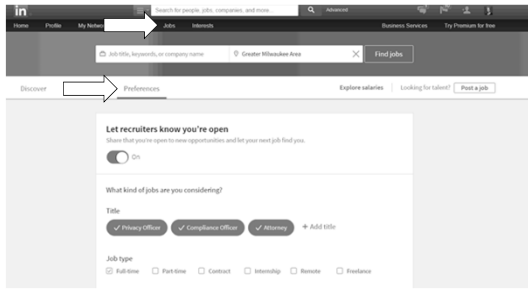
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### Signal Recruiters




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### Suggested Influencers & Groups

- *Consider following:* J.T. O'Donnell, John Nemo, Liz Ryan, Lou Adler, Lauren McDonald, Wendy Weiner, Dr. Travis Bradberry, Virginia Franco, Lisa Rangel, Bruce Hurwitz, Forbes, Paul Copcutt
- *Consider joining:* LinkedIn Job Seekers – free for 30 days
- *Groups:* HCCA, SCCE, International Association of Privacy Professionals, ISACA

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### Tips for Applying Online

- 1) Find a great job board(s)
- 2) Professionally branded resume
- 3) Customize with JobScan
- 4) Submit a cover Letter
- 5) Contact the job poster/ hiring manager/insider
- 6) If rejected consider sending a thank-you




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### Job Boards

- HCCA / SCCE (\*Gold for compliance professionals\*)
- Indeed
- LinkedIn
- Jobcase
- Local job boards
- Bar associations
- Flexjobs.com (work at home opportunities)
- Network w/friends for suggestions




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### Create a Strong Resume First Impression

- 6 second Rule
- Branded resume = Short **marketing document**
  - Prices range from \$199 - \$3,000 for resumes & packages
  - Mid-level → \$450 - \$700
  - Should be collaborative process




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### Resume Format - Header

- Have a headline something like this at the top of your resume:

JOHN SMITH JD, CHC, CHPC  
 123-456-7890  
 JOHNSMITH@GMAIL.COM  
 HTTPS://WWW.LINKEDIN.COM/IN/JOHNSMITH

- Key features: name, cell phone, email, LI Vanity URL
- You should use this same information for your email signature

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### Resume Format – Executive Summary

- Should be below your header - conveys a consistent brand message about who you are

PUT YOUR BRAND TITLE HERE USE A | TO SEPARATE TO ADD A DESCRIPTOR TO YOUR JOB TITLE

Now describe briefly in about 2-3 lines, who you are as a professional & what you deliver. What is your brand? Try to include keywords.

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### Resume Format – Core Competencies

- These are keywords that you will find in job descriptions
  - May need to tweak from job to job
- See the LI skills section for additional ideas
- Aim for 6-12 bullet points

CORE COMPETENCIES		
<ul style="list-style-type: none"> <li>✓ HIPAA</li> <li>✓ Risk Management</li> </ul>	<ul style="list-style-type: none"> <li>✓ Auditing</li> <li>✓ Communication Skills</li> </ul>	<ul style="list-style-type: none"> <li>✓ Management</li> <li>✓ Six Sigma Black Belt</li> </ul>

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### Sample Chronological Resume

**BRENDA MANNING JD, CHC, CHPC**

ANYWHERE, USA 12345  
 123-456-7890  
 My EMAIL ADDRESS HERE  
[HTTPS://WWW.LINKEDIN.COM/IN/BRENDAMANNING](https://www.linkedin.com/in/brendamanning)

**COMPLIANCE PROFESSIONAL | HEALTHCARE ATTORNEY**

1 – 2 SENTENCES ABOUT WHO YOU ARE & WHAT YOU BRING TO THE TABLE

**CORE COMPETENCIES**

- |  |  |   |
|--|--|---|
| <ul style="list-style-type: none"> <li>✓ HIPAA</li> <li>✓ Legal Compliance</li> <li>✓ Regulatory Compliance</li> </ul> | <ul style="list-style-type: none"> <li>✓ Risk Management</li> <li>✓ Privacy Law</li> <li>✓ Medical Compliance</li> </ul> | <ul style="list-style-type: none"> <li>✓ Data Privacy</li> <li>✓ Critical Thinking</li> <li>✓ Management</li> </ul> |
|--|--|---|

**RECENT RELEVANT EXPERIENCE**

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## Finishing the Resume



- Work experience
  - 10 years
  - Case by case
- Education – no dates
- Relevant Certifications / Licenses

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## Defeat Applicant Tracking Software

- <https://www.jobscan.co/>
- Many companies use ATS
- About 72% of resumes never seen by humans
- Past resume & ad, scan to compare
- Goal → 80% match
- Tweak keywords
- 5 free scans /mo or paid subscription

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## Match Rate

Great Job! You've reached 80% and increased your chances of being seen by a recruiter.

### Hard Skills

Hard skills are often skills learned through training, such as proficiency with specific software, tools, or other specialized skills. Below are the hard skills and their frequencies in your resume and job description. Skills denoted by **X** are found in the job description, but not your resume.

#### Resume

- 4 Hipsa
- X** Health
- 3 Legal
- 1 Operations
- 2 Training
- 2 Counsel
- 2 Research
- X** Policies
- 1 Content
- 1 Documenting
- 1 Investigations
- 1 Policies And Procedures
- X** Partnerships
- X** Medical Center
- X** Procedures

#### Job Description

- 24 Hipsa
- 11 Health
- 6 Legal
- 5 Operations
- 4 Training
- 4 Counsel
- 4 Research
- 2 Policies
- 1 Content
- 1 Documenting
- 1 Investigations
- 1 Policies And Procedures
- 1 Partnerships
- 1 Medical Center
- 1 Procedures

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### Show Off Your Writing Skills

- Cover Letters: Are they really necessary?
- Yes!
- Very few people do them
  - Demonstrates your writing abilities
- You can use "Dear Hiring Manager" if you have to
  - Try to find out the specific name of who it is going to

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### Reach Out After You Apply

- Don't just apply, sit back, wait 4 phone 2 ring!
  - Be proactive!
- After you apply try to locate the hiring manager or HR
  - Many HCCA listings & LI postings include
  - You can also call the company
  - Ask your connections
- Send brief email or inMail on LinkedIn
- Introducing yourself is a great start

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### Don't Wing It!



- Interview = *Not about YOU!*
- Homework, homework, homework!
  - The more you prepare the more you will be rewarded
- Consider a coach
  - Approximately \$200/hour 3 hours for \$500
- Research the company (Web, LI, Twitter)
- Research the interviewer

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### The Rejection Thank You

- Be gracious in rejection
- J.T. O'Donnell technique
- Letter not necessary, but nice email works
  - Thank person for their time & consideration
  - If you know about other opportunities, use this as an opportunity to see if you can get an interview for those positions
  - You never know when choice #1 isn't going to work out!

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### References

- Virginia Franco, *LinkedIn Great to Haves and Can't Do Withouts*, June 5, 2016, available at <https://www.linkedin.com/pulse/linkedin-great-haves-cant-do-withouts-virginia?published=t>
- Virginia Franco, *Three Key Differences Between LinkedIn and Your Resume*, June 5, 2016, available at <http://virginiafrancoresumes.com/three-key-differences-between-linkedin-and-your-resume/>
- Catherine Conlan, *5 Ways Your Resume Is Screaming Unprofessional*, available at <https://www.monster.com/career-advice/article/ways-resume-screams-unprofessional>
- Wendy Weiner, *The Top 5 Things Holding Your Executive Resume Back from Being Effective*, June 27, 2016, available at <https://www.linkedin.com/pulse/top-5-things-holding-your-executive-resume-back-from-trk-prof-post>
- Wendy Weiner, *Times New Roman, Dubbed The 'Sweatpants' Of Fonts, Is A Bad Choice For Résumés: Typography Experts*, April 29, 2015, available at [http://www.huffingtonpost.com/2015/04/28/times-new-roman-resume-best-worst-fonts\\_n\\_7167390.html](http://www.huffingtonpost.com/2015/04/28/times-new-roman-resume-best-worst-fonts_n_7167390.html)
- John Nemo, *Free Video Training: How to Create a Killer LinkedIn Profile*, available at <http://linkedinriches.com/profile/>
- You can find certified resume writers, interview coaches etc.. at <http://careerthoughtleaders.com>

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## 1 Create a Strong LinkedIn Profile First Impression

- **All Star Profile**
  - Professional looking photo
  - Branded headline
  - 2,000 character summary
  - Key word rich
  - Achievement oriented
- **Make Profile Public**
- **Activate Recruiter Tab**
- **Be Active!**
  - Comment, post, join groups, publish
- **Network!**
  - Go beyond your industry

## 2 Create a Successful Resume and Application

- **Goal: Create Brief Marketing Document**
  - Well organized & streamlined
  - Use bullets to break up text
  - Center headings
  - Brutally edit
  - 6-12 core competencies
  - Be honest
  - Key word rich
  - Leave dates of education off
  - Achievement / results oriented
  - Be professional (no ornate fonts, colored paper, photos or emojis)
  - Don't state the obvious (team player, detail oriented)
  - Aim to apply mid-week
- **Email your materials in a professional manner**  
 (include a cover letter, save document with professional title John.Smith.ComplianceOfficerResume, include a brief note with your email and send from a professional sounding email address)

## 3 Have a Winning Interview Experience

- **Details Make the Difference** (avoid perfumes, clean car, arrive 10 min early, be kind to receptionist)
- **Prepare, Prepare, Prepare**
  - Research common interview questions and write out the answers
  - Never seem rehearsed
  - Research the company and your interviewer
  - Watch an online body language video
  - Mirror the energy of your interviewer
  - Bring copies (job description, resume, questions, etc.)
- **Always Express Appreciation and Always Follow-Up**

## 4 Be a Virtual Super Star!

Phone Interview	Video Chat Interview
<ul style="list-style-type: none"> <li>▪ Use landline for optimal sound quality</li> <li>▪ Stand up for optimal voice quality</li> <li>▪ Smile 😊</li> <li>▪ Tape notes in front of you</li> <li>▪ Have interviewer's photo in front of you</li> </ul>	<ul style="list-style-type: none"> <li>▪ Stage your background</li> <li>▪ Check lighting</li> <li>▪ Research best online colors and patterns</li> <li>▪ Verify camera positioning</li> <li>▪ Do a test run in your outfit</li> <li>▪ Verify power source</li> <li>▪ Place critical post-it notes on laptop edge</li> </ul>

Session 410:

Medicare FDRs and Compliance Programs:  
What the Feds Expect and Tips for Ensuring  
Your Organization Satisfies the Requirements

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HCCA 21<sup>th</sup> Annual Compliance Institute

Catherine M. Boerner, Boerner Consulting LLC  
Heather Fields, Reinhart Boerner Van Deuren s.c.  
Jenny M. O'Brien, UnitedHealthcare

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Presentation Overview

- Understand the current status of Medicare managed care compliance program requirements for "first tier" and "downstream" and "related" entities
- Learn how to effectively achieve compliance
- Gain insights for negotiating compliance program provisions in managed care agreements

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FDRs =  
"First tier",  
"Downstream" and  
"Related" entities

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**FDRs: Who is a First Tier Entity?**

- **First Tier Entity** - A party that enters into a written arrangement with a Medicare Advantage Organization ("MAO") or Part D plan sponsor to provide:
  - Administrative services (e.g., marketing, utilization management, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, provider credentialing); or
  - Health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program (e.g., independent practice association, hospital, PHO)

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**FDRs: Who is a Downstream Entity?**

- **Downstream Entity** – A party that enters into a written arrangement with a First Tier entity for the provision of administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program
  - Hospital within a health system that has entered into a system level agreement
  - Credentialing verification organization

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**FDRs: Who is a Related Entity?**

- **Related Entity** - Any entity that is related to the sponsor by common ownership or control and either: (1) performs some of the sponsor's management of functions under a contract of delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the sponsor at a cost of more than \$2,500 during a contract period

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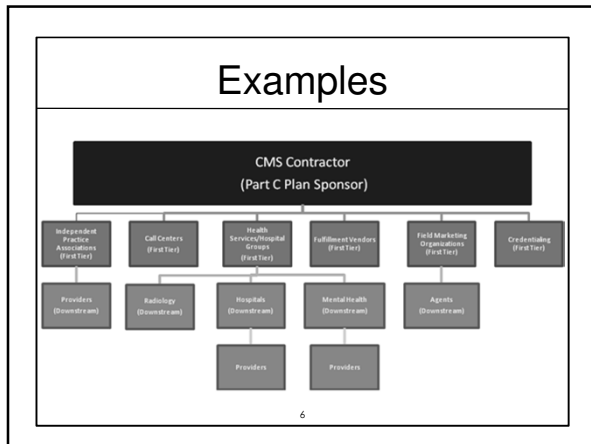
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- ### FDR Spotting: CMS' Factors To Consider
- Impact on enrollees
  - Extent of interaction with enrollees (orally or written)
  - Access to PHI
  - Decision-making authority
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**So.....Now What?!**  
**IF FDR, THEN COMPLY WITH**  
**PART C/D COMPLIANCE**  
**PROGRAM REQUIREMENTS**

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### What are FDRs Required to Do?

- Regulatory (and Organizational) Expectations
  - Sponsors/FDRs need to exercise oversight of subcontractor's compliance efforts (e.g., vendor management program), if Part C/D administrative, management or clinical functions are delegated
  - FDRs must maintain an effective compliance program that meets the compliance program requirements for Medicare Part C/D plans
  - FDRs must have systems in place to train employees regarding FWA (if no deemed status) and general compliance (e.g., standards of conduct, HIPAA)
  - FDRs must investigate, correct and document all instances of suspected non-compliance

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### The Seven Elements: Compliance Program Requirements

CMS requires that an effective compliance program must include seven core requirements:

1. Written Policies, Procedures, and Standards of Conduct
2. Compliance Officer, Compliance Committee, and High-Level Oversight
3. Effective Training and Education
4. Effective Lines of Communication
5. Well-Publicized Disciplinary Standards
6. Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks
7. Procedures and System for Prompt Response to Compliance Issues

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### Assessing Compliance

- Review CMS' audit program - Part C and D Compliance Program Effectiveness (CPE) Program
  - CPE Self-Assessment Questionnaire
  - CPE Compliance Officer Questionnaire
- Conduct a gap analysis:
  - Compare your current program against CPE requirements
  - Compare your program to your MA/Part D contracts

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**CMS Part C and D Compliance  
Program Effectiveness (CPE)  
Program Area**

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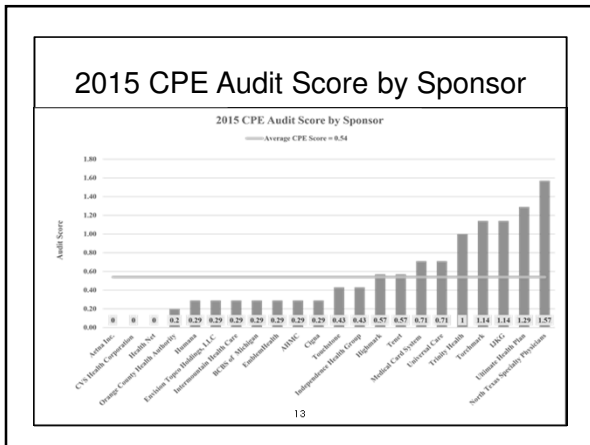
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2015 CPE Most Common Conditions: Condition Language	Citation Frequency 2011- Present	Percentage of Sponsors Affected 2015
Sponsor did not have an effective system to monitor first tier, downstream related entities' (FDRs') compliance with Medicare program requirements	3 out of 6	36.3%
Sponsor did not provide evidence that general compliance information was communicated to its first tier, downstream related entities (FDRs)	2 out of 6	27.2%
Sponsor did not have procedures to ensure that its first tier, downstream related entities (FDRs) are not excluded from participation in federal health care programs.	1 out of 6	27.2%

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2015 CPE Most Common Conditions: Condition Language	Citation Frequency 2011- Present	Percentage of Sponsors Affected 2015
Sponsor's compliance officer or his/her designee does not provide updates on results of monitoring, auditing, and compliance failures (i.e. Notices of Noncompliance to formal enforcement actions) to: • compliance committee, • senior executive/CEO, • senior leadership, and • governing body	3 out of 6	27.2%
Sponsor did not establish and implement a formal risk assessment and an effective system for routine monitoring and auditing of identified compliance risks.	3 out of 6	27.2%

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### 2017 CMS Program Audit Process

CMS will send routine engagement letters to initiate audits beginning February 21, 2017 through September 25, 2017.

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### CPE Audit Process and Data Request

- 2017 Program Audit Process Overview
- Attachment I – CPE Audit Process Data Request
- Attachment I-A – CPE Self-Assessment Questionnaire
- Attachment I-B – CPE Compliance Officer Questionnaire
- Attachment I-C – CPE Organizational Structure Governance PPT
- Attachment I-D – CPE FDR Oversight Questionnaire
- Attachment I-E – CPE SIU FWA Prevention and Detection Questionnaire

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**Universe Preparation & Submission**

- Attachment I – CPE Audit Process Data Request
  - Appendix A – Compliance Program Effectiveness (CPE) Record Layouts
    - Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout
    - Table 2: Employees and Compliance Team (ECT) Record Layout
    - Table 3: Internal Auditing (IA) Record Layout
    - Table 4: Internal Monitoring (IM) Record Layout

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**Universe Preparation & Submission**

- Appendix A – Compliance Program Effectiveness (CPE) Record Layout
  - Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout
    - First-tier entities that have entered into a written agreement with a sponsor to provide administrative or health care services to Medicare enrollees under the Part C and/or D program that have been audited or monitored within the audit review period.

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**CPE Self-Assessment Questionnaire**

- FDR Oversight Sponsor Accountability for and Oversight of FDRs
- FDR Oversight Written Policies and Procedures and Standards of Conduct
  - Do you ensure that either your Standards of Conduct and Ps & Ps or comparable Standards of Conduct and Ps & Ps are distributed to FDR's employees within 90 days of hire / contracting and annually thereafter?
- FDR Oversight Effective Training and Education
- FDR Oversight Monitoring and Auditing FDRs
- FDRs: Procedures and System for Prompt Response to Compliance Issues

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**CPE Compliance Officer Questionnaire**

- What are some of the tools used to keep the compliance department up-to-date on tasks and assignments that have been delegated to both operational and FDRs?
- Provide an example of a compliance issue you had to deal with during the audit review period that involved a Medicare operational area and/or a first-tier, downstream or related entity (FDR) and impacted a significant number of your enrollees from receiving their health or drug benefits time in accordance with CMS requirements. Describe what happened and how you handled it.
- Provide an example of a time when communicating compliance issues to the compliance committee, senior management or governing body regarding was challenging. Briefly discuss how you handled it.

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**CPE FDR Oversight Questionnaire**

- How long have you been employed with the sponsor and been involved with overseeing FDRs?
- Who or which business operations are involved with the pre-contractual assessment to ensure contractual and regulatory obligations are met.
- Describe specific examples of the types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?
- Provide examples of the types of periodic monitoring reports your organization receives from FDRs?
- What are a few of the challenges or issues with effectively overseeing FDRs your organization has experienced within the audit review period (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.).

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**Compliance Training**

- Two types of required training: (1) General Compliance; and (2) Fraud, Waste and Abuse ("FWA")
- Must be completed within 90 days and annually thereafter
- FDRs must maintain certificates or documentation of training completion and must furnish to CMS upon request
- Deemed status:
  - FDRs that have met the FWA certification requirements through enrollment in the Medicare program are deemed to have met the FWA training requirement
  - Still need to complete the general compliance training

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**Compliance Training Options**

- **February 10, 2016** CMS Memo – “Additional Guidance – Compliance Training Requirements and Audit Process Update
- Now three options for training:
  - (1) FDRs can complete the general compliance and/or FWA training modules located on the CMS MLN
  - (2) Sponsors and FDRs can incorporate the content of the CMS standardized training modules from the CMS website into their organizations’ existing compliance training materials/systems
  - (3) Sponsors and FDRs can incorporate the content of the CMS training modules into written documents for providers (e.g. Provider Guides, Participation Manuals, Business Associate Agreements, etc.)

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**Who Needs to Be Trained?**

- MA plans should work with FDRs and specify which positions within the FDR must complete the training.
- FDRs (e.g. hospitals, labs, providers) should contact the sponsor’s compliance officer and discuss the December 28, 2015 and February 10, 2016 “ Additional Guidance – Compliance Program Training Requirements and Audit Process Update” memorandums to determine the critical roles within an FDR that are subject to the compliance training requirement.

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**Who Needs to Be Trained?**

- Examples of critical roles that should clearly be required to fulfill the training requirements:
  - Senior administrators or managers directly responsible for the FDR’s contract with the Sponsor.
  - Individuals directly involved with establishing and administering the Sponsor’s formulary and/or medical benefits coverage policies and procedures.
  - Individuals involved with decision-making authority on behalf of the Sponsor (e.g. clinical decisions, coverage determinations, etc.).
  - Reviewers of beneficiary claims and services submitted for payment; or
  - Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

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**Examples of Who to Train:**

- Providers (e.g. Physicians, Chiropractors, Dentists)
- Nurses and nurses' aides
- Laboratory and radiology technicians
- Pharmacists and pharmacy technicians
- Therapists
- Social Workers
- Home Health Aides
- Medical coding staff
- Medical records staff
- Medical directors
- Billing staff, including certified coders, and pharmacy or medical claims processors

27 Aetna, June 2016

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**Examples of Who Not to Train:**

- Housekeeping and custodial staff
- Cafeteria workers
- Grounds and maintenance workers
- General receptionists and front desk coordinators (without access to PHI/member ID cards)
- Retail staff (e.g., gift shops, pharmacy)
- Non clinical administrative and clerical staff (e.g. human resources, payroll, administrative assistants)
- Machine repairmen
- Purchasing agents/assistant or logistics coordinators

28 Aetna, June 2016

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**CPE Audit Process**

- Tracer Evaluation
  - Sample Selection
  - Tracer Case Summary
  - Supporting Documentation
- Audit Elements
  - Prevention Controls and Activities (1.1 – 1.6)
  - Detection Controls and Activities (1.1 – 1.7)
  - Correction Controls and Activities (1.1 – 1.2)

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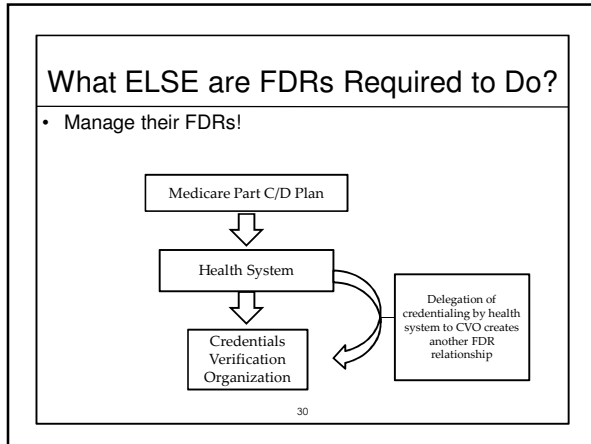
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- ### Elements of an Effective Vendor Oversight Program
- Structured Procurement Process
  - Proper Identification and Classification
  - Communication Strategy
  - Training and Education
  - Risk Management
  - Vendor Off-Boarding
- 31
- 3/8/2017

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- ### Structured Procurement Process
- Effective oversight begins with formal procurement processes including accountability for sourcing, contracting and purchasing goods and services from vendors
  - Processes may include:
    - Formal engagement policies and procedures
    - Formal sourcing review
    - Formal contractual agreement between the organization and the vendor
    - Use of a structured contract management system
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**Proper Identification and Classification**

- Organizations should have formal process to properly identify and classify vendors
- Processes may include:
  - Designations of the specified delegated service
  - Cost of delegated service
  - Impact and level of access to the end consumer
  - Access to Personally Identifiable Information (PII), Personal Health Information (PHI), or Payment Card Industry (PCI)
  - Relationship to government contracts

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**Communication Strategy**

- Effective communication between the organization and the vendor is critical to ensure a successful relationship
- Processes may include:
  - Your organization's code of conduct
  - Policies and procedures directly related to the specified delegated service
  - Main contracts for managing the relationship between the organization and the vendor
  - Distribution of performance metrics
  - Frequency of performance meetings
  - Communication protocols for compliance concerns
    - Compliance Liaison

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**Training & Education**

- When an organization delegates administrative functions to a vendor, they are not simply delegating a task ... they are sharing their organization expectations around culture, mission and values
- Materials should include:
  - Organization's Code of Conduct
  - General compliance expectations/information
  - How to report suspected Fraud, Waste, Abuse and other compliance concerns
  - Operational performance metrics/expectations
  - Scope of delegated functions

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**Risk Management**

- Vendor performance must be monitored similar to business performance to ensure delegated functions are being performed as expected/contracted
- Types of Monitoring:
  - Vary dependent on delegated services
  - Key performance measures
  - Compliance with contractual requirements
  - Consider survey/attestations
- Remediation:
  - Reporting and escalation process
  - Validate and test corrective actions
  - Consequences in contract for non-compliance

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**Vendor Off-Boarding**

- While effective on-boarding is important – don't forget a check list when off-boarding
- Risks to Monitor
  - Exposure to PHI, etc.
  - Need to get information for regulatory audits after relationship ends
  - Reputational Risk
  - Unnecessarily providing monetary compensation to vendor once contract ends

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**Effectively Negotiating  
Compliance Program Provisions  
in Part C/D Agreements**

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Ensure Legal/Compliance Staff Involved in Negotiation and Operationalization of Compliance Provisions

- Need process in place for managed care staff to coordinate with legal/compliance before negotiating/executing Part C/D contracts
- Need process in place to identify downstream entities and ensure required contractual provisions included
- Need process to review attestations and process any questionnaires related to compliance requirements
- Consider sample provisions regarding code of conduct, policies and procedures and training requirements (including who will be trained)

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Whose Code of Conduct?

- Many sponsors require use/dissemination of their code of conduct in their contracts
- FDR response:
  - CMS does not require that FDRs adopt the sponsors code of conduct
  - Effective compliance program cannot have multiple codes of conduct
  - Training efforts tailored to organization's code of conduct

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Who needs to be trained?

- Many sponsors have broad language regarding application of compliance training requirements
- FDR Response:
  - Limit training program to those critical roles within the FDR (others may not be subject to the compliance training requirement)
  - Refer sponsor to December 28, 2015 and February 10, 2016 " Additional Guidance – Compliance Program Training Requirements and Audit Process Update" memorandums for support

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**Audit Response Provisions**

- Many sponsors include broad audit rights in contract
- FDR Response:
  - Consider time/manner/scope of audit requirements
  - Consider allocation of audit costs

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**Compliance Attestations**

- Many sponsors have annual attestation process as part of vendor management
- FDR Response:
  - Consider identifying individual (by title) to whom attestation will be sent
  - Consider requesting form of attestation in advance (attachment to agreement)

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**Operationalizing the Agreement**

- Remember that final agreement requirements must be operationalized
  - Document completion of required training
  - Institute processes for downstream entity monitoring, if needed
  - Review policies and procedures regarding general compliance, FWA, nonretaliation and prompt response to compliance issues
  - Review compliance reporting mechanisms to ensure required reporting to sponsor occurs
  - Document exclusion checks

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## Questions?



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3/8/2017

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## Resources

- Regulatory Requirements: 42 C.F.R. § 422.503 and 42 C.F.R. § 423.504
- Compliance Guidance: <http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html>
- Training Materials: <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>

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# **2017 Program Audit Process Overview**

Medicare Parts C and D  
Oversight and Enforcement Group

Division of Audit Operations

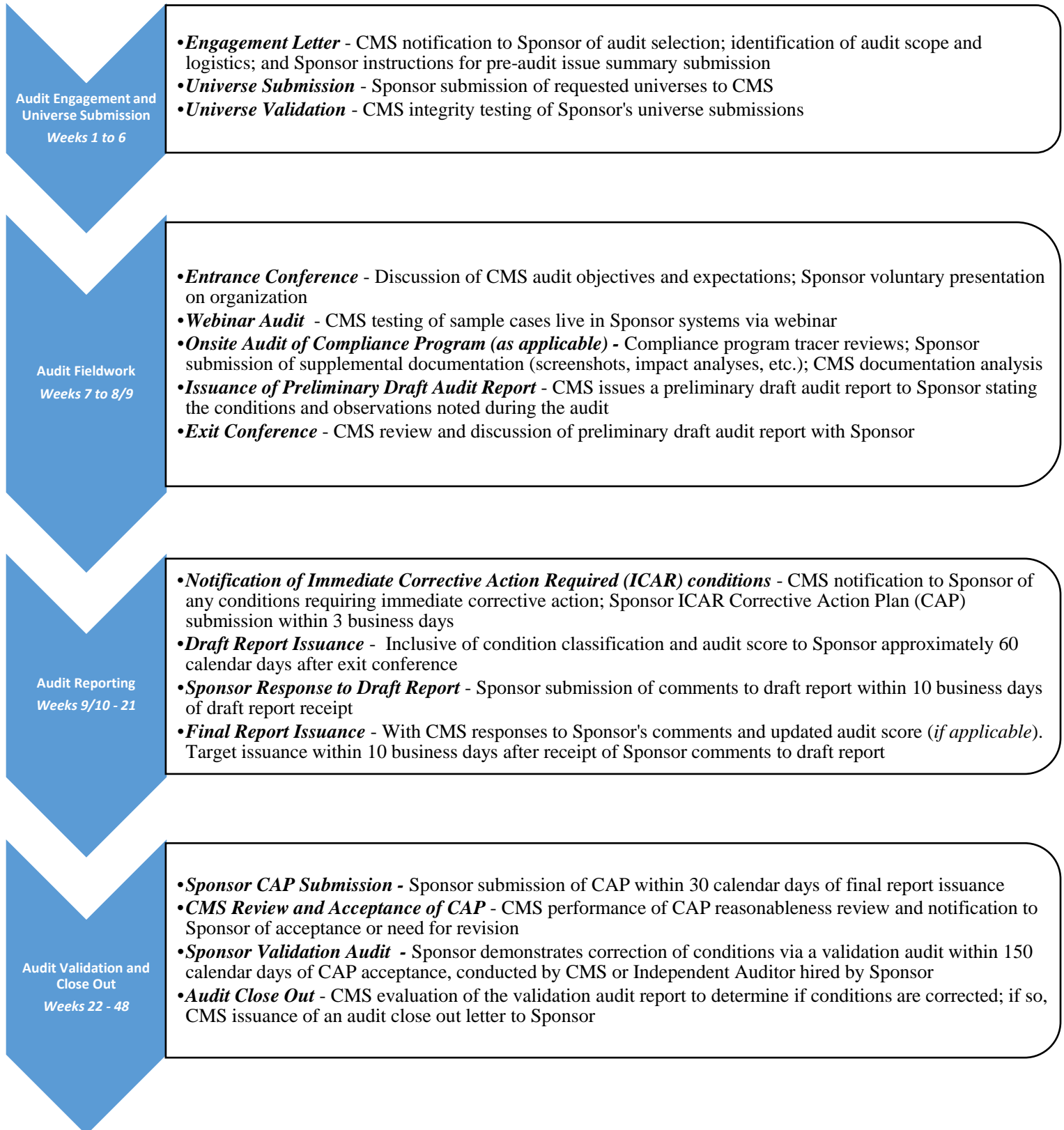
Updated December 2016

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# I. Executive Summary – 2017 Audit Process Timeline



## II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MOEG) is the Group within the Centers for Medicare & Medicaid Services (CMS) responsible for creating and administering the audit strategy to oversee the Part C and Part D programs. MOEG conducts audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs), collectively referred to as “sponsors,” that participate in these programs. These program audits measure a sponsor’s compliance with the terms of its contract with CMS, in particular, the requirements associated with access to medical services, drugs, and other beneficiary protections required by Medicare. On an annual basis, CMS solicits feedback on the audit process from industry stakeholders through a variety of mediums. CMS utilizes the feedback to update and improve audit operations as well as to explore new program areas that may need oversight.

This document outlines the audit process for 2017. CMS will send routine engagement letters to initiate audits beginning February 21, 2017 through September 25, 2017. Engagement letters for unscheduled audits may be sent at any time throughout the year.

## III. Summary of Audit Phases

The program audit consists of four phases:

- 1) Audit Engagement and Universe Submission
- 2) Audit Fieldwork
- 3) Audit Reporting
- 4) Audit Validation and Close Out

The sections below describe important milestones in each phase of the audit.

### 1. Audit Engagement and Universe Submission

**1.1 - Engagement Letter** – The Auditor-in-Charge (AIC) conducts a courtesy call to the sponsor’s Compliance Officer to notify the organization of the program audit. After the phone call, the AIC sends an audit engagement letter via the Health Plan Management System (HPMS) that includes the following information:

- Timeframe and location of the program audit
- Instructions for downloading audit process and data request documents from HPMS
- Plan documentation that must be submitted to CMS prior to audit fieldwork
- CMS facility/records access requirements
- Onsite Visit Information and Requests
- Key Personnel requirements

**1.2 - Follow-Up Call** – Within two business days from the issuance of the engagement letter, the CMS audit team conducts a follow-up call with the sponsor. The purpose of the

call is to provide an opportunity for the sponsor to ask questions about the engagement letter or audit process, as well as for CMS to emphasize important information within the engagement letter and outline next steps in the audit process.

**1.3 - Universe Request Calls** – Within 5 business days of the issuance of the engagement letter, CMS conducts universe request calls for each program area to discuss universe requests/record layouts and to answer questions as needed.

**1.4 - Universe Submission to CMS** – Within 15 business days of the engagement letter date, the sponsor must submit all requested universes to CMS following the instructions in the engagement letter.

**1.5 - Universe Integrity Testing** – Within 1 week of the receipt of universes, CMS conducts universe integrity testing to verify the accuracy of submitted universes. To conduct this test, CMS selects samples of cases in the universe and matches the information to the sponsor's live systems. CMS conducts these tests virtually via webinar.

**1.6 - Coordination of Audit Fieldwork Schedule** – The AIC coordinates with its team and the sponsor to schedule individual program area review sessions during the fieldwork phase of the audit. Within a week prior to the entrance conference, the AIC sends the finalized audit fieldwork schedule to the sponsor with the list of individual webinar sessions occurring each day during fieldwork to ensure the sponsor has appropriate staff available for each session. Please note, webinars for various program areas run concurrently, so different staff will need to be available to support each webinar. In addition, CMS aims to adhere to the sponsor's normal business hours, but may request alternative hours depending on the progress of audit fieldwork.

## **2. Audit Fieldwork**

**2.1 - Entrance Conference** – Audit fieldwork begins with an entrance conference held on the morning of the first day of fieldwork. The AIC will lead the meeting, review the schedule, and discuss expectations for the week. The sponsor will also have an opportunity to make a presentation about its organization.

**2.2 – Audit Sample Selection** – CMS selects samples from the submitted universes to test during audit fieldwork. CMS informs the sponsor of the sample selection via HPMS upload for each program area as follows:

- For CPE – CMS provides its selected tracer samples approximately two weeks prior to the entrance conference. Then, the sponsor must prepare tracer summaries for submission to the audit team by the entrance conference.
- For MTM – CMS provides its selected samples five business days before the scheduled webinars begin. Since MTM occurs during week 2 of fieldwork, CMS usually provides these samples on the date of the entrance conference.
- For SNP-MOC – CMS provides its selected samples two business days before the entrance conference.

- For all other program areas – CMS provides its selected samples for each day’s review approximately one hour prior to the start of the scheduled webinar.

**2.3 - Webinar Reviews** – After the entrance conference, webinar audits will begin as listed in the fieldwork schedule. CMS uses secure webinar technology and audit staff will monitor the webinar room and expel anyone who is unknown to the audit team or sponsor. The audit team will evaluate sample cases live in the sponsor’s system to determine whether the case is compliant or non-compliant. For cases deemed non-compliant, the sponsor must upload requested screenshots and other supporting documentation to HPMS. The classification and scoring of audit conditions is determined after receipt and review of all audit documentation by the audit team. This is discussed in more detail in the Audit Reporting section.

**2.4 - Onsite Compliance Program Effectiveness Audit (as applicable)** – Over a period of 4 to 5 days, the CMS compliance team conducts management interviews, system walk-throughs, and tracer sample reviews to determine the effectiveness of the sponsor’s compliance program. This audit usually occurs during the second week of fieldwork, or week 8 of the audit. For audits including MMP contracts, this audit will be conducted during week 9 (third week of audit fieldwork), instead of week 8. Compliance Program Effectiveness may not be included in the scope of all program audits.

**2.5 - Issuance of Preliminary Draft Audit Report** - At the conclusion of the audit fieldwork phase, the AIC issues a preliminary draft audit report to the sponsor identifying the conditions and observations noted during the audit. The AIC issues this report in HPMS at least one hour prior to the exit conference.

**2.6 - Exit Conference** – The final day of fieldwork concludes with an exit conference (conducted onsite if CPE is part of the audit). The audit team will walk through the preliminary draft audit report with the sponsor and discuss any other outstanding requests for information. During the exit conference, the Sponsor can ask questions about the findings and provide any follow-up information as appropriate.

### **3. Audit Reporting**

**3.1 – Notification of Immediate Corrective Action Required (ICAR) conditions** – Upon receipt of all audit documentation, the audit team will meet with Program Audit Consistency Teams (PACTs) for each program area included in the audit. PACTs serve as the subject matter experts on programmatic and audit policy for their respective program area and ensure consistency in classification of audit conditions across all audits. The PACTs will assist the audit team with the classification of conditions according to the following definitions:

**Immediate Corrective Action Required (ICAR)** - If CMS identifies systemic deficiencies during an audit so severe that they require immediate correction, the Sponsor is cited an ICAR. Identified issues of this nature would be limited to situations where the condition resulted in a beneficiary’s lack of access to

medications and/or services, or posed an immediate threat to beneficiary health and safety. The ICAR counts as 2 points in the audit scoring methodology.

**Corrective Action Required (CAR)** – If CMS identifies systemic conditions during an audit that must be corrected, but the correction can wait until the audit report is issued, the Sponsor is cited a CAR. While these issues may affect beneficiaries, they are not of such a severe nature that beneficiaries’ immediate health and safety is affected. Generally, CARs involve deficiencies with respect to non-existent or inadequate policies and procedures, systems, internal controls, training, operations, or staffing. The CAR counts as 1 point in the audit scoring methodology.

**Invalid Data Submission (IDS)** – CMS cites an IDS condition when the Sponsor fails to produce an accurate or complete universe within three attempts. An IDS is a new condition for 2016, and it is cited for each element that cannot be tested, grouped by type of case. As an example, CMS would cite an IDS condition if auditors were unable to evaluate timeliness for Sponsor’s coverage determinations (standard or expedited, pre-service, or payment) due to invalid data submission(s). The IDS condition counts as 1 point in the audit scoring methodology.

**Observations**—If CMS identifies cases of non-compliance that are not systemic, or represent an anomaly or “one-off” issue, the Sponsor is cited an observation. Observations do not count in the audit scoring methodology.

Once ICAR conditions are identified, the AIC will email the sponsor’s Compliance Officer (or primary point of contact for the audit), informing the sponsor of the ICAR conditions and that immediate corrective action must be taken within 3 business days to stop or prevent the non-compliance from recurring.

**3.2 - Draft Audit Report Preparation and Issuance to Sponsor** – CMS prepares a draft audit report (inclusive of condition classification and an audit score) with a target for issuance of 60 calendar days from the date of the final exit conference. The sponsor has 10 business days to respond to the draft audit report with comments to CMS. CMS takes into consideration and responds to any comments the sponsor has in regard to the draft audit report, and determines if the comments warrant a change to the final report.

**3.3 - Issuance of the Final Audit Report and Scoring** – CMS aims to issue the final audit report within 10 business days from receipt of the sponsor’s comments on the draft audit report. The final report contains the final audit score and classification of conditions noted during the audit.

**3.4 - Referral for Enforcement Action** – At the conclusion of the audit, the conditions noted in the audit will be referred to the Division of Compliance Enforcement for an independent evaluation of whether an enforcement action of Civil Money Penalties, sanctions, or contract termination is warranted.

**3.5 – Impact on Performance Measures** – Non-compliance found during the audit may adversely affect CMS Part C and Part D Star Ratings and/or Application Cycle Past Performance Reviews. For CMS Star Ratings, if the audit finds that a particular issue of non-compliance impacts the data source for a Star measure, the Star measure may be reduced to 1 Star if the data set is deemed inaccurate or biased (per CMS Star Ratings policy). As an example, a Star Ratings measure, which uses data reported to the Independent Review Entity (IRE) as the data source, may be reduced if the audit finds that a sponsor’s non-compliance resulted in the IRE failing to receive all cases as required for a given contract. For Past Performance Reviews, a sponsor may receive a negative past performance point if its core audit score represents an outlier when compared to all audit reports issued during the 14-month past performance period, consistent with the past performance review methodology CMS issues each year.

#### **4. Audit Validation and Close Out**

**4.1 - Submission of Corrective Action Plans (CAPs)** – Due to the immediate nature of ICARs, CMS requires that sponsors submit CAPs and remediate any ICAR conditions within three business days from formal email notification. It is critical that sponsors take immediate action to stop or prevent the non-compliance from occurring within three business days even if the CAP may take many weeks (or months) to fully implement.

Sponsors have 30 calendar days from the issuance of the final audit report to submit CAPs associated with CAR and IDS conditions. Normally, observations do not require a CAP; however, CMS does reserve the right to request CAPs for observations and will explicitly request this in the report when required.

Upon receipt of the CAPs, CMS performs a reasonableness review and notifies sponsor of either CAP acceptance or the need for additional information. CMS continues the reasonableness review process until it deems all CAPs acceptable.

**4.2 – Validation Audit**—CMS requires that sponsors demonstrate correction of conditions noted in the final audit report within 150 calendar days of CMS’ acceptance of all CAPs. CMS may conduct the validation audit or CMS may require the sponsor to hire an independent auditor to conduct the validation audit. CMS informs sponsors whether an independent auditor is required in the Final Audit report. If the validation audit finds that significant audit conditions are still present (not corrected), another validation audit may be required.

**4.3 - Audit Close Out**– If the validation audit demonstrates substantial correction of conditions has occurred, CMS will close the audit and send an audit close out letter to the sponsor.

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-Q)**

(Rev. 6, 10-2016)

Name of Sponsoring Organization:

MA-PD/PDP Contract Numbers:

Name/Title of Person(s) Completing Assessment:

Date of Assessment:

This version of the SA-Q tool is to be used with the Compliance Program Effectiveness Audit Protocol.

Sponsoring Organizations should not interpret every question as a mandatory CMS requirement, but rather as a guide to establish and maintain the core requirements of a compliance program to prevent, detect and correct Medicare program non-compliance and fraud, waste and abuse. This questionnaire is identical to the Medicare Part C and D Compliance Program Guidelines and can be used as a monitoring tool to assist sponsors with evaluating their compliance program for CMS requirements. While Element V of the Medicare Part C and D Compliance Program Guidelines – *Well Publicized Disciplinary Standards* – is a required and critical component of a compliance program, it has been omitted from this version of the SA-Q. However, sponsoring organizations must ensure structures and procedures are in place to successfully implement all required elements of a compliance program. Please note the use of this tool by itself does not constitute a formal audit of the compliance program. For example, the formal audit of the compliance program effectiveness should be meet the definition of “audit” noted in the Compliance Program Guidelines and performed by staff not affiliated in any way with the Compliance department.

Directions for completing the self-assessment questionnaire:

Please respond to each question according to the status of your compliance program during the audit review period.

If the answer is “YES” to any question below, check the “YES” box and provide a BRIEF description of what documents support that response in the “Documentation” column. The documentation description should also provide a cross reference (when applicable) to where this documentation can be located. For example, if your response is “YES” to the third question below (*“Do your written Ps & Ps and/or Standards of Conduct articulate the organization’s commitment to comply with all applicable Federal*

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

*and State standards including but not limited to statutes, regulations and sub regulatory guidance”), please indicate the section/page of the Standards of Conduct or policies and procedures where these compliance provisions are found.*

If the answer is “NO” to a question, check the “NO” box and document the rationale for the response in the “Documentation” column. For the limited situations when a question does not apply to your organization, enter “N/A” in the “YES/NO” box and document the rationale for the response in the “Documentation” column. If multiple individuals are responsible for the compliance program (e.g. Corporate Compliance Officer, Medicare Compliance Officer, SVP of Audit and Compliance) and have different responses to the questions, please consolidate responses and incorporate into one document.

Please specifically note the following when completing the questionnaire:

- “You” refers to your organization, not necessarily a specific person.
  
- “Employees” refer to employees, including senior management, who support your Medicare business.
  
- “Compliance Officer” refers to the compliance officer who oversees the Medicare business.
  
- “CEO” refers to the Chief Executive Officer of the organization or the most senior officer, usually the President or Senior Vice President of the Medicare line of business.
  
- “Compliance Program” refers to your Medicare compliance program.
  
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization’s management are to the board, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.
  
- Unless specific reference is made in the question to the term “governing body”, it means either the full board or a committee of the board of directors delegated to conduct oversight of the day-to-day operation of the Medicare compliance



**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

program on behalf of the full governing body.

- “FDRs” refer to the organization’s first-tier, downstream and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the Sponsor.

<b>Written Policies and Procedures and Standards of Conduct</b>  <i>42 CFR §422.503(b)(4)(vi)(A); 42 CFR §423.504(b)(4)(vi)(A)</i>				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Party or Department
1.	Do you have written policies and procedures (Ps & Ps) and/or Standards of Conduct that: (A through G)			
A.	Articulate the organization’s commitment to comply with all applicable Federal and State standards?			
B.	Describe compliance expectations as embodied in the standards of conduct?			
C.	Implement the operation of the compliance program?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

D.	Provide guidance to employees and others on dealing with potential compliance issues?			
E.	Identify how to communicate compliance issues to appropriate compliance personnel?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
F.	Describe how potential compliance issues are investigated and resolved by the organization?			
G.	Include a policy of non-intimidation and no-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials?			
2.	Are your Ps & Ps detailed and specific in their description of the operation of the compliance program?			
3.	Do you distribute your Standards of Conduct and Ps & Ps to your employees within 90 days of hire, when there are updates and annually thereafter?			
4.	Do you update your Ps & Ps to incorporate changes in applicable laws, regulations and other program requirements?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

Compliance Officer, Compliance Committee, Governing Body				
42 CFR §422.503(b)(4)(vi)(B) and 42 CFR §423.504(b)(4)(vi)(B)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
5.	Does your CEO receive your compliance officer's reports on the status and activities of the compliance program?			
6.	If your compliance officer does not report directly, in-person to your CEO, are his/her reports routed through the President of the division that houses the Medicare and/or through the President of the organization rather than through operational management?			
7.	Does your compliance officer have express authority (oral or written, preferably written) to make in-person reports to your CEO and governing body in the compliance officer's sole discretion?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
8.	Is your compliance officer employed by your organization, parent organization, or corporate affiliate?			
9.	If employed by your parent or corporate affiliate, does your compliance officer have detailed involvement in and familiarity with your Medicare operational and compliance activities?			
10.	Does your governing body periodically receive compliance reports on Medicare program noncompliance and Medicare fraud, waste and abuse (“FWA”) which include issues identified, investigated, and resolved?			
11.	If your compliance officer does not report in-person to your governing body, are his/her reports routed through the compliance infrastructure?			
12.	Is your compliance officer a full-time employee?			
13.	Does your compliance officer have both compliance and operational responsibilities?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
14.	Do you have a compliance committee whose responsibilities include oversight of the compliance program?			
15.	Does your compliance officer and compliance committee provide the governing body with regularly scheduled updates on the status and activities of the compliance program, including compliance program outcomes, the results of internal and external audits and about all government compliance enforcement activity?			

**Effective Training and Education**

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
16.	Do you establish, implement and provide effective training and education, addressing compliance and FWA for your employees, including temporary employees, volunteers and governing body?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
17.	Is your training for employees and board members provided within 90 days of hire/appointment and annually thereafter?			
18.	Do you maintain attendance, topic, certificates of completion and/or test scores for 10 years?			
19.	Do you ensure that your employees are aware of Medicare requirements related to their job functions?			
20.	Does your general compliance training include the reporting requirements and available methods for reporting noncompliance and potential FWA?			
21.	Do you provide training on FWA risks based on the individual's job function?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

Effective Lines of Communication				
42 CFR §422.503(b)(4)(vi)(D) and 42 CFR §423.504(b)(4)(vi)(D)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
22.	Do you have an effective method(s) to communicate information from your compliance officer to others, within a reasonable time frame, including changes in laws, regulations and sub-regulatory guidance, HPMS memos, as well as changes to your Standards of Conduct and Ps & Ps?			
23.	Do your Standards of Conduct and/or Ps & Ps require your employees and members of the governing body to report compliance concerns and potential FWA?			
24.	Do you have a system to receive, record, respond to and track compliance questions or concerns and reports of potential FWA from your employees, members of your governing body, FDRs and their employees and enrollees?			
25.	Does your system allow anonymous reporting and maintain confidentiality to the extent possible?			



**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
26.	Does your system emphasize your policy of non-retaliation and that of your FDRs'?			
27.	Is your system well-publicized throughout your facilities and those of your FDRs?			
28.	Are your reporting mechanisms user-friendly, easy to access and navigate and available 24 hours a day for employees, members of your governing body and FDRs?			
29.	Have you adopted, widely publicized and enforced a no-tolerance policy for retaliation or retribution against any employee, FDR, or FDR employee who reports potential FWA?			
30.	Do you educate your enrollees about the identification and reporting of FWA?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks  42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
31.	Do you have a system of ongoing monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements and all applicable federal and state laws?			
32.	Are adequate resources devoted to your audit function considering the scope of your Medicare Parts C and D programs, compliance history, current compliance risks and resources available?			
33.	Do you have a monitoring and auditing work plan that addresses risks associated with Medicare Parts C and D?			
34.	Does your compliance officer receive regular reports from the individuals or component conducting auditing monitoring activities, including providing the status and effectiveness of corrective actions taken?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
35.	Does your compliance officer or his/her designees provide updates on the results of monitoring and auditing activities to your compliance committee, CEO, senior leadership and governing body?			
36.	Have you established and implemented Ps & Ps to conduct a formal baseline risk assessment of the major compliance and risk areas in all Medicare operational areas?			
37.	Does your monitoring and auditing strategies prioritize (a) risks identified through CMS audits and oversight and through your own monitoring; and (b) those risks that have the greatest impact?			
38.	Do you periodically re-evaluate the accuracy of your baseline risk assessment?			
39.	Do you have an auditing and monitoring work plan that includes: (A through C)			
A.	A process for responding to all monitoring and auditing results?			
B.	A process for conducting follow-up reviews of areas found to be noncompliant to determine if corrective actions have fully address the underlying problems?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
C.	A schedule (with estimated target dates) that lists all auditing and monitoring activities for the calendar year?			
40.	Do you use appropriate methods to: (A through F)			
A.	Select operational areas for audit?			
B.	Select first tier entities for audit?			
C.	Determine sample size?			
D.	Extrapolate audit findings to the full universe, using statistically valid methods that comply with generally accepted auditing standards?			
E.	Apply specialized targeted techniques or stratified sampling methods driven by data mining, complaint monitoring and aberrant behavior?			
F.	Assess compliance with internal processes and procedures?			
41.	Do you have internal staff dedicated to the audit function? Are procedures in place to ensure auditors are independent of Medicare operations under review to prevent self-policing?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
42.	Are your auditors knowledgeable about CMS operational requirements for areas under review?			
43.	Does your audit staff have access to relevant personnel, information, records and areas of operation under review, including operational areas at plan and FDR level?			
44.	<p>Do you conduct a formal audit to evaluate the effectiveness of your compliance program at least annually (once a year)?</p> <p>NOTE: The formal audit should produce an audit report with results and identified root cause(s) and a corrective action plan should be a part of the evaluation. The CMS program audit of a sponsor's compliance program effectiveness does NOT satisfy this audit requirement. Sponsor must conduct its own audit of the effectiveness of its compliance program at least annually.</p>			
45.	Is the annual compliance program effectiveness audit conducted by persons other than your compliance officer and /or compliance department staff?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
46.	Do you share the results of the audits of the effectiveness of the compliance program with your governing body?			
47.	Do you review the OIG and GSA exclusion lists for your employees (including temporary employees), volunteers, consultants and the members of your governing body prior to hiring/contracting/appointment and monthly thereafter?			
48.	Do you utilize systems and data analysis for monitoring FWA?			
49.	Do you either have a Special Investigations Unit (“SIU”) or ensure that the responsibilities generally conducted by an SIU are conducted by your compliance department?			
50.	If you have an SIU, is it accessible through multiple channels, e.g. phone, mail, Internet message?			
51.	Do your SIU and compliance departments communicate and coordinate closely?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

Procedures and Systems for Promptly Responding to Compliance Issues  42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
52.	Do you make a reasonable inquiry into all compliance incidents/issues and potential FWA?			
53.	Do you require and ensure that your inquiries are well-documented?			
54.	Do you require and ensure that inquiries are initiated as quickly as possible, and not later than two weeks after the date the potential noncompliance or FWA is identified?			
55.	Do you undertake appropriate corrective actions that: (A through C)			
A.	Are designed to correct and prevent future noncompliance, including conducting a root cause analysis?			
B.	Are tailored to address the particular FWA, problem or deficiency identified?			
C.	Include time frames for specific achievements?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
56.	Do you continue to monitor corrective actions after their implementation to ensure that they are effective?			
57.	Do you ensure that noncompliance or FWA committed by your employees is documented and includes ramifications should the employee fail to satisfactorily implement the corrective action?			
58.	Do you maintain thorough documentation of all compliance deficiencies identified and the corrective actions taken?			
59.	Do you have procedures to refer potential FWA issues to the NBI MEDIC and serious issues of program noncompliance to CMS?			
60.	Do you conclude your investigations of FWA within a reasonable time after the activity is discovered?			
61.	Do you review past paid claims from entities identified in fraud alerts and remove them from their event data submissions e.g. PDEs?			



**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

FDR Oversight  Sponsor Accountability for and Oversight of FDRs  42 CFR §422.503(b)(4)(vi) and 42 CFR §423.504(b)(4)(vi)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
62.	Do you have a process or criteria for determining which delegated entities (and their employees) are properly identified as FDRs subject to Medicare compliance requirements?			
63.	Do you identify and communicate to your FDRs which FDR employees are subject to Medicare compliance requirements?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

FDR Oversight Written Policies and Procedures and Standards of Conduct 42 CFR §422.503(b)(4)(vi)(A) and 42 CFR §423.504(b)(4)(vi)(A)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
64.	Do you ensure that either your Standards of Conduct and Ps & Ps or comparable Standards of Conduct and Ps & Ps are distributed to FDR's employees within 90 days of hire / contracting and annually thereafter?			

FDR Oversight Effective Training and Education 42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
65.	Do you ensure that general compliance and FWA training is completed by your FDRs?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
66.	Do you ensure that your non-deemed FDRs' employees receive FWA training within 90 days of hiring/contracting and annually thereafter?			
67.	Do you require your FDRs to maintain records of their compliance and FWA training activities for their employees for ten years, as required?			

FDR Oversight Monitoring and Auditing FDRs 42 CFR §422.503(b)(4)(vi)(F) and 42 CFR §423.504(b)(4)(vi)(F)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
68.	Do you have a strategy to monitor and audit your first-tier entities?			
69.	Does your strategy for monitoring and auditing first-tier entities include: (A & B)			
A.	Ensuring that they are in compliance with Medicare Parts C and D program requirements?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

<b>No.</b>	<b>Description</b>	<b>Yes/No</b>	<b>Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)</b>	<b>Responsible Part or Department</b>
B.	Ensuring that they are monitoring their downstream entities?			
70.	Do you monitor and audit your related entities?			
71.	Does your monitoring and auditing work plan include the number of first-tier entities that will be audited and how the entities will be identified for auditing?			
72.	If you do not monitor and audit all of your first tier entities, do you perform a risk assessment to identify the high risk first-tier entities and then select a reasonable number to audit from the highest risk groups?			
73.	Do you have procedures to ensure that your FDRs are not excluded from participation in Federal health care programs? (42 CFR § 1001.1901)			
74.	Does your system include review of the OIG and GSA exclusion lists prior to hiring or contracting and monthly thereafter for FDRs and their employees either by you, your first entities, or the downstream entities themselves?			

**ATTACHMENT I-A**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM EFFECTIVENESS**  
**SELF-ASSESSMENT QUESTIONNAIRE (SA-O)**

FDR Oversight FDRs: Procedures and System for Prompt Response to Compliance Issues 42 CFR §422.503(b)(4)(vi)(G) and 42 CFR §423.504(b)(4)(vi)(G)				
No.	Description	Yes/No	Documentation (include specific page number, paragraph, section, system, location and/or brief explanation)	Responsible Part or Department
75.	Do you ensure that corrective actions are taken by first tier entities?			
76.	Do you continue to monitor FDR corrective actions after their implementation to ensure that they are effective?			
77.	Do you ensure that noncompliance or FWA committed by FDRs is well-documented and includes ramifications should the FDR fail to satisfactorily implement the corrective action?			
78.	Do you maintain thorough documentation of all deficiencies identified and the corrective actions taken?			

**Attachment I-C**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG**  
**COMPLIANCE PROGRAM EFFECTIVENESS (CPE)**  
**AUDIT**  
**Organizational Structure and Governance PPT Template**  
(Rev. 2, 10-2016)

Prepared by: [Sponsor's Name]  
[Date]

# **Instructions for Completing the Organizational Structure and Governance PPT Template**

- The Organizational Background and Structure (OBS) PPT provides valuable information regarding your organization's Medicare business, organizational structure, key personnel and compliance program operations for the CMS audit.
- This presentation is a central resource for CMS and will be referenced often during the audit.
- Sponsors are expected to create a customized presentation that includes specific information using this PowerPoint template; however, you are not limited to providing only this information.
- This presentation is an important part of your documentation submission.

# Table of Contents

- Basic Organization Information
- Corporate Governance & Accountability
- Medicare Business Operations & Organizational Charts
- Compliance Program Infrastructure and Processes



# Basic Organization Information

- History (including key milestones)
- Organization's lines of business and active Medicare contract numbers
- Location of Headquarters, operational and satellite offices
- Service Area/ Geographic Footprint
- For-Profit or Not-for-Profit
- Publicly-Traded or Privately-Held
- List all subsidiaries and affiliated corporations of parent company (include contract numbers, if applicable) lines of business
- Total Membership
- Number of MA/PDP covered lives vs. Total covered lives for all business

# Basic Organization Information

- Total number of employees
- Number of staff at each location
- Number and percentage of staff dedicated to Medicare C/D business operations
- Business combinations occurring within the past 12 months, currently in progress, or planned to take place within the next 6 months (e.g. mergers, acquisitions, novations, spinoffs)
- Percentage of business devoted to Medicare, Medicaid, Commercial
- Does your organization serve as a subcontractor or FDR to other sponsoring organization(s)?
- How many first-tier entities are currently delegated to perform Medicare functions on your organization's behalf?
- Identify your PBM and contract effective date(s)
- Do you utilize the same PBM for all Medicare contracts under the parent organization?
- Describe the functions that the PBM performs on your behalf.

# Basic Organization Information

## Revenue by Lines of Business

Product	2015	2016 (MM/DD/YY)	2016 (Annualized)
MA/MA-PD			
PDP			
Commercial			
Other (please specify)			
Total			

# Basic Organization Information

## Medicare Enrollment and Membership Growth

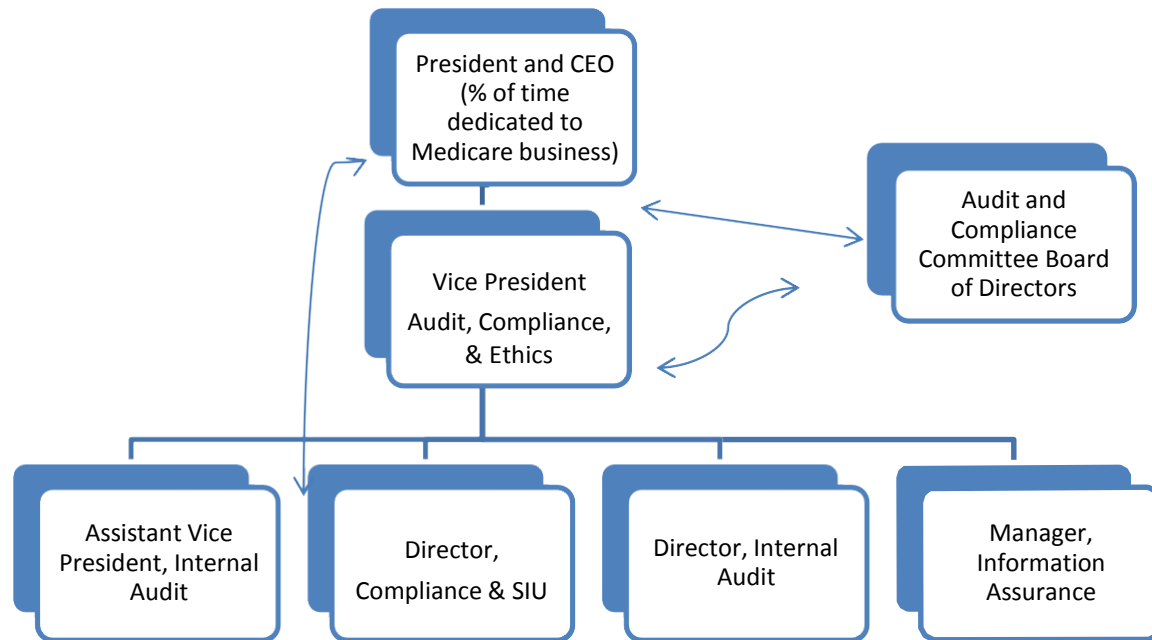
Year	December 31 membership	Membership Growth	% Growth
2015			
2016			
2017			

# Corporate Governance and Accountability

- Provide organizational charts depicting corporate structure and where the Medicare line of business fits into the sponsor's overall business.
- Briefly summarize the members and experience of the governing body overseeing the Medicare compliance program. If the organization does business with any governing body members' relatives, please identify the nature of the business relationship. Indicate if any of the governing body members and/or members of senior management are related to each other.
- Identify senior management responsible for the Medicare line of business.
- Provide individual organization charts and flow charts of Medicare Advantage (Part C) and/or Prescription Drug (Part D) business areas and processes (e.g., formulary administration, organization & coverage determinations, and appeals, grievances, claims, quality of care, special needs plans-model of care, enrollment, agent/broker oversight, compliance program, FDR oversight, etc.).

# Corporate Governance and Accountability

- Demonstrate your corporate governance structure, including governing body and accountable senior management responsible for Medicare Parts C/D business operations and compliance. – See example below.



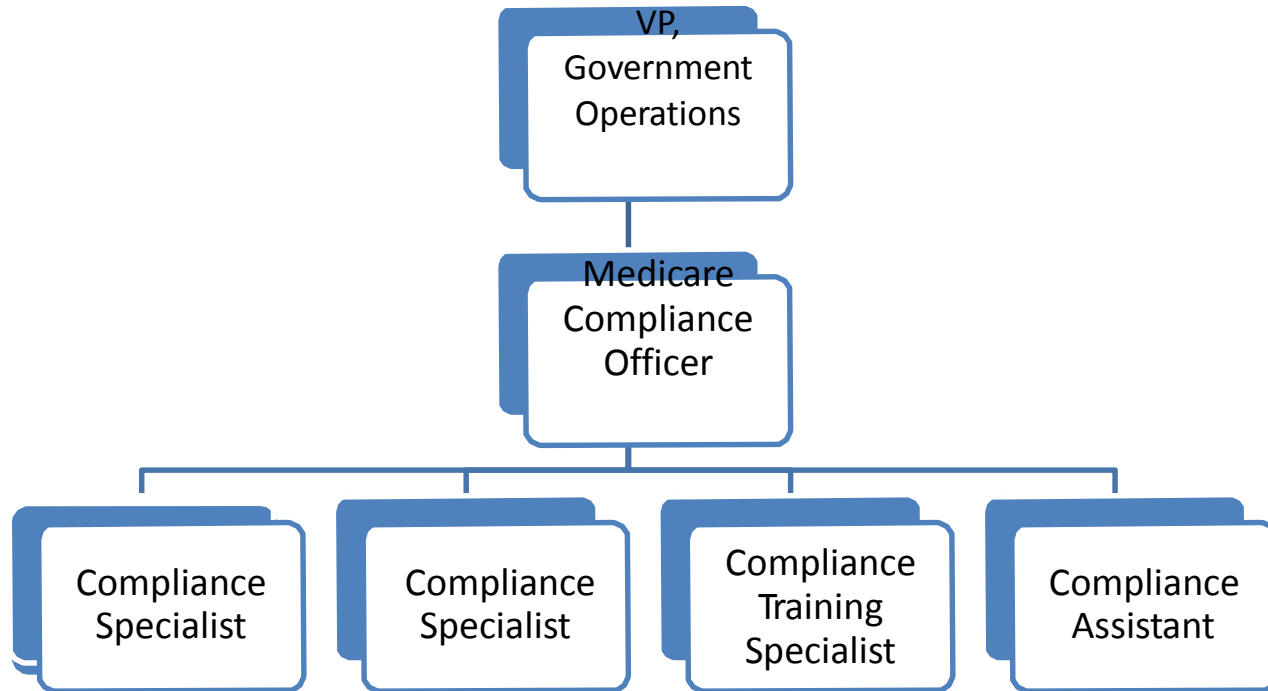
# Corporate Governance and Accountability

- Percentage of time senior executives dedicate to Medicare vs. other lines of business (list) – see example below.

<b>Name</b>	<b>Position</b>	<b>% Time Medicare</b>
John Doe	CEO	35%
Jane Doe	Compliance Officer	60%

# Medicare Business Operations & Organizational Charts

- Demonstrate your Compliance Program/Department and core Medicare Parts C and/or D business organizational structure, including senior management to whom Compliance Officer reports (include names of individuals and titles). – See example below.





# **Compliance Program Infrastructure and Processes Overview**

This section of the presentation provides an overview of the organization's standardized processes, tools and controls used to conduct the day-to-day oversight of compliance and FWA issues that may impact Medicare business operations. This information is critical for the tracer evaluation portion of the CPE audit.

# Compliance Program Infrastructure & Processes

- Describe any major changes to the compliance program infrastructure and business operations since the last CMS audit.
- Describe your relationship and communication with CMS (e.g. quarterly meetings with CMS Account Management, remediation with issues brought to sponsor's attention by CMS, etc.)
- Describe how and when the Standards of Conduct and policies and procedures are distributed to employees.
- What is the sponsor's definition of the term "employee"?
- If there is a compliance committee and/or Board-level committee that conducts day-to-day oversight of compliance issues on behalf of the full governing body, please indicate, and identify members by name.

# Compliance Program Infrastructure & Processes

- Explain how and when the sponsor provides compliance and FWA training for its employees.
- Discuss the sponsor's methods of educating employees and publicizing reporting channels (e.g. hotlines, intranet sites, posters, etc.)
- Describe how CMS Medicare regulations, requirements and interpretive guidance (e.g. annual call letter or HPMS guidance memoranda) are disseminated to the appropriate Medicare functions for implementation and quality control measures to confirm appropriate and timely implementation.
- Describe the methods used for tracking compliance issues through resolution and remediation (e.g. centralized tracking database, logs, etc.)

# Compliance Program Infrastructure & Processes

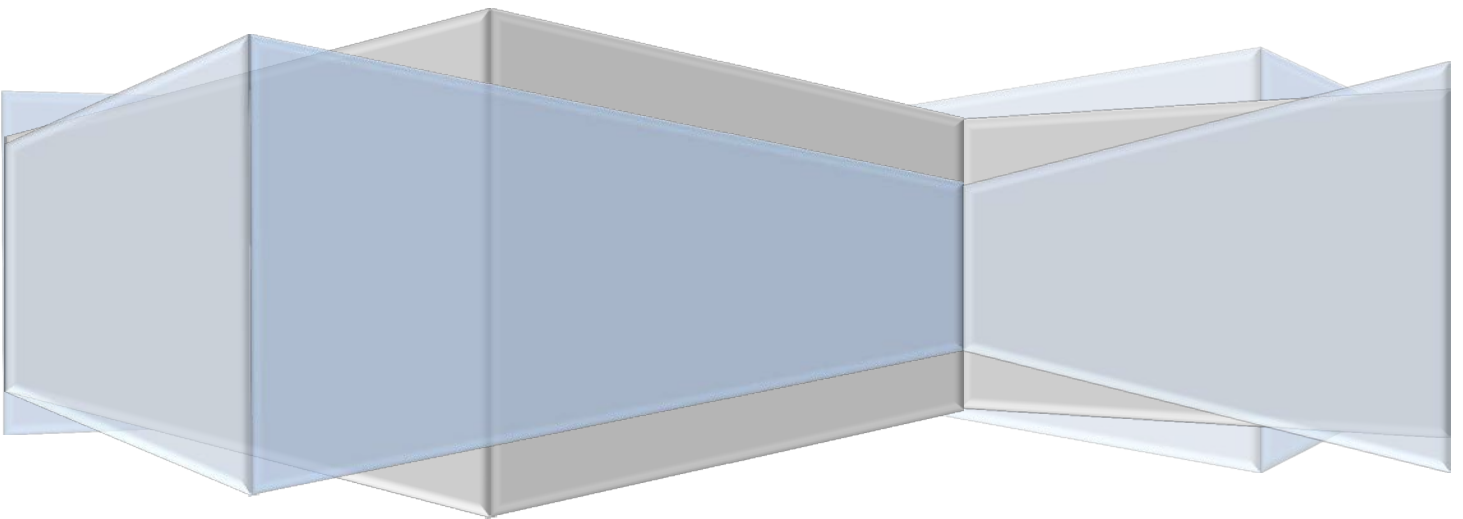
- Explain the criteria or provide a workflow for escalating compliance reports and issues from the Compliance Department to senior-level management, CEO and Board or board committee.
- Explain how the sponsor performs its risk assessment, consider risk factors and assigns risk scores.
- Describe the sponsor's system for assessing organizational performance against compliance requirements and standards (e.g. CMS regulations, laws, contract requirements, internal policies and procedures, etc).
- Describe how and when the sponsor creates and implements its auditing and monitoring work plans for the Medicare business operations.
- Describe the process for sharing the results of internal monitoring and auditing activities with parties within the organization.

# Compliance Program Infrastructure & Processes

- Explain how the sponsor tracks, measures and documents the effectiveness of their compliance program.
- Describe the sponsor's process for developing and managing corrective action plans and remediation efforts designed to correct noncompliance, ensure the root cause has been addressed and prevent recurrence.
- Describe how and when the sponsor checks its employees, board members and first-tier entities against the OIG and GSA exclusions databases.
- Describe the systems, data analysis and practices for monitoring and addressing Medicare healthcare and drug FWA.
- Describe the approach and mechanisms used to monitor FDRs performance against contractual and regulatory requirements.



**Part C and D Compliance  
Program Effectiveness (CPE)  
Program Area  
AUDIT PROCESS AND DATA REQUEST**



**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

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**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

## **Audit Purpose and General Guidelines**

1. **Purpose:** To evaluate the sponsor’s performance with adopting and implementing an effective compliance program to prevent, detect and correct Medicare Parts C or D program non-compliance and fraud, waste and abuse (FWA) in a timely and well-documented manner. The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities using these instructions (unless otherwise noted).
2. **Review Period:** The review period for the Compliance Program Effectiveness (CPE) audits is 1 year preceding and including the date of the audit engagement letter (prior Month, Day, Year through audit engagement letter Month, Day, and Year).
3. **Responding to Documentation Requests:** The sponsor is expected to present its supporting documentation during the audit and take screen shots or otherwise upload the supporting documentation, as requested, to the secure site using the designated naming convention and within the timeframe specified by the CMS Audit Team. . The screenshots must be provided to CMS via a Microsoft® Word or PDF document.
4. **Sponsor Disclosed Issues:** Sponsors will be asked to provide a list of all disclosed issues of non-compliance that are relevant to the program areas being audited and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the receipt of the audit start notice (which is also known as the “engagement letter”). Issues identified by CMS through on-going monitoring or other account management/oversight activities during the plan year are not considered disclosed.

Sponsors must provide a description of each disclosed issue as well as the status of correction and remediation using the Pre-Audit Issue Summary template (Attachment VIII). This template is due within 5 business days after the receipt of the audit start notice. The sponsor’s Account Manager will review Attachment VIII to validate that “disclosed” issues were known to CMS prior to receipt of the audit start notice.

When CMS determines that a disclosed issue was promptly identified, corrected (or is actively undergoing correction), and the risk to beneficiaries has been mitigated, CMS will not apply the ICAR condition classification to that condition.

**NOTE:** For CPE, CMS wants a list of all disclosed issues relating to a sponsor’s compliance program, not issues discovered during compliance activities (such as routine monitoring or auditing). For example: the sponsor disclosed an issue to CMS that during the audit review period the SIU failed to comply with a number of requests for additional information from the MEDIC and enforcement agencies.

5. **Calculation of Score:** CMS will determine if each condition cited is an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points). Invalid Data Submissions (IDS) conditions will be cited when a sponsor is not able to produce an accurate universe within 3 attempts. IDS conditions will be worth one point.

CMS will then add the score for that audit element to the scores for the remainder of the audit elements in a given protocol and then divide that number (i.e., total score), by the number of audit elements tested to determine the sponsor’s overall CPE audit score. Some elements and program areas may not apply to certain sponsors and therefore will not be considered when calculating



**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

program area and overall audit scores. Observations will be recorded in the draft and final reports, but will not be scored and therefore will not be included in the program area and audit scores.

6. **Informing Sponsor of Results:** CMS will provide daily updates regarding conditions discovered that day (unless the tracer has been pended for further review). CMS will provide a preliminary summary of the conditions at the exit conference. The CMS Audit team will do its best to be as transparent and timely as possible in its communication of audit findings. Sponsors will also receive a draft audit report which they may formally comment on and then a final report will be issued after consideration of a sponsor's comments on the draft.

**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

## **Universe Preparation & Submission**

1. **Responding to Universe Requests:** The sponsor is expected to provide accurate and timely universe submissions within 15 business days of the engagement letter date. CMS may request a revised universe if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. Sponsors will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. However, 3 attempts may not always be feasible depending on when the data issues are identified and the potential for impact to the audit schedule. When multiple attempts are made, CMS will only use the last universe submitted.

If the sponsor fails to provide accurate and timely universe submissions twice, CMS will document this as an observation in the sponsor's program audit report. After the third failed attempt, or when the sponsor determines after fewer attempts that they are unable to provide an accurate universe within the timeframe specified during the audit, the sponsor will be cited an Invalid Data Submission (IDS) condition relative to each element that cannot be tested, grouped by the type of case.

2. **Pull Universes and Submit Documentation:** The universes and documentation collected for this program area test the sponsor's performance in compliance program effectiveness. Sponsors will provide universes and supporting documentation that describe the framework and operation of its compliance program and universes to support the implementation of compliance activities conducted within the audit period.

**2.1. Documentation:** Sponsors should submit the following documentation in either a Microsoft Word (.docx), Microsoft Excel (.xlsx) or Portable Document File (PDF).

- Completed CPE Self-Assessment Questionnaire (Attachment I-A)
- Completed Compliance Officer Questionnaire (Attachment I-B)
- Customized Organizational Structure and Governance PowerPoint Presentation (Attachment I-C)
- Completed First-Tier Downstream and Related Entities (FDR) Operations Questionnaire (Attachment I-D)
- Completed Special Investigation Unit (SIU)/FWA Prevention and Detection Questionnaire (Attachment I-E)
- Standards of Conduct/Code of Conduct document (distributed to employees and FDRs during the audit review period)
- Corporate Compliance/Medicare Compliance/FWA Plan (or similar document in effect during the audit review period)
- Formal Risk Assessments and Compliance Performance Mechanisms that show the extent to which Medicare Parts C and/or D operational areas and FWA risks were identified and compliance goals were monitored during the audit review period
- Audit and Monitoring Work Plans (for internal operations and FDRs, in effect at any time during the audit review period)

**2.2. Data Universes:** Universes should be compiled using the appropriate record layouts as described in Appendix A. These record layouts include:

**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

- First-Tier Entity Auditing and Monitoring (FTEAM)
- Employee and Compliance Team (ECT)
- Internal Auditing (IA)
- Internal Monitoring (IM)

**NOTE:**

- For each respective universe, the sponsor should include all items that match the description for that universe for all contracts and PBPs in its organization as identified in the audit engagement letter.
- For each respective universe, the sponsor should include compliance and FWA activities.
- Please refer to Section 40 of the Medicare Parts C and D Compliance Program Guidelines for definitions, flowcharts and guidance on relationships between sponsor and first-tier entities.
- Please refer to Section 50.6 of the Medicare Parts C and D Compliance Program Guidelines for definitions and guidance for routine internal auditing and monitoring requirements and expectations.
- Please refer to Sections 50.6.9 and 50.6.10 for guidance on fraud, waste and abuse monitoring activities and SIU operations.

3. **Submit Universes to CMS:** Sponsors should submit each data universe in the Microsoft Excel (.xlsx) or Comma Separated Values (.csv) file format with a header row (or Text (.txt) file format without a header row) following the record layouts shown in Appendix A (Tables 1-4). The sponsor should submit its universes in whole and not separately for each contract and PBP. The sponsor should submit all documentation with its universes.

**Parts C and D Compliance Program Effectiveness (CPE)  
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## **Tracer Evaluation**

1. **Sample Selection:** In order to be effective, a sponsor's compliance program must be fully implemented and tailored to the sponsor's unique organization, operations, and circumstances. CMS will use a tracer method to evaluate implementation of applicable compliance elements and determine whether the sponsor's compliance program, as a whole system, functions in a way that is effective to address compliance and FWA issues in a timely and well-documented manner. CMS will select a sample of six (6) cases from the universes to trace the sponsor's response to compliance issues. It is not required that each case in the sample will cover all elements of a compliance program.

For example, a case pulled from the Internal Monitoring (IM) universe may involve a quality monitoring activity performed by a sponsor's quality improvement (QI) department to review and analyze untimely grievances. This activity identified compliance issues that involved additional training and education, communication with involved parties and revisions to processes, and other actions to correct and prevent the issue from recurring in the future. However, after a thorough root cause analysis was completed, the QI department and Compliance Officer determined the issues were isolated with limited beneficiary impact which required engagement by the Compliance Committee but not escalation to senior management or the governing body. While this case touched many of the seven elements of an effective compliance program, due to the detected issues having minimum impact on the Medicare business it was not necessary for the sponsor to implement all of the core requirements and actions identified in Compliance Program Elements I, II, and V.

2. **Tracer Case Summary and Documentation Reviews:**

**2.1. Tracer Case Summary:** For each selected case, sponsors should prepare a written document that provides the specific facts, rationales, and decisions and describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor in chronological order. The sponsor should ensure each tracer summary, at a minimum, addresses the following points:

- Overview of the issue(s) or activity
- Indicate which compliance and business operations units were involved in detecting and correcting the issue(s)
- Detailed explanation of the issue(s)/ activity (e.g., what the sponsor found, when the sponsor first learned about the issue, and who or which personnel/operational area(s) were involved.)
- Root cause analysis that determined what caused or allowed the compliance issue, problem or deficiency to occur
- Specific actions taken in response to the detected issue(s)/activity
- Processes and procedures affected and revised in response to becoming aware of the issue(s)/activity
- Steps taken to correct the issues/deficiencies at the sponsor or FDR levels, including a timeline indicating the corrective actions fully implemented or, if not implemented, when the sponsor expects the corrective action to be completed.
- Issue escalation (e.g. senior management, compliance oversight committees, governing body, etc.)
- Communication within the sponsor and with its FDRs

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- Prevention controls and safeguards implemented in response to the issue(s)/activity

Sponsors must document the facts of each tracer summary using the most effective and efficient method for their business. While the method used frequently by sponsors for tracer summaries are PowerPoint presentations (PPTs), sponsors may use other communication tools such as MS Word, story boards, and/or dashboards. A total of 6 tracer summaries must be submitted to CMS.

**2.2. Supporting Documentation:** During the onsite portion of the audit, CMS will review the summaries and supporting documentation during the tracer reviews with the sponsor to determine if applicable audit elements were effectively met. The sponsor will need access and provide screenshots only for the documents and data that are relevant to a particular case:

- Policies and procedures (Ps&Ps) reviewed and revised in response to detecting and correcting compliance issues.
- Evidence that compliance issues were communicated to the appropriate compliance personnel, senior management and oversight entities.
- Training provided in response to identifying and correcting compliance issues.
- Evidence of communication to the affected or involved business areas regarding the compliance issues.
- Evidence of the monitoring/auditing activities that occurred as a result of the detected issues.
- Evidence of sponsor's monthly screening to identify employees and FDRs excluded by the Office of Inspector General (OIG) and General Services Administration (GSA).
- Evidence of appropriate accountability and oversight by the sponsor when issues are detected at the FDR level, including response and correction procedures, communication, educational requirements and engagement with compliance department, operational areas and any oversight entities.
- Evidence/explanation of the root cause analysis performed to determine why the issue occurred.
- Description of the beneficiary and/sponsor impact as a result of the detected compliance issues.

**3. Submit Tracer Documentation to CMS:** Sponsors should be prepared to provide only the supporting documentation that is specific for each tracer either by uploading to the Health Plan Management System (HPMS) or providing onsite.

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## **Audit Elements**

### **I. Prevention Controls and Activities**

This audit element evaluates the sponsor's internal controls to reduce the number of potential non-compliance, FWA and regulatory violations from occurring within all Medicare business operational areas by employees and delegated entities. These compliance controls provide the framework for which the company and its employees operate, convey compliance expectations, prevent repeated issues from recurring and deter minor issues from becoming significant problems with adverse impact to the sponsor's operations and Medicare beneficiaries.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer review against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.

- 1.1. **Did the sponsor update and distribute their Standards of Conduct and Ps&Ps to their employees/FDRs when appropriate and within required timeframes?**
- 1.2. **Did the sponsor's compliance officer and compliance committee operate in accordance with CMS requirements?**
- 1.3. **Did the sponsor demonstrate appropriate accountability and reporting of Medicare compliance issues to appropriate senior management/executives and the governing body?**
- 1.4. **Did the sponsor have a governing body that exercises reasonable oversight of the Medicare compliance program?**
- 1.5. **Did the sponsor establish and implement effective training and education to ensure its employees, senior administrators and governing body members were aware of the Medicare requirements related to the job function, compliance and FWA?**
- 1.6. **Did the sponsor implement an effective monitoring system to prevent FWA in the delivery of Medicare Parts C and D benefits?**

2. **Tracer Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance.

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## **II. Detection Controls and Activities**

This audit element evaluates the sponsor's internal controls to monitor and detect potential and suspected compliance issues and activities. These compliance controls identify opportunities for the sponsor to improve the performance of Medicare business operational areas and the compliance program.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer review against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.
  - 1.1. **Did the sponsor implement a reporting system to receive, record, respond to, and track compliance concerns, questions and reports of suspected or detected non-compliance and FWA that allowed for anonymity and maintains confidentiality (e.g., telephone hotline)?**
  - 1.2. **Did the sponsor implement a risk assessment that identified areas of concern and major compliance risks for its Medicare business operational areas and beneficiaries?**
  - 1.3. **Did the sponsor implement an effective system for monitoring and auditing its internal Medicare Parts C and/or D operations and compliance program effectiveness?**
  - 1.4. **Did the sponsor review the OIG and GSA exclusion systems, as required, to ensure that none of their employees or FDRs were excluded or became excluded from participation in federal programs?**
  - 1.5. **Did the sponsor implement an effective monitoring system to detect and control FWA in the delivery of Medicare Parts C and D benefits?**
  - 1.6. **Did the sponsor properly monitor and audit its FDRs to ensure compliance with all applicable laws, regulations and sub-regulatory interpretive guidance with respect to the Medicare Parts C and/or D delegated functions and responsibilities?**
  - 1.7. **Did the sponsor implement effective communication, monitoring and auditing controls for detected issues involving its FDRs' compliance performance?**
2. **Tracer Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance.

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### **III. Correction Controls and Activities**

This audit element evaluates the sponsor's escalation processes, timely response and appropriate actions to correct the underlying problems after compliance issues and deficiencies are identified. These compliance controls provide immediate and reasonable response to the detection of misconduct and violations of the Medicare program.

1. **Apply Compliance Standard:** CMS will evaluate cases through the tracer review against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related CPE requirements not being met. Also, since some cases may not demonstrate all elements of an effective compliance program, it is acceptable if some of the questions below do not apply. Auditors will note for each question which case demonstrated the sponsor's compliance or non-compliance with the standard.

**1.1. Did the sponsor undertake timely and reasonable corrective action in response to compliance issues, incidents, investigations, complaints or misconduct involving Medicare non-compliance or FWA?**

**1.2. Did the sponsor implement timely corrective actions for detected issues involving its FDRs' compliance performance?**

2. **Tracer Case Results:** CMS will test each of the 6 cases through the tracer review. CMS will also conduct interviews while onsite to provide insight and additional information on the sponsor's compliance program. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may be associated with a single condition or multiple conditions of non-compliance.



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## Appendix

### Appendix A—Compliance Program Effectiveness (CPE) Record Layouts

The universes for the Parts C & D Compliance Program Effectiveness (CPE) program area must be submitted as a Microsoft Excel (.xlsx) or Comma Separated Values (.csv) files with a header row reflecting the field names (or Text (.txt) file without a header row). Do not include the Column ID variable which is shown in the record layout as a reference for a field's column location in an Excel or Comma Separated Values file. Do not include additional information outside of what is dictated in the record layout. Submissions that do not strictly adhere to the record layout will be rejected.

**Note:** There is a maximum of 4000 characters per record row. Therefore, should additional characters be needed for a variable (e.g., description of deficiencies), enter this information on the next record at the appropriate start position.

#### Table 1: First-Tier Entity Auditing and Monitoring (FTEAM) Record Layout

- Include:
  - First-tier entities (FTEs) that have entered into a written agreement with a sponsor to provide administrative or health care services to Medicare enrollees under the Part C and/or D program (e.g., PBM, claims processors, enrollment processes, fulfillment, call centers, credentialing, independent provider groups that manage/oversee a network of physicians).
  - Compliance and FWA audit and monitoring activities of first-tier entities that were conducted by the compliance department, operational areas and SIU to evaluate the compliance performance of first-tier entities.
  - Audit and monitoring activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the FDR level in the delivery of Medicare Part C and/or D benefits.
  - Audit and monitoring activities that reviewed reports from FDRs to detect non-compliance and FWA trends and abnormalities
  - Audit and monitoring activities to investigate allegations of non-compliance and fraudulent, wasteful, abusive or questionable behavior performed by FTEs (e.g. employee misconduct, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - Audit and monitoring activities initiated, started, re-opened or completed during the audit review period. This includes auditing and monitoring activities that may have started outside the audit review period, but were completed within the audit review period.
  - Audit and monitoring activities that are performed on a scheduled basis (e.g., weekly, monthly, quarterly, annually, ad-hoc), should be included in the universe each time it was performed.
  - Related entities acting as a first-tier entity to provide administrative or health care services.
  - Other audit or monitoring activities of downstream entities performed by the sponsor during the audit review period.
- Exclude:
  - First-tier entities that do not provide an administrative or health care service function related to the sponsor's Medicare Parts C and/or D contracts.

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- Audit and monitoring activities that are performed on a daily basis.
- First-tier entities that were not audited or monitored within the audit review period.
- Downstream or related entities that were not audited/monitored by the sponsor during the audit review period.

Column ID	Field Name	Field Type	Field Length	Description
A	Name of FTE	CHAR Always Required	100	Name of the first-tier entity (FTE) that was audited or monitored.
B	FTE function and responsibilities	CHAR Always Required	400	Brief description of the administrative or health care service function(s) and responsibilities the FTE conducts on behalf of the sponsor.
C	FTE Contract Effective Date	CHAR Always Required	10	Effective date of the FTE contract specific to the delegated Part C or Part D functions or services being reviewed or audited by the sponsor.  Submit in CCYY/MM/DD format (e.g., 2017/01/01).
D	Component	CHAR Always Required	100	Name of the sponsor's component(s), department(s) and/or operational area(s) that work in part or whole with the FTE.
E	Activity Type	CHAR Always Required	10	Enter whether the activity was an "audit" or a "monitoring" activity.
F	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a "compliance" or a "FWA" activity.
G	Activity Frequency	CHAR Always Required	10	Provide the frequency of the audit or monitoring activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
H	Activity Rationale	CHAR Always Required	200	Provide the rationale for conducting the audit or monitoring activity (e.g., monitoring activity was implemented because the function has an immediate impact on members' access to immediate medical care and prescription drugs).
I	Activity Description	CHAR Always Required	400	Provide a description of the audit or monitoring activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, pharmacy or provider claims, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).

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Column ID	Field Name	Field Type	Field Length	Description
J	Activity Start Date	CHAR Always Required	10	Date that the specific audit or monitoring activity was initiated, started or reopened by the sponsor. For example, if the sponsor started monitoring a function of the PBM to ensure it properly implemented its transition policy for new beneficiaries on January 1, 2017, that is the date that would be used for the date the audit or monitoring started.  Submit in CCYY/MM/DD format (e.g., 2017/01/01).
K	Activity Completion Date	CHAR Always Required	10	Date that the audit or monitoring activity ended. For example, if the sponsor completed monitoring a function of the PBM to ensure it properly implemented its transition policy for new beneficiaries on January 31, 2017, that is the date that would be used for the date the audit or monitoring completed.  Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer TBD (To Be Determined) if the audit or monitoring activity is currently in progress.
L	Identified Deficiencies	CHAR Always Required	3	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the audit or monitoring activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.
M	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.
N	Description of Deficiencies	CHAR Always Required	1000	Provide a summary of deficiencies, findings or issues identified during the audit or monitoring activity. If the audit or monitoring activity was identified in the pre-audit issue summary submitted to CMS, provide the issue number in the description.  Answer TBD if deficiencies have yet to be identified for an ongoing activity

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Column ID	Field Name	Field Type	Field Length	Description
O	Corrective Action Required	CHAR Always Required	200	<p>Yes (Y), No (N), or To Be Determined (TBD) indicator of whether corrective action was required for each deficiency/issue identified.</p> <p>Answer “Y” if every previously described deficiency identified during the audit or monitoring activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit or monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).</p> <p>Answer TBD if corrective actions have yet to be determined for an ongoing activity.</p>
P	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor and FTE in response to the noncompliance or potential FWA, including any root cause, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For an audit or monitoring activity that identified multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01 pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity. Answer N/A if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>

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Column ID	Field Name	Field Type	Field Length	Description
Q	Activity Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the audit or monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>

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**Table 2: Employees and Compliance Team (ECT) Record Layout**

- Include: all **current** employees of the sponsor (permanent, temporary, full-time, part-time) including: senior management, volunteers (e.g., unpaid interns) who have job duties related to the sponsor’s Medicare Advantage (Part C) and/or Prescription Drug (Part D) business, and members of the governing body (i.e. Board of Directors) responsible for oversight of the Medicare program who worked/served at any time during the audit review period.
- Exclude: individuals that have left the sponsor, terminated, resigned or do not work on the Medicare Parts C and/or D line of business as of the date of the audit engagement letter.

Column ID	Field Name	Field Type	Field Length	Description
A	Employee ID	CHAR Always Required	15	Internal employee ID assigned by the sponsor. Answer N/A if no employee ID was assigned.
B	Employee First Name	CHAR Always Required	50	First name of the employee or governing body member.
C	Employee Last Name	CHAR Always Required	50	Last name of the employee or governing body member.
D	Employee’s Title	CHAR Always Required	50	Position or title of the employee or governing body member.
E	Employee’s Organizational Component	CHAR Always Required	50	Component or department in which the employee works (e.g., appeals, marketing, customer service)
F	Physical Location	CHAR Always Required	100	Geographical or office location of the employee (e.g., Baltimore, MD. Central Headquarters)
G	Date of Hire or Appointment	CHAR Always Required	10	Enter the employee’s start date with the sponsor or governing body member appointment. Submit in CCYY/MM/DD format (e.g., 1940/01/01).
H	Employee Type	CHAR Always Required	20	Indicate whether the individual is a governing body member, full-time employee, part-time employee, temporary employee, or a volunteer.
I	Medicare Compliance Department Employee?	CHAR Always Required	1	Yes(Y)/No (N) indicator of whether the employee works for the Medicare Compliance Department.
J	Compliance Department Job Description	CHAR Always Required	1500	Briefly describe the job duties (e.g., internal audit, training, privacy, SIU) of the employee who works for the Compliance Department. Please also provide the length of time they have held that position.  Answer N/A if the employee does not work for or support the Compliance Department.

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Column ID	Field Name	Field Type	Field Length	Description
K	Compliance Committee Member?	CHAR Always Required	3	Yes(Y) or No (N) indicator of whether the employee or governing body member participates on a compliance committee that addresses Medicare compliance issues (e.g. corporate compliance committee, compliance and audit committee of the board, committee that focuses on the compliance of FDRs.
L	Compliance Committee Member's Role	CHAR Always Required	1500	Provide a summary of the role and/or expertise each employee brings as a member of the compliance committee (e.g., Manager of appeals & grievances responsible for addressing Part C appeals and grievance issues and concerns that severely impact enrollees and developing corrective action plans for the affected internal departments and FDRs.)  Answer N/A if employee is not a member of the compliance committee.

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**Table 3: Internal Auditing (IA) Record Layout**

- Include:
  - Compliance and fraud, waste and abuse (FWA) audit activities (formal review of compliance with a particular set of standards as base measures) performed by the sponsor to ensure that its internal business and/or operational areas are in compliance with Medicare Parts C and D program requirements and to ensure that corrective actions are undertaken timely and effectively.
  - Audit activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the sponsor level in the delivery of Medicare Part C and/or D benefits.
  - Audit activities that reviewed reports from internal operational areas to detect non-compliance and FWA trends and abnormalities.
  - Audit activities to investigate allegations of non-compliance and fraudulent, wasteful, abusive or questionable behavior performed by employees and board members involved in administering or overseeing the sponsor’s Medicare Part C and/or D operations (e.g. employee misconduct, internal operations, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - Audit activities initiated, started, re-opened or completed during the audit review period. This includes audit activities that started prior to the audit review period, but were completed within the audit period and activities that were started during the audit review period but not yet completed.
  - Audit activities that are performed on a scheduled basis (e.g., monthly, quarterly, annually, ad-hoc), should be included in the universe each time it was performed.
- Exclude:
  - Audit activities for non-Medicare lines of business (e.g., commercial, Medicaid) and audit activities performed for first-tier entities during the audit review period.
  - Audit activities that are performed on a daily basis.

Column ID	Field Name	Field Type	Field Length	Description
A	Component	CHAR Always Required	100	Name of the sponsor’s component, department or operational area that was audited.
B	Component Responsibilities	CHAR Always Required	400	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.
C	Auditor Type	CHAR Always Required	100	Indicate who was responsible for conducting the audit activity (e.g., compliance officer, internal audit department, appeals & grievances staff/manager, external audit firm). For internal staff, provide the name(s) of staff/department involved with conducting the audit activity. For external audit firms, provide the name(s) of the firm/company.



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Column ID	Field Name	Field Type	Field Length	Description
D	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a “compliance” or a “FWA” activity.
E	Audit Frequency	CHAR Always Required	10	Provide the frequency of the audit activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
F	Audit Rationale	CHAR Always Required	200	Provide the rationale for conducting the audit activity (e.g., audit activity was implemented because the function has an immediate impact on members’ access to immediate medical care and prescription drugs).
G	Audit Description	CHAR Always Required	400	Provide a description of the audit activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).
H	Audit Start Date	CHAR Always Required	10	Date that the specific audit activity was initiated, started or reopened. For example, if the sponsor started an audit of the appeals process/function within the sponsor on January 1, 2017, that is the date that would be used for the date the audit started.  Submit in CCYY/MM/DD format (e.g., 2017/01/01).
I	Audit Completion Date	CHAR Always Required	10	Date that the specific audit activity ended. For example, if the sponsor ended an audit of the appeals process/function within the sponsor on January 31, 2017, that is the date that would be used for the date the audit ended.  Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer TBD (To Be Determined) if the audit activity is currently in progress.
J	Identified Deficiencies	CHAR Always Required	3	Yes (Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the audit activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.

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Column ID	Field Name	Field Type	Field Length	Description
K	Number of Deficiencies	CHAR Always Required	3	<p>Provide the number of deficiencies, findings or issues identified.</p> <p>Answer TBD if deficiencies have yet to be identified for an ongoing activity.</p>
L	Description of Deficiencies	CHAR Always Required	1000	<p>Provide a summary of all deficiencies, findings or issues identified during the audit activity. If the audit was identified in the pre-audit issue summary submitted to CMS, please include the issue number.</p> <p>Answer TBD if deficiencies have yet to be identified for an ongoing activity.</p>
M	Corrective Action Required	CHAR	200	<p>Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each deficiency/issue identified.</p> <p>Answer “Y” if every previously described deficiency identified during the audit activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the audit activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).</p> <p>Answer TBD if corrective actions have yet to be determined for an ongoing activity.</p>

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Column ID	Field Name	Field Type	Field Length	Description
N	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For an audit activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01 pharmacy mail order audit activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity. Answer N/A if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>
O	Audit Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the audit activity were communicated or shared with sponsor's affected components, compliance department, senior management, and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>

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**Table 4: Internal Monitoring (IM) Record Layouts**

- Include:
  - Compliance and fraud, waste and abuse (FWA) monitoring activities (routine, scheduled and ad-hoc reviews as part of normal operations) performed by the sponsor to test and confirm internal business and/or operational areas are in compliance with Medicare Parts C and/or Part D program requirements and to ensure that corrective actions are undertaken timely and effectively.
  - Monitoring activities performed during the audit review period to identify and address potential or suspected non-compliance and FWA at the sponsor level in the delivery of Medicare Part C and/or D benefits.
  - Monitoring activities that reviewed reports from internal operational areas to detect non-compliance and FWA trends and abnormalities.
  - Monitoring activities to investigate allegations of non-compliance and fraudulent, wasteful, abusive or questionable behavior performed by employees and board members involved in administering or overseeing the sponsor’s Medicare Part C and/or D operations (e.g. employee misconduct, internal operations, fraudulent provider or pharmacy claims, fraudulent FTE invoices, misuse of Medicare beneficiary information, overpayments, complaints or tips received through hotlines, referrals, members, MEDIC, law enforcement, etc.)
  - All monitoring activities initiated, started, re-opened or completed during the audit review period. This includes monitoring activities that started prior to the audit review period, but were completed within the audit review period and activities that were started during the audit review period but not yet completed.
  - For monitoring activities that are performed on a scheduled basis (e.g., weekly monthly, quarterly, annually, ad-hoc), it should be included in the universe each time it was performed.
  
- Exclude:
  - Monitoring activities for non-Medicare lines of business (e.g., commercial, Medicaid).and monitoring activities performed for first-tier entities during the audit review period.
  - Monitoring activities that are performed on a daily basis.

Column ID	Field Name	Field Type	Field Length	Description
A	Component	CHAR Always Required	100	Name of the sponsor’s component, department or operational area that was monitored.
B	Component Responsibilities	CHAR Always Required	400	Brief description of what responsibilities the component, department or operational area conducts on behalf of the sponsor.

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AUDIT PROCESS AND DATA REQUEST**

Column ID	Field Name	Field Type	Field Length	Description
C	Monitor Type	CHAR Always Required	100	Indicate who was responsible for conducting the monitoring activity (e.g., compliance officer, internal audit department, appeals & grievances staff/manager, external audit firm). For internal staff, provide the name(s) of staff/department involved with conducting the monitoring activity. For external firms, provide the name(s) of the firm/company.
D	Compliance or FWA?	CHAR Always Required	10	Enter whether the activity was a “compliance” or a “FWA” activity.
E	Monitoring Frequency	CHAR Always Required	10	Provide the frequency of the monitoring activity (e.g. weekly, monthly, quarterly, annually, or ad-hoc).
F	Monitoring Rationale	CHAR Always Required	200	Provide the rationale for conducting the monitoring activity (e.g., monitoring activity was implemented because the function has an immediate impact on members’ access to immediate medical care and prescription drugs).
G	Monitoring Description	CHAR Always Required	400	Provide a description of the monitoring activity (e.g., operational area, training requirements, timeliness, accuracy of organization determinations and notifications, messaging errors, contractual agreements, unannounced or onsite audits, spot checks, compliance monitoring, targeted or stratified sampling, audit protocols).
H	Monitoring Start Date	CHAR Always Required	10	Date that the specific monitoring activity was initiated, started or reopened. For example, if the sponsor started monitoring of the appeals process/function within the sponsor on January 1, 2017, that is the date that would be used for the date the monitoring started.  Submit in CCYY/MM/DD format (e.g., 2017/01/01).

**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

Column ID	Field Name	Field Type	Field Length	Description
I	Monitoring Completion Date	CHAR Always Required	10	Date that the specific monitoring activity ended. For example, if the sponsor ended monitoring of the appeals process/function within the sponsor on January 31, 2017, that is the date that would be used for the date the monitoring ended.  Submit in CCYY/MM/DD format (e.g., 2017/01/01). Answer TBD (To Be Determined) if the monitoring activity is currently in progress.
J	Identified Deficiencies	CHAR Always Required	3	Yes(Y), No (N) or To Be Determined (TBD) indicator of whether any issues, deficiencies or findings were discovered during the monitoring activity. Answer TBD if deficiencies have yet to be identified for an ongoing activity.
K	Number of Deficiencies	CHAR Always Required	3	Provide the number of deficiencies, findings or issues identified.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.
L	Description of Deficiencies	CHAR Always Required	1000	Provide a summary of all deficiencies, findings or issues identified during the monitoring activity. If the monitoring activity is identified in the pre-audit issue summary submitted to CMS, please include the issue number.  Answer TBD if deficiencies have yet to be identified for an ongoing activity.

**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

Column ID	Field Name	Field Type	Field Length	Description
M	Corrective Action Required	CHAR Always Required	200	<p>Yes (Y), No (N) or To Be Determined (TBD) indicator of whether corrective action is required for each deficiency/issue identified. Answer TBD if corrective actions have yet to be determined for an ongoing activity.</p> <p>Answer “Y” if every previously described deficiency identified during the monitoring activity required a corrective action. Answer “N” if none of the previously described deficiencies required a corrective action. If some but not all of the previously described deficiencies from the monitoring activity required corrective action, specify which deficiencies needed a corrective action and separate by a number as needed (e.g., 1. Part D coverage determinations processed incorrectly – Y, 2. Part D coverage determinations Timeliness – N).</p> <p>Answer TBD if corrective actions have yet to be identified for an ongoing activity.</p>

**Parts C and D Compliance Program Effectiveness (CPE)  
AUDIT PROCESS AND DATA REQUEST**

Column ID	Field Name	Field Type	Field Length	Description
N	Corrective Action Description	CHAR Always Required	1000	<p>Provide a summary of the corrective action(s) implemented by the sponsor in response to the noncompliance or potential FWA, including any root cause analysis, timeframes for specific achievements and any ramifications for failing to implement the corrective action satisfactorily.</p> <p>For a monitoring activity that identifies multiple issues, separate the corrective actions implemented for each issue by a number as needed (e.g., 1. employee coaching was completed between 2017/02/01 and 2017/02/15 for the errors identified during the 2017/01/01, pharmacy mail order monitoring activity, 2. member remediation was conducted for 50 members that never received their approved medication).</p> <p>Answer TBD if corrective measures have yet to be determine for an ongoing activity.</p> <p>Answer N/A if corrective action was not taken or determined necessary by the sponsor for any of the identified issues.</p>
O	Monitoring Results Shared?	CHAR Always Required	500	<p>Provide a summary that describes how the results of the monitoring activity were communicated or shared with sponsor's affected components, compliance department, senior management and/or the FTE.</p> <p>Answer TBD if results have yet to be determined and shared with others for an ongoing activity.</p>



**ATTACHMENT I-B**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**COMPLIANCE OFFICER QUESTIONNAIRE (CO-Q)**

(Rev. 2. 10-2016)

**Name of Sponsoring Organization:**

**MA-PD/PDP Contract Numbers:**

**Name and Title of Person Completing Questionnaire:**

**Date of Completion:**

**Directions for Completing the Compliance Officer Questionnaire:**

This questionnaire will assist CMS with understanding the sponsoring organization's mechanisms for overseeing the performance and effectiveness of the compliance program from the compliance officer's perspective.

The responses to these questions may be discussed during the onsite portion of the CPE audit.

We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.

If multiple individuals are responsible for the operations and oversight of the compliance program (e.g. Corporate Compliance Officer, Medicare Compliance Officer, SVP of Audit and Compliance) and have different responses to the questions, please consolidate responses and incorporate into one document.

Please specifically note the following when completing the questionnaire:

- "You" refers to your organization, not necessarily a specific person.
- "Employees" refer to employees, including senior management, who support your Medicare business.
- "Compliance Officer" refers to the compliance officer who oversees the Medicare business.
- "CEO" refers to the Chief Executive Officer of the organization or the most senior officer, usually the President or Senior Vice President of the Medicare line of business.
- "Compliance Program" refers to your Medicare compliance program.
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization's management are to the board, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.

**ATTACHMENT I-B**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**COMPLIANCE OFFICER QUESTIONNAIRE (CO-Q)**

- “FDRs” refer to the organization’s first-tier, downstream and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the Sponsor.

Unless specific reference is made in the question to the term “governing body”, it means either the full board or a committee of the board of directors delegated to conduct oversight of the day-to-day operation of the Medicare compliance program on behalf of the full governing body.

1. How long have you been employed with the sponsor and served as the Compliance Officer of the Medicare line of business?

2. Briefly describe your background and how it relates to your role as an effective Compliance Officer for the sponsor.

3. Provide a general view of your responsibilities as the Compliance Officer.

4. Do you have any other responsibilities in addition to being the Compliance Officer for this organization? If yes, please describe those positions and responsibilities.

5. What are some of the tools used to keep the compliance department up-to-date on tasks and assignments that have been delegated to both operational and FDRs?

6. What resources do you use on a regular basis to keep the organization current on CMS compliance, audit, and enforcement information and activities?

7. Provide an example of a compliance issue you had to deal with during the audit review period that involved a Medicare operational area and/or a first-tier, downstream or related entity (FDR) and impacted a significant number of your enrollees from receiving their health or drug benefits time in accordance with CMS requirements. Describe what happened and how you handled it.

**ATTACHMENT I-B**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**COMPLIANCE OFFICER QUESTIONNAIRE (CO-Q)**

8. Provide an example of a time when communicating compliance issues to the compliance committee, senior management or governing body regarding was challenging. Briefly discuss how you handled it.

9. Describe a recent experience you had with a miscommunication with an employee(s) when dealing with suspected, detected or reported incidents of noncompliance or fraud, waste and abuse (FWA)? How did you or the compliance department solve the problem?

10. During the audit review period, have you ever had to make a decision when no or limited internal or CMS policy was available to provide guidance on how to handle the issue? Describe what happened and how you handled it.

11. What has been your experience in dealing with poor compliance performance of Medicare operations within your organization? Provide an example.

12. In your position as Compliance Officer, what types of decisions do you make at your level without consulting with senior management ultimately responsible for the Medicare Advantage and/or Part D contract with CMS? What are some of indicators that tell you to escalate the decision or issue to senior management?

13. CMS understands that every compliance issue is not presented to senior management or the governing body. Explain the criteria used by the compliance department for escalating issues to the CEO and senior management that present high-impact risks to the organization. Include how/when the parties are advised of operational and regulatory compliance activities (e.g. critical discussions with the CMS Account Manager, Notices of Non-Compliance, Civil Money Penalties, Marketing/Enrollment Sanctions, etc.).

14. How do you keep your organization current on CMS regulations, policy requirements and expectations for various operational areas?

15. How do you measure employee, FDRs and governing body member awareness and understanding of the compliance program?

**ATTACHMENT I-B**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**COMPLIANCE OFFICER QUESTIONNAIRE (CO-Q)**

16. What mechanisms are in place to communicate operational area concerns/issues to the compliance department?

17. What have been major obstacles with executing an effective compliance program which you have had to overcome in your role as the Compliance Officer? How did you deal with them?

18. What indicators tell you, as the compliance officer, that the Medicare compliance function/system is working well with finding and fixing compliance issues and fraud, waste and abuse incidents? Are they effective for your organization?

19. What suggestions or changes would you make to encourage transparency and strengthen the communication between your organization and CMS (e.g. Central Office, Regional Office, and Account Manager) as it relates to compliance issues?

20. Are there any recent initiatives or upcoming initiatives to improve the current state of your organization's compliance culture?

21. Would you like to share any best practices that may assist others with succeeding in this complex area of implementing and overseeing an effective compliance program?

22. Do you have any questions or comments for CMS?

**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,**  
**DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

(Rev. 2. 10-2016)

**Name of Sponsoring Organization:**

**MA-PD/PDP Contract Numbers:**

**Name and Title of Person Completing Questionnaire:**

**Date of Completion:**

**Directions for Completing the FDR Oversight Questionnaire:**

This questionnaire will assist CMS with understanding the sponsoring organization's accountabilities and oversight of its delegated entities to ensure their compliance with Medicare program requirements.

The responses to these questions may be discussed during the onsite portion of the CPE audit.

We recognize that your time is valuable and appreciate your availability to provide responses to our questions regarding the compliance program.

If multiple individuals are responsible for the operations and oversight of first-tier, downstream and related entities (e.g. Corporate Compliance Officer, Delegated Entity Compliance Officer, Vendor Management Group, etc.) and have different responses to the questions, please consolidate responses and incorporate into one document.

Please specifically note the following when completing the questionnaire:

- "You" refers to your organization, not necessarily a specific person.
- "Employees" refer to employees, including senior management, who support your Medicare business.
- "Compliance Officer" refers to the compliance officer who oversees the Medicare business.
- "CEO" refers to the Chief Executive Officer of the organization or the most senior officer, usually the President or Senior Vice President of the Medicare line of business.
- "Compliance Program" refers to your Medicare compliance program.
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization's management are to the board, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.
- "FDRs" refer to the organization's first-tier, downstream and related entities contracted to perform an administrative or healthcare service to enrollees on behalf of the Sponsor.

**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**

**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,  
DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

- “First Tier Entity” refers to any party that enters into a written agreement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
- “Downstream Entity” refers to any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written agreements continue down to the level of the ultimate provider of both health and administrative services.
- “Related Entity” refers to any entity that is related to an MAO or Part D sponsor by common ownership or control and
  1. performs some of the MAO or Part D plan sponsor’s management functions under contract or delegation
  2. furnishes services to Medicare enrollees under an oral or written agreement; or
  3. leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.
- If the Medicare contract holder is a wholly owned subsidiary of a parent company, references to the governing body, CEO and highest level of the organization’s management are to the governing body, CEO and management of the company (parent or subsidiary/contract holder) that the organization has chosen to oversee its Medicare compliance program.

**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,**  
**DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

1. How long have you been employed with the sponsor and been involved with overseeing FDRs?

2. Have you held any positions in the company, prior to being the person or a part of the team responsible for managing delegated entities?

3. Are delegated entities managed by one individual or a group of individuals/departments?

4. Provide a general overview of the delegated entity oversight program.

5. The method by which the analysis for determining whether a contracted entity is categorized as a FDR according to CMS' definitions is left to the discretion of the sponsoring organization. Please describe your criteria for determining which delegated entities are properly identified as FDRs subject to Medicare compliance requirements.

6. How many first-tier entities does your organization contract with to perform Medicare Parts C/D functions?

7. Who or which business operations are involved with the pre-contractual assessment to ensure contractual and regulatory obligations are met.

8. Once the contract has been initiated with the delegated entity, who or which business operations are responsible for tracking and monitoring the FDRs performance and day to day oversight for compliance issues?

9. Describe the mechanisms used for oversight activities (e.g. structure, risk assessment, specialized teams focused on specific functions, etc.)

**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,**  
**DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

10. Describe specific examples of the types of communications that exist between the Compliance Department and FDR Oversight regarding Medicare requirements, policy updates, performance concerns or issues with FDRs, specifically the first-tier entities such as your PBM, enrollment/membership functions, coverage or claims adjudication, network management, etc.?

11. How do you ensure that any compliance issues involving a FDR is communicated to the appropriate governance level (e.g. compliance committee, senior managers, Board of Directors, and/or the CEO)? Please provide a recent example/scenario.

12. What ongoing processes do you have to evaluate and assess the effectiveness of the delegation oversight program, such as a self-assessment tool, delegation compliance committee, scorecard, etc.?

13. How do you share information or train FDRs on your organization's culture, compliance and productivity expectations, CMS regulations, and policy for the Medicare function performed on the sponsoring organization's behalf?

14. Describe the training, education and communication program for FDRs (e.g. roles and responsibilities, compliance and FWA training, job-specific, exchange of information, compliance disclosures and failures, etc.).

15. Provide examples of the types of periodic monitoring reports your organization receives from FDRs?

16. Describe the strategy for monitoring and auditing your first tier entities for compliance regulatory requirements, downstream oversight, and implementation of corrective actions.



**ATTACHMENT I-D**  
**MEDICARE ADVANTAGE AND PRESCRIPTION DRUG COMPLIANCE PROGRAM**  
**EFFECTIVENESS (CPE)**  
**SPONSOR'S ACCOUNTABILITY FOR AND OVERSIGHT OF FIRST-TIER,**  
**DOWNSTREAM AND RELATED ENTITIES QUESTIONNAIRE (FDR-Q)**

17. What happens if a FDR fails to satisfactorily implement a corrective action plan or commits a serious act of noncompliance with Medicare requirement that affects enrollees from receiving their health care or drug benefit appropriately or timely?

18. What are a few of the challenges or issues with effectively overseeing FDRs your organization has experienced within the audit review period (e.g., PBM, sales brokers, entities with direct member contact, provider networks, etc.).

19. List a few of your accomplishments for FDR oversight during the audit review period? What are your priorities for delegation for the next two years?

20. Would you like to share any best practices that may assist others with succeeding in this complex area of overseeing and being accountable for FDRs' compliance with CMS regulatory requirements?

21. Do you have any comments or questions for CMS?



**POLSINELLI**

HCCA Compliance Institute 2017 — Session 411

*The Business Of Health Care Fraud Enforcement:  
A Pragmatic Discussion And Assessment*

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**Agenda**

- Noteworthy settlements, cases and the resulting enforcement trends
- Insights from financial statistics and governmental data
- “What it all means” - discussion of the trends and implications

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**POLSINELLI**

**NOTEWORTHY SETTLEMENTS, CASES  
AND THE RESULTING ENFORCEMENT  
TRENDS**

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### Settlement Trends

- **Pharma cases**
  - Daiichi Sanko (\$39M - honoraria and meals)
  - Pfizer (\$785M - alleged drug pricing)
  - Genentech (\$67M - effectiveness misrepresentations)
  - Valeant (\$54M free dinners and sham speaker payments)
  - Biocomparables (\$36M - off label marketing)
  - Forest Laboratories (\$38M - off label marketing)
  - Warner Chilcott \$125M (cash payments , expensive dinners)
  - Daiichi Sanko \$39M (honoraria and meals)

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### Settlement Trends

- **Large AKS-based settlements (non-pharma)**
  - DaVita \$389M (AKS allegations related to JVs)
  - Amedisys \$150M (home health medical necessity and AKS)
  - OmniCare \$124M (pharmacy and AKS w/NFs)
  - Millennium Health \$256M (free specimen testing cups)
  - Health Diagnostics Lab \$48.5M (free S&H, waiver of co-pay)
  - Olympus (\$646M – marketing & other inducements)
  - Respironics (\$35M – free call center support)
  - Tenet Health (\$513M – payments to pre-natal clinics)

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### Settlement Trends

- **Medical Necessity—Hospitals**
  - Premier Vein (\$400K, unlicensed staff)
  - St. Joseph (\$16.5M, heart surgery)
  - Health Man. Assoc. (\$1M, sinus endoscopy)
  - Baptist Health (\$2.5M, MS and brain disorders)
  - King’s Daughter Medical (\$41M, cardiac stents)

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**Settlement Trends**

- **Medical necessity—Long Term Care**
  - Kindred (\$125M)
  - Life Care Centers (\$145M)
  - No. American Health (\$28.5)
  - Westlake Convalescent (\$3.5M)

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**Settlement Trends**

- **Medical Necessity—Hospice**
  - Covenant Hospice \$10.1M (also billing issues)
  - Compassionate Care Hospice Group \$6M (failure to treat based on POC)
  - Good Shepherd Hospice \$4M
  - Guardian Hospice of Georgia LLC \$3M
  - Hospice of Citrus County \$3.2M
  - Serenity Hospice and Palliative Care \$2.2M (also AKS violations)

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**Settlement Trends**

- **Physician Employment (Stark and AKS)**
  - St. Mary (\$2.3M, admin of comp terms)
  - All Children's Florida (\$7M, FMV)
  - New York Heart (\$1.3M, comp based on referral volume)
  - Halifax Hospital (\$85M, bonus calculation)
  - Westchester Med Center \$18.8M (advanced money, forgave debt)
  - Citizens Medical Center (\$21.7M non-FMV)
  - Columbus Regional (\$34M non-FMV)
  - Adventist Health System (\$115M non-FMV and bonus calc)
  - North Broward Hospital (\$69.5M non-FMV)
  - Lexington Medical Center (\$17M -FMV)
  - Memorial University (\$10M - FMV and practice losses)

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**Settlement Trends**

- **Pharmacy and prescription opioid**
  - CVS (\$3.5M, 500 forged opioid prescriptions)
  - Cardinal Health (\$44M, failure to report suspicious opioid orders)
  - Costco (\$11.75M, inadequate opioid prescription process)
  - McKesson Corp. (\$150M, failure to report suspicious opioid orders)

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**Settlement Trends**

- **National investigations**
  - Kyphoplasty investigation: 130 hospitals totaling approximately \$105M
  - ICD investigation: 457 hospitals totaling \$250M
  - Inpatient vs. Outpatient (one-day LOS)
    - CHS: \$98M (7 *qui tams*)

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**Court Decision Trends**

- **General increase in Court of Appeals decisions**
  - 63 appellate decisions during the last year
  - Hard to see a trend in appellate rulings
  - Pleading standards and application of Rule 9(b) loomed large

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**Court Decision Trends**

- **Only material non-compliance creates FCA liability**
  - *Universal Health Services Inc. v. U.S. ex rel Escobar* (6/16/2016, unanimous Supreme Court)
  - Defendant can face FCA liability under an implied certification theory where failure to disclose noncompliance with statutory, regulatory, or contractual requirements is material to government’s decision to pay the claim
  - Little guidance on what “material” mean

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**Court Decision Trends**

- **Allegations of fraud and noncompliance must be alleged with particularity (Rule 9(b))**
  - *U.S. ex rel. Eberhard v. Physicians Choice Lab. Servs.*, 6th Cir., dismissed claims where relator failed to include “representative examples” or plead the submission of false claims
  - *U.S. ex rel. Kelly v. Novartis Pharm*, 1st Cir., affirmed dismissal because relators did not plead particular allegations about specific fraudulent claims for payment
  - *U.S. ex rel. Chase v. LifePath Hospice*, dismissed claims because relator failed to identify which Medicare claims were fraudulent

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**Court Decision Trends**

- **Courts: no FCA Liability for reasonable interpretation of ambiguous regulation**
  - *U.S. ex rel. Saldivar v. Fresenius*, 11<sup>th</sup> Cir (drug overfill billing)
  - *U.S. ex rel. Olson v. Fairview Health Servs. of Minn*, 8th Cir., (definition of “children’s hospital” was ambiguous )
  - *U.S. ex rel Donegan v. Anesthesia Assocs. of Kan. City*, 8th Cir., (definition of “emergence” from anesthesia was ambiguous and group’s interpretation was not unreasonable)
  - *U.S. ex rel. Wall v. Vista Hospice Care* (differing opinion on hospice eligibility insufficient to create FCA liability)

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## Enforcement Trends

- **Focus on individual is increasing**
  - Bostwick Lab owner pays \$3.75M to settle FCA suit (company paid \$6.5M )
  - No. American Health (board chair to pay \$1M of \$28.5M settlement)
  - Former CEO & Board Chair of Tuomey excluded and fined \$1M
  - Theranos CEO banned from owning a lab under CLIA
  - *Bohner v. Burwell*, court upheld exclusion of a pharma executive
  - Dec. 2016: Forest Park Hosp. - 21 people indicted related to payments from private pay hospital
  - Feb. 2017: former CEO of a HCA hospital in Atlanta indicted (alleged AKS violations)

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INSIGHTS FROM FINANCIAL STATISTICS  
AND GOVERNMENTAL DATA  
*No One Part of Industry is Immune*

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## Average of FCA Settlements by Industry

Average of FCA settlements from 2014-2016 (in millions)

Industry	Average Settlement (in millions)
Pharmaceuticals	~480
Hospitals and Health Systems	~280
Medical Devices	~160
Post-Acute	~150
Diagnostic Services	~100
DME	~40

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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Hospitals and Health Systems

Type of Behavior	2014	2015	2016
AKS & Stark	\$8.5M	-	-
AKS, Stark, & medically unnecessary services	\$16.5M	-	-
Billing for services in violation of coverage requirements	-	-	\$23M
False cost reports	-	\$12.9M	-
Improper donations to government for Medicaid	-	\$75M	-
Medically unnecessary services	\$36.7M	\$20M	\$27.6M
Stark	\$85M	\$216.2M	-
Stark & medically unnecessary services	\$40.9M	\$35M	-
Stark & upcoding	\$98.2M	\$48M	-
Upcoding	\$35M	\$48M	-
<b>Total</b>	<b>\$320.8M</b>	<b>\$455.1M</b>	<b>\$50.6M</b>

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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Post-Acute Care

Type of Behavior	2014	2015	2016
AKS	-	\$17M	\$1.8M
Billing for services by an excluded provider	-	\$6.5M	-
Billing for services w/o appropriate certification	-	\$5.6M	-
Deficient services	\$750K	-	-
Medically unnecessary services	\$3.9M	\$20M	\$173M
Medically unnecessary services & upcoding	\$25M	\$4.7M	-
Medically unnecessary and deficient services & upcoding	-	\$38M	-
Stark & medically unnecessary services	\$150M	-	-
Upcoding	-	\$10M	-
<b>Total</b>	<b>\$179.7M</b>	<b>\$101.8M</b>	<b>\$174.8M</b>

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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Pharmaceutical

Type of Behavior	2014	2015	2016
AKS	\$128.2M	\$460.7M	\$46.5M
Beneficiary inducement	\$6.3M	-	-
Billing for controlled substances w/o valid prescription	-	\$31.5M	-
Failure to meet quality standards	\$18M	-	-
Failure to reimburse Medicaid for drug costs	\$6M	-	-
Marketing of prescription for non-FDA approved use	-	\$171.9M	-
Medically unnecessary prescriptions by non-treating physicians	-	\$8.4M	-
Misleading statements to market and sell medication	\$63.8M	-	\$62.6M
Underpayment of rebates	-	\$54M	\$413M
<b>Total</b>	<b>\$222.3M</b>	<b>\$726.5M</b>	<b>\$522.1M</b>

21

Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Medical Device

Type of Behavior	2014	2015	2016
AKS	\$9.98M	\$2.6M	\$318.8M
AKS & promotion of device for non-FDA approved use	\$40.1M	\$13.5M	-
Distribution of adulterated medical devices	\$41.2M	-	-
Marketing and distribution of device for non-approved use	-	-	\$18M
Medically unnecessary devices or supplies	-	-	-
Selling devices to government that were manufactured outside of the US	-	\$12.7M	-
Unbundling	-	\$10.3M	-
Upcoding	-	\$1.3M	-
<b>Total</b>	<b>\$91.28M</b>	<b>\$40.4M</b>	<b>\$336.8M</b>

22

Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Durable Medical Equipment

Type of Behavior	2014	2015	2016
AKS	-	-	\$54.8M
Falsified medical documentation	-	\$7.5M	-
<b>Total</b>	<b>-</b>	<b>\$7.5M</b>	<b>\$54.8M</b>

23

Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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### Diagnostic Services

Type of Behavior	2014	2015	2016
AKS & medically unnecessary services	\$15.5M	\$254.1M	\$3.7M
Billing for services referred by non-physicians	-	\$2.9M	-
Falsified medical documentation	-	\$5.7M	-
Medically unnecessary services	-	\$15M	-
<b>Total</b>	<b>\$15.5M</b>	<b>\$277.7M</b>	<b>\$3.7M</b>

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Source: Office of the Inspector General, Health Care Fraud and Abuse Program Report

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**POLSINELLI**

**"WHAT IT ALL MEANS"**  
DISCUSSION OF THE TRENDS AND IMPLICATIONS

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**A Recent History. . .**

**HC FAC Data**

<b>2009 to 2016</b>	<b>&gt;\$17.9 bil.</b>
2016	\$3.3 bil
2015	\$1.9 bil
2014	\$2.3 bil

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**A Recent History. . .**

**Whistleblowers Driving Enforcement**

FY	NEW MATTERS <sub>1</sub>		SETTLEMENTS AND JUDGMENTS <sub>2</sub>				TOTAL QUI TAM AND NON QUI TAM
	NON QUI TAM	QUI TAM	NON QUI TAM TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL	
2008	161	379	312,193,480	1,042,582,229	12,678,936	1,055,261,165	1,367,454,645
2009	132	433	469,334,681	1,959,856,256	33,776,480	1,993,632,735	2,462,967,417
2010	140	576	647,383,493	2,280,378,123	106,890,899	2,389,269,023	3,036,652,516
2011	125	635	241,365,995	2,648,195,115	173,888,703	2,822,083,818	3,063,449,813
2012	144	652	1,608,112,863	3,342,218,074	44,973,343	3,387,189,418	4,995,302,280
2013	101	755	169,126,772	2,838,439,485	127,348,056	2,965,787,541	3,134,914,313
2014	97	715	1,676,564,228	4,371,182,653	81,378,451	4,452,561,104	6,129,125,330
2015	110	639	731,342,298	1,879,431,785	1,174,568,601	3,054,000,386	3,785,342,672
2016	143	702	1,856,329,432	2,800,043,469	104,984,935	2,905,028,403	4,761,357,835
<b>TOTAL</b>	<b>4,883</b>	<b>11,304</b>	<b>15,347,423,655</b>	<b>35,394,820,358</b>	<b>2,290,532,213</b>	<b>37,685,352,572</b>	<b>53,032,776,227</b>

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**What's Driving the Enforcement Environment?**

- Solvency of Medicare and Medicaid Programs
- "Pay and Chase"
- High ROI to government spend
- Whistleblowers
  - Relator monetary rewards and attorney fees
  - Growth area for plaintiffs' bar

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**What's Driving the Enforcement Environment?**

- Dedicated enforcement resources
  - Health Care Fraud and Abuse Control Account
  - ACA included more than \$350M in dedicated enforcement funding (over 10 years)
- Public and political pressure
  - Prescription opioid enforcement
  - Mylan Epi-pen (\$465M Medicaid settlement)

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**What's Driving the Enforcement Environment?**

- Lack of other distractions (or government priorities)
- Complex regulatory environment
  - Coding systems tend to fail at the edges
  - High levels of regulatory change
- Competitive business pressures

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**Impact on Health Care Industry**

**Resources for Patient Care** →

- Robust Compliance Program
  - Internal Audit
  - Training and Education
  - Management and Board Oversight
- Defending Investigations – even those w/out merit
  - DOJ must investigate all qui tams
  - Companies must cooperate

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**Predictions for 2017**

- Aggressive administrative actions (revocation, suspension, exclusions, non-enrollment)
- Appellate courts weigh in on the FCA's materiality standard, but no consistency or clarity
- No decrease in focus on long term care, hospice and home health, AKS and financial relationships
- Government commences / continues dragnet targeting opioid and controlled substances prescriptions
- Enforcement and rhetoric by DOJ and OIG about pursuing individuals (more "exemplar" cases, more exclusion cases)

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Questions or Comments?



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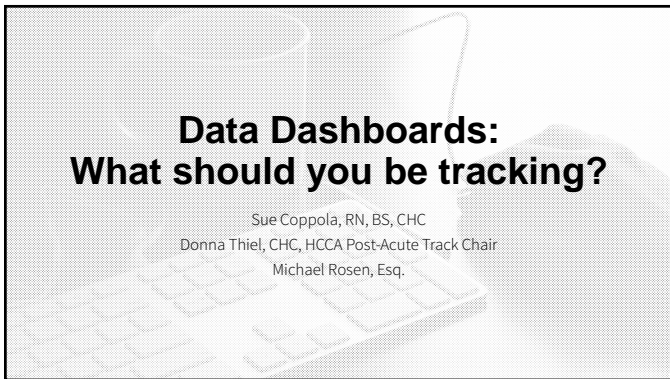
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## Data Dashboards: What should you be tracking?

Sue Coppola, RN, BS, CHC  
Donna Thiel, CHC, HCCA Post-Acute Track Chair  
Michael Rosen, Esq.

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Today's Presenter  
**Sue Coppola, R.N., B.S, CHC**

Sue Coppola, RN, BS, CHC, joined *Sunrise Senior Living* in 2015 as Senior Vice President of Care. In her role, Sue oversees all care-related programs and policies impacting Sunrise's communities. This includes the management of the Quality department for Sunrise in addition to the implementation of electronic health records and clinical operations.

With more than 25 years of leadership experience in health care, Sue possesses a wealth of expertise in clinical areas such as processes to monitor and validate outcomes, quality assurance and compliance.

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Today's Presenter  
**Donna J. Thiel, CHC**

Donna Thiel is the Director of the new Compliance Integrity division of ProviderTrust.

ProviderTrust, an exclusion and license monitoring SAAS company, is located in Nashville, Tennessee. With clients ranging from Acute Care, Post-Acute Care, LTC/Home Health, Renal Dialysis and Health Plans, thousands of compliance officers depend on ProviderTrust for their OIG exclusions and state license monitoring compliance dashboard.

Donna has over 30 years of experience in the long-term care industry with nearly 15 of those years in legal and compliance. She is the former Chief Compliance Officer of a nationwide post-acute health care company.

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Today's Presenter  
**Michael Rosen, Esq.**

Mr. Rosen, who co-founded ProviderTrust, an exclusion monitoring SAAS company, brings over 25 years of experience in founding and leading service-oriented business. He was formerly President of Kroll Background Screening, of the largest pre-employment background screening firms in healthcare.

He grew up in Nashville, Tennessee, graduated from the University of Texas and the University of Memphis Law School, and enjoys traveling and spending time with his family.

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### Today's Agenda

- The History of Data
- The importance of a Compliance Dashboard
- How do you decide which metrics to include?
- Sample Compliance Dashboards
- What to do with all that data?

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### Section 1 **The history of data**

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## The History of Data – The power of the 20<sup>th</sup> Century

### Think Horse Power.

Did you know? The term “dashboard” was the barrier of wood/leather at the front of a horse drawn carriage. Used to protect driver from debris.

### Then Think Automobile.

Advent of collecting engine metrics needed to see under the hood.

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## Google, circa 1997



Source: BT B&B

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## The History of Data

- So data dashboards went from protective barrier to protective communication
- Businesses today can't function without up to the minute data
- Visualization of data simplifies complex and sometimes unrelated data to share across company
- Real time data allows to pivot, respond and forecast- but need to decide what is important vs. “shiny”
- The right data metrics allow for increased compliance and improved quality outcomes

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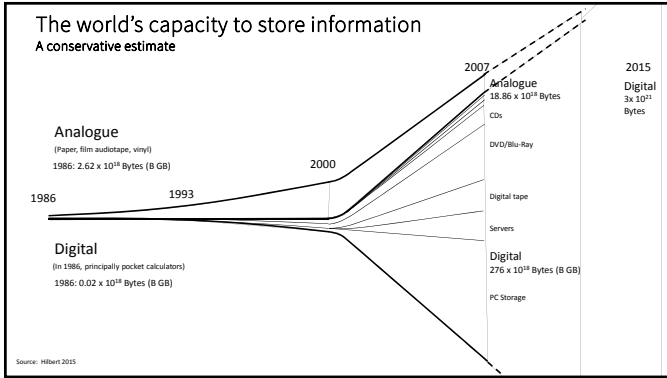
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### What Makes a Great Data Dashboard?

- **Discover, Design, Decompose and Deliver**
- Tricky: balance key overall with deep dive capabilities
- It's about catering for personalization and prioritization of the right metrics
- Keeps everyone on the same page = collaboration
- Contextualizes Data = automate process of data gathering and empower people with business intelligence
- Provides Social Intelligence = people want to be in the know

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### Stats Don't Lie: They have no hidden Agenda

- Avoid data entry errors
- Shows the good and the bad
- Ability to identify and correct negative trends
- Demonstrates good governance and performance over time
- Aligns strategies and organizational goals
- Essential that it fit on one page only

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Section 2

**Why is a dashboard so important?**

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**Why have a dashboard?**

- Saves you time
- Likely not to review individual reports
- Individual metrics may be misleading
- Metrics trended or grouped should tell a story
- Allows you to determine where to focus more time and resources
- Dashboards should make data management easier
- Turns data into information

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**Why have a Compliance Dashboard?**

- View of what is happening holistically
  - Not just your functional area
- Gives you the bigger picture
- Must see big picture to know where to ask more questions
- Allows you to see company-wide trends

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### Example of Big Picture Dashboard: Cyber Security



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### Dashboard Considerations

- Frequency of Data
  - Daily
  - Weekly
  - Monthly
  - Quarterly
  - Annually
- Trend Line
  - Benchmark
  - Peer Group
- How many metrics should be grouped together?
- Which metrics should be grouped together?
- How many dashboards?

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### Section 3

## How do you pick your metrics?

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### Roadblocks on the road to useful data




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### Initial Steps

- Identify key business risk drivers
  - Quality
  - Litigation
  - Government Trends
  - Financial
  - Satisfaction/Hotline
- Each business line will influence metrics
- Have to meet with key stakeholders to identify these key risk drivers
- Don't pick these in a vacuum

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### Sample Metrics

- |                                  |                                       |
|----------------------------------|---------------------------------------|
| • Quality of Care                | • High Risk Operational Risks         |
| • Compliance                     | • Internal Risk Assessment            |
| • Training                       | • New Operational Initiatives         |
| • Billing                        | • Government Focus Areas              |
| • Turnover                       | • Litigation Trends                   |
| • Customer/Employee Satisfaction | • Worker's Compensation               |
| • Staffing                       | • HIPAA (Breaches)                    |
| • Licensing                      | • Ethics and Compliance Hotline Calls |

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### How to organize your metrics?

Structure, process and outcomes

- Measurements of structure
  - Turnover/Retention
  - Staffing/Labor
  - Ethics Hotline Notification
- Process or System Measure
  - Falls, Weight Loss, Pressure Ulcers
  - Reporting of Allegations of Abuse/Neglect
  - Compliance with Mandatory Meetings or Processes
- Outcome measures
  - Regulatory/State Survey
  - Denial Trends
  - Financials (EBIDA, NOI)
  - Employee and Resident Satisfaction

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### Organize the information to support its meaning and use

- Think Studio apartment not 10 bedroom mansion

A studio apartment is a small space and each item serves a purpose; nothing is extraneous.

1. Visually identify and monitor at a glance
2. Single computer screen or report page
3. Most important trends, patterns and/or variances that are needed to think, reason and make informed decisions

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Section 4

### Sample dashboards

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### Quality of Care

- Specific areas identified as above benchmark and high risk; be sure to define what comprises the measures
- Government scrutinized quality metrics
  - Readmission to hospital also consider measuring mortality
    - RUG or DRG levels
    - Antipsychotic Medication Utilization
    - Significant Medication Errors
- Falls, Falls with Injury, Falls with Significant Injury
- Near Misses
- Elopement/Unsafe Leaving

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### Quality Dashboard Example

Facility	State	WTH Rate (20% or <)	Antipsychotic Rate (10% or <)	Fall Rate (3% or <)	Hgh. Med Error (2% or <)	Target Standard (6 and Above)	No Citis (6 and Below)	5 Star DMA Rates (6 or >)	24/7 Mx Coverage (60/100%)	Total Score	Total Possible Points	Percent	Rank	Previous Score
1	PA	10	10	0	10	6	10	10	10	60	60	81.25%	4	75.00%
2	PA	0	0	0	10	0	10	7	10	37	60	66.33%	20	57.00%
3	PA	10	0	10	10	10	10	0	0	50	60	62.50%	15	59.25%
4	PA	0	0	0	10	10	10	0	10	40	60	50.00%	18	62.50%

Facility	Percent	Rank	Facility	Percent	Rank
Fac 1	82.50%	1	Fac 7	61.25%	7
Fac 2	61.25%	2	Fac 8	60.50%	8
Fac 3	69.83%	3	Fac 9	57.83%	9
Fac 4	60.50%	4	Fac 10	57.83%	10
Fac 5	69.83%	4	Fac 11	57.83%	11
Fac 6	61.25%	6	Fac 12	56.50%	12

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### Compliance

- All Compliance Events
  - Calls
  - Investigations
  - Investigations, requests
- Volume of hotline calls
- Type of issues
- Number of anonymous vs. not
- Open investigations

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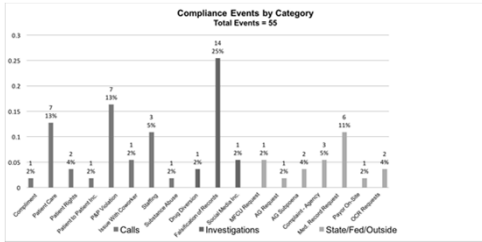
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### Compliance Event Dashboard Example



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### Board of Directors Dashboard

- High Level
- Big Picture of Compliance
- Color Coded vs. specific scores

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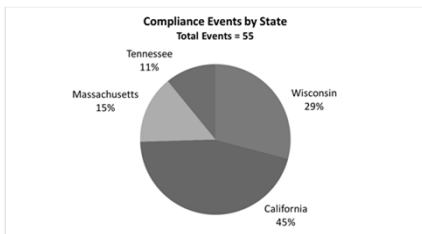
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### Board of Directors Example



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Section 5  
**Bringing data alive**

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Great, but what do we do with it?



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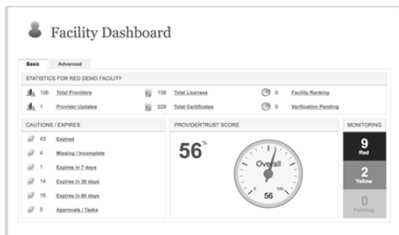
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Organize the information to support its meaning and use - *who is the audience?*



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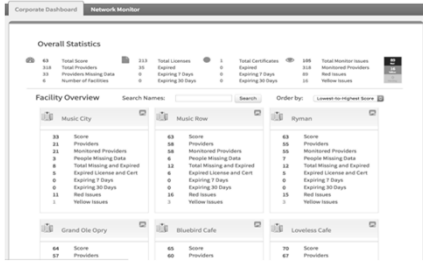
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Organize the information to support its meaning and use - *who is the audience?*




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### Looking at your results

- Metrics, targets thresholds
- Did you pick the right metrics?
- Are the definitions right?
- Were your metrics effective?
- Are you evaluating ongoing business needs?
- Ability to communicate and understand the business

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### Looking at your results

- Year over year
- Positive Trend or Negative?
- Do you need to modify?

Is there transparency in reporting?

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### Communicating Outcomes

Who Needs to Know?

- Line Management
- Department
- Compliance
- Legal
- Board

How to Capture Attention?

- Monthly Report vs. Interactive
- Dashboard Alert- when needed
- Ability to Update or Notation?
- How to track outcomes?
- Knowledge is Notice- Do Something!

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### CIA Impact

More input

- CIA requirements
- Monitor requirements
- OIG requirements

More Scrutiny

- Monitor participation in Compliance Committee
- Monitor participation in Board Meetings
- Quarterly/semi-annual reports/feedback from Monitor
- Annual feedback from OIG

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### Key takeaways

- There is more data available than ever before...it can be useful or useless
- There are new ways to make data meaningful
- There are new ways to gain knowledge from data
- Organizations are adapting at different paces but all are adapting

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**Questions**

Feel

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OPTUM™



**Navigating Medical Necessity Denials for All Payers**  
 Marc Tucker, DO, FACOS, MBA  
 Vice President, Clinical and Regulatory

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Agenda

- Background
- Best Practice Approach
- Denials Management
- Keys to Success
- Take Home/Q&A

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The Payer Landscape: Two Worlds

*The Same Processes and Rules Don't Apply*

**FFS Medicare / Medicaid**

**Regulatory Landscape:**

- IPFS
- OPFS
- QIO's
- OIG / DOJ

**Commercial Payers**

- Contract based
- Don't follow Two-Midnight rule
- Need to avoid self denials
- Avoid an increasingly prevalent trend:  
When health plans consistently deny inpatient authorizations, providers tend to stop appealing to avoid a perceived inevitable denial and resource burden.

OPTUM™

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The Benchmark & Medical Necessity

- Hospital stays (as opposed to inpatient hospital stays) spanning or approaching a 2 midnight stay should not be automatically changed to an inpatient admission.
- While generally Part A payment is available for cases meeting the 2 midnight benchmark, the appropriateness of Part A payment for these cases is governed by the following:

For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization. (2016 CY2016 OPFS, 80 Federal Register 70539)

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2-MN Rule Review: Benchmark and Presumption

**The 2-Midnight Presumption:**

"Under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption."

80 FR 70539

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Medical Necessity (MBPM, Ch. 1, Sec. 10)

**(T)he decision to admit a patient is a complex medical judgment** which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents."

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2+ Midnight Inpatient Audit Targets

- 2-MN cases are not *automatically* IP.
- **Cases with custodial care, care for convenience, or delays in care (CDC) are the highest risk for audit and denial.**
- There are no national standards defining what is custodial, delay, or convenience:
  - How does your facility define custodial care, care for convenience, and delays in care?
  - How are you reviewing for these?
    - A case that "only" meets OBS criteria for 2 nights *could* represent a CDC.
    - Commercial payers have targeted this for years.
- EHR is defining these terms for EHR clinical groups to be added to our EHR Logic™.**




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Custodial, Convenience, and Delay

- "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services where such expenses are for custodial care."
  - *Social Security Act, §1862(a)(9)*
- "CMS' longstanding instruction has been and continues to be that hospital care that is custodial, rendered for social purposes or reasons of convenience, and is not required for the diagnosis or treatment of illness or injury, should be excluded from Part A payment."
  - *CMS Q&A relating to Patient Status Reviews (3/12/14)*
- "Any evidence of systematic gaming, abuse or delays in the provision of care in an attempt to receive the 2-midnight presumption could warrant medical review."
  - *CMS Q&A relating to Patient Status Reviews (3/12/14)*




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What is a Denial? Non Medicare

Any situation in which payment is less than that which was contractually agreed upon for the services delivered:

- Complete denial
- Downgrades
  - IP to OBS
  - Acute to SNF
  - ICU to Acute
  - DRG change (Transmittal 565)
- Carved-out days/services




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Evaluation of Denials

Type of denial:

- Administrative
- Not medically necessary
- Non-covered service
- Experimental/Investigational
- Another provider (e.g. mental health)
- Patient not eligible
- No pre-authorization or pre-certification
- Out-of-time filing
- Error in billing

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The Balance of Power

- Hospitals have been preoccupied with Medicare so they have little infrastructure to combat commercial denials
- Payors have a cadre of full-time nurses/physicians in charge of issuing denials
- Physicians drive a large segment of cost and revenue for hospitals, these dollars need to be aggressively managed
- Need to know if physicians and the hospital have misaligned incentives from the same payor

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Commercial Levels of Appeal

- Different payers have different processes
- Know the contract!
- Levels of appeal
  - Concurrent
  - Retrospective
    - 2 or 3 levels (per contract)
    - External (IRO)

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Appeal Inappropriate Denials Early And Often

- Get paid for the services provided
- Draw a line in the sand
- Make the payor work for its money
- Empower case management
- **Best practice:** Appealing up to 85% of denials

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Important to Remember

- The clinicians' documentation in the medical record is more than just a communication vehicle for the clinical care team
- Multiple entities inside (e.g. CMs, Coding/Billing) as well as outside the hospital (e.g. payors, auditors, lawyers) will review the medical record
- **Remember:**  
If it isn't documented then it wasn't relevant to the decisions; hence, adds little weight to the appeal!

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Best Practice Approach

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Best Practice Approach

- Avoiding denials and successful appeals are best achieved through a best practice approach
- Recognize that your hospital will receive inappropriate denials, and be prepared to appeal
- Hospitals need to defend their decisions and advocate for their rights (and those of the patients)
- Admission decisions must be based on clinical evidence (i.e. medical necessity); but, there are regulatory and legal (i.e. contracts) considerations
- Educate medical staff on documentation best practices to avoid denials

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Best Practice Approach

- Specialize in denials management
- Physician Advisor (or team) training:
  - Commercial/Managed care contracts
  - Utilization management
  - Screening criteria (e.g. MCG®, InterQual®)
  - Negotiating skills
- Levels the playing field and aggressively pursues appropriate reimbursement
  - Criteria
  - Medical necessity
  - Contract terms
- Available for Medical Director calls

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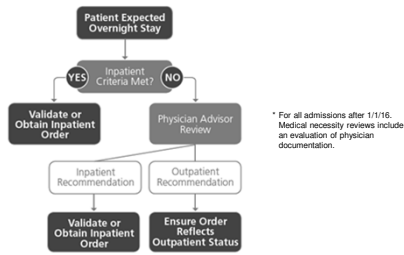
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Recommended UR Workflow\* (General)




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Concurrent Review Process (Medicare)

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- **Case Management Criteria-based Review**
  - IP screen applied to all Medical Necessity cases
  - Cases that fail are sent to a Physician Advisor
- **Physician Advisor Review**
  - Responsible physician contacted, if necessary
  - Provides a medical necessity recommendation regarding admission level of care
    - Order change
    - Documentation
  - CM is contacted with recommendation

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OPTUM 19

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Concurrent Review Process (Commercial)

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    graph TD
      A[Case not meeting screen or Denied] --> B[Case referred to Physician Advisor]
      B --> C[Physician Advisor manages appeals process]
      C --> D[Tracking]
      D --> E["• Financial  
• Payers  
• Physicians  
• Services"]
      E --> A
  
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OPTUM 20

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Benefits of Commercial Payor Admission Reviews

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**Commercial Admission Review**

- Streamlines case management UM processes and physician rules for documenting medical necessity across all payor types
- Ensures identification of cases meeting IP criteria upon 2nd level review
- A potential decrease in self denial rate of commercial payor cases

**Benefits For All Commercial Payor Admission Reviews**

- A consistent UM process across all patient and payor types
- Physician to appeal has knowledge of the case prior to a denial
- This experience enables trending of payor denials and high risk areas
- Physician rationale for IP can be leveraged during the appeals process

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OPTUM 21

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Retrospective Review

- Every denial is reviewed by a physician advisor
- Decides to appeal or not on a case-by-case basis
- Physician-authored letter composed
- Copy of chart and letter sent to payor
- Each case tracked through all stages of appeal
- An aggressive retrospective appeals program has a "trickle up" effect on concurrent denials:

**The payor is less likely to deny if they know there will be an appeal.**

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Denials Management

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Denials Management

- **You will be judged by your process!**
- Demonstrate a consistently followed Utilization Review process for every patient
- A consistent process must be paired with diligent oversight and data review
- Prove that the error rate within your hospital is not accurate by focusing on successfully appealing denials
- Identify procedural failures

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### Denials Management

- Data Review
  - Expected volume
  - Staffing requirements
  - Get data from contracts
    - Set up payor reference sheets
    - Find denials of which CMs are not aware
    - Self-denials
- Implementation
  - Educate CMs on process and mindset
  - Educate physicians
- Appeal early and appeal often
  - Retrospective appeal if peer-to-peer not successful
  - Tracking

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### Payor Reference Sheets

- Contract effective date, expiration date
- Termination notice required
- Renewal (auto, increases)
- Stop loss (type, rate, cap)
- Inpatient
  - DRG, per diem
  - Base rate
  - DRG CMI\*Base rate
  - High volume DRGs
- Outpatient
  - High dollar, high volume procedures
  - Observation payment (% of charges, fixed, per diem)

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### Self-Denials

- By aggressively denying cases over time, commercial payors have trained hospitals to **self-deny** cases that meet medical necessity:
- Cases that could have qualified for inpatient but failed first level inpatient screening
  - Observation cases that could have qualified for inpatient

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Self-Denials

- A symptom of self-denials is a high observation rate
- The primary drivers are:
  - Commercial payors will often give incentives to physicians to status patients as observation – hospitals don't see this
  - Hospitals are tired of fighting denials; payors make it difficult for hospitals to appeal
  - Hospitals have focused primarily on lowering their Medicare FFS observation rate
  - Hospitals track payor denials, not self-denials!
    - Decreasing denial rates or increasing overturn rates aren't necessarily desirable?
    - You want high appeal rates and \$ recovered

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"Invisible" Denials

The approach should be not to have a high "overturn rate," but delivering the highest net return by aggressively appealing almost every denial.

Would you rather overturn:

9 out of 10 (OT rate 90%)?

or

40 out of 100 (OT rate 40%)?

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Keys to Success

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Keys to Success – Avoiding Denials

Hospitals are frequently penalized for efficient care and/or rapid improvement of patients.

- Risk assessment is the key; BUT,
- **Documentation is the difference!**
  - Detail why the care is/was medically necessary as an inpatient
  - Document the why not just the what – **Explain!**
    - Summarize pertinent positives in assessment and plan
    - Document the thought process
  - What's obvious to us, may not be to the payers
- UR/CM need to communicate with physicians

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Keys to Success – Avoiding Denials

Critical factors:

- The judgment of the admitting physician referencing:
  - Standards of care
  - Evidence-based medical literature
  - Published clinical guidelines
  - Other relevant materials
- Utilization management criteria
- When applicable (i.e. Medicare):
  - NCDs/LCDs
  - CMS guidance

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Keys to Success – Medicare Appeals

- All medical records should be prepared to be appealed
- All appeals should be prepared as if they will need to go to highest level
- **3-Tiered approach:**
  1. **Clinical:** Strong medical necessity argument using evidence-based literature
  2. **Compliance:** Need to demonstrate that a compliant process for certifying medical necessity was followed
  3. **Regulatory:** Demonstrate, when applicable, that the denial is not consistent with the relevant regulations at the time of the admission

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Keys to Success – Commercial Appeals

- Appeal denials while the patient still in the hospital, or immediately post discharge (**This is your best chance!**)
- Develop a long-standing professional and respectful relationship with the payers
- Hold payors accountable for their decisions
- Know contracts: Does it makes financial sense to appeal?
- Important that CMs know when denials occur, and can start the appeals process
- Track appeals and outcomes
- You always have a right to appeal even when the denial occurs after the patient has been discharged



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Take Home

- Follow AR from beginning to end
- Best practice approach to avoid denials and succeed in appeals
- Physician involvement and communication *is critical!*
- Optimize resources



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Thank you

Contact information:  
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## Bundled Payments and Other Risk Arrangements for Post-Acute Care Providers

Shannon Drake, SVP, Chief Counsel  
Kindred at Home

Alan E. Schabes, Partner  
Benesch, Friedlander, Coplan & Aronoff LLP

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## Agenda

- Bundling arrangements
- Fraud and abuse considerations affecting bundling arrangements
- Bundling waivers under Federal Anti-Kickback Statute and Stark
- Collaboration/Contract Issues
- Swapping and fair market value
- What's Next?



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## Affordable Care Act (ACA) and Coordinated Care Initiatives

- The Centers for Medicare & Medicaid Innovation ("The CMS Innovation Center") was created by §3021 of the ACA (amending § 1115A of the SSA)
  - For purpose of testing "innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care."
  - Model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits.

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<h2>ACA and Coordinated Care Initiatives</h2>		
<ul style="list-style-type: none"><li>• <b>CMS Innovation Center</b> <a href="https://innovation.cms.gov/initiatives/index.html#views=models">https://innovation.cms.gov/initiatives/index.html#views=models</a></li><li>• <b>Past and Present Innovation Center Programs:</b><ul style="list-style-type: none"><li>• Nursing Home Value-Based Purchasing Demonstration</li><li>• Physician Group Practice Transition Demonstration</li><li>• Comprehensive Primary Care Initiative</li><li>• Accountable Care Organizations (ACO)</li><li>• Bundled Payments for Care (BPCI)</li></ul></li></ul>		
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<h2>The ACA Established ACOs</h2>		
<ul style="list-style-type: none"><li>• <b>ACO</b> - An organization of health care providers that agrees to be:<ul style="list-style-type: none"><li>▪ Accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it</li><li>▪ Share in the savings such activities generate for Medicare</li><li>▪ Financially responsible should costs exceed certain benchmarks</li></ul></li><li>• As of August 2016, ACOs have generated more than \$1.29 billion in total Medicare savings since 2012.</li><li>• A University of Michigan Population Studies Center research project is examining the impact of ACOs on post-acute care utilization; and the impact of changes in post-acute care spending and utilization on patient outcomes.</li></ul>		
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<h2>The ACA Established ACOs</h2>		
<ul style="list-style-type: none"><li>• <b>Examples:</b><ul style="list-style-type: none"><li>▪ Pioneer ACO Model</li><li>▪ Medicare Shared Savings Program ("MSSP") ACO Model</li><li>▪ Next Generation ACO Model</li><li>▪ ACO Investment Model (AIM)</li><li>▪ Medicare-Medicaid ACO Model (Dec 15, 2016)</li></ul></li></ul>		
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## Overview of Bundled Payments



**Bundled Payment** - Medicare offers a single lump sum for an entire episode of care related to a treatment or condition and that sum is then divided among all parties who provide services during that episode of care.

- 1991: coronary artery bypass graft surgery demo (CABG)
- 2009: Acute Care Episode (ACE)
- 2016: Oncology Care Model (OCM)

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## Bundled Payment v. ACO

<b>Bundled Payments</b>	<b>ACO</b>
<ul style="list-style-type: none"> <li>- Specific patients</li> <li>- Budget determined by hospital</li> <li>- Specific conditions</li> <li>- Specialist Focused</li> <li>- Organization keeps all savings</li> <li>- Payment from contracted org.</li> <li>- Less money (pilot project)</li> <li>- Up and Downside Risk</li> </ul>	<ul style="list-style-type: none"> <li>- Every patient</li> <li>- Budget determined by CMS</li> <li>- All conditions</li> <li>- Primary Care Physician Focused</li> <li>- Savings shared with Medicare</li> <li>- Payments from Medicare</li> <li>- More money involved</li> <li>- Up and Downside Risk</li> </ul>

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## Bundled Payment for Care Improvement (BPCI) Models

	Model 1 (Concluded 12.31.2016)	Model 2	Model 3	Model 4
<b>Episode</b>	All DRGs; all acute patients	Selected DRGs; hospital plus post-acute period	Selected DRGs; post-acute period only	Selected DRGs; hospital plus readmissions
<b>Services included in the bundle</b>	All Part A services paid as part of the MS-DRG payment	All non-hospital Part A and B services during the initial inpatient stay, post-acute period and readmissions	All non-hospital Part A and B services during the post-acute period and readmissions	All non-hospital Part A and B services (including the hospital and physician) during initial inpatient stay and readmissions
<b>Payment</b>	Retrospective	Retrospective	Retrospective	Prospective
<a href="https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-13-2.html">https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-13-2.html</a>				
<div style="display: flex; justify-content: space-between;"> <span>March 28, 2017</span> <span>HCCA Compliance Institute</span> <span>9</span> </div>				

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**BPCI Model 2: September 2015 Annual Survey  
Year 2 Evaluation**

- Majority of episode initiators were acute care hospitals.
- Medicare payments for hospitalization and 90 days post-discharge declined \$864 more for orthopedic surgery episodes at BPCI-participating hospitals than at non-participating hospitals because of reduced use of institutional post-acute care following hospitalization.
- Institutional post-acute care use declined for cardiovascular surgery episodes for BPCI.
- Participants indicated they tried to collaborate with area providers, especially post-acute care providers to improve care coordination and gain efficiency across an episode of care.
  - Participants indicated that it was challenging to establish relationships with other providers.
  - Patient education efforts were highlighted by participants, and may reported they focused on reducing post-acute care costs.

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**BPCI Model 3: September 2015 Annual Survey  
Year 2 Evaluation**

- Skilled nursing facilities (SNFs) were the most dominate participants, followed by home health agencies (HHAs).
  - Only 1 inpatient rehab facility, long-term care hospital, and physician group practice participated.
- Standardized SNF payments and SNF days for SNF-initiated BPCI episodes declined relative to the comparison group across almost all episode groups.
  - Did not result in statistically significant declines in total episode payments.
- Quality was maintained or improved except in 3 isolated instances.
- Post-acute care providers formed or augmented existing relationships with other post-acute care providers and hospitals and engaged third-party administrators and data management contractors.
  - Noted challenges include difficulty forming relationships with hospitals and physicians affiliated with different provider systems.

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**Comprehensive Care for Joint Replacement (CJR) Model**

On November 16, 2015, CMS finalized regulations regarding the Comprehensive Care for Joint Replacement (CJR) Model

- Acute care hospitals in 67 MSAs are receiving retrospective bundled payments for episodes of care for lower extremity joint replacement or reattachment of a lower extremity (LEJR).
  - MS-DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities)
  - MS-DRG 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities)
  - Separate episode target prices for MS-DRGs 469 and 470
- All related care (Part A and B) within 90 days of hospital discharge from the LEJR procedure are included in the episode of care, including hospital care, post acute care and hospital services, with certain exclusions.
- Began April 1, 2016.
- Repayment Risk: Y1 (0%) Y2 (5%) Y3 (10%) Y4-5 (20%)
- Gain Share Opportunity: Y1 (5%) Y2 (5%) Y3 (10%) Y4-5 (20%)

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### Announced Episode-based Payment Initiatives

- December 20, 2016 – Final Rule
  - Effective February 18, 2017 – 42 CFR Part 512.
- Acute Myocardial Infarction (AMI) Model
  - Covers Part A and Part B items and services provided to acute care hospitals from initial hospitalization through 90 days after discharge in retrospective bundled payments
- Coronary Artery Bypass Graft (CABG) Model
  - Covers Part A and Part B items and services through retrospective bundled payments related to CABG treatment and recovery, from initial hospitalization through 90 days after discharge.
- Surgical Hip and Femur Fracture Treatment (SHFFT) Model
  - Covers Part A and Part B items and services through retrospective bundled payments related to SHFFT and recovery from hospitalization through 90 days after discharge.
- Performance Period: July 1, 2017 – June 30, 2021
- Participating hospitals coordinate care across providers and suppliers, including post-acute providers.

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### Purpose of the Anti-Kickback Statute

AKS designed to prevent improper referrals, which can lead to:



- Overutilization
- Increased costs
- Corruption of medical decision-making
- Patient steering
- Unfair competition

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### Anti-Kickback Statute Overview



Prohibits asking for or receiving anything of value to induce or reward referrals of Federal health care program business

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### Statutory Elements 42 U.S.C. 1320a-7b(b)

Anti-Kickback Statute prohibits:

- Knowingly and willfully
- Directly or indirectly offering, paying, soliciting, or receiving
- Remuneration
- In order to induce or reward the referral or purchase of (or arranging for the purchase of) items or services for which payment may be made by a Federal healthcare program

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### Penalties for Kickbacks



Criminal fines up to \$25K; prison up to 5 years

Civil Money Penalty exposure, fines, program exclusion

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### Exceptions and Safe Harbors

- Statutory exceptions (Congress) / regulatory safe harbors (OIG)
- Transactions satisfying *all* elements of Safe Harbor will not be prosecuted. Transactions *not* satisfying all elements are not *per se* illegal, but are subject to a facts-and-circumstances analysis

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Other Fraud and Abuse Laws: Stark	
Anti-Kickback Statute 42 USC 1320a-7b(b)	Physician Self-Referral Law (Stark) 42 USC 1395nn
Referrals from everyone	Referrals from a physician
Any items or services	Designated health services
Intent required (knowing and willful)	No intent standard for overpayment (strict liability) Intent required for civil monetary penalties for <i>knowing</i> violations
Criminal and civil penalties	Not criminal
Voluntary safe harbors (if not in safe harbor, may still be legal)	Mandatory exceptions (if not excepted, illegal)
OIG advisory opinion process <a href="http://www.oig.hhs.gov/compliance/advisory-opinions/index.asp">http://www.oig.hhs.gov/compliance/advisory-opinions/index.asp</a>	CMS advisory opinion process <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html</a>
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Other Fraud and Abuse Laws: Beneficiary Inducement CMP	
Section 1128A(a)(5) of the Social Security Act provides that:	
<ul style="list-style-type: none"> <li>any person who offers or transfers remuneration</li> <li>to a Medicare or Medicaid beneficiary</li> <li>that the person knows or should know</li> <li>is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services</li> </ul>	
may be liable for civil money penalties of up to \$10,000 for each wrongful act.	
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Other Fraud and Abuse Laws: Beneficiary Inducement CMP - Exceptions	
<p>Certain exceptions, <i>e.g.</i>, Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts; Incentives to promote the delivery of preventive care; reduction in the copayment amount for covered Outpatient Department Services; offer of items for free or less than FMV if unadvertised, and not tied to other services reimbursed under Medicare or Medicaid and individual has financial need.</p> <ul style="list-style-type: none"> <li>Exceptions updated effective January 6, 2017.</li> </ul>	
<p><a href="http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf">http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf</a></p>	
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## Fraud and Abuse Waivers

- **Shared Savings Program Waivers** (Section 1899(f) of SSA)
  - Secretary may waive certain fraud and abuse laws **as necessary** to carry out the provisions of the Medicare Shared Savings Program.
  - October 29, 2015: OIG and CMS jointly published the Medicare Program; Final Waivers in Connection with the Shared Savings Program Final Rule.
- **Waivers for Innovation Center Models** (Section 1115A(d)(1) of SSA)
  - Secretary may waive certain fraud and abuse laws **as necessary** solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation.
  - As of early January 2017: Six groups of waivers issued, including those for the BPCI models and CJR.

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## Fraud and Abuse Waivers

- **Keep in Mind:** A waiver will apply to the arrangement(s) only if the individuals/entities seeking its protection are eligible to use the waiver and all conditions of the waiver are met.

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## Fraud and Abuse Waivers v. Program Waivers

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>

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Waivers for BPCI Models		
Sept. 13, 2012: OIG and CMS jointly issued waivers for specified arrangements involving BPCI Model 1 Participants.		
<ul style="list-style-type: none"><li>• Waiver of the AKS and physician self-referral law in connection with:<ul style="list-style-type: none"><li>▪ Incentive payments – sharing of cost savings earned pursuant to CMS-approved gainsharing methodology and conditions set forth in Waiver Notice and Participation Agreement between the hospitals and CMS.</li></ul></li></ul>		
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Waivers for BPCI Models		
July 26, 2013: OIG and CMS jointly issued waivers for specified arrangements involving BPCI Models 2, 3, and 4 Participants.		
<ul style="list-style-type: none"><li>• Waiver of the AKS and physician self-referral law in connection with:<ul style="list-style-type: none"><li>▪ Savings Pool Contribution – Internal Cost Savings contributed by Episode-Integrated Providers (EIPs)</li><li>▪ Incentive Payments – certain distributions from the BPCI Savings Pool</li><li>▪ Gainsharing Payments – made by Gainsharer Group Practice to Gainsharer Group Practice Practitioners</li></ul></li><li>• Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:<ul style="list-style-type: none"><li>▪ Patient engagement incentives – in-kind items or services provided by a Model Awardee, EIP, or Gainsharer to a Model Beneficiary</li></ul></li></ul>		
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Waivers for BPCI Models		
<ul style="list-style-type: none"><li>• Waiver of AKS:<ul style="list-style-type: none"><li>▪ Professional Services Fee – for Model 4 only, payments from hospitals to physicians and non-physician practitioners for professional services furnished to hospital inpatients</li></ul></li><li>• Each pursuant to conditions set forth in the applicable Waiver Notice and Participation Agreement</li></ul>		
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Waivers for BPCI Models		
<ul style="list-style-type: none"> <li>• BPCI Model 1: <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-1-Waivers.pdf">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-1-Waivers.pdf</a></li> <li>• BPCI Model 2: <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-2-Waivers.pdf">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-2-Waivers.pdf</a></li> <li>• BPCI Model 3: <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-3-Waivers.pdf">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-3-Waivers.pdf</a></li> <li>• BPCI Model 4: <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-4-Waivers.pdf">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/BPCI-Model-4-Waivers.pdf</a></li> </ul>		
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Waivers for CJR		
<p>November 16, 2015: OIG and CMS jointly issued waivers for specified arrangements involving CJR Model participants.</p> <ul style="list-style-type: none"> <li>• Waiver of the AKS and physician self-referral law in connection with:           <ul style="list-style-type: none"> <li>▪ Certain gainsharing and alignment payments between hospitals and providers or suppliers               <ul style="list-style-type: none"> <li>• Protects hospitals that share payments from CMS and hospital internal cost savings with other providers and suppliers.</li> </ul> </li> <li>▪ Certain payments from a physician group practice ("PGP") to members of the physician practice               <ul style="list-style-type: none"> <li>• Protects arrangements in which a PGP that received a gainsharing payment from a hospital in the CJR model distributes a portion of those funds to its practice collaboration agents.</li> </ul> </li> <li>▪ Each subject to certain conditions, including compliance with program rules.</li> </ul> </li> <li>• Waiver of the AKS and CMP prohibiting beneficiary inducements in connection with:           <ul style="list-style-type: none"> <li>▪ Certain patient engagement incentives that promote preventive care or certain clinical goals               <ul style="list-style-type: none"> <li>• Allows participant hospitals to provide in-kind items and services to beneficiaries in CJR model episodes.</li> </ul> </li> <li>▪ Incentives must comply with applicable program rules and waiver conditions.</li> </ul> </li> </ul> <p>• <a href="https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf">https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf</a></p>		
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The Limits of PAC Provider Collaboration		
<ul style="list-style-type: none"> <li>▪ Contracting and negotiating considerations</li> <li>▪ HHA Collaboration Examples:           <ul style="list-style-type: none"> <li>– 3 OIG Advisory Opinions</li> <li>– 1 reported enforcement action</li> </ul> </li> </ul>		
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**The Limits of PAC Provider Collaboration**

- 2006 Advisory Opinion 06-01
  - Home Health Agency (“HHA”) provided pre-operative in-home and telephonic safety assessments by a licensed PT to patients without compensation.
  - OIG concluded situation presented grounds for imposition of a CMP and indicated there was an AKS risk.
    - Free preoperative in-home assessment constitutes remuneration beyond nominal value that induces patient business, in violation of Inducement to Beneficiary CMP Law
    - Telephonic home safety assessments may be of nominal value (\$10 or less) but OIG said there weren’t enough facts to establish this.

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**The Limits of PAC Provider Collaboration**

- 2007 Advisory Opinion 07-16
  - HHA receives referral from surgeon when surgery scheduled; HHA makes one initial phone call to patient and reminds patient of referral and free choice.
  - HHA sends patient 2 educational videos of general application.
    - No patient specific information is provided.
  - OIG concluded it would not impose sanctions.
    - Videos furnished only after surgeon referral
    - Videos of general (not personalized) nature so useable by patient regardless of which HHA is ultimately selected.
    - Video unlikely to affect patient choice.
    - Video not provided by trained professional (such as a PT) so no personal relationship established.

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**The Limits of PAC Provider Collaboration**

- 2015 Advisory Opinion 15-12
  - HHA first selected by patient in discharge planning process; HHA employee contacts patient by phone to inquire of desire for initial visit and patient selects whether visit is by phone or in person. Visit is to facilitate transition to home care service. At visit, HHA provides overview of home care experience, gives written materials and contact info and shares pictures of care team; no diagnostic or therapeutic service provided.

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The Limits of PAC Provider Collaboration

- 2015 Advisory Opinion 15-12 (cont.)
  - OIG concluded intro visit is not remuneration to patient. No sanctions.
    - Nature of visit reflected no actual or expected benefit to patient.
    - Only generalized information provided.
    - Purpose of visit to make for a smooth transition.
    - No diagnostic/therapeutic care provided.
    - Patient had already selected HHA.

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The Limits of PAC Provider Collaboration

- 2016 OIG Enforcement Action
  - HHA provided free discharge planning services to Hospital patients. HHA had no written contract with Hospital. Services were of a type typically provided by Hospital discharge planners. Hospital accepted free discharge planning services from HHA.
  - Hospital self reported to OIG and Government aggressively pursued Hospital.
    - Hospital paid \$1.9 million.

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The Limits of PAC Provider Collaboration

- Government pursued Hospital because:
  - Potential steering violation – more than giving a list.
  - Alleged violation of AKS in that HHA gave free services to Hospital to obtain referrals for home care business.
  - Was outside of CJR and relaxed steerage prohibition in CJR; no application of CJR waiver
    - Noted CJR Gainsharing Waiver precludes in-kind remuneration.

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### The Limits of PAC Provider Collaboration

- OIG Advisory Opinions show progression of greater flexibility with key issues being (1) has HHA selection occurred before incentive (favorable); (2) is service more or less designed clinical relationship (if yes, unfavorable). Note – all 3 OIG AO's preceded the CJR/Bundled concepts.
- AKS enforcement matter raised steering issue and value of services to hospital without fmv compensation. Matter was outside of CJR with relaxed steering standard and potential CJR for some Gainsharing compensation.
- Challenges are to embrace new care redesign in CJR within the context of existing F&A Laws and develop arrangement that addresses various issues.
- 2 existing waivers in CJR have hurdles:
  - CMP waiver for beneficiary incentive requires HHA as agent; and incentive must occur during episode of care
  - Gainshare waiver covers payment not conduct.
- Concept has some risk but reach of CJR structure offers arguments.

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### CJR Collaboration Issue

- Pre-operative Visit in Advance of CJR Episode
  - Invert discharge to intake with full patient choice.
  - Part of care redesign / Collaboration agreement between anchor hospital and HHA includes "Incharge".
  - Patient on intake participates in CJR care plan with required CJR disclosure.
  - Pre-op / Pre-hab visit physician authorized with full patient consent.
  - Gainsharing methodology rewards HHA on a global basis (i.e. not per prehab visit) but based upon a base fee for incharge services with a bonus based on quality (eg. Readmissions, which is a CMP waiver goal).

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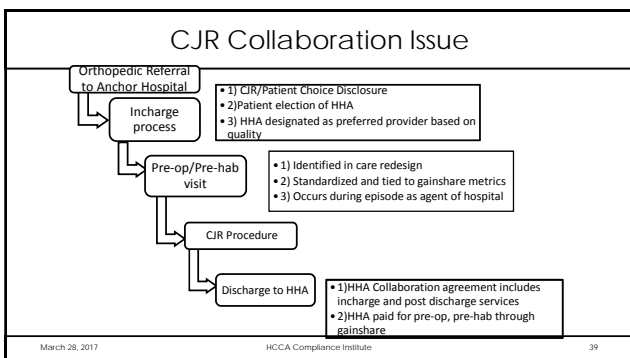
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<b>CJR Collaboration Issue</b>		
<ul style="list-style-type: none"> <li>▪ Issues                             <ul style="list-style-type: none"> <li>– How can HHA be “agent” under CMP waiver and “HHA” for follow up?</li> <li>– Does early selection of HHA overcome issue of patient inducement?</li> <li>– Is Hospital paying fair market value for the assessment services through Gainsharing payment?</li> <li>– What if no home health on discharge?</li> <li>– Is “prehab” too clinical under prior AOs?</li> <li>– Better if:                                     <ul style="list-style-type: none"> <li>• HHA first contact to patient waits until hospitalization and HHA is selected by patient before it does assessment.</li> <li>• Hospital agrees to payment to HHA if no home care ordered (if home care ordered, there is potential Gainsharing but no FFS billing)</li> </ul> </li> </ul> </li> </ul>		
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<b>“Bundling” Hypothetical</b>		
<p>ABC Hospital System (“ABC”) is a large tertiary hospital system in Cleveland, Ohio. ABC has issued a request for proposal (“RFP”) to post-acute care providers to participate in a comprehensive post acute care bundling arrangement. ABC has stated in the RFP that it will not contract with every post acute care provider and is looking for one comprehensive post acute care solution for its proposed bundling arrangement. The RFP states that, among the criteria that ABC intends to use are quality of care, pricing, patient outcomes and rehospitalization rates. LTC, Inc. is a large post-acute care provider in the Cleveland, Ohio market. They own and operate nursing homes, home health agencies and hospices.</p>		
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<b>“Bundling” Hypothetical</b>		
<p>LTC, Inc. wants to win the RFP and is considering the following alternatives:</p> <ol style="list-style-type: none"> <li>1. LTC is willing to offer its nursing home services with a per diem pricing that represents a significant discount from LTC’s standard pricing. LTC is willing to offer a less significant discount on its home health services. The LTC nursing home services proposal, standing alone, will cause LTC to lose money. However, when combined with the home health services, LTC expects to break even or generate a small profit.</li> <li>2. LTC is considering proposing a shared savings arrangement pursuant to which LTC will receive thirty percent (30%) of the savings generated from a selected baseline year and will also be obligated to pay thirty percent (30%) of the losses if the post acute care costs exceed the baseline year costs.</li> <li>3. ABC acknowledges that the bundling arrangement cannot be optimized without dedicated patient navigators. However, ABC cannot afford to hire these navigators. LTC is considering offering to provide the navigators to ABC for free as part of the overall proposal.</li> </ol>		
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## Swapping Overview



- "Swapping" – typically arrangements in which providers and/or suppliers give discounts on Medicare Part A services in exchange for referrals on Part D or Part B business
- Example: an LTC Pharmacy offers below market/discounted prices to SNF's on Part A drugs, which the SNF is responsible for paying for, in exchange for an agreement to provide access to higher paying reimbursable business on the SNF's Part D or B patients.

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## Swapping Overview

### • Red Flags to Look For:

- ♥ Rates below total costs of providing services suggest provider may swap these below-cost rates in exchange for separately billable, non-discounted Federal health care program business.
- ♥ Discounted prices to one buyer that are lower than the prices the provider offers to other buyers with similar volumes but no separately billable Federal health care program business.
- ♥ Discounts coupled with exclusive provider agreements or other agreements to refer Federal health care business.

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## OIG Advisory Opinion 10-26

- Unfavorable
- Proposed payment plans for emergency and non-emergency transportation services provided for Medicaid-covered residents of skilled nursing facilities
- Additional guidance cited: reference to swapping discussions in 2003 Compliance Program Guidance (CPG) for Ambulance Suppliers and 2008 Supplemental CPG for Nursing Homes

Page 5 – OIG Advisory Opinion No. 10-26

offered to the SNF that are below the supplier's total costs of providing the services—in the facts presented here—give rise to an inference that the supplier and the SNF may be "swapping" the below-cost rates on business for which the SNF bears the business risk in exchange for other profitable non-discounted Federal business, from which the supplier can recoup losses incurred on the below-cost business, potentially through overutilization or abusive billing practices.

Based on the facts presented here, we are unable to exclude the possibility that the Requester may be offering improper discounts to the SNF's for their Medicaid Transport Services business with the intent to induce referrals of more lucrative Federal business. Nor are we able to exclude the possibility that the SNF's may be soliciting improper discounts on business for which they bear risk in exchange for referrals of business for which they bear no risk. Indeed, the Proposed Arrangement poses a substantial risk of such improper "swapping" of business that may run afoul of the anti-kickback statute.

### III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on Janssen (referred to under sections 1120(b)(7) or 1128A(a)(7) of the Act) in those sections relate to the commission of acts described in section 1128B(1) of the Act in connection with the Proposed Arrangement. Any definitive conclusions regarding the existence of an anti-kickback violation requires a determination of

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OIG Advisory Opinion 12-09	
<ul style="list-style-type: none"> <li>• Favorable</li> <li>• Reduced-rate arrangements for the provision of therapy services at state-operated veterans' homes</li> <li>• Additional guidance cited: footnote reference to 1999 and 2000 OIG letters on swapping arrangements - available on OIG website; see also ad ops 99-2 &amp; 99-13</li> </ul>	<p style="font-size: small; margin: 0;"><sup>1</sup> See, e.g., OIG Advisory Opinions 99-2, 99-13, and 10-26; OIG's September 22, 1999 letter on Discount Arrangements Between Clinical Labs and SNFs, and OIG's April 26, 2000 letter on Discount Arrangements Involving Ambulance Companies, Hospitals, and Skilled Nursing Facilities.</p> <hr/> <p style="font-size: x-small; margin: 0;">Page 6—OIG Advisory Opinion No. 12-09</p> <p style="font-size: x-small; margin: 0;">evaluating whether an improper nexus exists between the discounted business and referrals of Federal health care program business in a particular arrangement, we look for indicia that the discounted rate is not commercially reasonable in the absence of other, non-discounted business. For example, rates that are below a provider's total costs of providing services give rise to an inference that the provider may be swapping the below-cost rates on business for which the buyer bears the business risk in exchange for separately billable, non-discounted Federal health care program business. Another pricing arrangement that raises significant concerns is one that involves discounted prices to one buyer that are lower than the prices the provider offers to other buyers with similar volumes of business, but no potentially available separately billable Federal health care program business. Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes (such as capitated arrangements) made in conjunction with explicit or implicit...</p>
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"Swapping" Hypothetical	
<p>ABC Rx is a long-term care institutional pharmacy. ABC Rx is growing rapidly and they badly want to enter into a long term contract with LTC, Inc., a large post-acute care provider. Currently, the LTC, Inc. nursing homes are paying for their Medicare Part A drugs at the state Medicaid allowable price. The LTC, Inc. nursing homes are also paying their current pharmacy for consulting pharmacists at \$30.00 per hour. ABC Rx offers to sell LTC, Inc. its Medicare Part A drugs at 95% of the state Medicaid allowable price and offers to provide consulting pharmacists at \$25.00 per hour. The ABC Rx offer is made with the expectation that ABC Rx will be the exclusive provider of institutional pharmacy services for all of the LTC, Inc. nursing homes, subject to patient choice, and would obtain all of the nursing homes' separately billable business, e.g., under Part B and Part D. At these rates, ABC Rx has a positive gross margin for the Medicare Part A drugs but ABC Rx pays its consulting pharmacists \$30.00 per hour. However, overall, ABC Rx would make a small profit on the arrangement, even if ABC Rx does not also become the exclusive provider of the nursing homes' separately billable business.</p>	
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What's Next?	
<ul style="list-style-type: none"> <li>▪ Repeal of ACA             <ul style="list-style-type: none"> <li>– Within hours of taking oath of office, President Trump signed an executive order "to seek the prompt repeal" of the ACA.                 <ul style="list-style-type: none"> <li>• Directs Secretary of HHS to interpret the regulations loosely.</li> </ul> </li> <li>– Rep. Tom Price, nominee for HHS Secretary believes bundled payment program is "experimenting with Americans' health."                 <ul style="list-style-type: none"> <li>• Participation is mandatory before knowing how it will affect access to care.</li> <li>• Will issue more detailed interpretations of ACA based upon executive order once confirmed.</li> </ul> </li> <li>– Will CMS Innovation Center, created by the ACA, disappear if/when ACA repealed or replaced?</li> </ul> </li> </ul>	
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Conclusion



Questions?

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*Medical device security –  
The transition from patient  
privacy to patient safety*

**Scott Erven**




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**Who i am**

**Scott Erven** - Managing Director – Healthcare Industries Advisory – Cybersecurity & Privacy

-  Medical Device Security Lead For PwC
-  Over 5 Years Leading Medical Device Security Research
-  Over 15 Years IT Security Experience
-  Over 5 Years Managing Security For Healthcare Systems & Providers

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**What we'll be covering today**

- 1** Why medical device security matters.
- 2** Vulnerabilities inside the medical device security landscape.
- 3** Are attacks a reality?
- 4** Diagnosis and problem awareness.
- 5** Treatment plans.

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## Why medical device security matters

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## Personal impact

- Many of us rely on these devices daily.
- When we are at our most vulnerable, we will depend on these devices for life.
- Even at times when we aren't personally affected, people we care about may be.



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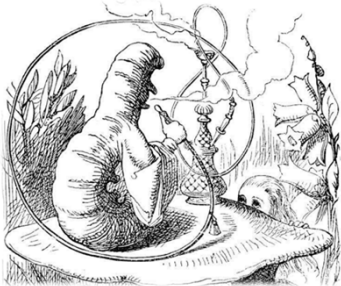
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## Malicious intent is not a prerequisite to patient safety issues



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**Research – Device vulnerabilities**

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**Device vulnerabilities**

- Weak default/hardcoded administrative credentials**
  - Treatment modification
  - Cannot attribute action to individual
- Known software vulnerabilities in existing and new devices**
  - Reliability and stability issues
  - Increased deployment cost to preserve patient safety
- Unencrypted data transmission and service authorization flaws**
  - Healthcare record privacy and integrity
  - Treatment modification

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**Research– Internet exposure**

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### Shodan search initial findings

Doing a search for anesthesia in Shodan and realized it was not an anesthesia workstation.

Located a public facing system with the Server Message Block (SMB) service open, and it was leaking intelligence about the healthcare organization's entire network including medical devices.



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### Initial healthcare organization discovery



Very large U.S. based healthcare system consisting of over 12,000 employees and over 3,000 physicians. Including large cardiovascular and neuroscience institutions.

Exposed intelligence on over 68,000 systems and provided direct attack vector to the systems.

Exposed numerous connected third-party organizations and healthcare systems.

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### Did we only find one?

No. We found hundreds!

**Generic Search Examples:**

shodan port:445 org:health*/clinic/hospital	
health* - <a href="http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital">http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital</a>	.health 148 hits
clinic - <a href="http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital">http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital</a>	clinic 18 hits
hospital: <a href="http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital">http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital</a>	hospital 119 hits
medical: <a href="http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital">http://www.shodanhq.com/search?q=port:445&amp;org:health*/clinic/hospital</a>	medical 255 hits

Change the search term and many more come up. Potentially thousands if you include exposed third-party healthcare systems.

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**Potential attacks – Physical**

- ▷ We know what type of systems and medical devices are inside the organization.
- ▷ We know the healthcare organization and location.
- ▷ We know the floor and office number.
- ▷ We know if it has a lockout exemption.



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**Potential attacks – Phishing/Pivot**

- ▷ We know what type of systems and medical devices are inside the organization.
- ▷ We know the healthcare organization and employee names.
- ▷ We know the direct public Internet facing system is vulnerable to MS08-067 and is Windows XP. We know the hostname of all these devices.
- ▷ We can create a custom payload to only target medical devices and systems with known vulnerabilities.



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**Are attacks a reality?**

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### Real world attacks – Honeypot research

What we were looking for...

- Using known default login information for remote access?
- Leveraging existing exploits for remote command execution?
- Custom malware?
- Malicious intent to interfere with the device (or worse, someone using the device)?
- Campaigns against specific vendor devices?

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### Real world attacks – The data

Data	
Honeypots	10
Successful logins (SSH/Web)	55,416
Successful exploits (Majority is MS08-067)	24
Dropped malware samples	299
Top 3 Source Countries	Netherlands, China, South Korea
HoneyCreds login	8

HoneyCred logins are unique to the honeypot ssh/web service, someone did some research.

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### Real world attacks – Conclusion

What did the attacker do once he got in? **>>> Nothing**

Did they realize they had root on a MRI machine? **>>> Probably not**

Are there compromised medical devices calling back to a command and control server? **>>> Absolutely**

Did the command and control owners know what the information they are sitting on? **>>> Didn't appear so**

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**Problem awareness**

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**Problem awareness**



- 1 **Medical devices are increasingly accessible** due to the nature of healthcare
- 2 **HIPAA focuses on patient privacy, not patient safety.**
- 3 **U.S. Food and Drug Administration does not validate cyber safety controls.**
- 4 **Malicious intent is not a prerequisite for adverse patient outcomes.**

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**Technical properties**

**Exposed, vulnerable systems**

- All software has flaws.
- Connectivity increases potential interactions.
- A software-driven, connected medical device is a **vulnerable, exposed** one.

**Lack of patient safety alignment in medical device cyber security practices**

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**Treatment plans**

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**A shift in how we think about medical technologies**

<p><b><u>Before</u></b></p> <ul style="list-style-type: none"> <li>Devices are connected to patients physically </li> <li>Data obtained from devices are stored on paper or locally </li> <li>Devices are physical products </li> <li>Care is hand-administered at a health care location </li> <li>Physical access is needed to view health data </li> </ul>	<p><b><u>Now</u></b></p> <ul style="list-style-type: none"> <li>Devices are connected wirelessly to patients and other devices </li> <li>Data obtained from devices are stored in the cloud </li> <li>Devices include software and even databases of health information </li> <li>Care is available to patients in the palm of their hand through apps </li> <li>Health data can be accessed anywhere on earth </li> </ul>
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**A shift in how we think about regulating medical devices**

*Traditional considerations meet technology*

<b>Traditional</b>	<p><b>Safety</b> </p> <p>Is a medical device safe for use in humans? Does it cause adverse events? Are its risks tolerable in relation to its benefits?</p>
<b>Evolving</b>	<p><b>Efficacy</b> </p> <p>Is a device effective for its given purpose? What is the magnitude of the effect?</p>
<b>Evolving</b>	<p><b>Quality</b> </p> <p>After approval, a device must be kept safe and effective through adherence to quality manufacturing standards established by FDA</p>
<b>Evolving</b>	<p><b>Security</b> </p> <p>Once a medical device is networked with other devices or the internet, is it still safe and effective?</p>

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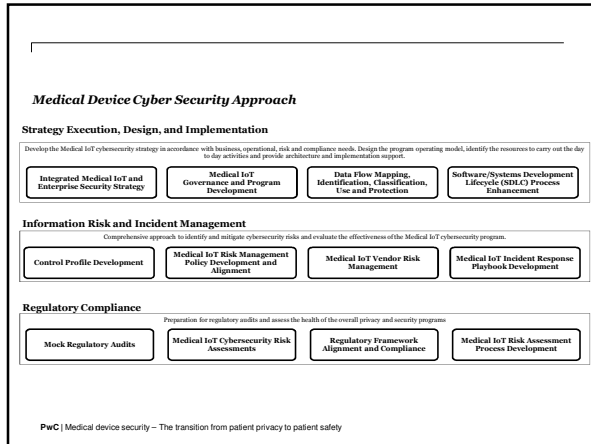
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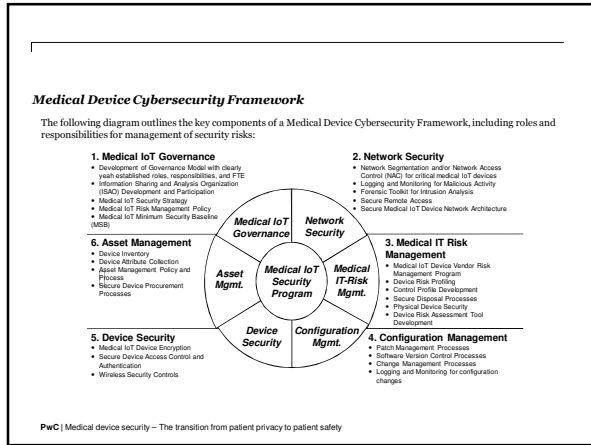
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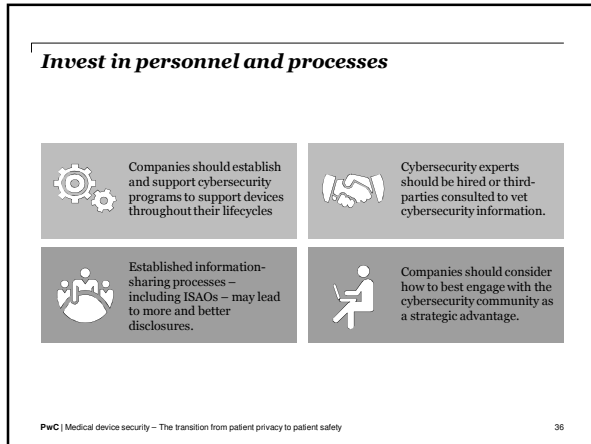
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**Support can lead to opportunity**



Device companies can become **essential partners** to healthcare providers by helping them support and secure their devices and networks.

Device companies can benefit by giving providers a level of **comfort and assurance** about product security, potentially leading to increased sales, and insight into how their devices are used and misused, **benefiting future device development**.

PwC | Medical device security – The transition from patient privacy to patient safety 37

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**Thank you**

**Contact**  
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E: scott.erven@pwc.com



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**PHYSICIAN  
ENGAGEMENT IN THE  
COMPLIANCE PROCESS**

R. Brett Short, CHC, CHPC, Chief Compliance Officer,  
UK HealthCare  
Sarah Couture, RN, CHC, Associate, Aegis Compliance  
and Ethics



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**Physician Engagement Principles**

- Tone at the top
- Relationships are essential
- Culture can make or break
- Physician engagement is already occurring in other areas of your organization
- What do your physicians care about?



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**Physicians As Leaders: Identifying opportunities for physicians to engage in compliance program oversight**

**WHAT DO PHYSICIANS  
NEED TO KNOW?**



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### Compliance Current Events

- Regulation changes, enforcement news, advisory opinions
- OIG Work Plan
- Trends: in your state; in their specialty
- OIG enforcement summary

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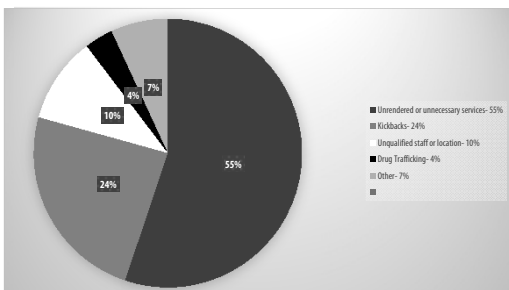
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### January Summary of Criminal and Civil Enforcement



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### Federal Health Care Fraud and Abuse Laws

- **The False Claims Act**
- **The Anti-Kickback Statute**
- **The Physician Self-Referral Law**
- **The Exclusion Authorities**
- **The Civil Monetary Penalties Law**
- **Criminal Health Care Fraud Statute**

<https://oig.hhs.gov/compliance/provider-compliance-training/files/HandoutLegalCitations508.pdf>

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### Ongoing Compliance Topics

- False Claims Act
  - "Know or should have known," no proof of intent to defraud required
  - Lack of documentation: so either medical necessity not supported, or services not rendered.
  - Using unlicensed personnel- seeing more of this
- Stark/kickbacks- relationships with vendors, labs, DME/drug/device suppliers
- Contracts- leases, medical directorships,
- Consulting and royalties
- NPPs
- COI
- Research
- Copay waivers, discounts
- HIPAA
- Coding and billing
- Personal and entity audit results
- Personal and entity denials trends

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### OIG Physician Compliance Education

- <https://oig.hhs.gov/compliance/physician-education/index.asp>
- <https://oig.hhs.gov/compliance/provider-compliance-training/index.asp>

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**Physicians as Partners:** opportunities in the day-to-day operations of the compliance program

### WHAT DO PHYSICIANS NEED TO UNDERSTAND?



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### Opportunities

- Larger entity versus smaller entity
- If compliance program is brand new or a re-work is in order, engage physicians in baseline discussions
- Individual physician partnerships, or advisory group of physicians, or both? What about physicians as compliance liaisons in their areas of influence?

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### 7 Elements and Physician Engagement

- Policies/Procedures
- Compliance officer/compliance committee
- Training and education
- Effective lines of communication
- Internal monitoring and auditing
- Well-publicized disciplinary guidelines
- Investigation and corrective action

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### Responding to specific issues with physician involvement

- Development of task force surrounding a hot button issue
- New guidance or regulation communication
- Monitoring findings

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Physicians as champions: leveraging relationships to demonstrate program compliance

## WHAT CAN PHYSICIANS OWN?

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Where could physician champions or an advisory group carry the compliance message to the physician community?

- Communication with physician community about **policy** changes and how changes affect practice
- Physician **leadership** within compliance committee
- Physician champions take **education** to their own community

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Where could physician champions or an advisory group carry the compliance message to the physician community?

- Physician partners can carry compliance data or benchmarks to the physician community, and foster a greater **transparency** between compliance and physicians
- An active role by engaged physicians could have **great effects** on audit results, denials, and reimbursement

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When a physician or group of physicians catch the vision of compliance and are engaged in the reasons and benefits of an effective compliance program, the relationship between compliance and the physicians at your organization will undoubtedly grow and become less siloed and more collaborative.

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### Where Can Physician Engagement Lead?

- Effectiveness and reach of compliance program
- Decreased risk of issues and people falling through the cracks
- Decreased risk of enforcement and litigation against physician and against entity
- Enhanced patient care
- Accurate revenues, decreased risk of denials, and better audit outcomes
- Opportunity for Compliance to lead; display value of Compliance program

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### Where can I start?

- Large entity versus small entity
- Know what language *YOUR* physicians speak
- Grow your relationships with physician leaders
- Take a look at culture and tone at the top
- Start with the 7 elements
- Consider physician compliance advisory group or finding compliance liaisons

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**Questions?**



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**Managed Care Fraud:  
Enforcement and Compliance  
HCCA Compliance Institute**

March 28, 2017

**Pamela Coyle Brecht, Partner**  
Pietragallo Gordon Alfano Bosick & Raspanti, LLP

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**Risk Area: False Data and/or Certifications**

- Certifications
- Risk adjustment data
- Encounter data

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**Risk Adjustment:  
Audit & Enforcement Environment**

- Center for Public Integrity "**Medicare Advantage Money Grab**"
- Letters from Senators Grassley and McCaskill asking federal officials to step up oversight of Medicare Advantage health plans.
- **Government Accountability Office** estimated "**improper payments**" to Medicare Advantage plans at more than **\$12 billion** in 2014.
- HHS subpoenas issued to MAOs
  - DaVita Healthcare (Jan. 2015): requesting Medicare Advantage documentation dating back to January 1, 2008.

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**Improper Payments: CMS Estimates Unsupported Diagnoses Linked to \$1.7 Billion (Nearly 10%) of All Part C Payments**

- MA Organizations received approximately \$170 billion to provide coverage to nearly one-third of all Medicare beneficiaries in 2015.
  - GAO-17-223, MEDICARE ADVANTAGE Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments, <http://gao.gov/assets/690/682145.pdf>
- CMS estimates 9.5% of payments to MAOs are improper because they submit unsupported diagnoses to CMS.
  - OIG Work Plan 2017, page 27, <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/HHS%20OIG%20Work%20Plan%202017.pdf>

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**Risk Adjustment Data Validation (RADV) Audits**

- 42 C.F.R. § 422.311(a).
- CMS uses RADV audits to test the accuracy of risk adjustment.
- CMS uses the right to retrospectively audit for support of any risk-adjusted payments received by an MAO.
- RADV Audit encompasses review of medical records and clinical documentation that led to the payment.
- MAOs are formally notified of a RADV audit and have a set amount of time to provide the requisite support for the cases selected for audit.
- Risk adjustment evaluations begin with coding assessments but data submission and population health also assessed.

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**GAO (2014): CMS Must Ensure Complete & Accurate Encounter Data to Support \$250 Billion in Expected Future Part C Payments**

- GAO letter to Rep. Levin, Ways and Means, H.R., 7/31/2014
- "...CMS contracts with MA organizations (MAO) to provide covered services to beneficiaries who enroll in one of their plans..."
  - April 2014: CMS had 571 contracts with MAOs that served nearly 15.5 million enrollees, approximately 30 % of all Medicare beneficiaries.
  - Congressional Budget Office projects that enrollment in MA plans will increase to about 21 million enrollees by 2023. Medicare payments to MAOs expected to grow from \$154 billion (2014) to \$250 billion (2023).
  - "...As the MA program expands, setting appropriate payments to MAOs and making Medicare a more prudent purchaser of health care services will remain critical."

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**Medicare Part C: Encounter Data**

- **2014 GAO report identifies vulnerabilities in oversight of MAOs, notes CMS lacked the following safeguards:**
  - Analysis of encounter data for completeness and accuracy;
  - Medical records review to verify encounter data; and
  - Summaries of encounter data review findings.

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**Part C Best Practices: Risk Adjustment**

- Establish communications with providers; identify contact personnel for medical record requests or other RADV activities.
- Determine how medical records can and will be supplied to the MAO (i.e., hardcopy or electronic) based upon the technological capabilities of the MAO and the provider.
- Encourage continual education of both plan personnel and providers on the proper maintenance of medical records and coding accuracy and develop communication with providers on the RADV process and the possibility of a RADV audit by the plan or CMS.
- Understand risk adjustment profile.
- Review and determine:
  - Top ten HCC's by volume and intensity; and
  - Top utilizing providers by provider type (physicians, hospitals); and
  - Any claims or record rejections from CMS; and
- Educate providers going forward.

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**Risk Area: Kickbacks**

- **The Federal Anti-Kickback Statute**, 42 USC § 1320a-7b (b) is a criminal statute that prohibits any person from knowingly and willfully, soliciting, receiving, offering or paying remuneration (anything of value) in exchange for referrals for services that are covered by federally insured health care programs (e.g. Medicare and Medicaid). A violation of the AKS is a felony punishable by up to five years in prison and/or fines up to \$25,000.
- Exclusion Risk: Conviction under the AKS results in mandatory exclusion from federal health care programs.
- **The Affordable Care Act** codified and clarified that violations of the Anti-kickback Statute can also result in civil liability under the Federal False Claims Act, 31 USC § 3729-3733 (the "FCA") as well as administrative penalties under the Civil Monetary Penalties Law.
- *Example in MA context:* Florida health plan self-disclosed and agreed to pay over a \$250K fine in connection with allegedly offering "to increase the capitation rates paid to four physicians in exchange for the referral of their patients to [health plan] and . . . increas[ing] the capitation rates of two of the four physicians."

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**Risk Area: Medical Loss Ratio**

ACA MLR=

$$\frac{\text{Medical care claims} + \text{Quality improvement expenses}}{\text{Premiums} - \text{Federal and state taxes, licensing, and regulatory fees}}$$

- MLR existed long before ACA; was used to evaluate performance of managed care companies.
- Affordable Care Act (ACA)- Created consistent federal standard and modified the calculation.
- Plans that fail to meet the minimum MLR of 85% are required to remit partial payments to HHS
  - ≤ 85% for three consecutive years, suspension of plan enrollment for two years;
  - Less than 85% for five consecutive years, the Secretary terminates the plan contract.
- Quality improvement expenses include activities that improve patient outcomes, safety, wellness, quality, transparency, or outcomes through enhanced health information technology. Administrative expenses, e.g., insurance broker and agent compensation or fraud prevention activities not included.

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**Risk Area: Medical Loss Ratio (cont'd)  
Case Example: WellCare**

- Allegations: WellCare misled Medicaid regulators in Florida and intentionally misstated and improperly attributed certain unallowable expenses in order to manipulate MLRs and avoid a refund to the state and, by extension, improperly inflated earnings.
- Civil and Criminal investigations of alleged Medicare and Medicaid overbilling.
- Outcomes:
  - 2009: DPA and \$80MM (\$40 MM restitution/ \$40MM forfeiture).
  - 2010: Settled shareholder litigation for \$200MM.
  - 2011: Five executives indicted (including former CEO, CFO, General Counsel).
  - 2012: Civil Settlement of FCA allegations for \$137.5MM.
  - 2013: Four executives tried and convicted.
  - 2014: Former CEO sentenced to 36 months in prison.

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**Medicare Managed Care  
Compliance Best Practices**

1. **Look to Your Certifications and Those Who Sign Them!**
2. **Review Data Submissions and Reports Sent to CMS and Other Government Agencies.**
3. **Consider MCO Obligations to Audit, Investigate and Police Providers.**
4. **Review OIG Reports and Work Plans: identify areas on the radar of enforcement (encounter data reviews, risk adjustment investigations, focus on kickbacks, etc.).**
5. **Take internal reports related to Medicare Managed Care Compliance seriously.**
6. **Self-Report promptly (60-Day Rule).**

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**Medicaid Managed Care: Risk Areas and Best Practices**

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**January 2017:  
OIG's Focus on FWA in the Medicaid Program**

- Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, HHS-OIG, testimony before the House Committee on Oversight and Investigations, 1/31/2017
  - “Protecting Medicaid from fraud, waste, and abuse is an urgent priority because of its impact on the health of vulnerable individuals and its fiscal impacts on Federal and State spending.”
  - “As of September 2016, more than **74 million individuals** were enrolled in Medicaid, and the total Medicaid spending for fiscal year (FY) 2016 was **\$574 billion**.” In 2015, **\$230 billion was for Managed Care**.
  - “OIG has consistently identified effective administration and strengthening the program integrity of Medicaid is among the top management challenges facing HHS.”
  - “OIG has a unique role in Medicaid program integrity: administer and oversee Federal grants to State Medicaid Fraud Control Units (MFCUs), which investigate and prosecute Medicaid provider fraud.

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**January 2017:  
OIG's Focus on FWA in the Medicaid Program**

Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, HHS-OIG, 1/31/2017 (cont'd)

- Entities responsible for Medicaid program integrity: OIG, CMS, State Medicaid Agencies, **Managed Care Contractors**.
- **OIG investigations** of Medicaid fraud, 2016
  - 348 criminal actions, 308 civil actions, **\$3 billion recovered**.
- **State MFCU investigations**, 2015
  - 1,889 indictments, **\$744 million recovered**.
- OIG recommendation: “**States should suspend Medicaid payments to providers when there are credible allegations of fraud**.” SSA § 1903(i)(2), as amended, by the ACA § 6402(h)(2).

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**Medicaid Managed Care Enforcement**

- OIG's focus for 2017 to protecting the Medicaid program from fraud, waste, and abuse, includes:
  - Medicaid MCO Drug Claims: MCO capitation payments should not include claims for reimbursement for drugs not covered by the Medicaid program because there was no rebate payable (i.e., the drug was dispensed beyond the termination date);
  - Health-Care Acquired Conditions: Medicaid MCOs should not be paying providers for inpatient hospital services for treating provider preventable conditions. ACA, 2702, implementing 42 CFR 447.26 (prohibits federal payments for provider preventable conditions).
  - MCO Payments for Services After Beneficiaries' Death: OIG will identify Medicaid managed care payments with dates of service after the beneficiaries' date of death.

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**Fraud Related to Medicaid Waivers**

- Section 1115 Waivers: States use funds in ways that do not conform to federal statutory and regulatory requirements.
  - ACA - Section 1115 waivers to allow state Medicaid expansion beyond the flexibility allowed by law.
  - CMS has denied 1115 waivers. I.e., work requirements as a condition of eligibility.
- ACA: In 2015, Federal Medicaid spending grew by 12.6%, and states by 4.9%. The federal increase was driven by newly-eligible enrollees under the ACA who were fully funded by the federal government.
- Section 1915(b) Waivers: Specific type of waiver which permit states to place Medicaid enrollees in managed care plans or long term services and supports (LTSS) for home and community-based services to those who would otherwise be institutionalized.
- Terms of waiver included in MCO provider contracts. For example, the 1915(b) waiver requires that the MCO to "assess each enrollee identified by the State to identify any ongoing special conditions that require a course of treatment or regular care monitoring." The state must also have "a mechanism to identify persons with special health care needs."
  - Once identified, the MCO must provide care management to these enrollees.

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**Medicaid Managed Care Fraud, 1915(b) Waiver  
*US ex rel Herzog and Rupert v CareSource*  
 \$26 Million Ability-to-Pay Settlement**

- 1915(b) waiver obtained by the State of Ohio, included identification, specific assessment, and the implementation of care plans for Children with Special Healthcare Needs (CHCN)
- These requirements were memorialized in the MCO provider agreement.
- The relators were MCO nurses who provided critical piece of the puzzle in a complex regulatory and provider agreement-driven program.
- Compliance/Enforcement: Is the MCO Providing All Covered Services?
  - Federal Statutes, regulations, 1915(b) Waiver applications;
  - Managed care contracts between the state agency and the MCO
  - The compliance issue: is the MCO providing the services as required by the waiver and managed care contract?
  - The Agency/Defendant's Opening Position: What wasn't provided was "a throw Away Service" (not "material").

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**Medicaid Managed Care  
Compliance Best Practices**

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
- Compliance officer and committee accountable to senior management.
- Effective training and education for compliance officer and other employees.
- Effective lines of communication between compliance officer and organization's employees.
  - Anonymous must mean that. Don't discourage use of hotline. Maintain a log of hotline reports, and actually investigate them.
- Internal monitoring and auditing.
  - Detection through claims data analysis, auditing suspicious activities.
- Prompt response and corrective action when offenses are detected.

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**Questions?**

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**Sampling & Statistical Methods  
Utilized in Health Care Compliance**

Frank Castronova, PhD, Pstat  
Wayne State University

Andrea Merritt, ABD, CHC, CIA  
Partner  
Athena Compliance Partners

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**Agenda**

- Review the various types of sampling used in compliance auditing, including a discussion of stratification.
- Discuss extrapolation
- Questions

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**Fraud, Waste, and Abuse**

- CMS is now combating Fraud, Waste, and Abuse through nationally coordinated strategies.
  - New data analytics
  - Pattern recognition methods
  - Analysis tools
- Extrapolation is not likely in automated reviews, but very likely in complex review, especially for inpatient claims or high dollar value claims.

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### Internal Efforts

- Increase internal auditing and monitoring efforts while integrating statistical expertise, when needed.
  - Valid samples are imperative.
  - If validity can be challenged, estimates and conclusions drawn for the universe are not sustainable.
- Ready to execute a response strategy in the case of a government audit
  - Add statistical expertise to a response team
    - Always verify government statistics and extrapolation is appropriate.

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### Purpose of Sampling

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates that before using extrapolation to determine overpayment amounts, there must be a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error.
- The purpose of sample is to use a portion of the population of interest to generalize back, or infer to, the population of interest.
- Saves time and money.

CMS Program Integrity Manual 8.4.1.2

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### Why Sample?

- The characteristics of interest of the population are unknown
- Save time
- Save money

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## Types of Samples

- Probability samples
  - The probability of selecting any one element from the population is known and equal.
- Non probability samples
  - The probability of selecting any one element from the population is not known and are not equal.



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## Types of Probability Samples

- Simple random sampling
- Systematic sampling
- Stratified sampling
- Cluster Sampling

*These methods should yield samples that have characteristics that are very close to those of the population*

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## Simple Random Sampling

Each member of the population has an equal and independent chance of being selected

- Steps to follow:
  - Define the population of interest
  - List all members of the population
  - Randomly select members from the population using some type of random process, e.g., computer program

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### Simple Random Sampling Considerations

Use this method when the population members are similar to one another.

- Advantage:
  - Ensures a high degree of representativeness
- Disadvantage
  - Time consuming and tedious



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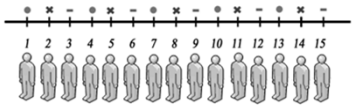
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### Systematic Sampling

Here every nth item is selected

Steps to follow

- Make sure population is not sorted in any way
- Divide the population size by the desired sample size
- Choose a starting point at random
- Select every nth item from the starting point



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### Systematic Sampling Considerations

- Use when the population members are similar to each other
- Advantage
  - Ensures a high degree of representativeness
- Disadvantage
  - Less random than simple random sampling because once the starting point is determined, each member does not have the same chance of being selected

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## Stratified Sampling

- Used to assure that the strata in a population are fairly represented in the sample
  - Especially important when the distinguishing factors (strata) are related to what is being studied
- Steps to follow
  - Members of each strata are listed separately
  - A random sample from each strata is selected

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## Stratified Sampling Considerations

- Used when the population is heterogeneous and contains different groups, some of which are related to the topic of the study
- Advantages
  - Ensures a high degree of representativeness of all of the strata or layers in the population

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## Cluster Sampling

- Used when units of individuals are selected rather than the individuals themselves
- Steps to follow
  - Identify the units of interest
  - Randomly select a sample of the units
  - Examine each element within each selected unit

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## Cluster Sampling Considerations

- Use when the population consists of units rather than individuals
- Advantages
  - Easy and convenient
- Disadvantages
  - Members of units may be too different from each other

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## Sampling Problems

- Sampling Error
- Bias



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## Sampling Error

- Sampling error is the lack of fit between the sample and the population
- Sampling error is the difference between the characteristics of the sample and the population from which the sample was selected and is a natural occurrence
- The larger the sampling error, the less the sample results can be generalized to the population

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## Minimizing Sampling Error

- Increase the sample size as much as possible and reasonable
- Use probability sampling methods rather than non probability sampling methods
- At the extreme, conduct a census rather than perform sampling

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## Biased Sample

- A biased sample is one in which the method used to create the sample results in a sample that is systematically different from the population
- Any generalization about the population made with a biased sample will not be valid.
- Solution is to use a randomly selected sample.

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## Sample Size Considerations

- Confidence desired
- Level of variability in the population
- Precision level
  - Also know as effect size



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## Confidence Level & Precision

- Example:
  - Confidence Level = 95%
  - Precision = 7%
  - Sample Mean = \$50
- Interpretation:
  - We can be 95% confident that the population mean will be between \$46.50 and \$53.50 (\$50 + or - 7%)

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## When Will a Larger Sample Size Be Needed

- A larger sample size will be needed when the amount of variability within groups is greater
  - As elements become more diverse, a larger sample size will be needed to represent all of them
- The difference between groups gets smaller
  - As the difference between groups gets smaller, a larger sample will be needed to reach the "critical mass" where the groups can differ.

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## Final Sampling Issues

- Record (patient) substitution
- Projection of sample findings to the population



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### Record Substitution

- Once a sample is selected, records (patients) can not be substituted.
- Doing so invalidates the original sample and precludes the projection of findings back to the population



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### Projection of sample findings

- Since a valid random sample is a representation , or a "mirror image" of the population, it is defensible to project sample findings onto the population from which the sample was drawn
- This projection can include any characteristic of the sample

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### Types of Non Probability Samples

- Convenience sampling
- Quota sampling

*These methods will probably yield samples that have characteristics that are not close to those of the population*

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### Convenience Sampling

- Used when the units of interest are “captive”
- Steps to follow
  - Select the “captive” population
  - Select the sample



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### Convenience Sampling Considerations

- Used when the members of the population are convenient to sample
- Advantages
  - Convenient and inexpensive
- Disadvantage
  - Results can not be generalized to the population

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### Quota Sampling

- Used when a stratified sample is desired, yet proportional stratification is not possible
- Steps
  - Decide on strata definitions
  - Choose individuals in each strata until quota is reached

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### Quota Sampling Considerations

- Use when strata are present and stratified sampling is not possible
- Advantages
  - Insures some degree of representativeness of all the strata in the population
- Disadvantage
  - Results can not be generalized to the population

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### Definition of Data Mining

- Data mining is the process of sorting through large amounts of data and picking out relevant information. It is usually used by business intelligence organizations, and financial analysts, but is increasingly being used in the sciences to extract information from the enormous data sets generated by modern experimental and observational methods.

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### Modeling

- Predictive modelling is the process by which a model is created or chosen to try to best predict the probability of an outcome. In many cases the model is chosen on the basis of detection theory to try to guess the probability of a signal given a set amount of input data, for example given a claim determining how likely that it is compliant.

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## Predictive Modeling Methods

- Neural Networks
- Social Network Analysis
- Decision Trees
- Discriminant Analysis
- Logistic Regression

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## Basic Inferential Statistical Methods

- Student t Test
- Analysis of Variance
- Chi-Square Analysis
- Regression Analysis

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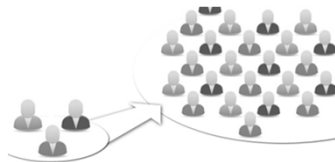
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## Extrapolation of sample findings

- Since a valid random sample is a representation , or a "mirror image" of the population, it is defensible to project sample findings onto the population from which the sample was drawn
  - This projection can include any characteristic of the sample



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## Can OIG or others use Sampling and Extrapolation?

Determine overpayment in a manner that minimizes government's administrative burden.

- CMS Ruling 86-1.
  - Explains HCFA's authority to use statistical sampling to estimate overpayments made to physicians and suppliers. The ruling recognizes that statistical sampling conserves the resources of the Medicare program when reviews are performed on a large universe of claims.
- 42 U.S.C. § 1395gg(b) authorizes the Secretary to recoup from a provider or supplier "if more than the correct amount has been paid"
- 42 C.F.R. § 405.371 allows recoupment if a determination is made that a provider/supplier to whom payments are to be made has been overpaid.

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## First Legal Case Finding Extrapolation Valid

- *Chaves County Home Health Service, Inc. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991), *cert. denied*, 402 U.S. 1091 (1992).
- Statistical sampling does not violate due process "so long as extrapolation is made from a representative sample and is statistically significant."




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## American Hospital Association

- November 20, 2014: AHA wrote the OIG regarding use of increased extrapolation; request to halt reviews and the demands to repay improperly extrapolated amounts.
  - Short inpatient stays
  - Not offsetting the amount of Part B payments with estimated overpayments
  - Using extrapolation without a clear process to challenge the OIG's sampling and extrapolation methodology through the claims appeal process
  - Misapplying or misinterpreting Medicare requirement

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## American Hospital Association

- January 15, 2015 response:
  - OIG's application of a physician-order requirement is supported by legal authority; OIG consulted with CMS.
  - Medicare requires that a service must be reasonable and necessary to be payable. Admitting physician would expect the patient to stay 24 hours or more.
  - CMS is responsible for administering Medicare and contracts with MACs to process and pay claims. Providing an offset to the Part A overpayment with Part B reimbursement figures is not within the scope of these OIG reviews.
  - CMS allows for reopening of claims at any time provided that there is reliable evidence that the initial determination was procured by fraud or similar fault.
  - Use of statistical sampling in Medicare is well established and has repeatedly been upheld on administrative appeal within the Department and by Federal courts.

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## Recent – FCA Cases

- The AHA and Catholic Health Association urged the U.S. Court of Appeals to affirm a lower court ruling that relators seeking damages and penalties under the False Claims Act cannot use statistical sampling to prove a case challenging the exercise of medical judgment by a physician.
- DOJ's announcement on Oct. 24, 2016, that it reached a \$145 million settlement agreement with Life Care Centers of America Inc. and its owner to resolve allegations of FCA violations for submitting false claims to Medicare and TRICARE.

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## Questions

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Partner, Athena Compliance Partners

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***How and when should you leverage internal audit?***  
March 28, 2017



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***Agenda***

- Internal Audit foundation
- 3 lines of defense
- Trends in consultative & value enhancement work
- Why you should care
- Key takeaways



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***What are your initial thoughts on internal audit?***



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**What are your initial thoughts on internal audit?**

Boring! Adversaries!

Who? Strategic Partner? Nuisance!

Blocking and tackling

Gotcha! Financials

Sleepy time!

PwC 4

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**Internal audit overview**

**What is internal audit?**

“Internal auditing is an **independent, objective assurance and consulting** activity designed to add value and improve an organization’s operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.”

*-The Foundation for the IIA Standards*

<p><b>Define</b></p> <ul style="list-style-type: none"> <li>Align objective of review with management goals</li> <li>Define scope of review</li> <li>Prepare planning / scope memo</li> <li>Determine resources and budget</li> </ul>	<p><b>Assess</b></p> <ul style="list-style-type: none"> <li>Conduct planning meetings</li> <li>Prepare data collection plan</li> <li>Collect preliminary data</li> <li>Establish detailed approach to review</li> </ul>	<p><b>Analyze</b></p> <ul style="list-style-type: none"> <li>Establish capability of the process</li> <li>Identify risk to meeting objectives &amp; goals; to organization</li> <li>Identify the root cause (control / process breakdown)</li> </ul>	<p><b>Recommend</b></p> <ul style="list-style-type: none"> <li>Develop feasible recommendations to reach goals</li> <li>Aggregate root causes addressed by same recommendations</li> <li>Agree findings &amp; recommendations with management</li> </ul>
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PwC 5

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**Wait! Before we go on...**

...isn't internal audit the same as compliance or quality assurance?

Great question!

What do you think?

Are they the same? How should they differ?

PwC 6

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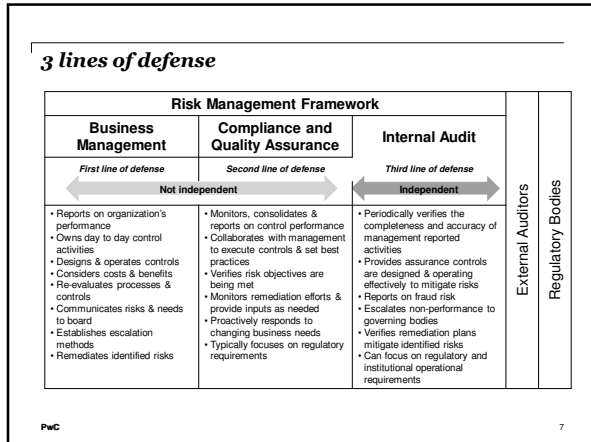
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### Internal audit vis-à-vis compliance

	Internal Audit	Compliance
<b>Definition</b>	Independent, objective assurance and consulting activity designed to add value and improve operations	Preserve corporate integrity and adherence to a code of organization ethics and ensure compliance with regulatory matters
<b>Purpose</b>	<ul style="list-style-type: none"> <li>➢ independent appraisals of governance, risk and control</li> <li>➢ review reliability and integrity of financial information</li> <li>➢ safeguarding of assets</li> <li>➢ review consistency with operational goals and objectives</li> <li>➢ recommend operating improvements</li> </ul>	<ul style="list-style-type: none"> <li>➢ encourage the use of internal controls to monitor adherence to applicable regulations</li> <li>➢ effect change as necessary to achieve regulatory compliance</li> <li>➢ create organizational compliance policy and procedure, compliance training</li> <li>➢ protect and secure PHI</li> <li>➢ implement HIPAA Privacy and Security standards</li> </ul>
<b>Authority</b>	Audit Committee Charter Internal Audit Charter	Compliance Program Compliance Committee Charter
<b>Management Relationship</b>	Independent with no operational responsibilities; reports directly to Board or Audit Committee; does not own policies	Operational responsibility for administering the compliance program; reports to management; may create and / or own policies
<b>Expertise</b>	Primarily with internal controls	Primarily in regulatory matters
<b>Internal Controls</b>	Confirm internal controls are designed and operating effectively	Understand, help design and encourage the use of internal controls

PwC 8

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- ### State of the internal audit profession
- Shifting from retrospective → prospective
  - Innovation
  - Moving from value protection → value enhancement
  - Alignment with business objectives & strategic initiatives
  - Collaboration with second line of defenses
  - Right mix of talent and business acumen
  - Effective & timely communication
  - Follow-up and monitoring process
- PwC 9

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**Questions**

**For questions, contact:**

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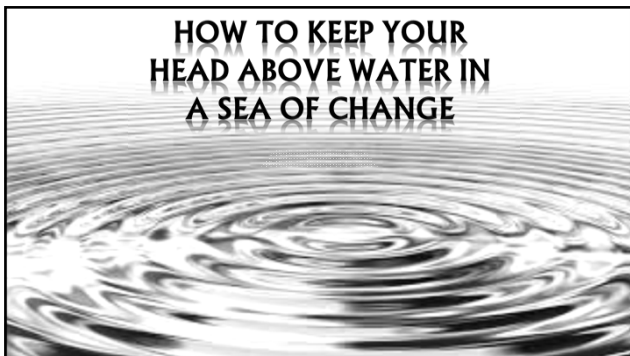
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## HOW TO KEEP YOUR HEAD ABOVE WATER IN A SEA OF CHANGE

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**Meet The Presenters**



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**Discussion Objectives**

- Strategies**

✔ Strategies to identify what types of change your organization is dealing with and how to respond accordingly so you aren't left wondering "how did I get here?"
- Friends or Enemy**

✔ The friends and enemies of a successful Compliance Professional... which do you possess?
- What Now?**

✔ Ever left wondering, now that I am here, what do I do next? We have some best practices that will help you define a path forward

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"Change is the ***only*** constant in life"  
- Heraclitus, a Greek philosopher

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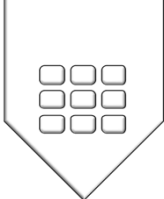
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**STRATEGIES**

Strategies to identify what types of change your organization is dealing with and how to respond accordingly so you aren't left wondering "how did I get here?"

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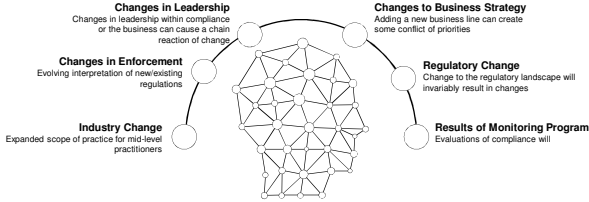
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**The Many Faces of Change**  
Integrated Blocks Infographic



- Changes in Leadership**  
Changes in leadership within compliance or the business can cause a chain reaction of change
- Changes to Business Strategy**  
Adding a new business line can create some conflict of priorities
- Regulatory Change**  
Change to the regulatory landscape will invariably result in changes
- Results of Monitoring Programs**  
Evaluations of compliance will
- Industry Change**  
Expanded scope of practice for mid-level practitioners
- Changes in Enforcement**  
Evolving interpretation of new-existing regulations

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**Types of Change\***



<b>Developmental</b> Identify a need to make improvements to an existing compliance program	<b>Transitional</b> Identify a need to implement a brand new element of your compliance program	<b>Transformative</b> Identify external circumstances that cause you to need to react accordingly
<b>Refine &amp; Define</b>	<b>Plan &amp; Implement</b>	<b>Recognize &amp; Survive</b>

\*As defined by Management Training Specialist:  
<http://www.mistraining.com/blog/three-types-of-change.htm>

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### Developmental Change

#### What causes developmental change?

- Program evaluation
- Audits (internal/external)
- Continuous Improvement
- New Employees

#### What does developmental change feel like?

- Progress
- Invigorating
- Planned & Organized
- High engagement with stakeholders



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### Transitional Change

#### What causes transitional change?

- Regulatory Change
- Enforcement Trends
- Data Analytics
- Audit Results

#### What does transitional change feel like?

- Stretched beyond "norm"
- Challenging but manageable
- Planned & Organized
- Create short-lived tension



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### Transformational Change



#### What causes transformational change?

- Regulatory Change
- Change in Enforcement
- Changing Leadership

#### What does transformational change feel like?

- Disruptive
- Uneasiness/Challenging
- Reactive
- May create conflict

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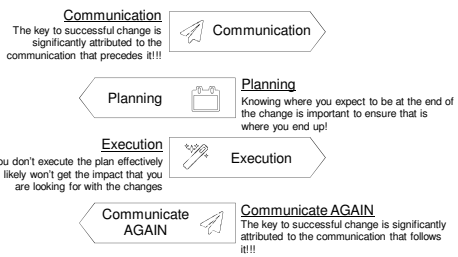
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### Pointers for Effective Change Management




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### FRIEND OR ENEMY

The friends and enemies of a successful Compliance Professional...  
Which do you possess?

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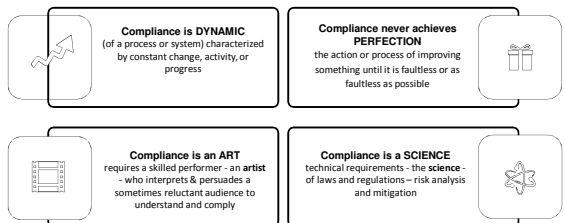
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### Facts You Must Consider

Compliance Professional Realities



There will always be, "What's Next?" and this reality must be embraced.

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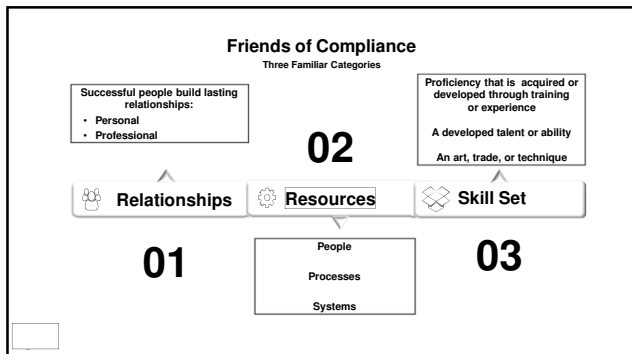
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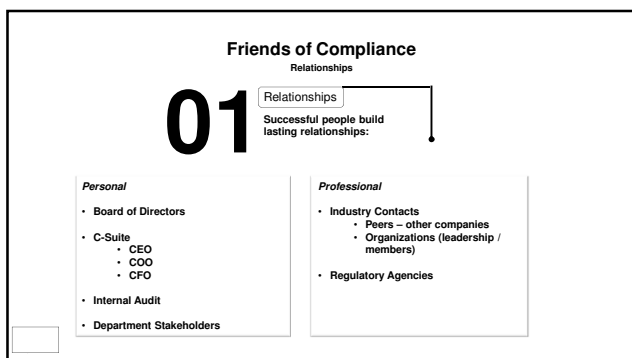
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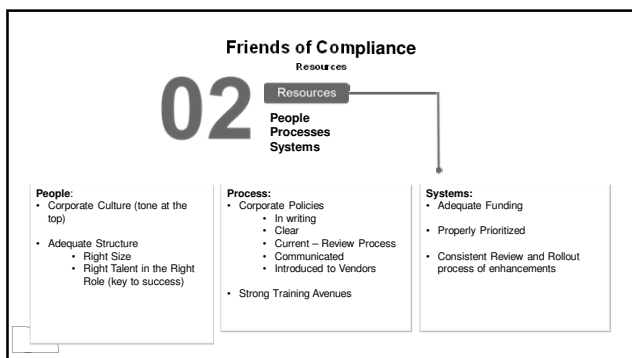
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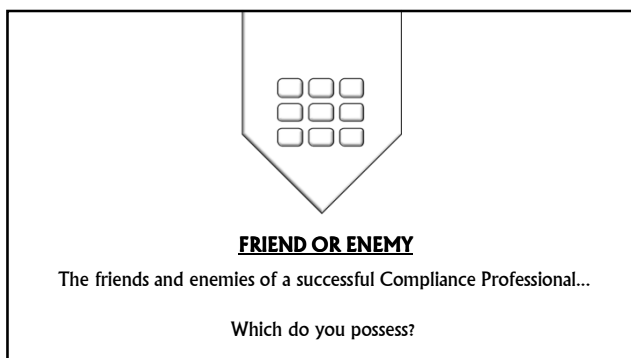
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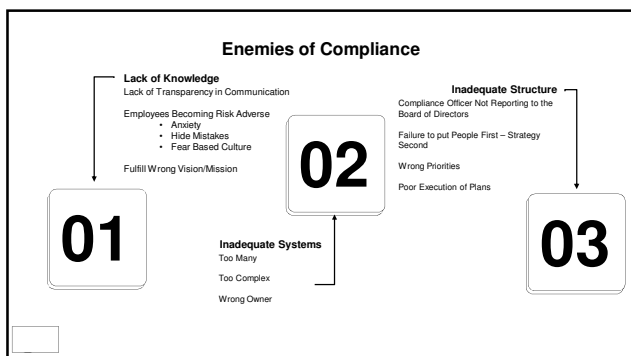
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### Caution! Warning Signs of Rough Seas Ahead!!

<p><b>Lack of Vision</b> Leaders who lack vision cannot inspire teams, motivate performance, or create sustainable value. <i>How is your VISION?</i></p>	<p><b>Lack of Performance</b> Leaders who consistently fail are not leaders, no matter how much you wish they were. <i>How is your PERFORMANCE?</i></p>	<p><b>Lack of Communication Skills</b> Leaders with poor communication skills are normally short-lived in their position. <i>How are your COMMUNICATION skills?</i></p>
<p><b>Lack of Investment in Others</b> Leaders who are not fully committed to investing in those they lead will fail. <i>Are you INVESTED in the success of your team?</i></p>	<p><b>Lack of Accountability</b> Leaders don't blame others, don't claim credit for the success of their team, but always accept responsibility for failures that occur on their watch. <i>How is your ACCOUNTABILITY?</i></p>	<p><b>Lack Ability to Adapt &amp; Refine</b> Leaders don't become insecure, complacent or disgruntled by change, but rather use it to energize themselves and the people around them. <i>How is your ABILITY TO ADAPT?</i></p>



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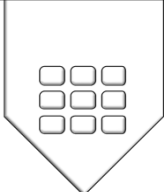
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### WHAT NOW?

Ever left wondering, now that I am here, what do I do next?

We have some best practices that will help you define a path forward

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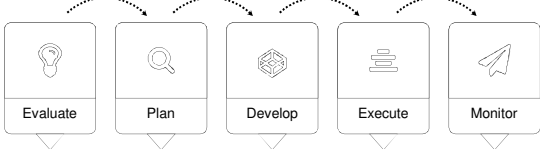
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### What is Our Process?

What is Our Process ?



<ul style="list-style-type: none"> <li>• Type of Change</li> <li>• Resources Needed</li> <li>• Stakeholder Alignment</li> <li>• Change Busters/Promoters</li> </ul>	<ul style="list-style-type: none"> <li>• Identify what success looks like</li> <li>• Determine success measures</li> <li>• Align resources to tasks with defined timelines</li> </ul>	<ul style="list-style-type: none"> <li>• Put the plan into action</li> <li>• Determine inflection points along the way</li> <li>• Assess progress and modify accordingly</li> <li>• Accountability is key</li> </ul>	<ul style="list-style-type: none"> <li>• Communicate, Communicate, Communicate!!!!</li> <li>• Launch the enhancement/new program element</li> </ul>	<ul style="list-style-type: none"> <li>• Evaluate success measures</li> <li>• Data analytics</li> <li>• Audit the results</li> <li>• Get feedback from the front lines</li> </ul>
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**Fundamentals of Change Management**

  
**Communication**

Tell them what your going to tell them  
Tell them!!  
Tell them what you told them

  
**Transparency**

Being transparent means being responsible with the information you have and sharing it appropriately with your stakeholders  
**NO SURPRISES!**

  
**Training**

Training **MUST** be considered in your program, changing practices is a hard --- a lack of training can be a rate limiting step to seeing the fruits of your labor

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**Join the JV (Joint Venture) Team!**  
**Best Practices for Providers, Payers and Vendors**

Eric Sandhusen  
Director of Corporate Compliance & Privacy Officer

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**Disclaimer**

The information, statements, examples and scenarios provided are exclusively those of the presenters and are not intended to describe any position or experience of Northwell Health or its affiliates.



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**Objectives**

- Overview of Different JV Models
- Decision-Making and Joint Governance
- Auditing, Monitoring and Reporting
- Compliance Program Challenges & Best Practices



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### Focus on Compliance in Joint Ventures

Best Practices for Compliance Programs Within an Existing Joint Venture

- Identify Standards
- Examine Challenges
- Propose Solutions

*Governance, regulatory and legal issues are addressed only as background and as they impact Compliance Program development, implementation and maintenance.*



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### Overview of Different JV Models



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### Joint Ventures – Why?

Best align diverse partners and purposes

- Leverage resources
- Balance individual strengths & weaknesses
- Speed to market
- Market dominance



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### Joint Ventures – Why?

- Vertical integration
- Clinical Efficiency & standardization
- Manage business threats
- Share financial risks




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### Joint Ventures – Who?

#### Complementary Partners

- Service Lines
- Industry
- Geography
- Access to Capital
- Specific Expertise




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### Common Elements of JV Agreements

- Contribution Agreement
- Governance Agreement
- Management Agreement

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**JV Models**

- Purchased assets
  - Seller JV (Hospital seeks Investors)
  - Buyer JV (Investors seek Clinical Entity)
- New Enterprises (“Shelf” JV)
- Contractual Joint Ventures



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**Ownership Models**

- Equity ownership models
  - Contributions
  - Valuation
- REIT partnerships
- Contractual Joint Ventures
- Management Services Agreements



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**JV Compliance Risks**

- **OIG Special Fraud Alert (August 1989, reprinted December 1994)**  
 (<https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>)  
 Key Concerns
  - Investors
  - Business Structure
  - Financing and Distribution
- **OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the AntiKickback Statute (Nov 1999)**  
 - <https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf>
- **OIG Special Advisory Bulletin (April 2003)**  
 (<https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf>)
  - Remuneration for Referrals
  - Improper Incentives
  - Reduced competition



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### Five Risk Indicators (OIG)

Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business.

Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts out substantially all the operations of the new business.

Manager/Supplier is an established provider of the same services as the Owner's new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business.

Owner and the Manager/Supplier share in the economic benefit of the Owner's new business.

Aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner. -OIG 04/2003



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### "Suspect" Contractual Joint Ventures (OIG, 2014)

- New Line of Business
- Captive Referral Base
- Little or No Bona Fide Business Risk
- Status of the Manager/Supplier
- Scope of Services Provided by the Manager or Supplier
- Remuneration
- Exclusivity

-OIG, 04/2003



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### Example

A hospital establishes a subsidiary to provide DME. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

-OIG 04/2003



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### Example

A DME company sells nebulizers to federal health care beneficiaries. A mail order pharmacy suggests that the DME company form its own mail order pharmacy to provide nebulizer drugs. Through a management agreement, the mail order pharmacy runs the DME company's pharmacy, providing personnel, equipment, and space. The existing mail order pharmacy also sells all nebulizer drugs to the DME company's pharmacy for its inventory.

- OIG 04/2003



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### Example

A group of nephrologists establishes a wholly-owned company to provide home dialysis supplies to their dialysis patients. The new company contracts with an existing supplier of home dialysis supplies to operate the new company and provide all goods and services to the new company.

- OIG 04/2003



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### Discounted Goods/Services

Another problem exists where an entity, which is both a provider and supplier of items or services and joint venture partner with referring physicians, makes discounts to the joint venture as a way to share its profits with the physician partners.

-OIG 04/2003

Non-payment for services (debt forgiveness, capital calls, in-kind contributions of goods/services)



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### Safe Harbor Guidelines (OIG, 1999)

- No more than 40% of the total value of the investment interests in the venture may be held by investors who are in a position to make or influence referrals to the entity, furnish items or services to the entity, or otherwise generate business for the entity.
- No more than 40% of the entity's gross revenue from health care items and services may come from investor referrals or business otherwise generated by investors.
- The terms on which an investment interest is offered to investors who are in a position to generate business for the entity may not be different from the terms offered to other investors.
- The terms on which an investment interest is offered to an investor may not be related to the previous or expected volume of referrals or business generated from that investor.




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### Safe Harbor Guidelines (cont'd)

- An investor who is in a position to refer patients to the entity may not purchase the investment interest with funds borrowed from the entity or with a loan guaranteed by the entity.
- The entity may not market or furnish the entity's services to investors and non-investors differently.
- The entity may not require investors to make referrals to the entity.
- The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the investor's capital investment.

- OIG, 1999




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### Due Diligence

- Deficit Reduction Act certification
- Policy & Procedure review
- Documentation of Compliance Program
- Public Domain (Exclusion lists, Open Payments, OCR breach filings)




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Decision-Making and Joint Governance



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**Decision Making and Joint Governance**

- Managing diverse interests for partners buy-in
- Voting Rights
  - Ownership Stake
  - Reserved powers
  - Odd-number of Director(s)
  - Outside Director(s)



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**Decision Making and Joint Governance**

- Delineating Compliance Program responsibility
- Defining a Code of Conduct
- Policy Convergence
- Conditions of Default



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Compliance Program  
Development,  
Implementation, and  
Maintenance in JVs

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**Standard Compliance Program Requirements**

- Compliance Officer & Committee
- Policies & Procedures
- Lines of Communication
- Training & Education
- Auditing & Monitoring
- Disciplinary Standards
- Remediation & Response
- Accountability – reporting and assessment




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**Appoint Compliance Officer**

- Independence
- Authority
- Resources
- Access



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### Appoint Compliance Officer

NY OMIG Guidance on Compliance Officers  
"vested with the day-to-day operation"

- "Wholly-owned" (holding company):
    - Can be employed by either/both
  - Partially owned or Joint Venture:
    - Must be an Employee of the JV entity
    - Can also be employed by JV participant
- "no unity of ownership and control"

[http://www.omig.ny.gov/images/stories/compliance\\_alerts/20150330\\_Compliance\\_Guidance\\_2015-02\\_final.pdf](http://www.omig.ny.gov/images/stories/compliance_alerts/20150330_Compliance_Guidance_2015-02_final.pdf)



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### Reporting Responsibilities

Reporting to:

- Legal
- CEO
- Compliance Committee
- Board

Managing reporting relationships with multiple entities requires significant coordination



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### Compliance Committee

May be:

- Sub Committee of Board
- Full Board
- Management Company
- Coordination with parent entities



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**Policies and Procedures**

- Adopt and/or Adapt?
  - Review parent entities' policies
  - Assess differences
    - Operational
    - Cultural
  - Gap analysis
  - Communication
  - Approval & Implementation

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**Policies and Procedures Must Meet...**

Legal Requirements (examples):

- FMV / Related Party
- Breach response
- Lines of Communication

Ethical Standards (examples):

- Gifts policy
- Professional Courtesy
- Charity Care

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**Training**

- Will reflect Policy Analysis Adoption
  - New training
  - Single Entity training
  - Hybrid (modular) training
- Board & Staff
- Management Services Providers

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### Risk Assessment / Work Plan

**Billing:**

- Charge capture
- Coding
- Documentation



**Regulatory:**

- Contract performance (MSA)
- Stark provisions/protections (FMV)
- HIPAA/HITECH

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### Auditing & Monitoring

- Leveraging Participant Resources
- Defining scope
- Maintaining separation of interests
- Clarifying contractual definitions
  - Clinical Quality Management
  - Productivity Benchmarks
  - Substantial participation

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### Remediation and Response

- Identification of potential problem
  - Work Plan findings
  - Internal/external reports
- Referral to Legal Counsel
  - Communication (to Board, Agencies)
- Investigation
  - Applicable regulations
  - Determination of facts
- Implement response/remediation

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### Potential Pitfalls

- Split decisions (50-50 governance)
- Risk tolerance
- Off-contract arrangements
- Conflicts of Interest/Business Associates
- Maintaining confidentiality

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### References Resources Acknowledgements

The Hospital Joint Venture Handbook: Ken Marlow, Barry Sagraves; The Governance Institute® accessed at: <http://www.juniperadvisory.com/wp-content/uploads/2016/01/The-Hospital-Joint-Venture-Handbook-January-2016.pdf>

Joint Venture Governance: an Often Overlooked Success Factor: Barry S. Bader, Elaine Zablocki and Carlin Lockee; *GREAT BOARDS, Spring 2007*, accesses at: <http://www.greatboards.org/newsletter/reprints/GB-ivgovernance-07.pdf>

Safe Harbors Allow Smoother Sailing For Physician-hospital Joint Ventures: John W. Jones Jr., *Physician's News Digest (12/2004)*, accessed at: <http://www.pepperlaw.com/publications/safe-harbors-allow-smoother-sailing-for-physician-hospital-joint-ventures-2005-01-04/>

Forming a Joint Venture - Legal Guidelines: Jeffrey S. Baird, JD; *Medtrade, 04/25/2016*, accessed at: <http://www.medtrade.com/news/general-healthcare/Forming-a-Joint-Venture-Legal-Guidelines-2956.shtml>

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### Questions?

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## Investigative Interviewing: What Researchers Have Found Works and Doesn't Work

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## About Michael Johnson

- CEO of Clear Law Institute, which provides hundreds of online compliance, legal, HR, and investigations courses
- Former attorney in the US Department of Justice
- Has provided investigations seminars to dozens of Fortune 500 companies and organizations such as the EEOC and the United Nations
- Graduate of Duke University and Harvard Law School



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## Overview

- What scientists have found are the best ways to interview witnesses to ensure that you:
  - Gather the most information, and
  - Best assess credibility

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Assessing Credibility

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How good are you at detecting deception and truthfulness?

I believe I can correctly identify if a person is lying or telling the truth the following percentage of time:

- a) 25%
- b) 50%
- c) 75%
- d) 90%
- e) 100%

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Select all that apply—On average, liars are more likely than truth tellers to:

- a. Avoid eye contact
- b. Become fidgety
- c. Increase their blink rate
- d. Look up and to the right

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### Examining “cues to deception”

- We tend to pay attention to “cues to deception” that have not been scientifically validated and are not reliable predictors of lying
- Three factors that impact how people may behave when lying
  - Emotion
  - Cognitive effort
  - Attempted impression management

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### Liars are NOT more likely than truth tellers to:

- a. Avoid eye contact (DePaulo 2003, Mann 2012 and 2013)
- b. Become fidgety (Mann 2002)
- c. Increase their blink rate (Leal & Vrij, 2008)
- d. Look up and to the right (Porter 2012)

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### How well does the average person spot lies?

- The average person can correctly spot what percentage of lies? (Bond & DePaulo 2006)
- Average person does better at spotting lies by just hearing the person or by both hearing and seeing the person’s face? (Leach 2016)
- Observers tend to focus on demeanor, but it’s a poor predictor of truthfulness (Levine 2011)
- Focus on listening instead of looking

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Interviewing Strategies

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Interviewing style

- Primary goal is to get the person to talk
- Journalist, not a prosecutor at trial
- Be suspicious, but don't show your suspicion
- Avoid "confession-seeking" techniques

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Cognitive Interview ("CI")

- The CI is the most widely researched investigative interviewing technique in the world
- Obtains around 50% more detail than standard interview techniques
- Shown to make it easier to spot deception

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### Stages of the Complete CI

- Introduction/Rapport
- Free Narrative
- Drawing
- Follow up questions
- Reverse order technique
- Challenge

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### Introduction/rapport building

- Start with casual conversation on non-threatening topics

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### Free Narrative

- "Please tell me everything you can and give me as much detail as possible."

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### Length of Responses and Amount of Detail

- In response to a request for a narrative answer, liars tend to provide a bare-bones account with little detail (Colwell 2007)

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### Request for drawing

- "Now that you've told me what happened, I'd like you to draw the event. Drawing the event can give you another opportunity to recall details that you may have forgotten. It can also help me get a better understanding of exactly what happened."

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### Drawings can be hard for those who are being deceptive

- Drawings give truth tellers another opportunity to tell the story and display what occurred, which often results in additional details
- Compared to truth-tellers, liars tend to:
  - Provide few, if any, additional details in the drawing
  - Have greater difficulty in making the drawing
  - Display more inconsistencies between their previously provided verbal free narrative and the drawing (Vrij 2009)

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### Follow-up questioning

- Ask for clarification and elaboration
  - Liars typically do not elaborate much or offer additional details (Colwell 2007)

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### Sensorial Details

- Can ask about sensorial details, which are more difficult for liars to make up
  - “Take a moment and think about the event again. Is there anything else you may have seen, heard, or felt during this experience?”
- Liars provide fewer perceptual details that can be verified than truth tellers (Nahari 2014).

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### Reverse-order technique

- “We are going to try something that sometimes helps people remember more details. I’d like you to tell me what happened, but this time start from the end and go to the beginning.”
- Truth tellers provide more detail

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### Reverse order technique

- Research shows that deceptive persons have unusual difficulty telling their fabricated stories backwards
- Studies have shown that people are better able to spot deception when person is required to tell story in reverse order (Evans 2013)

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### Reverse order study (Evans 2013)

- Half of participants instructed to tell what they did in reverse order
- % of lies accurately detected
  - Control: 18%
  - Reverse Order: 75%

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### Try to ask unexpected questions

- If you ask an unexpected question and the person is lying, the person will have to make up a story on the spot.
- Come back to the topic later in the interview
- Unexpected questions can be useful where you have two people giving a joint alibi and they are being interviewed separately (Vrij 2009)
- Look especially for inconsistencies relating to time and space

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### Results from a study with two people giving a joint alibi

- On the basis of consistency of the answers to:
  - Spatial questions, 80% of liars could be correctly classified
  - Drawings, 75% of liars could be correctly classified (Vrij 2009)

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### Other issues to address in “he said/she said” cases

- Motive to lie
- Corroboration

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### Challenge stage

- Don't challenge the person until the very end
- Remain respectful, even soft-spoken

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### Direct challenge at the very end

- Example: "I think that you have not been truthful with me"
- Liars tend to not provide additional information. Instead, they may deflect an answer with responses like, "I'm sorry you don't believe me" or "Why would I lie?" (Geiselman 2012)
- Most truthful subjects will give a firm denial and then offer additional information to support their story (Geiselman 2012)

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## STUDY OF CI'S EFFECTIVENESS IN DETERMINING TRUTHFULNESS AND DECEPTION

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### Mean Truth Ratings (8-point scale) by Interview Stage

At the end of each stage of the interview, study participants were asked to rate how deceptive or truthful they thought the person was being.

1 = Very likely deceptive  
8 = Very likely truthful  
4.5 = midway point

Event	Rapport	Narrative	Drawing	Follow-Up Q's	Reverse Order	Challenge
True	<b>5.34</b>	5.17	5.17	5.49	<b>7.17</b>	<b>7.70</b>
False	<b>4.84</b>	4.17	3.34	2.84	<b>1.49</b>	<b>1.49</b>

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## Summary

- Listen instead of look
- Require witness to do most of talking
- Use some or all elements of the Cognitive Interview

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## Bibliography

- Bond & DePaulo (2006). Accuracy of Deception Judgments. *Review of Personality and Social Psychology*.
- Colwell (2007). Assessment Criteria Indicative of Deception (ACID): An Integrated System of Investigative Interviewing and Detecting Deception. *Journal of Investigative Psychology and Offender Profiling*.
- DePaulo, Lindsay, Malone, Muhlenbruck, Charlton, and Cooper (2003). Cues to Deception. *Psychological Bulletin*.
- Evans, Michael, Meissner, and Brandon (2013). Validating a New Assessment Method for Deception Detection: Introducing a Psychologically Based Credibility Assessment Tool. *J. Appl. Res. Mem. Cogn.*

32

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## Bibliography

- Geiselman (2012). The Cognitive Interview for Suspects (CIS). *American Journal of Forensic Psychology*.
- Hartwig, Granhag, Stromwall, and Kronkvist (2006). Strategic Use of Evidence During Police Interviews: When Training to Detect Deception Works. *Law of Human Behavior*.
- Kassin, S. M., & Fong, C. T. (1999). "I'm innocent!": Effects of training on judgments of truth and deception in the interrogation room. *Law and Human Behavior*, 23, 499–516.
- Leach, Ammar, England & Remigio (2016). Less Is More? Detecting Lies in Veiled Witnesses. *Law and Human Behavior*.

33

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## Bibliography

- Leal & Vrij (2008). Blinking During and After Lying. Journal of Nonverbal Behavior.
- Mann, Ewens, Shaw, Vrij, Leal, and Hillman (2013). Lying Eyes: Why Liars Seek Deliberate Eye Contact. Psychiatry, Psychology and Law.
- Mann, Vrij, and Bull (2002). Suspects, Lies, and Videotape: An Analysis of Authentic High-Stake Liars. Law and Human Behavior.

34

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## Bibliography

- Nahari and Vrij (2104). Exploiting Liars' Verbal Strategies by Examining the Verifiability of Details. Legal and Criminological Psychology.
- Vrij et. al. (2009). Drawings as an innovative and successful lie detection tool. Applied Cognitive Psychology.
- Vrij, Leal, Granhag, Mann, Fisher, Hillman, and Sperry (2009). Outsmarting the Liars: The Benefit of Asking Unanticipated Questions. Law and Human Behavior.

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## Questions?

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Health Care Compliance Association  
 21<sup>st</sup> Annual Compliance Institute  
 March 28, 2017

**“COMPLIANCE, THE C-SUITE, AND THE BOARD OF DIRECTORS: WHAT TO REPORT AND HOW?”**

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 LMelamed@vgroupholdings.com

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**OIG Issuances**

- Annual Work Plan
- Compliance Program Guidances (CPGs)
- Fraud Alerts, Special Advisory Bulletins
- Corporate Integrity Agreements (CIAs)
- “Compliance 101” Educational Materials and Podcasts

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### Prior Board Guidance

- *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007)
- *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors* (2004)
- *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (2003)

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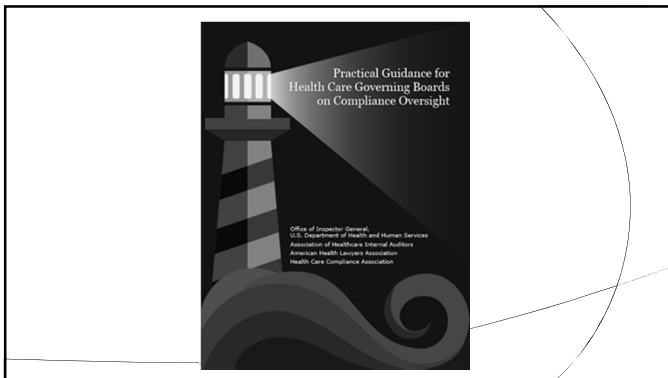
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### OIG: *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (April 2015)

- Board must act in good faith in the exercise of its oversight responsibility, including making inquiries to ensure:
  - A corporate information & reporting system exists and
  - The reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course

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### OIG Guidance to Boards

- Ensure that management is aware of the Guidelines, compliance program guidance, and relevant CIAs
- Ensure that Board members are periodically educated on the organization's highest risks
- Develop a formal plan to stay abreast of changing regulatory landscape and operating environment

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### OIG Guidance to Boards

- Add to Board, or periodically consult with, experienced regulatory, compliance, or legal professional
- Receive compliance & risk related information in a format sufficient to satisfy the interests or concerns of members and to fit their capacity to review that information

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### OIG Guidance to Boards

- Consider conducting regular "executive sessions" (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication
- Risk areas include referral relationships and arrangements, billing problems (e.g., upcoding, submitting claims for services not rendered and/or medically unnecessary services), privacy breaches, and quality-related events

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### OIG Guidance to Boards

- When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within organizations
- Monitor new areas of risk: increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement

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### OIG Guidance to Boards

- Boards of entities that have financial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws
- Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments (60 day repayment rule)

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### Sample Board Certification

"The Board of Directors has made a reasonable inquiry into the operations of Center's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Center has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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### Sample Management Certification

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [department] with all applicable Federal health care program requirements, obligations of the CIA, and Center's policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [department] is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

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### Government's Interest in Individuals' - Impact on C-Suite and Boards of Directors

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### Government's Ongoing Interest in Individual Culpability is Not New

**Criminal Trials of Former Health-Care Executives Set to Begin**

**Former top WellCare execs sentenced to prison in fraud case**

By Rachel Lunden | May 19, 2014

#### In Guilty Plea, OxyContin Maker to Pay \$600 Million



From left, Kenneth B. Chou, CEO of Purdue Pharma, Dr. Paul D. Goldenberg, the company's former medical director, and Richard Pridemore, Purdue's president.

**Doctors, health care executives accused of Medicare fraud**

**STORY HIGHLIGHTS**

- NEW: You will find out the few who caught the system, HHSR says
- More than 50 doctors, health care executives indicted
- Nearly 40 face allegations of falsely billing Medicare
- Officials stress government's commitment to combating health care fraud



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**Government's Ongoing Interest in Individual Culpability is Not New**

- InterMune
- Wellcare
- Bostwick Laboratories
- GlaxoSmithKline
- Tenet Healthcare
- Purdue Pharma

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**InterMune**

- In 2006, InterMune resolved civil and criminal liability
  - \$37M penalty
  - Deferred Prosecution Agreement
  - 5 Year Corporate Integrity Agreement
- In 2009, InterMune's then CEO, Scott Harkonen, was convicted of felony wire fraud
- In 2011, OIG notified Harkonen of mandatory exclusion for 5 years

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**Wellcare**

- In 2009, WellCare entered into a Deferred Prosecution Agreement
  - Also paid \$40 million in restitution and forfeited an additional \$40 million
- In 2012, WellCare paid an additional \$137.5M to settle allegations under the False Claims Act
- U.S. Attorney's office also pursued criminal charges against several former Wellcare employees, including former CEO Todd Farha and former CFO Paul Behrens

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### Bostwick Laboratories

- In 2013 and 2014, Bostwick settled two matters for an aggregate \$6.5M to resolve allegations of violating the Federal False Claims Act by offering kickbacks to physicians in exchange for referrals

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### The Yates Memo

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### Pre-Cursors to the “Yates Memo”

- 1999 Holder Memo – “Bringing Criminal Charges Against Corporations”
  - Framework for prosecutors
  - Emphasized taking action against individuals
- Thompson Memo
- McNulty Memorandum
- Filip Memo

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# The Yates Memo



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## Policy 1

*To be eligible for **any** cooperation credit, corporations must provide to the Department all relevant facts about the individuals involved in corporate misconduct*

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## Policy 2

*Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation*

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DOJ's Civil and Criminal Divisions -  
Working Together

- Assistant Attorney General for the Criminal Division, Leslie Caldwell, September 17, 2014:

"[e]xperienced prosecutors of the Fraud Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open up a parallel criminal investigation. Those prosecutors then coordinate swiftly with the Civil Division and U.S. Attorneys Office as to the best ways to proceed in parallel investigations ".

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Policy 3

*Criminal and civil attorneys handling corporate investigations should be in routine communication with one another*

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Policy 4

*Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for individuals*

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Policy 5

*Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individual in such cases must be memorialized*

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Policy 6

*Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay*

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**Acting Associate AG Baer –  
Remarks of June 9, 2016**

- ⦿ Individual accountability applies with equal force and logic to the department's civil enforcement
- ⦿ Holding individuals accountable for corporate wrongdoing – even through civil enforcement actions – provides a powerful deterrent against future misconduct
- ⦿ Department attorneys to make sure they are examining the potential liability of individual actors at the outset of an investigation into corporate wrongdoing
- ⦿ Reaching a resolution with the company does not end the inquiry into whether and which individuals should also be pursued
- ⦿ Do not assume individuals will be released from FCA liability in corporate settlement

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**Acting Associate AG Baer –  
Remarks of June 9, 2016**

- Implications that civil accountability for corporate executives hold for companies seeking cooperation credit:
  - Disclosure expected of all facts relating to individuals involved, regardless of hierarchy
  - There is nothing in the individual accountability policy that requires companies to waive attorney-client privilege
  - Cooperation does not require a company to characterize anyone as "culpable"
  - Timing is of the essence. A company should come in as early as possible
  - Prompt voluntary disclosure by a company is viewed favorably
  - A thorough defense investigation may result in better negotiated resolutions

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**The Yates Memo In Action**

- 10/29/15 - DOJ announces Warner Chilcott's agreement to pay \$125 million to resolve criminal and civil liability arising from alleged illegal marketing of certain drugs.
- Same day, DOJ announces the indictment of W. Carl Reichel, a former Warner Chilcott president, with conspiring to pay kickbacks to physicians to induce them to prescribe the company's drugs.
- DOJ Press Release: "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."
- June 17, 2016 – after two days of deliberations – the jury acquitted Reichel.

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**The Yates Memo In Action**

- 12/1/15  
**Osceola Laboratory and Founders agrees to pay \$8.5 million to resolve false billing case**
  
- 12/18/15  
**Splint supplier and its president to pay over \$10 million to resolve False Claims Act allegations**

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### The Yates Memo In Action

9/19/16

**North American Health Care Inc. to pay \$28.5 million to settle claims for medically unnecessary rehabilitation therapy services**

Chairman of the Board and Senior Vice President of Reimbursement Analysis to pay an additional \$1.5 million

1/26/17

**Former Executive of Tenet Healthcare Corporation Charged for Alleged Role in \$400 Million Scheme to Defraud**

Among other things, alleges false and fraudulent statements to HHS-OIG in connection with Tenet's 2006 the CIA, including falsely certifying compliance with the terms of participation in the Medicare and Medicaid Programs, and the terms of the CIA

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### Ralph J. Cox III (September 2016)

- Former CEO of Tuomey Healthcare System
- \$1 million settlement and four-year exclusion
- Exclusion extends to management or administrative services paid for by federal health care programs

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### DOJ's Criminal Fraud Division and Compliance

#### "Evaluation of Corporate Compliance Programs"

- Acquisition Due Diligence
- Root Cause Analysis
- *Board and Senior Management Involvement: The DOJ wants to see that the company's top management and board are committed to compliance and involved in (a) adequately funding and monitoring the compliance program, (b) remediation of identified noncompliance, (c) direct reporting from the compliance officer, and (d) access to outside auditors and experts.*
- Dedication to Compliance
- Robust Auditing

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### Communicating with the Board

- ⦿ Not everything is a burning platform
  - Don't sweat the small stuff
- ⦿ Know when to provide the 30,000 foot view vs. highlight the REAL risks
- ⦿ When do you run to Board of Managers about a compliance issue and bypass your C-suite?
- ⦿ When do you spend the money and make the call to outside counsel?

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### I think I have a problem, now what do I do?

- ⦿ Confirm the "problem"
- ⦿ Is it a regulatory issue or business decision
  - Who needs to know?
  - Which stakeholders should be involved?
  - Should my organization's legal team be involved?
  - Do you need to consult with outside counsel?
- ⦿ How do you document your investigation and your recommendations?
- ⦿ Weigh the exposure risks to the organization

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### Forming an action plan

- ⦿ Can you direct how the investigation should be conducted?
  - Who to bring into the investigation?
  - How deep to look into the problem?
  - Can you limit what time frame to investigate?
  - Who should be making these decisions?
  - Do you bring your Board into the decision making process?

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### How do I weigh the risks to my organization?

- ⦿ Each step along the way there are business decisions to be made
- ⦿ Weighing the business risk:
  - What's the cost?
    - patient safety
    - regulatory risks
    - reputation (yours and your employer's)
  - Whose job is it to weigh the risk?
  - What's your duty as CO if you don't agree?

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### Briefing The Board

- ⦿ When communicating – **GET/KEEP their attention**
- ⦿ Focus on the "high risk" compliance issues that will impact the business (don't sweat the small stuff)
- ⦿ Identify how compliance issues may impact the organization AND them personally
- ⦿ Provide real numbers/demonstrate real impact
- ⦿ Highlight industry trends and enforcement actions that may impact the business

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### Briefing Leadership

- ⦿ Show examples of other organization / Board Of Mangers who are similarly situated
- ⦿ Be selective on what documentation / handouts you provide
- ⦿ Don't forget attorney-client privilege
- ⦿ Be mindful of their time
- ⦿ Show your progress and success stories, and positive impact on the business
- ⦿ Don't surprise your C-suite

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### Understand your role in the organization

- ⦿ Know your scope of authority in your organization
- ⦿ Remember that compliance is interdisciplinary and should be enterprise-wide
- ⦿ Understand your organization's appetite for risk vs. potential exposure to liability
- ⦿ Consider what is a legal decision and what is acceptable business risk
- ⦿ The less your hair is on fire, the more effective you will be

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### Practical Tips

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#### PRACTICAL TIP 1

##### ***If You Haven't Heard ... Make Sure Your Organization Has an Effective Corporate Compliance Program***

- ⦿ An Effective Compliance Program's Goal is to ferret out improper conduct
- ⦿ Investigators are asking for information about organizations' Corporate Compliance Programs
- ⦿ Proactively Have Third Parties Verify the Program's "Effectiveness"
  - OIG CIA's are now requiring external reviews

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PRACTICAL TIP 2

***Maintain and Protect the Privileges, But Keep in Mind that Internal Investigations May Be Shared with the Government***

- ⦿ Attorney Client Privileged Communications
- ⦿ Attorney Work Product Doctrine
- ⦿ DOJ does not require waiver of privileges BUT may be encouraged and ultimately the corporate officers and directors may choose to waive privilege

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PRACTICAL TIP 3

***Review Coverage and Indemnification Provisions***

- ⦿ Review D&O Insurance Policy to determine extent of coverage (and any limitations that may apply)
- ⦿ Review corporate policies and employment agreement and obligations to indemnify and exclusions that may apply

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PRACTICAL TIP 4

**Toolkit for Health Care Boards**

- ⦿ Evaluate the Compliance Program
  - Ask questions that assess the compliance program
  - Protect the compliance officer's independence by separating the role from legal counsel and other senior management
  - Learn how quality, patient safety and compliance information flows to the board
  - Ensure that the organization can validate the accuracy of its quality data
  - Talk to employees
  - Perform self-assessments

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**PRACTICAL TIP 4 - CONTINUED**  
**Examples of Structural Questions**

- How is the compliance program structured and who are the key employees responsible for its implementation and operation?
- How is the Board structured to oversee compliance issues?
- How does the organization's compliance reporting system work?
- How frequently does the Board receive reports about compliance?
- Does the compliance program address the significant risks of the organization?

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**PRACTICAL TIP 4 - CONTINUED**  
**Examples of Operational Questions**

- How has the Code of Conduct been incorporated into corporate policies across the organization?
- Has management taken affirmative steps to publicize the importance of the Code to all its employees?
- Does the Compliance Officer have sufficient authority to implement the compliance program?
- How is the Board kept apprised of significant regulatory and industry developments?
- Does the organization have policies that address the appropriate protection of whistleblowers?
- Are the board and senior management working to foster a culture of compliance?

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**QUESTIONS?**




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**How to Use and Not Abuse MGMA and Other Survey Data in FMV Compliance Programs: Why Flawed Data Usage Leads to Increased Compliance Risk**

Timothy R. Smith, Senior Managing Director, Ankura Consulting Group  
Meghan M. Wong, MS, Assistant Director, Data Solutions, MGMA

Health Care Compliance Association  
2017 Compliance Institute  
March 28, 2017 – National Harbor, MD

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**General Disclaimer**

This program is a general discussion of legal and business issues; it should not be relied upon as legal, valuation, business, financial, or other professional advice.

The panelists will provide their own views and not those of their current or past employers or clients.

Not all slides will be covered in detail. Some are for reference only.

The slides are the result of the collaboration of the panelists and reflect their individual and collective thoughts and observations.

This presentation may include a discussion of hypothetical scenarios. Any hypothetical scenarios are intended to elicit thoughtful and lively discussion, but do not represent actual events.

This program may include a discussion of certain ongoing or settled *qui tam* or other lawsuits. The discussion is based on publicly available documents and allegations in the lawsuits. We wish to remind participants that allegations are allegations only. We also wish to remind participants that the list of cases and related issues we discuss may not be comprehensive.



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**Session Overview**

Part I: Regulatory/Enforcement Context

Part II: Examining Industry Usage of Survey Data

Part III: The Reality of the Data

Part IV: Appropriate Data Use and Solutions

Part V: Question and Answer



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### Part I: Regulatory/Enforcement Context



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### Regulatory/Enforcement Context

**2005 OIG Compliance Guidance.**

Is the determination of FMV based upon a reasonable methodology that is uniformly applied and properly documented?

**Applicable Guidance (From the Stark Commentary).**

**Phase I (2001) – Flexible Methods:** To establish the FMV of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm’s-length transactions who are not in a position to refer to one another.

**Phase I (2001) – Internal vs. Independent Surveys:** We agree that there is no requirement that parties use an independent valuation consultant for any given arrangement when other appropriate valuation methods are available. However, while internally generated surveys can be appropriate as a method of establishing FMV in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.



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### Regulatory/Enforcement Context

**Applicable Guidance (From the Stark Commentary).**

**Phase II (2004) – No Bright Line Standard:** We appreciate the commenter’s desire for clear “bright line” guidance (for determining FMV). However, the statute covers such a wide range of potential transactions that it is not possible to verify and list appropriate benchmarks or objective measures for each. Moreover, the definition of FMV in the statute and regulation is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies.

**Phase III (2007) – Reliance on Salary Surveys:** We emphasize, however, that we will continue to scrutinize the FMV of arrangements as FMV is an essential element of many exceptions. Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating FMV. Ultimately, the appropriate method for determining FMV for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors.

**Phase III (2007) – Burden of Documenting FMV:** The statute and regulations provide a definition of FMV for purposes of section 1877 of the Act. The parties to a transaction or an arrangement are in the best position to ensure that the remuneration is at FMV and to document it contemporaneously. If questioned by the government, the burden would be on the parties to explain how the transaction meets the FMV compensation exception requirements.



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### Regulatory/Enforcement Context

#### Recent Enforcement Actions Involving Physician Compensation

<b>New York Heart Center</b>	<b>\$1.33 million</b>
Infirmity Health System	\$24.5 million
All Children's Health System	\$7 million
Halifax Hospital	\$85 million
King's Daughters Medical Center	\$40.9 million
Tuomey Healthcare System	\$72.4 million
Adventist Health System	\$115 million
North Broward Hospital District	\$69.5 million
Columbus Regional Health	\$35 million
Dr. Andrew Pippas	\$425 thousand
Westchester Medical Center	\$18.8 million
Citizens Medical Center	\$21.8 million




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### Regulatory/Enforcement Context

Reference to survey data is prominent in enforcement cases

- Government's expert in the *Tuomey* and *Halifax* cases
- Tuomey's expert in the *Tuomey* case
- *Citizens' Medical Center* Case
  - Citizens' argued physicians made around national median; thus FMV
  - Judge ruled against motion to dismiss, concluding practice losses and pay increases created doubt about FMV, regardless of survey benchmarking
- Benchmarking above 75<sup>th</sup> and 90<sup>th</sup> percentiles mentioned frequently in whistleblower complaints as evidence of compensation paid for referrals

*Citing practice losses is becoming the leading economic indicator of compensation exceeding FMV in recent enforcement cases*




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### Part II: Examining Industry Usage of Survey Data




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### Examining Industry Usage of Survey Data

Using survey data to define the US market

- Thinking the survey data fully represents all US physicians
- Thinking the survey data fully represents a specific local market based on national or regional data

Using specific percentiles of survey data to set floors and ceilings for physician compensation

- Defining market compensation based on specific percentiles
- Assuming wRVUs (or collections) are the definitive driver of physician compensation
- One-to-one relationship based on reported percentiles
- Median rate x wRVUs = market compensation

Basing FMV solely on survey data using one or two production-based methods

*Note: this presentation will critique the above usage.*




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### Examining Industry Usage of Survey Data

Using survey data to define the US marketplace

- Physician employment by health systems
  - Citing MGMA percentage of reporting physicians employed by health systems
  - Used by media outlets, industry presentations, etc.
- Specific percentiles as national rates
  - Survey median as US national median
  - Over the 90<sup>th</sup> percentile as "most highly paid in the US"
  - Used by qui tam relators, industry presentations, DOJ
- Respondent characteristics
  - ACO participation, value-based payments, etc.
  - Industry searching for data; surveys provide such data on respondents

*Note: this presentation will critique the above usage.*




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### Examining Industry Usage of Survey Data

Selection of specific percentiles for FMV

- Medians
  - "It's going to take the median to hire a replacement physician."
  - "Any physician should be able to move somewhere and make the median compensation per wRVU rate."
- Specific percentiles or range of percentiles
  - "FMV is up to the 75<sup>th</sup> percentile."
  - "Physicians over the 90<sup>th</sup> percentile are not FMV."
  - "FMV is the 25<sup>th</sup> to the 75<sup>th</sup> percentile."
  - "FMV is the median to 75<sup>th</sup> percentile."
- Support for selecting percentiles
  - "This is how everybody does it."
  - "This is what we see in our practice."
  - "I heard it at a conference or webinar so it must be true."

*Note: this presentation will critique the above usage.*




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### Examining Industry Usage of Survey Data

#### Matching compensation and production

- Percentile matching: total compensation
  - Total compensation should match with the benchmarked level of production
    - Example: physician at the 65<sup>th</sup> percentile for wRVU production should be paid the 65<sup>th</sup> percentile total compensation
  - Stacking analysis: problem if total comp from all elements (clinical, call, admin) benchmark higher than production
    - Example: total comp at 85<sup>th</sup> percentile, but production at 65<sup>th</sup>
- Percentile matching: compensation rate
  - Compensation rate (per wRVU or collections %) should match with the benchmarked level of production
    - Example: physician at the 65<sup>th</sup> percentile for wRVU production should be paid the 65<sup>th</sup> percentile compensation per wRVU rate

*Note: this presentation will critique the above usage.*




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### Part III: The Reality of the Data




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### Primer on Statistics

#### Inferential statistics

- Sample of a population is analyzed
- Characteristics of sample are extrapolated to the population: sample reflects the population
- Requires a representative sample of the population
  - Requires randomized or other sampling techniques to provide for a representative sample

#### Descriptive statistics

- Description of a given data set
- Presents analysis of a given data
- Sample not developed as an "academic, statistically significant" representation of a population




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**Primer on Statistics**

Surveys are a description of a nonrandom sample of U.S. physicians

- Voluntary participation
- Trade associations or client relationships
- Concentrations in characteristics of respondents
  - Large multispecialty groups and health system practices
  - MGMA provides filters for reporting data based on specific characteristics

**Implications for using survey data**

- Not based on randomized or representative sampling methods
- Not an “academic, statistically significant” representation of the U.S. physician marketplace
- Provides a broad picture of the range of compensation and production for responding physicians who are a part of the U.S. physician market
- Requires informed use and judgment in making inferences and conclusions about specific physicians relative to survey data




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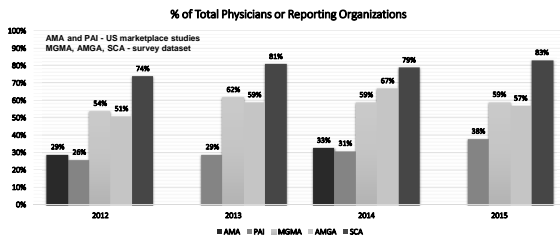
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**Physicians Employed by Health Systems**




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**Implications of Survey Sample Analysis**

Limits “truth claims” made based solely on survey data

- Survey percentiles as US marketplace benchmarks
- Ranges of compensation and production may be different
- Patterns and relationships between compensation and production may be different
- Limitations in making inferences about all US markets, local markets, and specific physicians
- Characteristic trends
- Alternative payment model trends

Improper usage leads to an inaccurate market analysis

- Misinformed FMV or CR analysis based on any survey trends




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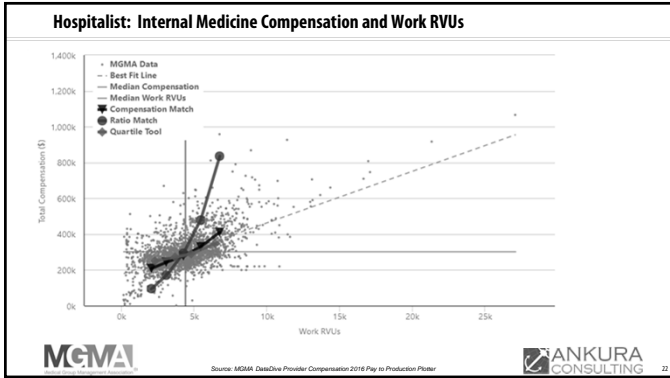
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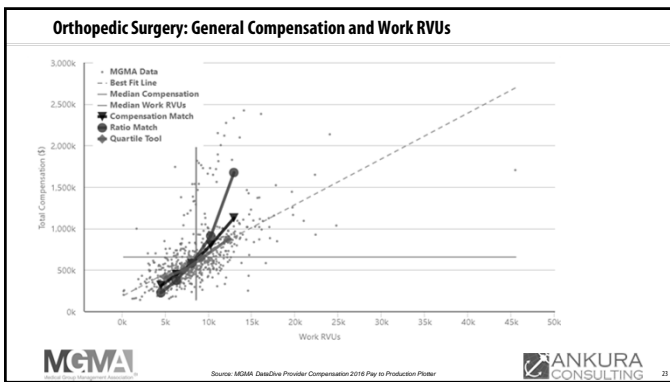
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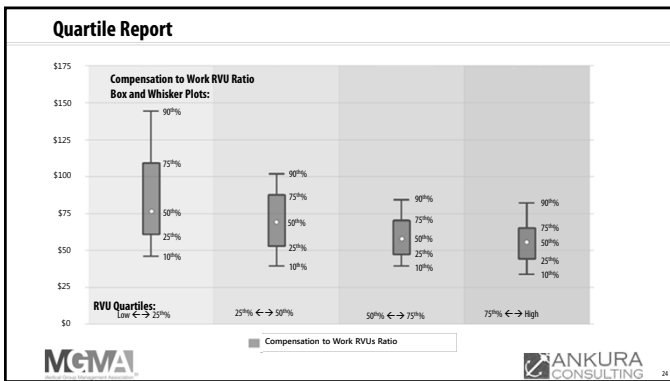
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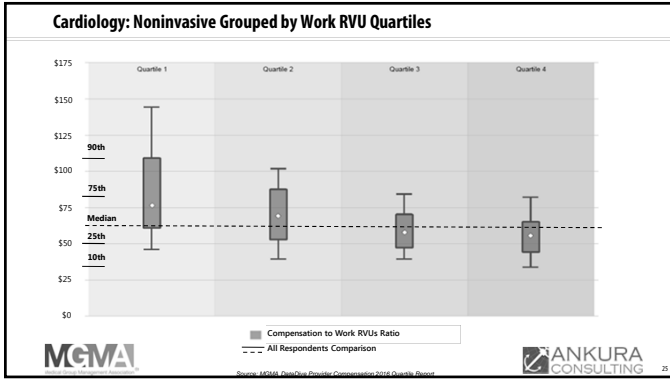
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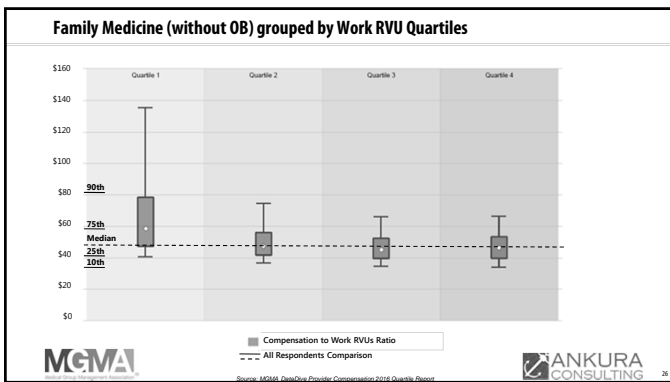
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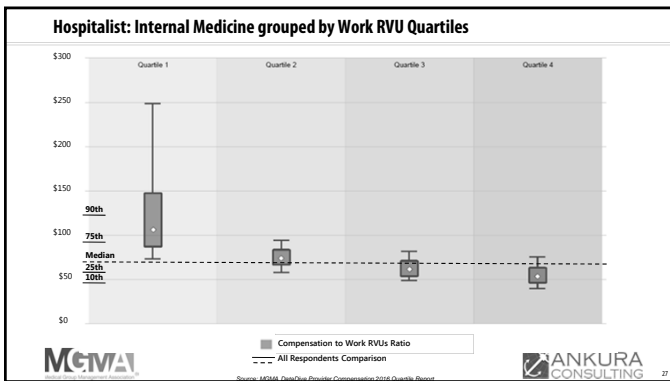
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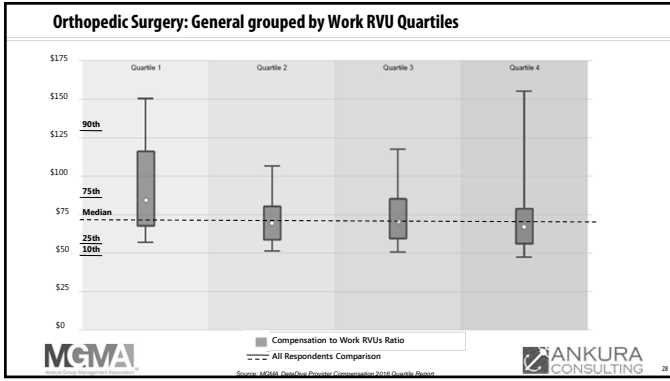
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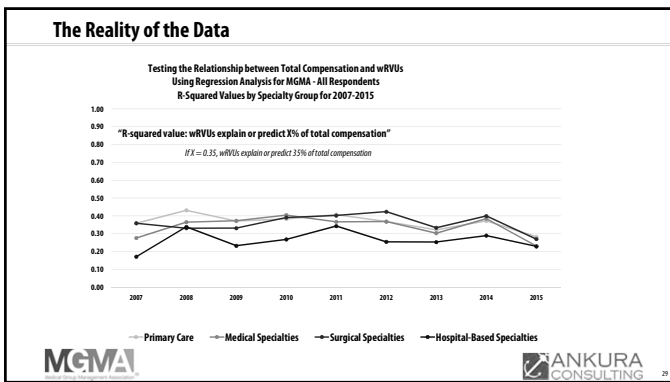
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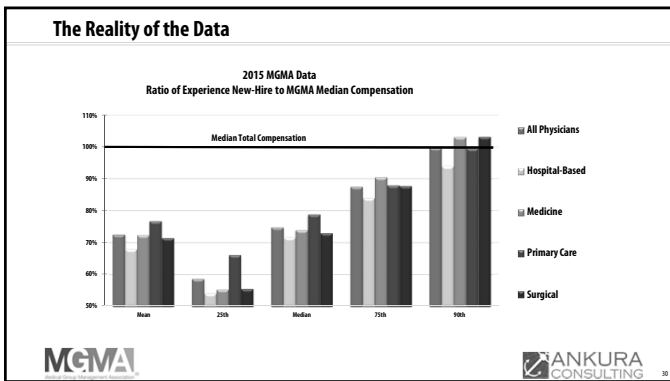
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### The Reality of the Data

Wide dispersion of compensation levels relative to production

- Wide range of compensation per wRVU at any given level of production
- Median compensation rate varies by level of production
- Percentile matching is not supported by the data
- Selecting percentiles as universal rates of FMV does not comport with the dispersion of the data
- Most newly hired physicians don't make the median total compensation as a starting salary
- wRVU production does not explain or predict the majority of total compensation for all respondents without appropriate parameters in place
  - May explain more for certain subgroups



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### The Reality of the Data

Factors driving wide dispersion of compensation levels relative to production

- Local market commercial payer rates
- Payer mix
- Service mix
  - Ancillaries
  - Nonproduction services: call coverage, administrative
- Profits on nonphysician providers
- Cost efficiency

Ignoring these other factors in using survey data can lead to practice losses



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### Part IV: Appropriate Data Use and Solutions



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**Avoid Common Misuses of MGMA Data**

Inappropriate use of MGMA Data includes:

- Using total compensation as a benchmark, and adding on-call, incentives, etc. on top
- Defaulting to high percentile benchmarks when not appropriate to the situation
- Not applying data filters when applicable
- Dividing across tables to get ratios
- Matching productivity percentiles to ratio percentiles
- Using total compensation for newly hired physicians




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**Best Practices for Survey Usage**

Remember to:

- Pay attention to survey data definitions
- Use survey data as a guide, and use multiple sources
- Use the median as the central point of a dataset; not the mean/average
- Start with current practice realities and level-set physician expectations
- Apply necessary filters to specific scenarios
- Utilize the Pay to Production Plotter and Quartile Tool for both data applications and education
- If in doubt, contact Data Solutions for data clarification




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**FMV Usage and Solutions**

Valuation is not based on prescribed formulas

- IRS Revenue Ruling 59-60 (influential valuation text)
  - "No formula can be devised that will be generally applicable to the multitude of different valuation issues..." ( § 3.01)
  - "Because valuations cannot be made on the basis of a prescribed formula..." ( § 7)

Key to the market approach is comparability of the subject to the market data

- Comparable services
- Comparable conditions and markets
- Independent parties (without referral relationships)

Comparability of survey data

- Respondent characteristics
- Definitions of reported metrics




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### FMV Usage and Solutions

Benchmarking and robust multifactor economic analysis to evaluate comparability

- Multiple metrics: production, revenue, cost
  - *Physician compensation is not singularly determined by wRVUs*
  - Multiple factors affect physician compensation and economics of physician practices
- Every physician and practice is not supposed to be at the median
  - By definition, most will not be!
  - *The median is neither a floor nor a ceiling!*
- High or low benchmarking in and of itself is not determinative of operational or compliance issues
- Do you understand the key economic drivers of the subject physician's practice relative to survey data?
- Do you know why your health system's practices lose money?
- Rigorous economic analysis is needed




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### FMV Usage and Solutions

Standard appraisal methodology

- Consideration of three approaches to value
  - *But, current healthcare compensation valuation practice ignores the cost and income approaches*
- Outside of healthcare, the rest of the valuation world uses market data along with the cost and income approaches
  - See IRS Reasonable Compensation Job Aid
  - Value of professional services = net earnings generated
  - Tax court cases using the independent investor test
- Use the cost and income approaches too
  - Earnings-based compensation with adjustments
  - RBRVS model – every dollar collected has a job
    - Proportion for work = physician comp and benefits
    - Proportion for practice expense + malpractice = overhead
  - *It's CMS' own payment allocation methodology!*




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### FMV Usage and Solutions

Misnomers about cost and income approaches

- Involves valuing referrals - *Not True!*
  - Income approach values each service separately – must estimate each earnings stream individually and stack them
  - Survey data includes profits on ancillaries – it's baked into the compensation levels at undetermined levels

Misuse of survey data can lead to practice losses

Become informed data users not abusers




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**Question and Answer**

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This presentation is made solely for educational purposes and the matters presented herein do not constitute legal, valuation, business, financial or other professional advice.



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Timothy Smith  
Mark O. Dietrich

Second Edition

by Getty Images

Excerpt from:  
BVR/AHLA Guide to  
**Valuing Physician  
Compensation  
and Healthcare  
Service  
Arrangements**

AHLA

**BVR**  
What It's Worth

American Health  
Lawyers Association



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# Chapter 26. On the Use and Misuse of Survey Data: An Interview With MGMA

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## Chapter 26. On the Use and Misuse of Survey Data: An Interview With MGMA

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*Editor's note: Timothy Smith, CPA/ABV, senior managing director, Ankura Consulting, interviewed Meghan Wong, assistant director, data solutions, Medical Group Management Association.*

### 1.0 Understanding What Survey Data Do and Do Not Represent

**TS:** *Meghan, first of all I'd like to thank you for taking time to do this interview for the BVR/AHHA Guide to Valuing Physician Compensation and Healthcare Service Arrangements. I should note for the readers that this is not the first time you and I have spoken about the subject of using survey data to set physician compensation.*

**MW:** Yes, we did a webinar for BVR back in December 2013 titled "The Use and Misuse of MGMA Data in Healthcare Valuations." We discussed various MGMA survey products and talked about how the valuation community was using MGMA's data. You also did a webinar for AHHA with another MGMA staff, Rachel Weber, in August of 2016 about the use of MGMA's data for compensation valuation. So, yes, we've talked about the use of MGMA's data by the valuation community going back several years.

**TS:** *Let's start out by discussing MGMA's interest in commenting on how its data are used in setting physician compensation in the marketplace, including how they are used in determining fair market value for regulatory compliance purposes. What's important for MGMA about how its data are used in the industry?*

**MW:** We want users to understand the credibility of the data we publish—all survey information goes through a rigorous editing process to ensure its accuracy. We also stress that MGMA data should be used to help guide decisions in conjunction with other information and not as a stand-alone metric. We also are clear that MGMA data should never be used to limit competition or be used in any way that is in violation of antitrust laws.

**TS:** *Many in the healthcare industry cite MGMA's data as representing the U.S. physician marketplace. I see stories in the trade press that say physician compensation has increased by X% because that was the increase for a given specialty in the most recent MGMA survey. In addition, lots of industry players frequently cite MGMA as indicative of national compensation levels for physicians. What's your reaction to these kinds of claims about the MGMA data?*

**MW:** We are not saying this is a one-to-one representation of the universe of medical practices that are in the country. This is strictly a survey sample. We do have the most comprehensive data set within the industry,



with over 80,000 providers in both physician-owned and hospital-owned practices, but it lends itself to being misquoted. There have been times in news articles where reporters will look to MGMA survey respondent demographics and say this is what the ownership trends look like for the country. We want to make sure we are very upfront about the fact that, while this is a robust data set, it is based on a sample of the practices that are responding to our survey.

There is the legal notice and disclaimer that we make sure we put in all of our surveys that states MGMA does not purport to offer advice that may be construed as specifically applicable to individual situations. The measures in our reports are descriptive statistics that are calculated from member and nonmember survey responses. We are really just providing this as a tool for consumers to utilize and inform them when they are building their own compensation plans or analyzing their practices. We definitely don't want any of our information to say that this is what it has to be or limit productivity or compensation in any way.

*TS: Would you explain what you mean by descriptive statistics, and how does descriptive statistics contrast with inferential statistics? As I understand it, for inferential statistics, random sampling or other techniques are used to develop a sample of a population that is intended to be representative of that population. An example of inferential statistics are political polls, where pollsters select a sample of voters and attempt to extrapolate to the entire U.S. electorate based on the sample.*

**MW:** MGMA survey data take a sample of the United States healthcare business population and report back descriptive statistics on that sample: mean, median, standard deviation, and percentile representations. Our data are meant to be utilized as a business tool and not a statistically significant data set that relies on more academic hypothesis testing and random sampling

*TS: So, when we think about and use industry survey data, we need to understand that the data are not designed to be statistically representative of the U.S. marketplace for physicians. Rather, the survey data are an accurate data portrayal or description of those practices and physicians who responded to the survey in a given year. Is that a correct understanding of what the data are and what they represent?*

**MW:** That is correct. Speaking for MGMA, our data reports are valid business tools and not meant to be used as academic statistical data sets, as is the case with other survey reports in the industry.

*TS: I'd like to explore the implications of knowing industry survey data reflect descriptive statistics rather than inferential statistics. Would this mean, for example, that one could not use the percentage of practices or physicians from health system-owned practice reporting to be the percentage of physicians nationally who work in health system-owned practices? I see presentations where individuals use this percentage in industry surveys such as MGMA as proof the majority of physicians in the U.S. are now employed in health system-owned practices.*

**MW:** Yes, we see various parties using the data in this way, even though the data are not intended to be used as an academic data set for extrapolating to the U.S. population of physicians. We try to inform such users about the actual nature of the data. For example, a *New York Times* article in the spring of 2010 misquoted MGMA Physician Compensation Survey demographic data as being predictive of the national trend. More hospital-owned practices had begun filling out MGMA surveys in previous years, yet the reporter extrapolated that to the entire country. Even though we reached out to correct that statement at the time of publication, that same "fact" comes back to us every year, with people wanting "updated data on the trend." MGMA continues to educate, but search engines on the internet have made the original article easy to access, which leads to continued misinterpretation of our data.

**TS:** *What about claims that certain physicians are among the most highly paid in the U.S. because their total compensation exceeds the MGMA 90th percentile? Is that a factual inference one can make based on benchmarking against the survey?*

**MW:** Of the sample of MGMA survey participants, those physicians that fall at and above the 90th percentile are among the highest providers in that data set. Again, as MGMA data represent descriptive statistics, these physicians at the 90th are not the “ceiling” of the country but rather the highest paid physicians in our particular sample.

Of note, there are outlier compensation figures above the 90th and below the 10th percentiles that are trimmed out of our data sets based on various review procedures we complete. First, we apply a statistical formula across all data sets that trims out (high and low) outliers, if present. Next, we manually look at the data for anomalies and large shifts in median from the previous year to identify whether perhaps only one group of physicians are skewing the data set up or down. Some of these trimmed figures may have been entered as the result of survey respondent error, but there are also cases where those outlier compensations are genuine for those individual physicians. Regardless of why the data were entered into our survey, singular outliers are suppressed from the data set to reinforce the delivery of a sound business tool. Our data analysis procedures support the goal of providing benchmarks that are not skewed by these outliers.

**TS:** *Let’s talk about the regional data. MGMA provides descriptive statistics for its sample based on geographic areas or section of the country, as do many other industry surveys. What is the intention of reporting the data according to these sections and how did MGMA select the states that go into each geographic section?*

**MW:** MGMA identified the states that go into the four regions of Eastern, Midwest, Southern, and Western several decades ago. We have maintained these same regions over time to maintain the integrity of trending information across all of our survey products. MGMA does offer other regional breakouts as well, such as Minor Region and State.

**TS:** *Industry users often look to data from their geographic section as being a better indication of the marketplace for their physicians. Does MGMA observe that there are trends in each region that are unique to the markets in that region? Also, do you observe that regional statistics reflect trends in every state or market within the region?*

**MW:** The more detailed the data set is around a specific comparison practice, the more applicable it will be. Again, we urge data users to look to MGMA data as a guide and use discretion when applying benchmarks. If a data user is able to drill down to the state level, that is preferable to looking at just region. For example, comparing Colorado to the Western section is helpful, but it’s even better to compare to just the state of Colorado so that other states are not mixed into the comparison (Utah, California, Nevada, etc.) For some markets, additional analysis of other data sources may be needed to supplement analysis of that area, for example, in states as large as California, where there are various differing markets even within the state.

### 2.0 The Correct Understanding and Use of Medians

**TS:** *Let’s spend a little bit of time talking about the correct view of medians in survey data and how they should be viewed or understood by industry data users. Would you step us through how medians are calculated and what they mean or signify for a given data set?*

**MW:** We suggest that data users stay away from utilizing the mean as a representative of the survey sample. We urge people to instead use the median (with very few exceptions) as the representative of the sample because it is not going to be influenced by extreme outliers.

**TS:** *Is the median the most significant data point in a data set? Is the median the most frequently observed data point?*

**MW:** Median is where 50% of respondents fall above and 50% fall below in the sample. It is not the floor of the data set; rather, it's the central point. The median is a good starting point when looking at a metric, but data users should be comfortable using data that fall above and below that percentile, commensurate with practice characteristics, physician experience, and productivity.

Also, the most frequently occurring data point in a data set is going to be the mode, not the median. The mode can occur anywhere along the data array—it doesn't necessarily have to be the low, middle, or high point.

**TS:** *Many market participants in the healthcare industry, including a lot of valuers, think the MGMA median compensation per wRVU rate or the median total compensation level is the industry norm or national benchmark for what any given physician should make. How does MGMA think about these kinds of ideas about the reported median?*

**MW:** I think the median is a great high-level look at what a specialty is reporting that it earns across the nation, specific to our sample. But there are going to be many environmental factors or marketplace factors that play into what physicians are being compensated. It's also worth keeping in mind the total compensation figure is going to include other things external to productivity, such as on-call or medical directorship stipends. Total compensation by no means should be used as a base salary figure because it does include multiple facets.

When we say to look at the median as a representative, it is really just a starting point. Someone who is working in California is going to be earning at a median something much different than someone who is working in West Virginia. There are different marketplace factors that are in play. That is why we make MGMA data tools so robust in that you can filter by those different geographic sections, or ownership types, because those aspects affect compensation. The overall median might not be the catchall, be-all for all individuals out there.

**TS:** *To connect the issue of the median back to our prior discussion about descriptive nature of the survey data, can one claim MGMA medians are the national norms for physician compensation? Can one say the MGMA median is U.S. national median compensation level?*

**MW:** I think there is not one flat target rate for everyone within the marketplace. Compensation per work RVUs is no different than just regular compensation. There are going to be different factors at play, not just the location of the practice, but also what the provider's patient mix looks like and also the ability of the practice to reimburse on those procedures. There are many different factors that are involved with compensating particular physicians, and there should never really be a catchall for everyone regardless.

**TS:** *A lot of people think the MGMA median total compensation amount is the amount of compensation needed to recruit or employ a new, but experienced, physician. They say it will take at least the median compensation level to incent an experienced physician to come to a new job in a physician practice. Does MGMA have any data or information that would speak to this belief about recruiting a new physician?*

**MW:** In actuality, we have a starting salary survey, and that is going to be more appropriate because it includes guaranteed compensation for new physicians. We found that new physicians are often earning less than

established physicians in a practice, as they haven't had time to build their panel size yet. All of the data within the starting salary data set are guaranteed salary figures for those first-year physicians in a practice, which is much more appropriate to use over the total compensation figure for established physicians. Also, within that data set, we allow the user to filter by whether the provider is new from residency or fellowship or whether the provider is experienced and just new to a practice.

### 3.0 Understanding Reported Percentiles as Part of a Data Set

**TS:** *What exactly are percentiles, and how are the data organized into percentiles?*

**MW:** We take a group of data points for a specific specialty and metric and report the corresponding position of the data relative to the group. So when we say a family medicine work RVU data point is at the 25th percentile, it means that 25% of those work RVUs falls below it and 75% of the work RVUs falls above it.

All data are arranged in order, from lowest to highest in value on the scale from 0 to 100. Essentially, a straight line is drawn from one value to the next, and those lines and values are how we are able to provide descriptive percentiles for the values.

From a methodology standpoint, we don't report any values above the 90th or below the 10th percentiles.

**TS:** *Why do industry surveys report the specific percentiles of the 10th, 25th, median or 50th, 75th, and 90th? Is there something magical about these specific percentiles in statistics?*

**MW:** Reporting descriptive statistics by quartiles is a general way to show the range of a data set. Within MGMA DataDive, users can further customize the percentiles they want to see anything from the 10th to the 90th percentile, including the counts, mean, and the standard deviation. Each of those percentiles for a given metric and specialty are simply identifying that value's relative position in the data set, compared to the rest of the group of data.

**TS:** *What inferences, if any, can be made about physicians who benchmark above or below any of these commonly reported percentiles? Does benchmarking really indicate anything specific about a data point besides where it falls among all the other data points in the data set?*

**MW:** If physician data compared to survey data shows that they fall above or below a percentile, it only means that they rank with that population. For example, a pediatrician with compensation that falls below the 10th percentile means that more than 90% of the pediatric compensation values are higher than his or her compensation. You would have to dig deeper into reasons why he or she is earning low compensation, beyond just looking at the survey data. The benchmarks are just the starting point.

**TS:** *Many industry participants seem to be suspicious of a physician making in excess of the 90th percentile of MGMA or other survey data. Is there anything suspect, anomalous, or indicative of overpayment simply because a physician benchmarks about a given percentile, including the 90th?*

**MW:** We have an "out-of-range" editing condition that is triggered when folks report that this physician is earning a high compensation, say more than \$1 million. We reach out to that participant and say, "Did you accidentally enter in an extra zero here? It looks like this particular physician is making a lot of money."

Actually, in some cases, extremely high salary is not a mistake. They go on to explain the different responsibilities and roles that the particular physician has to fill that necessitates them to be earning compensation that is much higher than their peers. While it is rare, that is just inherent in being part of the 90th percentile. They are a very small subset of the population, but it is not unheard of, and it does happen. This emphasizes the point that there can't be a blanket statement of "this is what is necessary for everyone," across the board. Appropriate metrics and percentiles are always going to be based on the situation for the particular practice and the particular physician.

#### **4.0 The Relationship Between Production and Compensation in the Data**

**TS:** *For several years now, the marketplace has been setting compensation based on production levels, primarily using wRVUs, but also professional collections. From MGMA's perspective, what relationship exists between compensation and production?*

**MW:** Generally speaking, the more providers earn in wRVUs and collections, the more they earn in compensation. However, this isn't always the case. I alluded to the fact that someone might be earning more compensation but be producing fewer work RVUs or collecting less than their peers. There could be items such as directorship responsibilities or oversight on different administrative tasks that take up their time that would factor into their compensation more than just what they are doing in a clinical capacity, just as one example. There is no one sole metric that you can utilize to say that it is the perfect predictor of compensation. It is always going to be a mix of things.

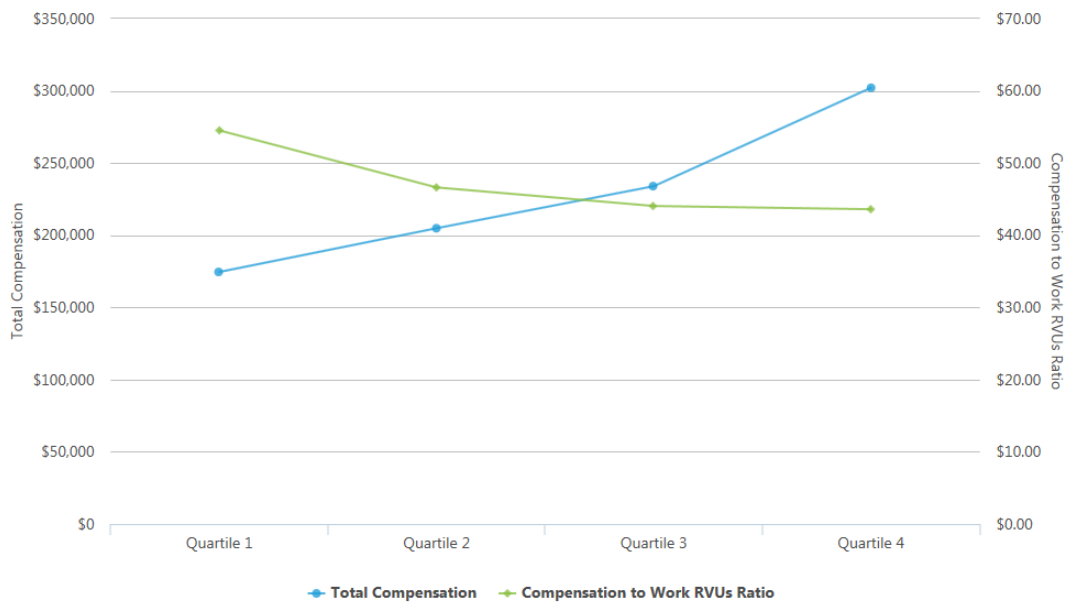
**TS:** *A commonly used method for establishing physician compensation, particularly for FMV purposes, is the so-called percentile matching method. Under this method, a physician is paid a level of total compensation commensurate with his or her benchmarked level of production using survey data. For example, if a physician's wRVUs benchmark at the 65th percentile, the physician should be paid the 65th percentile total compensation level from the survey. What is your reaction to this method? Do the data have this direct level of correspondence between production, such as wRVUs, and total compensation?*

**MW:** It is hard to say that there is a one-to-one correlation between the two because the individual at the 65th percentile of compensation is not necessarily the same physician who is at the 65th percentile of work RVUs or collections. While you can use it as something that is informing you when you are building a compensation plan, it's not appropriate to make that one-to-one correlation and say this is exactly the same physician who is always earning or producing this many RVUs and should always be compensated at this level, first and foremost because there are different samples within the two tables. Looking at the differing provider and group counts for each specialty across the tables is a clear indicator of that.

As mentioned previously, productivity is not the only thing all physicians are compensated on, so that is another reason to not assume percentile matching is a one-to-one correlation.

**TS:** *A related or variation of percentile matching is the idea that, if a physician benchmarks at a given percentile for wRVUs, he or she should be paid the corresponding compensation-per-wRVU rate. In other words, if a physician produces wRVUs at the 75th percentile, he or she should be paid at the 75th percentile compensation-per-wRVU rate. Is this method correct?*

**MW:** MGMA data suggest that, as a physician produces more wRVUs, the physician earns more in total compensation. Conversely, as the physician produces more and earns more, *the amount of compensation per unit of wRVU actually declines*. Exhibit 1 is a snapshot of what that total compensation and total compensation-per-wRVU ratio look like across wRVU quartiles, as reported in MGMA's 2015 provider compensation report based on 2014 data.

**Exhibit 1. Total Compensation and Compensation-to-wRVUs Ratio by Quartile**

Source: Primary care specialty in Enterprise version of MGMA DataDive Provider Compensation 2015.

In this exhibit, Quartile 1 consists of wRVUs that fall between the lowest reported metric and 3,900, Quartile 2 between 3,900 and 4,800, Quartile 3 between 4,800 and 5,800, and Quartile 4 between 5,800 and highest reported metric. The physicians who fall in Quartile 1 report the lowest compensation, and, as productivity increases across quartiles, you can see total compensation increases as well.

What you'll also notice is that the ratio of total compensation to wRVU is higher for those in Quartile 1, and, as productivity increases across the quartiles, that ratio actually decreases.

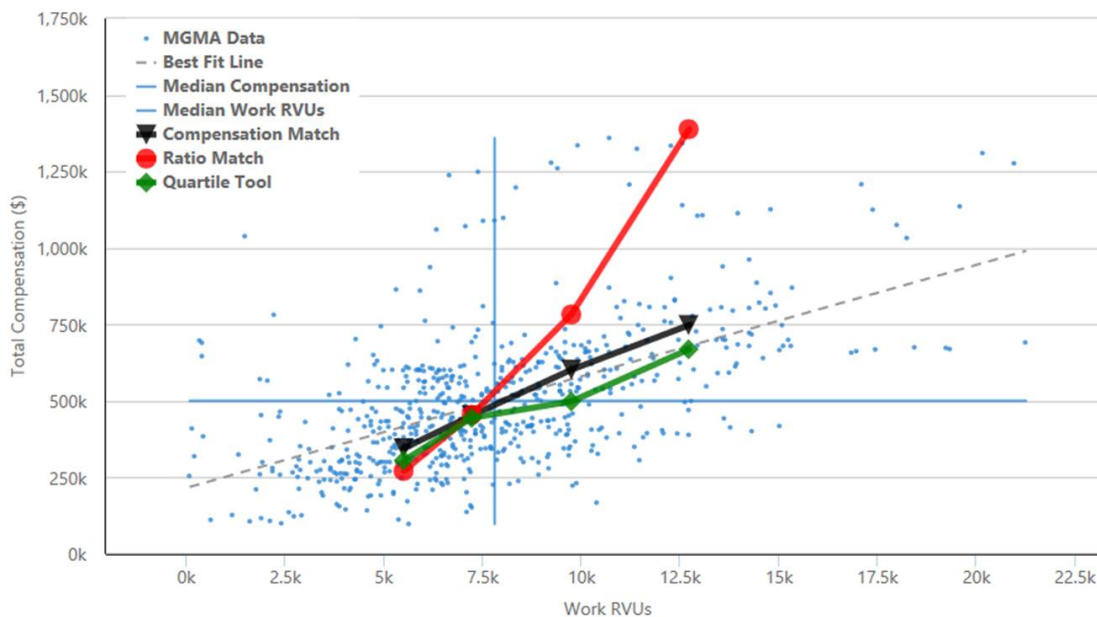
Physicians with high ratios at low quartiles of productivity might be newer in a practice and are working off of some form of guaranteed compensation while they build up their patient base. And, conversely, physicians with higher productivity are likely on a volume-driven compensation plan—hence, their higher compensation earned.

We always recommend starting at the median total compensation-per-wRVU ratio figure and likely adjust down from there. You have to keep in mind that practices can't continue to pay out physicians at an exponential rate of compensation per production. If someone in the fourth quartile of productivity were paid at the same rate per work RVU as the first quartile, he or she would be making a lot more compensation, but the ability of the practice to actually pay out at that amount would be greatly reduced.

Anecdotally, I've seen that groups tend to use a tiered approach so that the ratio actually drops down lower as providers increase in productivity. Their compensation is still going up, but it is just not going to be at an exponential, and unsustainable, rate.

**TS:** *To further analyze the question of compensation and production, let's look at the example you developed from MGMA's Pay-to-Production Plotter tool. Exhibit 2 shows the actual data for respondents reporting both total compensation and wRVUs for the specialty of noninvasive cardiology. Why don't you step us through this exhibit and what it shows?*

Exhibit 2. Data for Respondents Reporting Both Total Compensation and wRVUs for Noninvasive Cardiology



Source: Enterprise version of MGMA DataDive Provider Compensation 2015.

**MW:** First, you’ll note the small dots scattered across the graph. Those are individual physicians who have provided both total compensation, which is laid out on the y-axis, and work RVUs, which are laid out on the x-axis. The bold horizontal and vertical lines on the graph represent the median for total compensation and work RVUs, respectively. The dashed line represents the best fit line, which is calculated from both metrics from these physicians to show their relationship. Users should look to this line as a guide and illustration of the relationship between the compensation and productivity.

The black triangle series represents percentile matching from the work RVUs table to the compensation table, based on the 10th percentiles plus four quartiles. So the first marker in the triangle series shows the 10th percentile in work RVUs plotted against the 10th percentile in compensation, and so on. You’ll see that if someone were to follow this method, they’d tend to underpay and overpay a physician for his or her work in comparison to the best fit line. I’ll note that the best fit line and this line matching wRVUs and total compensation look very close in this chart, for this specialty. However, keep in mind that the axis scale is in increments of \$250,000, so even slight shifts can result in great discrepancies. In essence, I wouldn’t recommend using the compensation matching method.

The red circle series represents percentile matching from work RVUs to the compensation/work RVUs ratio table. While the red circle series underpays physicians at first, it rapidly overpays physicians as their productivity increases. This illustrates that paying physicians a ratio rate equal to their productivity rate is not sustainable.

Finally, the green diamond series represents data from our Quartile Tool. This tool provides the best representation of physicians across productivity levels because it accounts for all the providers in a particular quartile and then shows the range of data across each of those four groups. The exhibit here plots the median compensation and work RVUs from each of the quartiles.

**TS:** *Let's look at these lines one at a time. Let's begin with the line matching the compensation rate with the wRVU production level based on percentile matching, which is the red circle line in the chart. Would you explain how that line was calculated and what it represents?*

**MW:** Often, people assume that a provider earning a certain percentile in work RVUs needs to earn the commensurate percentile in compensation-per-work RVU ratio. As I mentioned before, that's actually not what the data reflect. Generally speaking, the more a physician produces, yes, the more he or she earns in salary, but the less he or she earns per unit of RVU. But, if a user applies the matching methodology, and pays a physician who produces at the 80th percentile of work RVUs at the 80th percentile of compensation-per-work RVU ratio, the user will end up paying that physician an unsustainably high salary.

**TS:** *Would you step us through your analysis and opinion of this compensation model when comparing it to the actual data in Exhibit 2?*

**MW:** Percentile matching on the compensation per work RVU ratio underpays and quickly overpays physicians, compared to the data set. You can use the best fit line or even the green diamond quartile tool line as your guide for what most of the data are doing. There is a general pattern to the placement of the majority of data points, and that matching methodology contradicts the reported data.

**TS:** *Now's let discuss the line matching total compensation with production based on percentile matching, which is the black triangle line in the exhibit. Would you explain how that line was calculated and what it represents?*

**MW:** The compensation matching line takes physician work RVU data at the 10th, 25th, 50th, 75<sup>th</sup>, and 90th percentiles and matches them to corresponding compensation data at the same percentiles. While this method resulted in a series that more closely resembled the best fit line and quartile tool data, it is still not sound methodology. I mentioned previously that the 75th percentile of one table does not automatically reflect the same physicians at the 75th percentile in another table—the samples are at least slightly different. We always recommend utilizing something like the quartile tool, where you can look at salary and productivity data for the same physicians in a set range. That way, there is no guessing or hoping that the samples across tables are similar enough. Again, I'll note that this compensation matching line looks close to the best fit line in the sample chart due to scaling, but the reality of the data can show greater shifts that you can't predict using that methodology.

**TS:** *Well, let's discuss the "best fit" line. That line is based on linear regression. Would you explain the "best fit" line and what it means?*

**MW:** We calculate the best fit line for each specialty across productivity and compensation in the Pay-to-Production Plotter. What that line shows is the relationship between those two metrics in that given sample. It provides a general guide of how the data "behaves" across the spectrum of values. As MGMA data are descriptive statistics, we always recommend this line as a simple guide and to be used with care since our data are not from a random sample. Also, applicable filters should be put in place to most clearly understand the relationship between salary and productivity (such as organization ownership and compensation plan.)

**TS:** *Let's talk about the green diamond line that is based on the quartile data. Would you step us through how that line is calculated?*

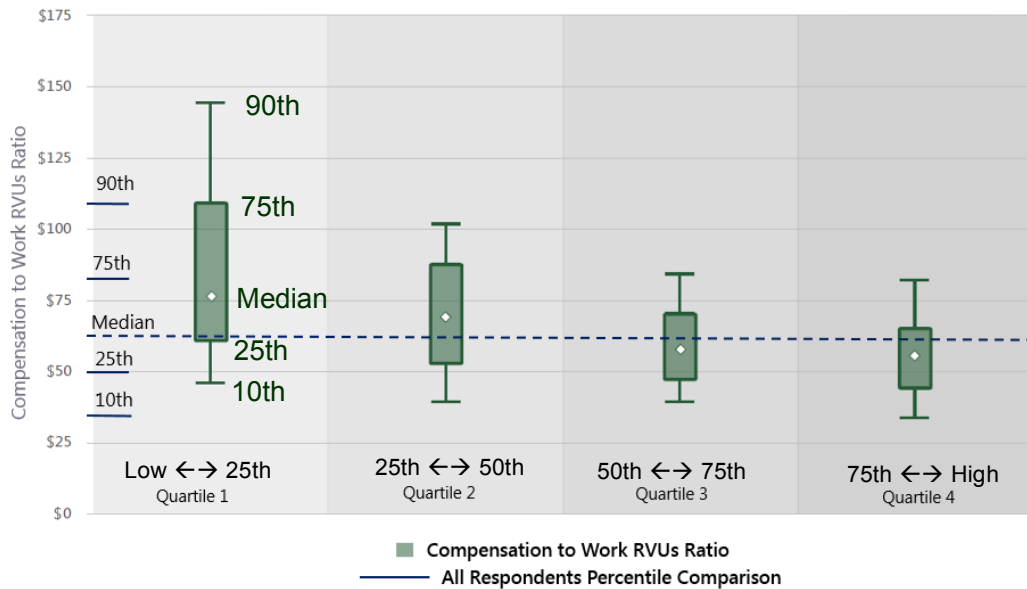
**MW:** Quartiles are calculated for work RVUs by dividing them into four equal sections. For those physicians falling in each quartile of productivity, their corresponding compensations are calculated, and the median



compensation of each quartile is reported, along with the median work RVU in each quartile. This way we are looking at the midpoint of each of these four sections.

**TS:** *You've provided us with another exhibit that shows the range of compensation-per-wRVU rates for each quartile of data. I think this exhibit can help to understand compensation rates by quartile of production. Would you first explain Exhibit 3 in terms of how the numbers are calculated and how to understand the visually elements of the exhibit?*

**Exhibit 3. Cardiology: Noninvasive Grouped by Work RVU Quartiles**



**MW:** Exhibit 3 illustrates the quartile tool. Here, we've grouped noninvasive cardiologists into four equal-sized groups (or quartiles) based on their work RVUs. Quartile 1 represents those cardiologists up to the 25th percentile of work RVUs (from the lowest data point up to 5,502.) Quartile 2 represents those cardiologists with 25th to median work RVUs, Quartile 3 from median to 75th, and Quartile 4 from 75th to the highest work RVU data point. Then, we've calculated the compensation per work RVU descriptive statistics for each of these four groups.

The range of compensation-per-wRVU ratios for each quartile is represented by a box-and whisker-chart. The lowest portion of the box represents the 25th percentile of compensation-per-wRVU ratio, the dot in the middle represents the median, and the top end of the box represents the 75th percentile. The whiskers below and above extend to the 10th and 90th data points, respectively.

The lines on the y-axis represent the 10th through 90th percentiles for all respondents, regardless of quartile group. Using this exhibit as an example, you can see that those producing under the 25th percentile in work RVUs in Quartile 1 are actually reporting higher compensation per work RVUs than those who produce more work RVUs. Also, the 90th percentile of compensation-per-work RVU data for all respondents is only reflected in those physicians performing the least amount of work. This tends to debunk the percentile matching theory of data across tables when it comes to productivity and ratios.

**TS:** *The most obvious feature of this exhibit is that rates for the first quartile are really out of synch with the rest of the quartiles. The quartile median is well above the overall median for all respondents, the 75th percentile quartile rate is about*

*the same as the 90th for all respondents, and the 90th percentile rate is much, much higher than the overall 90th percentile. Why is the first quartile so different?*

**MW:** The first quartile reinforces the caution that should be taken when using anything beyond the median of compensation-per-work RVU ratio data. Physicians who earn a normal salary but produce less in work RVUs are often subsidized by their practice perhaps because they are building out their panel size. As such, the resulting ratio of compensation to work RVU is going to be high, just due to the math.

**TS:** *We've discussed two exhibits that look at the specialty of noninvasive cardiology. Would you expect for the data to be similar with other specialties? What other data patterns might we expect to see?*

**MW:** Data need to be analyzed on a case-by-case basis. I would expect the general behavior of data to be the same across like specialties, but each specialty type has its own nuance in how much productivity is produced and how those physicians are typically paid.

### 5.0 Common Misuses of MGMA Survey Data

**TS:** *Are there any misuses of MGMA data that you commonly observe in working with users of the data? What are the top misuses and why are these uses not appropriate?*

#### 5.1 Dividing Across Tables/Calculating Ratios Using Different Tables

**MW:** A common misuse of our data specific to the *Physician Compensation and Production Survey* or the *Provider Compensation* survey in DataDive is dividing across tables to achieve ratios. Our tables have different populations. You are going to see, for example, that the physician compensation tables are always going to have larger counts than any of the productivity tables because physician compensation is a required question. We are always going to have more physicians in this table.

You can look at the comparison. Collections, for example, the differences in the provider and medical practice count—there are two different samples and two different populations within these tables. If you are dividing descriptive specifics across these two samples, you are not comparing like information. We actually create MGMA ratio tables, so we will have tables that already say compensation per collections or compensation per work RVU.

We are calculating that on the individual basis for each individual provider and then compiling the descriptive statistics. We always urge folks to utilize that to inform them instead of developing their own ratio table.

#### 5.2 Misuse of Data From the Cost Survey

**MW:** Another common misuse is how data from the *Cost Survey* or *Cost and Revenue* module from DataDive is used for benchmarking. We always urge folks to use that when thinking about the practice as a whole, but, if they are benchmarking individual physicians, don't use the per-FTE data—go back to the physician compensation report because it is definitely going to be the best resource for individual.

A common misuse of the *Cost Survey* is that folks tend to add up the subcategories in the staffing tables. You will see in the exhibit on the bottom right that folks might try to add up those different ancillary support staff and wonder why it adds up to 0.91 instead of the 0.73 you see. For one thing, we don't always get all of our response rates for all of those different support staff types, and there might be outliers there as well that need to be trimmed out. If folks need to utilize total support staff lines, we always suggest they use the total line and try not to add between the different categories.

Something else that happens is that folks will divide across tables in the *Cost Survey* and the *Physician Compensation and Production Survey* or the online version, the *Provider Compensation* survey in DataDive. Those are definitely two separate survey populations. They can be informative or interesting to look at, the different benchmarks from each survey, but you can't derive direct correlation from collections in the *Cost Survey* to collections in the *Provider Compensation* survey data. The *Cost Survey* is going to include the technical component in collections, as well as monies related to any drug charges, whereas, in the *Provider Compensation* data, collections will only reflect the providers' professional contribution.

### 5.3 Use of Charges

**MW:** Another common misuse of MGMA data is relying on professional gross charges. We do still include those tables within the book and DataDive. They are interesting to take a look at and maybe stay informed, but they are always going to vary between practices. We always recommend that folks utilize something that is more consistent and standardized such as RVUs or collections as physician performance benchmarks because what one practice is charging is never going to be the exact same as another practice down the street.

There are definitely more consistent benchmarks found within the relative value units or professional collections.

**TS:** *I often see valuers and other market participants claiming operational or other problems with physicians who benchmark at the 25th percentile for this or that metric. Their only evidence of such problems is benchmarking levels. For example, I once saw a valuation report that concluded a practice has revenue cycle problems simply because collections per wRVU benchmarked around the 25th percentile. I heard another valuator say he has never met a 25th percentile physician. What do you say to those who think low benchmarking alone is proof of operational or other problems with a physician or practice?*

**MW:** In your example, it's true that the particular practice does not have as much revenue as others within our survey sample, but only looking at one benchmark hardly tells the entire story. Anyone using benchmarking data has to look at multiple facets of the situation. Is the level of expense per wRVU also low? If so, there might not be an issue at all. Also, what does the payer mix look like? What do other practices in that market look like? As we've mentioned previously, benchmarks are pieces in a larger story. It is necessary that survey users take into account influencing characteristics specific to each provider and practice they are evaluating.

### 6.0 MGMA's Quality Review Processes in Publishing Data

**TS:** *MGMA follows specific procedures every year in reviewing data submissions to ensure the integrity and quality of the data. Would you step us through your processes?*

**MW:** We begin the data editing process as soon as a participant enters information into the survey, in real time. We give them the option to review their information before submitting and let them know if we identify missing required values, data that defy logic (e.g., work RVUs that are greater than total RVUs), and data that are out of expected range (e.g. physician earning \$2 million). Once the participant submits the survey, any outstanding data edits are run and sent to them for their corrections. We follow up via email and phone to clarify responses, if we don't hear back. After we've received all of the responses, we'll run a statistical formula over the data set to automatically remove high and/or low outliers. Next, we manually walk through the data set to identify any further data that skews the data up or down. We take six to seven levels of data analysis to ensure the accuracy of the information we're reporting.

**TS:** *Earlier in the interview, you mentioned data trimming. Would you explain what you mean by data trimming and what are the criteria for trimming data out of the data set?*

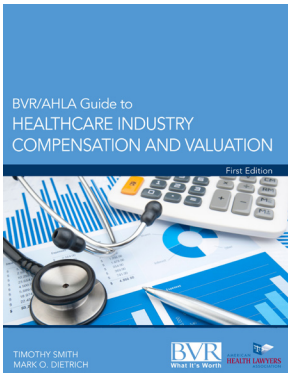
**MW:** Again, we apply a statistical formula that trims high and/or low outliers from a data set. After that, upon manual review of the data, if we view data at one extreme or the other, or even throughout, that does uphold the integrity of the data set, we can opt to suppress that information. We look to shifts in medians from year to year and the standard deviation relative to the data set to help guide our analysis.

**TS:** *Over the years, I've heard some valuers criticize the metric collections from professional charges as being inaccurate because it really includes total collections, including those from technical component services. These valuers say practices are reporting total collections rather than professional collections. The reason they make this claim is that the physicians they value all have collections that benchmark low in comparison to wRVUs. Also, many practices state they cannot calculate professional collections. Does MGMA run any quality checks on the data reported for professional collections?*

**MW:** MGMA runs a variety of validations on survey information submitted. We request only professional collections and total RVUs with no technical component included, as the compensation survey's goal of the *Provider Compensation* data is to measure a provider's professional performance. We also require a designation of level of technical component included in productivity, as a double check on the data. As a result, the standard MGMA collections and total RVU tables only include data with 0% technical component included.

We also have validations on the range of numbers, so, if someone is selecting 0%, but they are providing very high collections or total RVUs, we have a data edit that asks participants to clarify the figure.

**TS:** *Meghan, thank you very much for taking time to address these questions. We very much appreciate you providing insight and feedback on usage of MGMA's data.*



Edited by:  
Timothy Smith  
Mark Dietrich

## BVR/AHLA Guide to Healthcare Industry Compensation and Valuation

The *BVR/AHLA Guide to Healthcare Industry Compensation and Valuation* is the first comprehensive body of knowledge for the emerging appraisal discipline of compensation valuation (CV) in the healthcare industry. This must-have resource for appraisers, consultants, attorneys, and industry participants who deal with physician compensation arrangements includes a robust 42 chapters and practice aides that present a systematic treatment of both the theory and practice of compensation valuation.

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Are You Billing the New PT and  
 OT Evaluation Codes Properly?

HCCA COMPLIANCE INSTITUTE  
 TUESDAY, MARCH 28, 2017, SESSION 603  
 Nancy J Beckley, MS, MBA, CHC  
 Shawn M Halcsik, DPT, MEd, RAC-CT, CPC, CHC

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Presenters



**Shawn M Halcsik, DPT, MEd, RAC-CT, CPC, CHC**  
Corporate Compliance Officer  
Encore Rehabilitation



**Nancy J Beckley, MS, MBA, CHC**  
President & Founder  
Nancy Beckley & Associates LLC  
NancyBeckley.com

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Objectives

- Understand definitions of new PT and OT evaluation codes
- Learn the components that will determine the level of the evaluation code billed
- Take away an audit tool to ensure your therapy department's compliance

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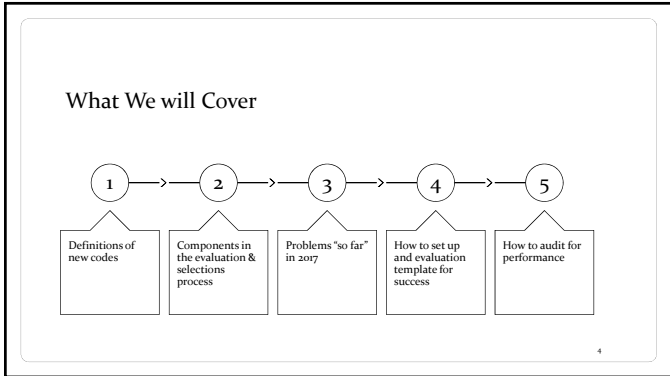
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## New Evaluation Codes

WHO, WHAT, WHEN, WHERE AND WHY

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### Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions, Activity Limitations, Participation Restrictions	Stability	Clinical Decision Making	Typical Face to Face Time
97161	Low Complexity Eval	None	1-2	Stable	Uncomplicated	20 minutes
97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

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### Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions, Activity Limitations, Participation Restrictions	Stability	Clinical Decision Making	Typical Face to Face Time
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97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

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### Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions, Activity Limitations, Participation Restrictions	Stability	Clinical Decision Making	Typical Face to Face Time
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97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

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### Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions, Activity Limitations, Participation Restrictions	Stability	Clinical Decision Making	Typical Face to Face Time
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97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

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Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions	Stability	Clinical Decision Making	Typical Face to Face Time
97161	Low Complexity Eval	None	1 or more	Stable	Uncomplicated	20 minutes
97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

**Clinical Patterns assessed in initial evaluation classification**  
Aggravating and easing signs  
Response to examination

**Clinical Decision Making**

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Physical Therapy Eval Codes

New CPT	Description	Personal Factors & Comorbidities	Body Structures & Functions	Stability	Clinical Decision Making	Typical Face to Face Time
97161	Low Complexity Eval	None	1 or more	Stable	Uncomplicated	20 minutes
97162	Moderate Complexity Eval	1-2	3 or more	Evolving	Moderate complexity	30 minutes
97163	High Complexity Eval	3 or more	4 or more Elements	Unstable	Unpredictable Clinical Presentation	45 minutes

**Guideline only**  
Typical expected face to face time  
Not really a factor in determining complexity

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Occupational Therapy Eval Codes: "Questions"

New CPT	Description	Performance Deficits	Clinical Decision Making	Comorbidities Affecting Occupational Performance	Modification or Assistance to Complete Eval	Approximate Face to Face Time
97165	Low Complexity Eval	1-3	Low complexity	None	None	30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	60 minutes

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**Occupational Therapy Eval Codes**

New CPT	Description	Performance Deficits	Clinical Decision Making	Relating to physical, cognitive or psychosocial skills) which result in activity limitations and/or participation restrictions		Approximate Face to Face Time
97165	Low Complexity Eval	1-3	Low complexity			30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	60 minutes

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**Occupational Therapy Eval Codes**

New CPT	Description	Performance Deficits	Clinical Decision Making	Comorbidities Affecting Occupational Performance	Based on analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of treatment options.	
97165	Low Complexity Eval	1-3	Low complexity	None	None	30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	60 minutes

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**Occupational Therapy Eval Codes**

New CPT	Description	Performance Deficits	Clinical Decision Making	Comorbidities Affecting Occupational Performance	Mod or Alt to C	Must show how comorbidity affects occupational performance
97165	Low Complexity Eval	1-3	Low complexity	None	None	30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	60 minutes

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### Occupational Therapy Eval Codes

New CPT	Description	Performance Deficit	Performance			Modification or Assistance to Complete Eval	Approximate Face to Face Time
			Low complexity	Moderate complexity	High complexity		
97165	Low Complexity Eval	1-3	Low complexity	None	None	None	30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	Max	60 minutes

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### Occupational Therapy Eval Codes

New CPT	Description	Performance Deficit	Performance			Modification or Assistance to Complete Eval	Approximate Face to Face Time
			Low complexity	Moderate complexity	High complexity		
97165	Low Complexity Eval	1-3	Low complexity	None	None	None	30 minutes
97166	Moderate Complexity Eval	3-5	Moderate complexity	Maybe	Min-Moderate	Min-Moderate	45 minutes
97167	High Complexity Eval	5 or more	High complexity	Yes	Max	Max	60 minutes

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### Contrasting PT & OT Evaluation Complexity

	PT	OT
History	Personal Factors and comorbidities as they affect the plan of care	Occupational Profile, including review of medical and/or therapy records Comorbidities as they affect occupational performance
Clinical Decision Making	Using standardized instruments and measureable assessment of functional outcome	Includes an analysis of the occupational profile, problem focused assessment and consideration of treatment options
Clinical Findings	<ul style="list-style-type: none"> <li>• Body Structures and Functions</li> <li>• Activity Limitations</li> <li>• Participation Restrictions</li> </ul> Using standardized tests and measurements	<ul style="list-style-type: none"> <li>• Physical</li> <li>• Cognitive</li> <li>• Psychosocial Skills</li> </ul> As related to current functional performance
Clinical Presentation	Stable? Evolving? Unstable; Unpredictable	Degree of modification of tasks or assistance necessary to enable patient to complete evaluation

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**PT Evaluation Process**

- History
  - Personal factors, comorbidities
- Examination of body systems
  - Body structures & functions, activity limitations, participation restrictions
- Clinical presentation
  - Stable, evolving, unstable
- Clinical decision making
  - Complexity in plan of care

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**OT Evaluation Process**

- Occupational Profile & history
  - Record review
  - Review PLOF w/patient (physical, cognitive, psychosocial)
- Assessment
  - Identify impairments (physical, cognitive, psychosocial)
- Clinical decision making
  - Level of assessment
  - Number of treatment options
  - Task Modifications

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**ICF Definitions**

- **Body functions** - The physiological functions of body systems (including psychological functions).
- **Body structures** - Anatomical parts of the body such as organs, limbs and their components.
- **Impairments** - Problems in body function and structure such as significant deviation or loss.
- **Activity** - The execution of a task or action by an individual.
- **Participation** - Involvement in a life situation.
- **Activity limitations** - Difficulties an individual may have in executing activities.
- **Participation restrictions** - Problems an individual may experience in involvement in life situations.
- **Environmental factors** - The physical, social and attitudinal environment in which people live and conduct their lives. These are either barriers to or facilitators of the person's functioning.

Source: WHO 2000 R,10 21

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### ICF Definitions

- Functioning is an umbrella term for **body function, body structures, activities and participation**. It denotes the positive or neutral aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors).
- Disability is an umbrella term for impairments, activity limitations and participation restrictions. It denotes the negative aspects of the interaction between a person's health condition(s) and that individual's contextual factors (environmental and personal factors).

Source: WHO 2001:8,10 22

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### ICF Components and Domains/Chapters

Source: WHO 2001:29-30 23

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### Physical History, Examination & Assessment

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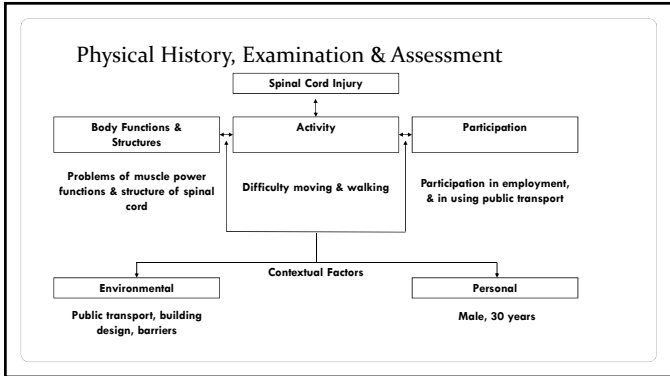
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**Auditing for Compliance**

UPCODING, UNDERCODING AND WHO KNOWS HOW TO CODE?

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- Why?
- Ensure billed code is supported by the documentation
  - Identify needed changes in your EMR to support the codes
  - Identify additional education focus areas related to the codes

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### When?

- For the first year of implementation of these codes, CMS has decided not to revise Medicare Benefits Policy Manual to reflect the new codes and has instructed auditors to hold off on audits for this first year

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### How?

- Develop an audit tool based on code definitions
- Test your tool!
  - IRR if multiple auditors
- Determine audit sample size
  - Be Realistic

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LOCATION:	PATIENT NAME:	DOB:	THERAPIST:
History	Total # Checks	Check all IMPACTING POC, if not impacting POC then do not check: <input type="checkbox"/> Comorbidity 1 <input type="checkbox"/> Comorbidity 2 <input type="checkbox"/> Comorbidity 3 <input type="checkbox"/> Sex <input type="checkbox"/> Age <input type="checkbox"/> Coping Style <input type="checkbox"/> Social Background <input type="checkbox"/> Education <input type="checkbox"/> Employment <input type="checkbox"/> Careg (Current Experience) <input type="checkbox"/> Release Factors <input type="checkbox"/> Character	
Examination	Total # Checks	Body Systems: Musculoskeletal (Symmetry, ROM, Strength, Height, Weight, Pain, Posture): <input type="checkbox"/> Head <input type="checkbox"/> Neck <input type="checkbox"/> Back <input type="checkbox"/> ME <input type="checkbox"/> UE <input type="checkbox"/> Trunk Neurovascular: <input type="checkbox"/> Balance <input type="checkbox"/> Gait/Locomotion <input type="checkbox"/> Transfers <input type="checkbox"/> Bed Mobility <input type="checkbox"/> Patient Control/Training Cardiovascular/Pulmonary (SBP, RR, Edema) <input type="checkbox"/> Integumentary (Wound/Healed, Skin Function, Color, Integrity, Wound) <input type="checkbox"/> Other (Ability to Make Needs Known, Consciousness, Orientation, Learning Performance, Expected Behaviors/Emotional Response) Activity Limitation: <input type="checkbox"/> Bed Mobility <input type="checkbox"/> Transfers <input type="checkbox"/> Locomotion Level <input type="checkbox"/> Stairs <input type="checkbox"/> Bathing <input type="checkbox"/> Dressing <input type="checkbox"/> Toileting <input type="checkbox"/> Self Feeding <input type="checkbox"/> Hygiene/Toileting <input type="checkbox"/> Reading/Overhead <input type="checkbox"/> Cereal <input type="checkbox"/> Soup <input type="checkbox"/> B/R <input type="checkbox"/> Carry <input type="checkbox"/> Stand <input type="checkbox"/> Sleep <input type="checkbox"/> M <input type="checkbox"/> Continence <input type="checkbox"/> Other Participation Restrictions: <input type="checkbox"/> Walk <input type="checkbox"/> Climb <input type="checkbox"/> Churn <input type="checkbox"/> Community Activity <input type="checkbox"/> Drive <input type="checkbox"/> Volunteer <input type="checkbox"/> Interpersonal Ref/Ship <input type="checkbox"/> Meal Prep <input type="checkbox"/> Cleaning <input type="checkbox"/> Shop <input type="checkbox"/> Laundry <input type="checkbox"/> Medication Admin <input type="checkbox"/> Personal Hygiene <input type="checkbox"/> School <input type="checkbox"/> Other	
Clinical Presentation		<input type="checkbox"/> Stable w/pt <input type="checkbox"/> Evolving with <input type="checkbox"/> Unstable & <input type="checkbox"/> Unpredictable <input type="checkbox"/> Resolving <input type="checkbox"/> Changing Characteristics	
Code	History	Examination	Clinical Presentation
Low complexity - 97161	<input type="checkbox"/> None	<input type="checkbox"/> 1-2	<input type="checkbox"/> Stable/Uncomplicated <input type="checkbox"/> Low
Moderate complexity - 97162	<input type="checkbox"/> 1-2	<input type="checkbox"/> 3+	<input type="checkbox"/> Evolving with <input type="checkbox"/> Moderate
High complexity - 97163	<input type="checkbox"/> 3+	<input type="checkbox"/> 4+	<input type="checkbox"/> Changing Characteristics <input type="checkbox"/> High
PT EVAL CPT CODE SUPPORTED: <input type="checkbox"/> 97161 (Low) <input type="checkbox"/> 97162 (Moderate) <input type="checkbox"/> 97163 (High)			

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**PT: History**

Check all IMPACTING POC, if not impacting POC then do not check:

Comorbidity 1    Comorbidity 2    Comorbidity 3

Sex    Age    Coping Style    Social Background    Education

Profession    Past / Current Experience    Behavior Pattern    Character

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**PT: Examination**

Body Systems/Structure/Function:

Musculoskeletal (Symmetry, ROM, Strength, Height, Weight, Pain, Posture):

Head    Neck    Back    LE    UE    Trunk

Neuromuscular:

Balance    Gait/Locomotion    Transfers    Bed Mobility

Motor Control/Learning

Cardiovascular/Pulmonary (HR, RR, BP, Edema)

Integumentary (Pliability (texture), scar formation, color, integrity, wound)

Other (Ability to Make Needs Known; Consciousness; Orientation; Learning Preference; Expected Behavioral / Emotional Response)

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**PT: Examination**

Activity Limitation:

Bed Mobility    Transfers    Locomotion Level    Stairs    Bathing

Dressing    Toileting    Self Feeding    Hygiene/Grooming

Reaching Overhead    Bend    Squat    Lift    Carry    Stand

Sleep    Sit    Continence    Other

Participation Restriction:

Work    School    Church    Community Activity    Drive    Volunteer    Interpersonal Rel'ship

Meal Prep    Cleaning    Shop    Laundry

Medication Mgmt    Personal Finances    School    Other

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PT: Clinical Presentation

- Stable and/or uncomplicated characteristics
  - Signs/symptoms remain localized to body structure/function
- Evolving clinical presentation with changing characteristics
  - Signs/symptoms peripheralizing or changing
  - Weight Bearing changes
- Unstable and unpredictable characteristics
  - Pattern of signs/symptoms difficult to establish
  - Red Flags
  - Medical Issues Impacting – orthostatic

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Location:	Patient Name:	DOB:	Therapist:
Occupational Profile & History	<input type="checkbox"/> Brief History Including Review of Records Relating to Presenting Problem	<input type="checkbox"/> Expanded Review of Records & add'l review of physical, cognitive, psychosocial hx related to current func. performance	<input type="checkbox"/> Review of Records and Extensive Add'l review of physical, cognitive, psychosocial hx related to current func. performance
Assessment (performance deficit)	Total # of Checks Body Structure/Function/Physical Skills: <input type="checkbox"/> Balance <input type="checkbox"/> Mobility <input type="checkbox"/> Strength <input type="checkbox"/> Endurance <input type="checkbox"/> FIM <input type="checkbox"/> GAC <input type="checkbox"/> Sensation <input type="checkbox"/> Dexterity <input type="checkbox"/> Vision <input type="checkbox"/> Hearing <input type="checkbox"/> Vestibular <input type="checkbox"/> Proprioception <input type="checkbox"/> Pain <input type="checkbox"/> ROM <input type="checkbox"/> Tone <input type="checkbox"/> Coordination <input type="checkbox"/> Weight		
	Cognitive Skills: <input type="checkbox"/> Attention <input type="checkbox"/> Perception <input type="checkbox"/> Thought <input type="checkbox"/> Understanding <input type="checkbox"/> Problem Solving <input type="checkbox"/> Sequencing <input type="checkbox"/> Learning <input type="checkbox"/> Memory <input type="checkbox"/> Emotional <input type="checkbox"/> Consciousness <input type="checkbox"/> Orientation <input type="checkbox"/> Temperament/Personality <input type="checkbox"/> Energy/Drive		
	Psychological Skills: <input type="checkbox"/> Intra-personal Interaction <input type="checkbox"/> Habits <input type="checkbox"/> Routines & Behaviors <input type="checkbox"/> Coping Strategies <input type="checkbox"/> Environmental Adaptation		
Clinical Decision Making	<input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> High <input type="checkbox"/> Problem Focused Assessment <input type="checkbox"/> Detailed Assessment <input type="checkbox"/> Comprehensive Assessment <input type="checkbox"/> Limited # of Treatment Options <input type="checkbox"/> Several Treatment Options <input type="checkbox"/> Multiple Treatment Options <input type="checkbox"/> No Considerables <input type="checkbox"/> May have considerables impacting occupational performance <input type="checkbox"/> Presence of considerables impacting occupational performance <input type="checkbox"/> No Modification of Tasks or assist necessary to complete evaluation <input type="checkbox"/> Min-Max Modification of Tasks or assist with assess necessary to complete eval <input type="checkbox"/> Significant Modification of Tasks or assist with assess to complete eval		
Code:	Occupational Profile & History	Performance Deficit	Clinical Decision Making
Low Complexity - 97165	<input type="checkbox"/> Brief	<input type="checkbox"/> 1-3	<input type="checkbox"/> Low
Moderate Complexity - 97166	<input type="checkbox"/> Expanded	<input type="checkbox"/> 3-5	<input type="checkbox"/> Moderate
High Complexity - 97167	<input type="checkbox"/> Extensive	<input type="checkbox"/> 5+	<input type="checkbox"/> High
OT EVAL CODE SUPPORTED: <input type="checkbox"/> 97165 (Low) <input type="checkbox"/> 97166 (Moderate) <input type="checkbox"/> 97167 (High)			

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OT: Occupational Profile & HX

<input checked="" type="checkbox"/> Brief History Including Review of Records Relating to Presenting Problem	<input type="checkbox"/> Expanded Review of Records & add'l review of physical, cognitive, psychosocial hx related to current func. performance	<input type="checkbox"/> Review of Records and Extensive Add'l review of physical, cognitive, psychosocial hx related to current func. performance
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**OT: Assessments (Performance Deficits)**

- Body Structure/Function/Physical Skills:
  - Balance  Mobility  Strength  Endurance  FMC  GMC  Sensation
  - Dexterity  Vision  Hearing  Vestibular  Proprioception  Pain  ROM
  - Tone  Continence  Wound
- Cognitive Skills:
  - Attention  Perception  Thought  Understand  Problem Solve  Sequencing
  - Learn  Memory  Emotional  Consciousness  Orientation
  - Temperament/Personality  Energy/Drive
- Psychosocial Skills:
  - Interpersonal Interaction  Habits  Routines & Behaviors  Coping Strategies
- Environmental Adaptations

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**OT: Clinical Decision making**

Low	Moderate	High
<input type="checkbox"/> Problem Focused Assessment	<input type="checkbox"/> Detailed Assessment	<input type="checkbox"/> Comprehensive Assessment
<input type="checkbox"/> Limited # of Treatment Options	<input type="checkbox"/> Several Treatment Options	<input type="checkbox"/> Multiple Treatment Options
<input type="checkbox"/> No Comorbidities	<input type="checkbox"/> May have comorbidities impacting occupational performance	<input type="checkbox"/> Presence of comorbidities impacting occupational performance
<input type="checkbox"/> No Modification of Tasks or assist necessary to complete evaluation	<input type="checkbox"/> Min-Mod Modification of Tasks or assist with assess necessary to complete eval	<input type="checkbox"/> Significant Modification of Tasks or assist with assess is necessary to complete eval

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**Practice Makes Perfect**

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PT AND OT CASE STUDIES

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Case Study 1

- Patient presents to PT with a new onset CVA with R hemiparesis, swallow dysfunction, and R distal tib/fib fracture as a result of a fall when suffered infarct. Precautions: NWB R LE and thickened liquids.
- Comorbidities include HTN with new medication after CVA requiring close monitoring and knee OA with pain with weight bearing with ID'd need for TKR in future. Patient lives alone in a one story home with a 4 step entry with handrail bilateral, tub/shower combo, laundry in basement.
- No AD/AE prior. Was independent with functional mobility and ADL/IADL. Examination: Strength R UE 2/5; L UE 4/5 and R LE 2/5 except testing prevented by cast; L LE 4-/5. PROM intact.
- Bed mobility with moderate assist. Transfer with slide board with moderate assist. Unable to ambulate. Balance FIST score 8/56. BP: 130/70 rest; 150/75 activity. HR 70 rest and on betablocker. Goal is to return home alone.

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Case Study 2

- 76 year old female admitted following a 3 day hospital stay with new dx of CHF. PMH include diabetes, L TKR 5 yrs post, and renal failure with dialysis. Resides in senior apt with supportive son living nearby.
- PLOF independent in all aspects of mobility and self cares. She was completing simple meal prep, housekeeping, and laundry tasks without difficulty in apartment. Son assisted with shopping, med management and personal finances. SOB with all tasks, O2 at 4L and O2 sat's at 87% with activity requiring frequent rests and max cuing on breathing technique.
- She requires mod A for UE/LE dressing, bathing, and toileting tasks. L hand grip 10 pounds and R hand grip 5lbs, overall MMT BLE and BUE 3/5; Barthel 65/100; Berg 25/56. Functional reach 5 inches in stand.
- Pt reports pain at 4/10 in BUE shoulders and BORG scale is 17/20 with all tasks. BP varies 100/90 to 150/100. Weight upon eval 190 pounds with edema noted in BLE. Referral made to ST as slight memory and problem solving issues noted during OT evaluation.

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Case Study 3

- 69 year old female presents to OT for lymphedema evaluation of left UE following mastectomy. Prior to surgery and development of lymphedema was completely independent, working part time data entry for her son's business, babysat grandson 2x/week, attended monthly bookclub, and participated in gardening club.
- Currently she is unable to lift grandson, having difficulty with typing for data entry, notes decreased grip strength, feels clumsy with dressing with buttons and zippers, and has pain 5/10.
- Exam findings include edema, grip strength loss, skin intact, FMC deficits, and ROM loss at elbow, wrist and digits. Treatment plan is MLD and bandaging with HEP instruction.

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Case Study 4

- 69 year old female presents to outpatient PT for evaluation of neck pain and numbness and tingling in face and intermittent dizziness. PMH includes COPD with frequent use of steroids and on O2, rheumatoid arthritis, B TKR requiring continued use of two wheeled walker, and BMI of 44.
- PLOF independent with ADLs, assist with IADLs, ambulatory with two wheel walker, stairs independent with bilateral handrails and socially very active with family and friends.
- Reports since onset of s/s requires assist on stairs tub/shower transfers, LB ADLs and showering due to worsening s/s and fear of falling due to onset of dizziness. In addition she has not been able to attend her social functions with friends/family.
- Due to s/s clinician begins with upper cervical stability tests which are positive resulting in call to physician for orders for imaging.

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Essential References & Tools

- Definitions
- Code descriptions
- APTA
- AOTA
- ICF
- Cheat Sheet
- Audit Tools



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Summary & Q & A

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HOW CAN WE HELP YOU?

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What Can You Do?

- 1. Familiarize yourself with the evaluation complexity matrix for PT & OT
- 2. Run through some PT & OT cases studies prior to conducting an audit
- 3. Audit to ensure documentation supports complexity
- 4. Make a cross walk to your EMR

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Presenters



**Shawn M Halcsik, DPT, MEd, RAC-CT, CPC, CHC**  
Corporate Compliance Officer  
Encore Rehabilitation



**Nancy J Beckley, MS, MBA, CHC**  
President & Founder  
Nancy Beckley & Associates LLC  
NancyBeckley.com

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Location:

Patient Name:

DOS:

Therapist:

Occupational Profile & History		<input type="checkbox"/> <b>Brief</b> History Including Review of Records Relating to Presenting Problem	<input type="checkbox"/> <b>Expanded</b> Review of Records & <b>add'l review</b> of physical, cognitive, psychosocial hx related to current func. performance	<input type="checkbox"/> Review of Records and <b>Extensive Add'l review</b> of physical, cognitive, psychosocial hx related to current func. performance
Assessment (performance deficits)	Total # of Checks	<p>Body Structure/Function/Physical Skills:</p> <input type="checkbox"/> Balance <input type="checkbox"/> Mobility <input type="checkbox"/> Strength <input type="checkbox"/> Endurance <input type="checkbox"/> FMC <input type="checkbox"/> GMC <input type="checkbox"/> Sensation <input type="checkbox"/> Dexterity <input type="checkbox"/> Vision <input type="checkbox"/> Hearing <input type="checkbox"/> Vestibular <input type="checkbox"/> Proprioception <input type="checkbox"/> Pain <input type="checkbox"/> ROM <input type="checkbox"/> Tone <input type="checkbox"/> Continenence <input type="checkbox"/> Wound <p>Cognitive Skills:</p> <input type="checkbox"/> Attention <input type="checkbox"/> Perception <input type="checkbox"/> Thought <input type="checkbox"/> Understand <input type="checkbox"/> Problem Solve <input type="checkbox"/> Sequencing <input type="checkbox"/> Learn <input type="checkbox"/> Memory <input type="checkbox"/> Emotional <input type="checkbox"/> Consciousness <input type="checkbox"/> Orientation <input type="checkbox"/> Temperment/Personality <input type="checkbox"/> Energy/Drive <p>Psychosocial Skills:</p> <input type="checkbox"/> Interpersonal Interaction <input type="checkbox"/> Habits <input type="checkbox"/> Routines & Behaviors <input type="checkbox"/> Coping Strategies <input type="checkbox"/> Environmental Adaptations		
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	<input type="checkbox"/> Problem Focused Assessment	<input type="checkbox"/> Detailed Assessment	<input type="checkbox"/> Comprehensive Assessment	
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	<input type="checkbox"/> No Comorbidities	<input type="checkbox"/> May have comorbidities impacting occupational performance	<input type="checkbox"/> Presence of comorbidities impacting occupational performance	
	<input type="checkbox"/> No Modification of Tasks or assist necessary to complete evaluation	<input type="checkbox"/> Min-Mod Modification of Tasks or assist with assess necessary to complete eval	<input type="checkbox"/> Significant Modification of Tasks or assist with assess is necessary to complete eval	
Code:	Occupational Profile & History	Performance Deficits	Clinical Decision Making	
Low Complexity -- 97165	<input type="checkbox"/> Brief	<input type="checkbox"/> 1-3	<input type="checkbox"/> Low	
Moderate Complexity--97166	<input type="checkbox"/> Expanded	<input type="checkbox"/> 3-5	<input type="checkbox"/> Moderate	
High Complexity--97167	<input type="checkbox"/> Extensive	<input type="checkbox"/> 5+	<input type="checkbox"/> High	
<b>OT EVAL CPT CODE SUPPORTED:   <input type="checkbox"/> 97165 (Low)   <input type="checkbox"/> 97166 (Moderate)   <input type="checkbox"/> 97167 (High)</b>				

LOCATION:

PATIENT NAME:

DOS:


THERAPIST:

History	Total # Checks	Check all IMPACTING POC, if not impacting POC then do not check: <input type="checkbox"/> Comorbidity 1 <input type="checkbox"/> Comorbidity 2 <input type="checkbox"/> Comorbidity 3 <input type="checkbox"/> Sex <input type="checkbox"/> Age <input type="checkbox"/> Coping Style <input type="checkbox"/> Social Background <input type="checkbox"/> Education <input type="checkbox"/> Profession <input type="checkbox"/> Past / Current Experience <input type="checkbox"/> Behavior Pattern <input type="checkbox"/> Character		
Examination	Total # Checks	Body Systems: Musculoskeletal (Symmetry, ROM, Strength, Height, Weight, Pain, Posture): <input type="checkbox"/> Head <input type="checkbox"/> Neck <input type="checkbox"/> Back <input type="checkbox"/> LE <input type="checkbox"/> UE <input type="checkbox"/> Trunk Neuromuscular: <input type="checkbox"/> Balance <input type="checkbox"/> Gait/Locomotion <input type="checkbox"/> Transfers <input type="checkbox"/> Bed Mobility <input type="checkbox"/> Motor Control/Learning <input type="checkbox"/> Cardiovascular/Pulmonary (HR, RR, BP, Edema) <input type="checkbox"/> Integumentary (Pliability (texture), scar formation, color, integrity, wound) <input type="checkbox"/> Other (Ability to Make Needs Known; Consciousness; Orientation; Learning Preference; Expected Behavioral/Emotional Response)  Activity Limitation: <input type="checkbox"/> Bed Mobility <input type="checkbox"/> Transfers <input type="checkbox"/> Locomotion Level <input type="checkbox"/> Stairs <input type="checkbox"/> Bathing <input type="checkbox"/> Dressing <input type="checkbox"/> Toileting <input type="checkbox"/> Self Feeding <input type="checkbox"/> Hygiene/Grooming <input type="checkbox"/> Reaching Overhead <input type="checkbox"/> Bend <input type="checkbox"/> Squat <input type="checkbox"/> Lift <input type="checkbox"/> Carry <input type="checkbox"/> Stand <input type="checkbox"/> Sleep <input type="checkbox"/> Sit <input type="checkbox"/> Continance <input type="checkbox"/> Other  Participation Restriction: <input type="checkbox"/> Work <input type="checkbox"/> School <input type="checkbox"/> Church <input type="checkbox"/> Community Activity <input type="checkbox"/> Drive <input type="checkbox"/> Volunteer <input type="checkbox"/> Interpersonal Rel'ship <input type="checkbox"/> Meal Prep <input type="checkbox"/> Cleaning <input type="checkbox"/> Shop <input type="checkbox"/> Laundry <input type="checkbox"/> Medication Mgmt <input type="checkbox"/> Personal Finances <input type="checkbox"/> School <input type="checkbox"/> Other		
Clinical Presentation		<input type="checkbox"/> Stable &/or Uncomplicated	<input type="checkbox"/> Evolving with Changing Characteristics	<input type="checkbox"/> Unstable & Unpredictable Char.
<b>Code:</b>	<b>History</b>	<b>Examination</b>	<b>Clinical Presentation</b>	<b>Clinical Decision Making</b>
Low Complexity -- 97161	<input type="checkbox"/> None	<input type="checkbox"/> 1-2	<input type="checkbox"/> Stable/Uncomplicated	<input type="checkbox"/> Low
Moderate Complexity-- 97162	<input type="checkbox"/> 1-2	<input type="checkbox"/> 3+	<input type="checkbox"/> Evolving with Changing Characteristics	<input type="checkbox"/> Moderate
High Complexity--97163	<input type="checkbox"/> 3+	<input type="checkbox"/> 4+	<input type="checkbox"/> Unstable/Unpredict.	<input type="checkbox"/> High
<b>PT EVAL CPT CODE SUPPORTED:   <input type="checkbox"/> 97161 (Low)   <input type="checkbox"/> 97162 (Moderate)   <input type="checkbox"/> 97163 (High)</b>				

**Study of 1000 Vendor Security Practices**  
March 28, 2017

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**Peter N. Merrill, Dartmouth Hitchcock Health System**  
**Danny Mimnaugh, CORL Technologies**



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**Presentation Agenda**

**Regulatory Guidelines - Peter**


- Responsibilities
- Regulatory Challenges
- Breach data
- Case Study – The Ponemon Institute

**Introduction into the Third-party Security Risk Management World**

- HCO's third-party profiles
- Vendor Security Risk Management Program overview
- Keys to an effective VSRM program

**Miscellaneous info on VSRM**

- Program Weaknesses
  - Why??
- Collaboration amongst peers
- Assurance
  - Types of Assurances
- Will Business Associate Reimburse?



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**Third-party Breach Risks**

**Regulatory**


- CE remains responsible for Breach Notification
- HIPAA rule requires organizations to assess the risk to a breach of PHI wherever it is created, received, maintained or transmitted and to put measures in place to safeguard the information.

**Reputational**

- Headlines
- Undermines Patient Trust
- Undermines Employee Trust

**Financial**

- Breach Notification is Expensive
  - Mailings
  - Call Centers
  - Credit Monitoring
  - Staff Time
- OCR Penalties for non compliance with HIPAA Rule (e.g., St. Elizabeth's Medical Center)
- Will Business Associate Reimburse?



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Regulatory Challenges

What is required to comply with HIPAA?

- As a covered entity and business associate you are required to assess the risk to the confidentiality, integrity and availability of ePHI. This includes assessing the safeguards that your vendors have in place to protect ePHI that they store, access, transmit or process for you.

**RISK ANALYSIS:** Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the third-party.

This is what NIST says:

- Establish Process for Measuring Contract Performance and Terminating the Contract if Security Requirements Are Not Being Met
- Conduct periodic security reviews.
- See NIST SP 800-66, Section #4 "Considerations When Applying the HIPAA Security Rule." Available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/nist80066.pdf> – PDF

*"Based on tips from whistleblowers, HHS' Office for Civil Rights fined St. Elizabeth's Medical Center, part of Boston-based Steward Health Care, \$218,400 for using an Internet-based document sharing application to store documents containing PHI without first analyzing the risks associated with the platform. This lack of risk analysis put the PHI at risk."*



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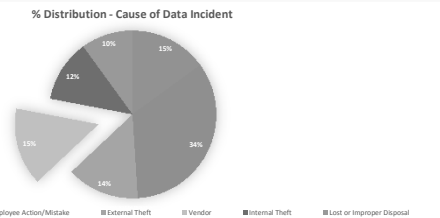
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Regulatory Challenges

Information surrounding Data Breaches?

- According to the BakerHostetler 2016 Data Security Incident Response Report, roughly 15% of Data Incidents were caused by Third Party Vendors the below diagram breaks down the different causes for Data Incidents during the 2016 study:



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The Ponemon Institute: *Tone at the Top and Third Party Risk*

- Third party risk** has substantially increased due to disruptive technologies including the Internet of Things (IoT) and migration to the Cloud.
- The consequences of not managing third party risk can be extremely costly**, as organizations represented in this research spent an average of approximately \$10 million to respond to a security incident as a result of negligent or malicious third parties.
- Most third party risk management programs are generally in formal** and not effective, as most respondents admit that improving third party relationships is not a top risk management objective.



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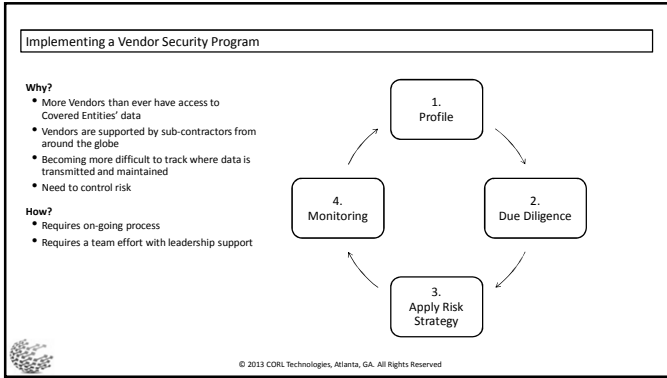
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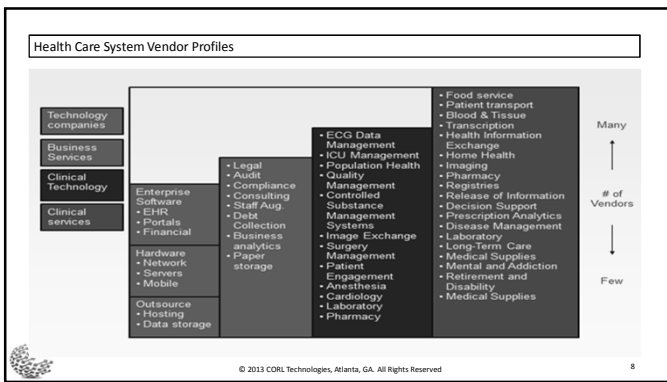
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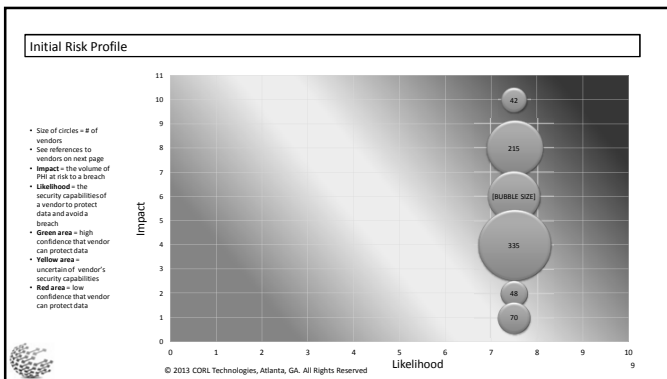
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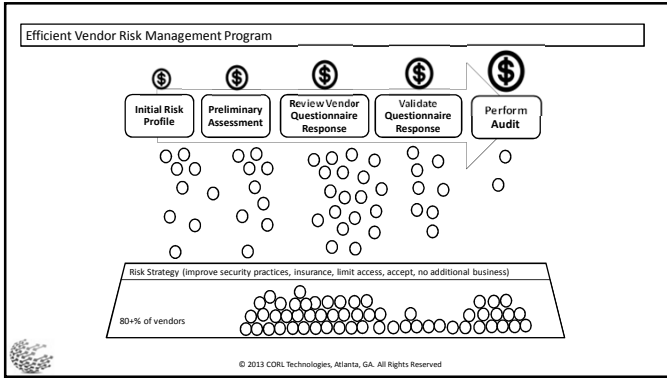
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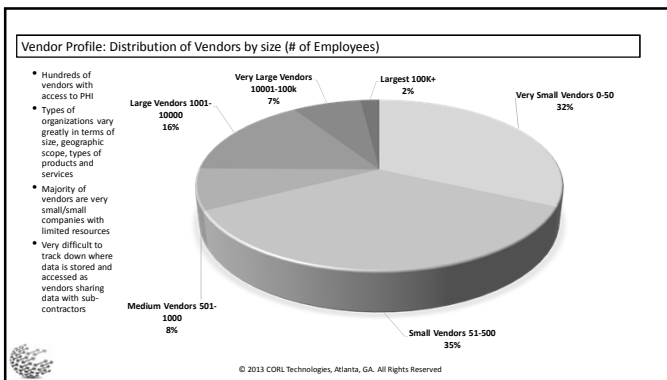
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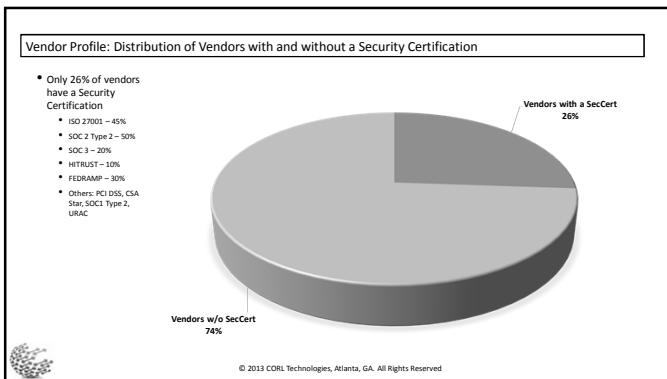
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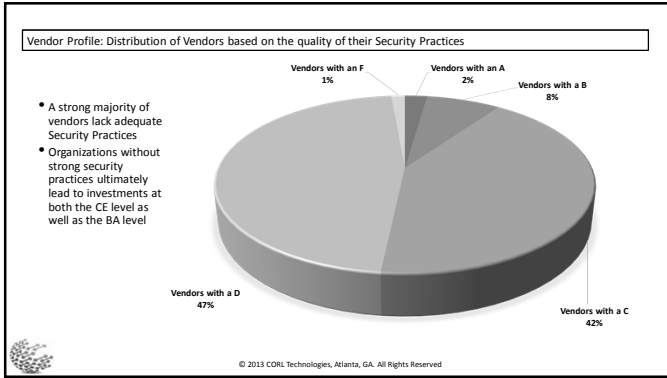
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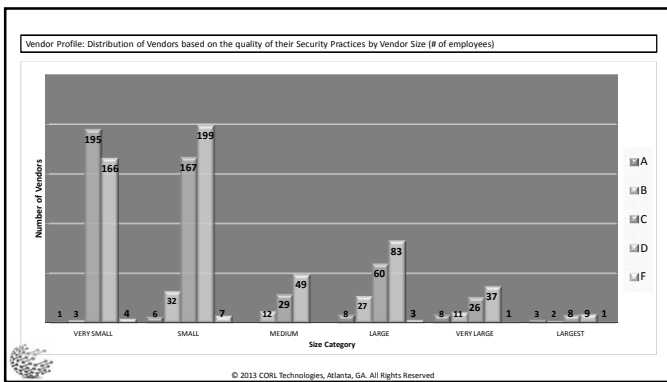
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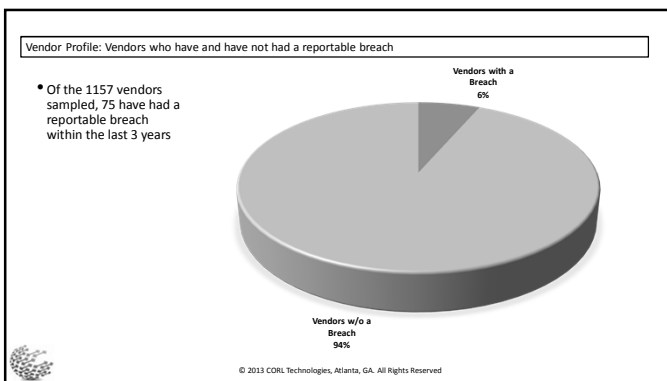
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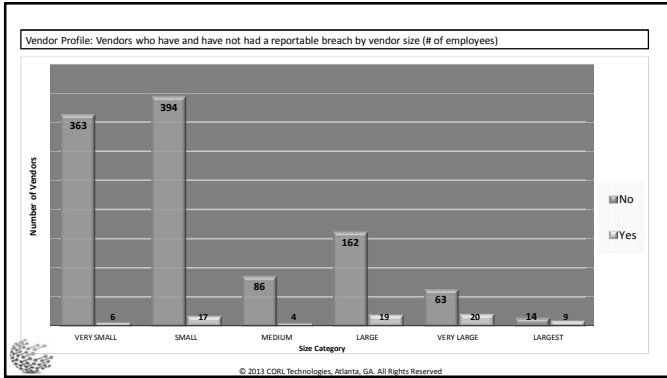
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Common Vendor Information Risk Management Program Weaknesses

**Leadership communication**

- Difficultly to accurately communicate risk exposure to leadership
- Communication is inconsistent

**Vendor communication and accountability**

- Communication is sporadic, inconsistent and unclear
- Absence of linkage between vendor information management failures and contract management

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Why are there Weaknesses

**Seeing the forest for the trees...**

- Too busy gathering data...  
...leaves limited time for risk management.
- Unclear objectives for vendor information risk management...  
... 'check the box' compliance or true reduction of risk?
- Lack of executive level reporting.
- Disconnect from contract management.

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Collaborative Approach to Vendor Security Risk Management

- Legal/Compliance
- Procurement/Contracting
- IT
- Frequent Users (Finance, Revenue & Reimbursement, Quality)

✓ Review existing contracts to search for frequent users



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Focus on Assurance

- Third party audit – Assurance
- Review of evidence of control described in a response to a questionnaire – Assurance
- Response to a questionnaire – Information not Assurance
- Interview with vendor – Information not Assurance
- Status update from vendor – Information not Assurance
- Vendors responsibility to provide Customer assurance that information is safeguarded



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Security Audits/Certification

- **SOC 2, Type II:** covering security, availability, processing integrity, confidentiality and privacy, and applying your (sometimes CSA) standards, is the more comprehensive audit.
- **Type II** means tested, **Type I** only noted as policy.
- The term **SSAE 16** alone can be interpreted as a SOC 1, focusing on controls only to the extent “material” to financial reporting.
- **ISO 27001:** int'l standard - certification for management frameworks for security. (ISO 27017 is new cloud-specific standard)
- **PCI-DSS 3.0 standard:** Security of payment networks.
- **CSA Cloud Controls Matrix (CCM):** cloud security playbook
- **FedRAMP:** federal standard



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**Red Flags for Initial Security Assessment**

- **Assessment partially completed and vague responses**
- "We already performed a security assessment & everything was fine."
- "We've been in the industry a long time and nobody has asked us these questions before."
- "HIPAA doesn't require that we answer these questions."
- "We don't need to do a security assessment because it's a big company and they have good security."
- "You don't need to worry; we only capture employee data, not patient data."
- **Refusal to let you contact the subcontractor who is actually handling the data**



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**Who/What to Assess?**

- Who houses the data?
- How does the data get from the source to the end recipient?
- Follow the trail and assess all points along the way
- Remember: The trail may not be a straight line!



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**Example: Risk Reduction Terms**

- Obtaining Independent Security Assessment - provide evidence
- Developing a plan to address issues - provide evidence
- Requiring adherence to a timeline
- Allowing for termination of contract for failure to meet timelines
- Indemnification



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Care New England Health System (CNE): Third-party Breach

- Care New England Health System (CNE) has agreed to pay \$400,000 and employ a corrective action plan to settle HIPAA violations.
- The breach, which was reported to the OCR in 2012 by Women and Infants Hospital in Rhode Island, a business associate of CNE, included missing unencrypted backup tapes that held PHI of some 14,000 individuals.
- The business associate agreement between the two entities, originating in 2005, had not been updated until the 2015 OCR Investigation, and did not incorporate revisions required under the HIPAA Omnibus Final Rule.

<http://www.healthcareitnews.com/news/care-new-england-pays-400000-hipaa-fine-lost-phi-business-associate-breach>

As we see in this particular case, vendor/B.A. security can be the unlocked backdoor to healthcare data. As the healthcare provider, it is ultimately your responsibility to safeguard Protected Health Information, and perform due diligence on vendors with PHI access.




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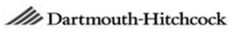
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Questions?



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THANK  
YOU




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How to Develop Benchmarking  
**scorecards**  
*Transitioning to Risk-Based Physician Auditing*



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**What We Are Going To Cover**



- 1** *Review Current Audit Activity*
- 2** *Reactive vs. Proactive Auditing*
- 3** *What Metrics to Look at?*
- 4** *Understanding Peer Group Data*
- 5** *How to Calculate the Metrics*
- 6** *Incorporate Risk Thresholds*
- 7** *Tying Everything into an Audit Plan*

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**Trinity Health** 22 State Diversified Network



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## Big Data

### Current Audit Activity

- Government has refined their data analytics for "Smarter" Investigations and prosecutions
- More techniques are being developed to target "high-risk physicians" at the federal and state level (cooperation)
- Healthcare investigations are "bipartisan" and will continue no matter who controls congress
- State Medicaid programs are doing more auditing and monitoring (examples)
- 60-day repayment rules (explain) (can't bury your head in the sand)
- Data transparency

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Type	Contractors	Comments
Medicare Administrative Contractors (MACs)	• National Government Services	• Process claims and provider payments • Reduce payment error rates
Zone Program Integrity Contractors (ZPICs)	• Cahaba Safeguard Administrators	• Focus on identifying fraud • All providers • Data mining and analysis
Supplemental Medical Review Contractor (SMRC)	• Strategic Health Solutions	• Nationwide claim review • All providers • Data mining and analysis
Comprehensive Error Rate Testing Contractors (CERT)	• Multiple contractors	• Annual audits to determine FFS error rates • All provider types
Recovery Audit Contractors (RACs)	• CGI Technologies (Medicare) • HMS (Medicaid)	• Identify over and under payment errors
DHHS – Office of Inspector General (OIG)	• N/A	• Audits and investigations • Annual Work Plan published
Department of Justice (DOJ)	• N/A	• Enforcement actions under the False Claims Act
Medicaid Inspector General	• IL Dept. of Healthcare and Family Services	• Aggressively using extrapolation for repayment liabilities

Who is **AUDITING?**  
Healthcare Providers ?

*An Example: Illinois*

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### A Typical Trend: Reactive Auditing

- The current reactive approach to auditing and monitoring
  - Just responding to audit requests
  - Conducting documentation reviews entirely in random
  - Benchmarking without a set action plan
- Reasons why this reactive approach is still being used
  - Data issues
  - Understanding benchmarking
  - Restricted FTE and tech resources
  - Fear of knowing



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### Becoming Proactive with Provider Benchmarking

- Develop benchmarking and data analytic capabilities that mirror methods being used by the OIG, DOJ, CMS etc.
- Focus your limited auditing and monitoring resources towards providers based on risk
  - Reduce workload on the auditing team
  - Provide transparency throughout the organization and increase the effectiveness of strategic planning
    - Due diligence of new practices

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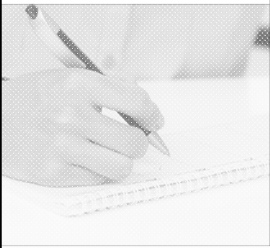
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### What Metrics to Look at?



- 01 Utilization Benchmarking**
  - E/M level coding peer comparisons
  - Modifier usage
  - Top billed procedure analysis
- 02 Highly Productive Provider Analysis**
  - Visit per day analysis
  - wRVU analysis
  - Harvard RUC time study
- 03 Payments Analysis**
  - Medicare payments analysis

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### Before You Get Started: Defining Your Peer Group

- CMS Utilization Raw Data
  - Sub-Specialty Bias
  - Payer Mix Bias
- MGMA – Surveys and Benchmarking Data
  - Understand Volume of Data Included (Total / Specialty / Locality)
- CMS Utilization & Payments Data
  - Line Item Data Not Included on Services Performed on Small Number of Patients



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20 Physician/Orthopedic Surgery

207X00000X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery
207XS0114X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Adult Reconstructive Orthopaedic Surgery
207XX0004X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Foot and Ankle Surgery
207XS0106X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Hand Surgery
207XS0117X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Orthopaedic Surgery of the Spine
207X00001X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Orthopaedic Trauma
207XP3100X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Pediatric Orthopaedic Surgery
207XX0005X	Allopathic & Osteopathic Physicians/Orthopaedic Surgery, Sports Medicine

### Example of CMS Sub-Specialty Bias

- Understanding the make-up of the peer group data is critical when attempting to make determinations on the results

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### E/M Level Coding Peer Comparisons

	National Peer		1st Quarter 2015				
	UNL	UNL	Vol.	DIR	Gross \$	Adjusted \$	Work Rsv
99211	1.79%	0.00%	0	-2%	\$0.00	\$484.15	0
99212	11.79%	0.22%	3	-12%	\$133.04	\$6,836.14	1.44
99213	51.42%	0.44%	6	-51%	\$440.40	\$50,473.94	5.82
<b>99214</b>	<b>30.14%</b>	<b>94.59%</b>	<b>1330</b>	<b>64%</b>	<b>\$143,812.90</b>	<b>\$99,348.47</b>	<b>1999.00</b>
99215	4.80%	0.74%	10	-4%	\$1,457.20	\$2,096.41	21.30

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### Modifier Usage

Focus On

- 24
- 25
- 58
- 59
- 62
- 63
- 76
- 78
- 80
- AS

	National Peer		1st Quarter 2015		
Description	UNL	UNL	Vol.	DIR	
Mod 24 Unrelated E/M in Post-Op Period	0.00%	0.00%	3	0.00%	
<b>Mod 25 Significant, Separate E/M on Same Day</b>	<b>0.62%</b>	<b>10.50%</b>	<b>363</b>	<b>10.40%</b>	
Mod 58 Staged/Related Procedure in Post-Op Period	0.00%				
Mod 59 Distinct Procedural Service	0.90%	1.33%	46	0.37%	

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1st Quarter 2015							National Peers	
Fee	Rank	UOL	Vol.	DRE	Gross \$	Rank	UOL	
99231	\$108.13	1	12.96%	1330	7.60%	\$143,812.90	3	5.36%
99236	\$230.22	2	9.68%	932	0.00%	\$214,565.04		0.00%
36435	-	3	6.23%	639	5.66%	\$0	18	0.57%
89610	-	4	4.72%	484	0.00%	\$0		0.00%
36436	-	5	3.07%	313	0.00%	\$0		0.00%
80048	-	6	2.94%	302	0.00%	\$0		0.00%
99232	\$204.44	7	2.47%	254	0.00%	\$51,927.76		0.00%
93000	\$17.39	8	2.28%	234	0.00%	\$4,022.46		0.00%
99233	\$39.74	9	2.28%	234	0.00%	\$9,399.16		0.00%
99235	\$273.90	10	2.20%	232	0.00%	\$63,544.80		0.00%
79430	\$493.02	11	2.21%	227	0.00%	\$111,915.54		0.00%
93293	\$53.71	12	2.18%	224	0.00%	\$12,033.04		0.00%
80061	-	13	2.12%	218	0.00%	\$0		0.00%
84550	-	14	2.08%	213	0.00%	\$0		0.00%

Top Billed Services Analysis




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### Understanding Medicare Payment Data

- CMS released a data file containing information on Medicare payments made to providers.
- Years Currently Available
  - 2012
  - 2013
  - 2014
- Key Benchmarking Analytics
  - Total Payments
  - Number of Patients
  - Payments Per Patient




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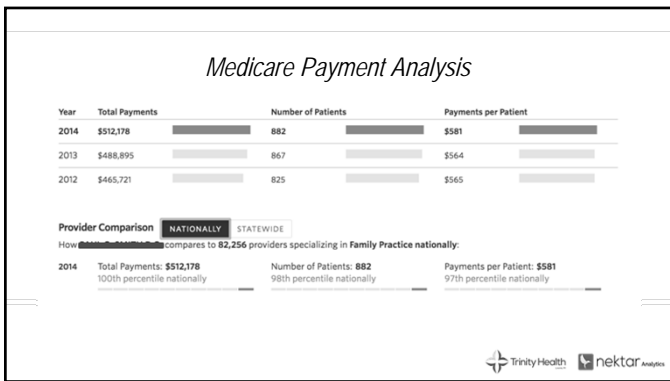
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### Visit Per Day Analysis

Develop an internal average per day analysis:

- Use MGMA data
- Physician paid claims
- CPT codes, volume, date of service
- MGMA Visit Data 70th, 80th, and 90th
- Outlier?
- How many visits per day?

CPT Code	Typical Time for Code
99212	10 min
99213	15 min
99214	25 min
99215	40 min

Criteria	MGMA Percentiles			
	Actual	70th	80th	90th
Total Days Worked	256	240	240	245
Total Encounters	6764	4508	5067	6127
Avg Encounters / Day	26	19	21	25
Total Work RVUs	9439	5672	6279	7390

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### Highly Productive Physicians

- Special care must be taken with "highly productive" physicians
  - Example:* Physicians with annual wRVUs > 90th% of industry benchmarks
  - Example:* Physicians that have billed a high number of hours based on Harvard RUC time study
  - Specialties such as cardiology, neurosurgery, orthopedics
- Evaluate need for additional audit procedures to evaluate
  - Medical appropriateness of services
  - Adherence to industry professional standards

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### The Importance of Incorporating Risk Thresholds

- Creates a standardized approach to know when a provider is an outlier
- Streamlines the analysis process by filtering out the providers that are not a risk
- Scorecards can be created by combining multiple analysis thresholds together

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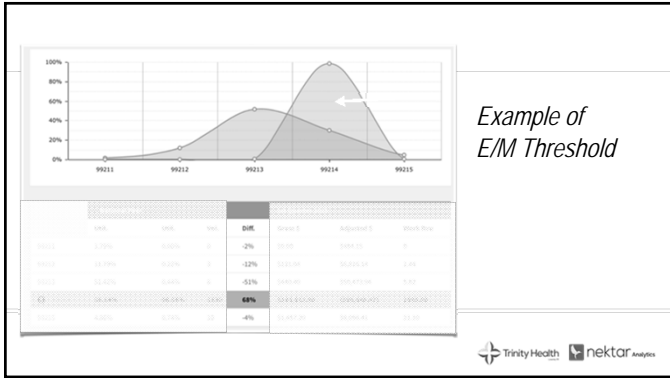
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*How Thresholds Help Prioritize*

Provider	Specialty	All Risk CPT	CPT Vol	CPT Util.	CPT Diff.
JULIA A MATTSON MD	Obstetrics & Gynecology	99214	1330	98.59%	68.00%
XIANG LIU MD	Diagnostic Radiology	99213	1025	89.75%	54.00%
REZA J DAUGHERTY MD	Diagnostic Radiology	99213	1792	74.14%	38.00%
MINCHUL FRANCIS SHIN MD	Diagnostic Radiology	99213	1991	70.06%	34.00%
TIMOTHY JAMES EDEN CRNP	Nurse Practitioner	99214	1213	67.02%	29.00%
LEONARD ROSENBAUM MD	Diagnostic Radiology	99214	568	64.91%	41.00%
SARA C GAVENONIS MD	Diagnostic Radiology	99213	1875	64.32%	28.00%
KRISTINA SIDDALL MD	Diagnostic Radiology	99213	2048	63.82%	28.00%
RALPH P IERARDI MD	Vascular Surgery	99215	48	32.65%	30.00%

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Category	Cpt	Description	Applicable Util.	Gross \$
> SR Hours			0.00%	\$0.00
New Office	99204	OFFICE/OUTPATIENT VISIT NEW	100.00%	\$15,616.22
Est Office	99214	OFFICE/OUTPATIENT VISIT EST	98.59%	\$143,812.90
Init Hospital	99223	INITIAL HOSPITAL CARE	93.73%	\$51,927.76
Subs Hospital	99231	SUBSEQUENT HOSPITAL CARE	50.43%	\$9,299.16
New_Ext Consults	99244	OFFICE CONSULTATION	90.67%	\$12,563.00
Excessive Billing	93351	STRESS TTE COMPLETE	2.26%	\$63,544.80

*How Benchmarking & Thresholds Work Together*

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### Benchmarks & Thresholds Incorporated to Build a Complete Risk Assessment for Your All Providers

*View Excel Example*



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**Spike in Data/Outliers..Next Steps**



- Ask questions:
  - New hire
  - Software problems
  - New service line
  - Operational issues
- Do a deeper data dive
- Review records – validate (create audit plan)




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**Disclaimer**

- Disclaimer is very important:
  - The analyses are for benchmarking purposes only and to assist in prioritizing areas for further review by hospital management
  - Coding and billing is dependent upon the services rendered by the hospital as determined to be medically necessary and appropriate based on the patient's presenting medical condition
  - No conclusions regarding the accuracy of coding and billing, nor compliance with government and third-party payer rules and regulations can be made without further review of the provider's underlying medical records documentation


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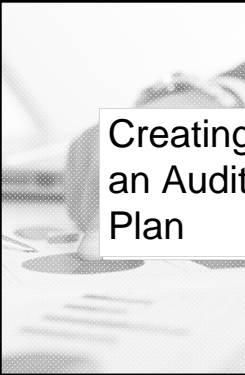
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## Creating an Audit Plan

- Risk based approach to auditing and monitoring
  - Review benchmarking results to assess outliers
  - Review alternate methods of reducing the scope of the audit based on specialty, volume and revenue. Examples:
    1. Only significant outliers should be considered for audit (Thresholds)
    2. 65% - 80% of primary care revenue is based on established E/M visits
    3. Usually a few services account for 70% - 80% of net revenue for specialty practices
    4. Review the highly productive physicians first

*See Handout*

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## Creating an Audit Plan

- Sampling process/consideration:
  - Retrospective claims (prior 3 months)
  - Non-statistical sampling e.g. judgment sampling
  - Population is stratified (stratums) based on benchmarking
  - Sample size – small samples based on risk
  - Extrapolation – NONE
    1. Since the sample size was controlled by the auditor it cannot be measured
- Analysis of Sample
  - Provider documentation in comparison to CPT codes
  - Accuracy of diagnoses
  - Accuracy of place of service codes
  - Functionality an use of the EMR system

*See Handout*

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## Creating an Audit Plan Pt 2

- Error/Accuracy Rate – NONE
- Findings Categories:
  - **Observations\*** – Observations which may affect the accurate assignment of the diagnoses, procedures or compliance with other program requirements and require a management response and corrective action plan.
  - **Incidental Matters** – Matters noted during the review that do not require a management response.
- Audit Cycle – at risk providers every year all other providers 3-5 year cycle.

\* Observations identified are subject to the following internal Policy, "Correction of Errors in Federal and State Health Care Program Payments"




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## Using Benchmarking for Acquisitions – Due Diligence \_\_\_\_\_

- Benchmarking of data is key initial step in due diligence for physician employment or acquisitions
  - Identify potential risks prior to closing
    1. Go or No Go
  - Identify compliance issues
  - Identify opportunities for integration
    1. Education
    2. Coding and Billing Hold

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<p><b>01</b> Cloning</p> <p><b>02</b> Incident 2 – use NPPs etc</p> <p><b>03</b> Copy Paste</p> <p><b>04</b> Provider Based</p> <p><b>05</b> Medically Necessary</p>	<h2>Current Issues / Challenges _____</h2> 
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### Questions & Contact Information

*Please reach out if you have questions or need help starting risk assessment benchmarking and building a proactive audit plans.*

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# THE RISK

## BASED APPROACH TO Auditing and Monitoring Employed Physicians

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*Trinity Health's Simple 7-Step Audit Process to Proactively Reduce Their Compliance Risk while Maintaining Maximum Resource Efficiency.*

*Andrei M. Costantino, MHA, CHC, CFE  
Vice President of Integrity & Compliance - Trinity Health*

# STEP 1

## Identify Potential Risk Via Benchmarking

Benchmark employed physician data to external data sources to determine if the physician is an outlier compared to their peer group.

The following benchmarks should be considered:

*A) E/M Bell Curve Analysis*

*B) High Risk Modifiers*

*C) High Dollar (Reimbursed) Surgical and Imaging Services*

*D) Visits per Day*

*E) wRVUs Analysis*

*F) Analysis of Ancillary Services*

*G) Medicare Reimbursement (CMS Utilization & Payments Database)*

To conduct these type of analytics you can either:

- 1) Create the analysis from scratch leveraging CMS reference data and either excel or an in-house BI Solution
- 2) Investigate the current reporting capabilities of your EMR or Practice Management Software
- 3) Utilize a third-party analytics tool that specializes in these type of compliance analytics

***Discuss alternate methods of reducing the scope of the audit based on specialty, volume and revenue. For example:***

- ***65%-80% of primary care revenue is based on established E/M visits***
- ***Usually a few services account for 70% - 80% of net revenue for specialty practices***
- ***Review highly productive physicians first***

## **STEP 2**

### **Focus On Your Outliers**

Significant outliers from the benchmarking analysis should be considered for audit. (Create guidelines regarding what constitutes a significant outlier).

Goal is to audit services that make up 60% to 80% of net revenue.

## **STEP 3**

### **Sample Process & Considerations**

A) Retrospective claims (prior 3 months)

B) Non-statistical sampling – judgment sample. Sample language – "It is important to note that very small samples generate greater sampling risk (i.e. margin for error), therefore, the results cannot be extended or extrapolated to reach any conclusions regarding the population as a whole." Or, "The sample selection was controlled by the auditor and cannot be measured."

# Sample Process & Considerations Continued

C) Population is stratified (stratums) based on benchmarking.

D) Sample size – small samples based on risk. For example, the risk assessment identified 99214 as an outlier. The audit should consist of 3-5 claims for E/M code 99214 to determine if the documentation meets the level billed.

F) Extrapolation – NONE, since the sample size was controlled by the auditor it cannot be measured.

## STEP 4

### The Analysis of the Sample

Assess the nature of the claims to evaluate the medical records documentation in comparison to the billed claims using the following information:

- Provider progress notes
- CMS 1500 claims data
- The Centers for Medicare and Medicaid Services (CMS) 1995 or 1997 Documentation Guidelines for Evaluation and Management (E/M) services  
[http://www.cms.hhs.gov/MLNEdWebGuide/25\\_EMDOC.asp](http://www.cms.hhs.gov/MLNEdWebGuide/25_EMDOC.asp)
- The 2016 International Classification for Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)
- Current Procedural Terminology (CPT)



# The Analysis of the Sample Continued

- Medicare Claims Processing Manual, Pub 100-04, Chapter 12, §20, Medicare Physicians Fee Schedule (MPFS)  
<http://www.cms.gov/manuals/downloads/clm104c12.pdf>
- Medicare Claims Processing Manual, Pub 100-04, Chapter 12, §30.6.1, Selection of Level of Evaluation and Management Services  
<http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>
- Medicare Claims Processing Manual, Pub 100-04, Chapter 12, § 30.6.1.1 - Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>
- AHIMA, Guidelines for EHR Documentation to Prevent Fraud  
[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_033097.hcsp?dDoc Name=bok1\\_033097](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_033097.hcsp?dDoc Name=bok1_033097)
- Medicare Program Integrity Manual, Pub 100-08, Chapter 3, §3.3.2.4, Signature Requirements  
<http://www.cms.hhs.gov/manuals/downloads/pim83c03.pdf>

## Review the following:

A) Provider documentation in comparison to CPT codes, place of service and diagnoses reported for claims submission.

B) The accuracy of diagnoses, submitted on claim forms, in sequencing and specificity as documented in the medical record.

C) The accuracy of place of service codes reported on the claim.

D) The functionality and use of the EMR system in relation to 1) authorship integrity; 2) system audit functionality, and 3) documentation integrity.

**Functionality and Use of an EMR, review the following risk areas:**

A) **Authorship integrity:** The origin of recorded information that is attributed to a specific individual or entity. When there are multiple authors or contributors to a document, all signatures should be retained so that each individual's contribution is unambiguously identified.

B) **Audit Integrity:** Audit trail functionality allows for determination of who created the document, if and when corrections or amendments were made to the documentation, who made the changes, or the nature of the change. EHRs that lack adequate audit trail functionality create uncertainty as to the integrity of health record documentation.

C) **Documentation integrity:** A provider not fully aware of the consequences of defaulting information or templates and/or cut and copy functions may fail to take the time necessary to review all defaulted data for changes and leave incorrect information in the record. This can lead to an inappropriate clinical picture and the accuracy of the entire documented entry may be questioned.

## STEP 5

### Error/Accuracy Rate

The determination of a pass/fail error rate threshold should be based on the health systems's own internal policies.

# STEP 6

## Categorizing Your Findings

A) **Observations**\* - Observations which may affect the accurate assignment of the diagnoses, procedures or compliance with other program requirements and require a management response and corrective action plan.

B) **Incidental Matters** – Matters noted during the review that do not require a management response.

\*- *Observations identified are subject to the following Trinity Health internal policy, "Correction of Errors in Federal and State Health Care Program Payments"*

# STEP 7

## The Audit Cycle

The recommended audit cycle is the following:

- At risk providers every year
- All other providers 3-5 year cycle

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### For Additional Questions:

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Health Care Compliance Association  
2017 Annual Compliance Institute

**Self-Disclosure: Obligations, Options, Outcomes**

David Fuchs, Office of Inspector General, U.S. Department of Health and Human Services  
Tony Maida, Partner, McDermott Will & Emery, LLP  
Frank E. Sheeder, Partner, Alston & Bird, LLP

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Agenda

- Obligations: What are the rules
- Options: How to decide whether to disclose and where to disclose
- Outcomes: What to expect in resolving the disclosure under each option

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Obligations

- Is there an overpayment?
  - Pay attention to legal authority (statute, regulation, sub-regulatory guidance)
  - Condition of payment or participation?
- Is there fraud liability exposure?
  - Legal and factual question
- 60 Day Rule
  - How does U.S. ex rel. Kane v. Continuum impact the analysis?
- Contractual Requirements
- Kindergarten Rule
- What is the government's expectation to disclose?

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### Options: Deciding Where to Disclose

- If you decide there is an overpayment or potential liability, where to report and return:
  - Contractor Refund
  - CMS SRDP
  - OIG SDP
  - State Medicaid agencies
  - DOJ



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### Self-Disclosure Options

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"> <li>• Simple process/ minimizes legal fees</li> <li>• No reduction in amount</li> <li>• No release of any kind</li> <li>• Six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Track record suggests likelihood of reasonable settlement</li> <li>• Stark only</li> <li>• 1877(g)(1) release</li> <li>• <i>De facto</i> six-year lookback period</li> </ul>	<ul style="list-style-type: none"> <li>• Benchmark 1.5 multiplier</li> <li>• Release of CMPL and exclusion</li> <li>• Potentially reduce FCA exposure</li> <li>• Updated guidelines</li> <li>• Six-year SOL</li> </ul>	<ul style="list-style-type: none"> <li>• Release of State authorities only</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• SOL varies</li> </ul>	<ul style="list-style-type: none"> <li>• Broadest release</li> <li>• Uncertainty on posture and penalty amount</li> <li>• Experience may vary widely</li> <li>• Six-year SOL</li> </ul>

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### OIG Self-Disclosure Protocol

- What not eligible
  - Errors or overpayments where no potential violation of CMPL
  - Requests for opinion on whether there is a potential violation
  - Stark-only conduct
  - Settlement less than \$10,000 (\$50,000 for AKS)



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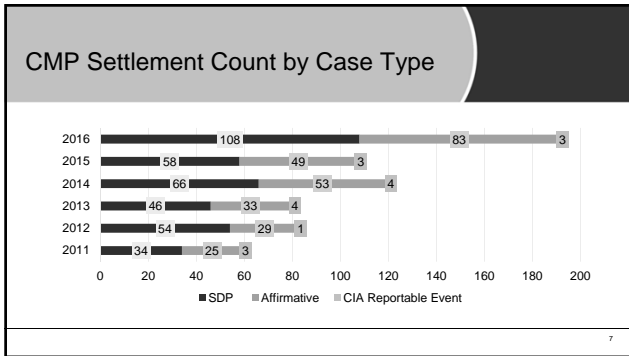
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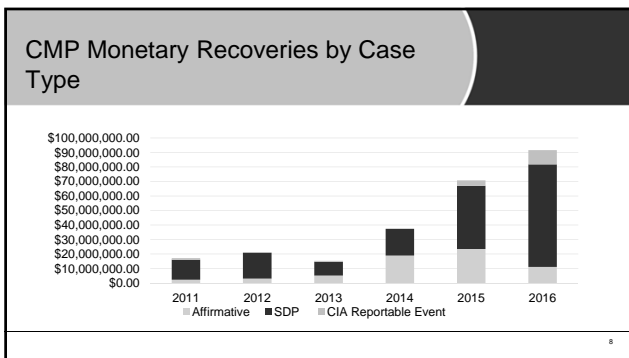
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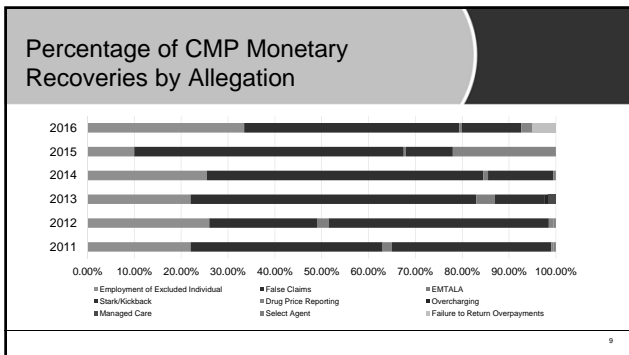
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### OIG SDP Resolutions

- Benchmark 1.5 multiplier
  - Claims Calculation
    - All claims or statistical sample of 100 claims minimum
    - Use point estimate (not lower bound)
  - Excluded persons – salary and benefits-based
  - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- Does not secure FCA release, but can help limit exposure, including 60-day issues
- More predictable process, but DOJ may become involved

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### Common Mistakes Providers Make in the OIG Self-Disclosure Protocol

- States in the initial disclosure or at settlement that there is no fraud liability.
- Does not identify potential laws violated.
- Discloses the conduct too early.
- No plan to quantify damages.
- Conduct only violates the Stark law.
- Refuses to pay a multiplier.
- Lack of cooperation.
- Argues damages should be calculated in a manner contrary to the revised SDP.

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### Outcomes: Disclosure Pros and Cons

**Pros**

- Legal duty if received overpayment
- Start from positive place
  - Good corporate citizen
  - Effective compliance program
- Can be prepared
- Less disruptive
- Lower multiplier more likely
- Presume no CIA/exclusion
- Closure
- Less reputational effect possible

**Cons**

- Some pathways are less predictable than others
- Payment usually necessary
- Not place to get agency's opinion
- Can be long process
- Referrals among agencies possible
- Follow on actions by private insurance or states
- Some publicity still happens

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Appendix

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Overpayment Statute: ACA, *Section 6402(a)*;  
 SSA *Section 1128J(d)*; 42 U.S.C. § 1320a-7k(d)

- **In general.** If a person has received an overpayment, the person shall –
  - report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  - notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- **What is an “Overpayment?”**
  - The term “**overpayment**” means any **funds** that a person receives or retains under subchapter XVIII or XIX of this chapter to which the person, after **applicable reconciliation**, is not entitled under such subchapter.

Overpayments and False Claims

- **Deadline for reporting and returning overpayments.** The later of –
  - the date which is 60 days after the date on which the overpayment was identified; or
  - the date any corresponding cost report is due, if applicable
- **Enforcement:** If an overpayment is retained past the deadline, it may constitute an “obligation” under the False Claims Act.
  - False Claims Act: imposes liability for “knowingly concealing or knowingly and improperly avoiding or decreasing an obligation” to pay the United States. (31 USC 3729(a)(1)(G))
  - ACA also created new CMLP action for a penalty of up to \$10,000 per item or service and three times the amount claimed and exclusion for “Any person . . . that **knows** of an **overpayment** . . . and does not report and return the overpayment in accordance with [section 6402].”



### Final Rule, 81 FR 7954 (February 12, 2016)

- Regulatory provisions interpreting the Overpayment Statute (42 C.F.R. 401.301-5)
  - Lookback period
    - 6 years from the date the overpayment was identified
  - How to report and return
    - Use the “most appropriate mechanism” based on the “nature of the overpayment”
  - Meaning of identified
    - When a provider or supplier “has determined, or should have determined through the exercise of reasonable diligence, that [it] received an overpayment and quantified the amount of the overpayment”
    - “Should have determined” means the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment

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### When does the 60 day clock start?

- CMS said providers have time to conduct the “reasonable diligence” before the 60 day clock starts to run
  - After receiving “credible information” the provider needs to undertake reasonable diligence
  - CMS articulated a 6 month “benchmark” for conducting reasonable diligence, except in “extraordinary circumstances” such as Stark issues, natural disasters, or states of emergency
  - The 60 day clock starts to run when either:
    - When the reasonable diligence is completed, or
    - On the day the credible information was received and the provider failed to conduct reasonable diligence (and an overpayment in fact was received)

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### What does “reasonable diligence” mean?

- Reasonable diligence includes both:
  - Proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments; and
  - Investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment
- CMS believes that “undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of ... Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on a failure to exercise reasonable diligence if the provider or supplier received an overpayment”

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### What does "credible information" mean?

- Includes information that supports a reasonable belief that an overpayment may have been received
- Determining whether information is credible is a fact-specific inquiry
- Examples:
  - Government or contractor audit results
    - "Obligation to accept or appeal" – or disagree with findings but not appeal
    - Scope of duty to review is limited to the issue audited
  - However, providers may need to review claims beyond the audit time period to meet the 6 year lookback period
  - General government work, such as the OIG Work Plan or CMS transmittals, do not constitute "credible information" triggering the rule's obligations. CMS encourages providers to use publically available sources to inform their compliance program planning
- Hotline complaints
  - May qualify as credible information depending on facts
  - Preamble gives examples of single detailed complaint or multiple complaints about the same issue
- Significant increases in Medicare revenue with no apparent reason

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### Thank you!

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**Caring**

Geisinger Health Plan

## CMS provider accuracy

Risk assessment and monitoring strategies  
Medicare Advantage plans

Geisinger Health Plan may refer collectively to Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Specialty Insurance Company, unless otherwise noted.

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### Who is Geisinger?

- Integrated health system
- Clinical side
  - 12 hospital campuses
  - 1,600 employed physicians
  - 30,000+ employees
- Health Plan
  - All lines of business
  - 560,000+ members
  - 110 hospitals
  - 30,000+ primary care and specialist providers



Geisinger Medical Center

Geisinger Health Plan

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### Agenda

- Regulations
  - Understanding the Centers for Medicare and Medicaid Services (CMS) expectations
- Assessment
  - Determining the risk for your company
- Actions
  - Improving processes to increase accuracy
- Monitoring
  - Establishing routing activities to measure compliance

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### Regulatory expectations

- 2016 CMS fall conference included a session dedicated to review results and outline expectations
- Complaints and congressional inquiries led to pilot audit
- Focus on accuracy
  - Marketing to prospective members
  - Informed decision making
  - Ability to contact providers
  - Network availability standards



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### CMS audits

- 2016 round one audit
  - February through August
  - 54 parent organizations
  - 108 providers per organization
- Provider focus
  - Primary care providers
  - Oncologists
  - Ophthalmologists
  - Cardiologists

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### CMS review elements

Provider name
National Provider Identification (NPI)
Provider specialty
Practice name
Phone number
Street address
Does the provider work at the location?
Is the plan accepted at location?
Is the provider accepting/not accepting new patients?



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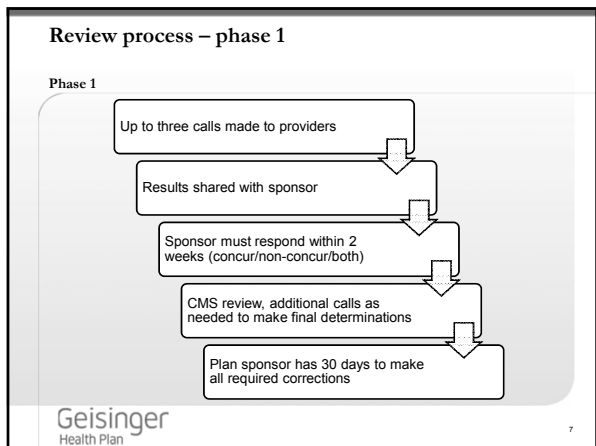
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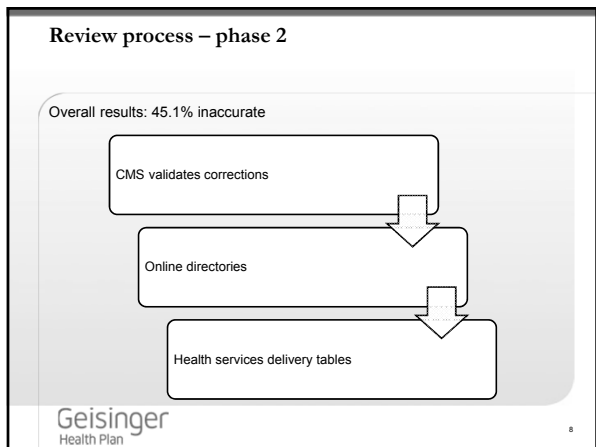
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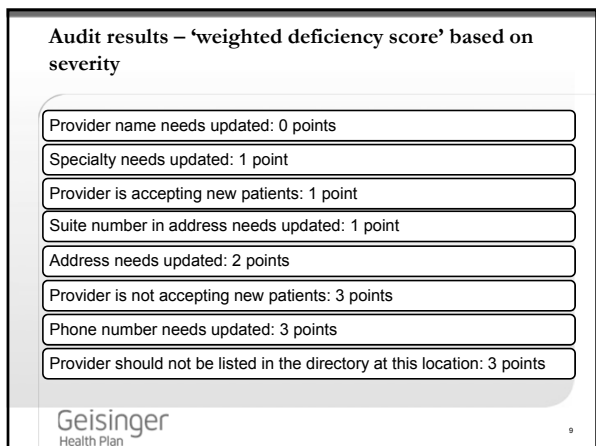
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### How is the weighted deficiency score calculated?

- Maximum deficiency score example
  - Provider locations x 3

- Weighted final deficiency score example
  - Sum of location deficiency scores/maximum deficiency score

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### Phase one audit results

Parent organizations	Deficiency score range	Compliance action
2	1.77% to 4.63%	No action taken
31	19.66% to 39.48%	Notice of non-compliance
18	41.37% to 58.79%	Warning letter
3	65.08% to 70.75%	Warning letter with business plan request

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### Regulatory expectations

**State level**

- Pennsylvania (Notice 2015-07 45 Pa.B. 5744)
  - Pennsylvania law prohibits unfair or deceptive acts or practices by insurers, including publishing or circulating an advertisement, announcement, or statement which is untrue, deceptive, or misleading. If a person receives health care services from a provider listed in the insurer's provider directory as in-network, and the insurer then attempts to settle that claim as if the provider were out-of-network, her department will consider this to be an unfair claim settlement practice.
- New Jersey (§ 11:24C-4.6 Standards for accuracy of provider directory information)
  - Carriers shall confirm the participation of any provider who has not submitted a claim for a period of 12 months or otherwise communicated with the carrier in a manner evidencing the provider's intention to continue to participate in the carrier's network and for whom no change in provider status has been reported by CAQH.

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**Assessment**

- How often is your online directory updated?
- Is there a process in place to make updates?
- Do you have any providers listed at more than six locations?
- Have you received any member complaints?
- How many providers have not filed a claim within the last 12 months?
- Call providers randomly
  - Compare information to what is online and verify that it is being reviewed by CMS

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**Actions for improvement – start now!**



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**Direct provider outreach**

- Provider outreach
  - Vendor services (call centers or those offering full range of solutions)
  - Health plan alliance-type organizations
  - Call blitz; contact all network providers
- Challenges
  - Accuracy of third party information
  - Time consuming
  - Inconsistent information depending on who you speak to at providers office

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### Creating tools and processes

- Create tools and develop processes to update information
  - Instruct front-line phone contact center to verify provider information upon receiving calls
  - Give providers the ability to update info via a web portal
  - Require confirmation of information at each logon
- Challenges
  - Dependent on providers initiating contact

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### Direct mail

- Hard copy direct mail reminders
  - Include in provider communications
- Challenges
  - Static communication
  - Does not require provider action

**Update your information**  
 It is essential that we have your current information in order to best serve GHP members and ensure you receive important communications. You can update your information conveniently through our online tool. Visit the Healthcare Providers section at [TheHealthPlan.com](http://TheHealthPlan.com), or look in Provider Tools on the GHP plan central page at [NavNet.net](http://NavNet.net) for links to the form. Options include:

- Add - add a provider or location (credentialing required for new providers)
- Change - indicate changes to an existing provider's profile, office location, TIN, etc.
- Both - make both additions and changes on one form
- Term - initiate a provider termination or remove a practice location
- Upload documents - attach existing files and documents that describe your changes

GHP asks that you review your demographic information on a monthly basis and report any changes or updates. You can verify your current provider profile by using the Find Providers function on the left navigation bar at [TheHealthPlan.com](http://TheHealthPlan.com) to search the online directory for your office.  
 If you have any questions on how to use the online add/change form, please contact your account manager at 800-876-5337.

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### Provider orientation

- Update and/or highlight new provider orientation
  - Presentations and hard copy materials
  - Stress importance of updated/correct directories
- Challenges
  - Time between orientation and any changes
  - Amount of information distributed at orientation
  - Dependent on provider action

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### Utilizing claim information

- Utilizing claim information
  - Develop reporting to identify providers with zero claims activity over the past 12 months
  - Contact providers to verify network status
  - Remove providers who do not respond
- Challenges
  - Time consuming to develop reports and send letters via mail
  - Costly (especially if sending via certified mail for no first response)

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### Correcting addresses

- Develop process to contact providers with incorrect address (returned mail, incorrect fax number, etc.)
  - Notify employee(s) responsible for accuracy of returned mail or fax
  - Utilize alternative information such as e-mail and phone
- Challenges
  - Timeliness
  - Manual process
  - Limited alternative information

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### Updating contractual language

- Update contractual language
  - Include provision to hold provider financially responsible for any compliance actions taken by regulators; including monetary reimbursement
- Challenges
  - Provider acceptance
  - Legal costs associated with contract changes and enforcement

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### Verifying contact information

- Verify contact information whenever a provider calls with a prior authorization request
  - Modify call scripts to gather information at the beginning of every call
- Challenges
  - Additional time on phone for staff
  - Provider discontent

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### Audit readiness for immediate improvement

Focus on updating areas highlighted by CMS

- Cardiology
- Oncology
- Ophthalmologists
- Primary care

Perform call blitz activities

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### Monitoring

- Communication
  - Compliance and audit staff call providers weekly to verify information
  - Develop process to notify provider network team of changes
  - Improve communication channels
- Tracking and reporting
  - Implement tracking system to identify providers that have not been contacted
  - Report results via metrics
  - Mimic CMS scoring



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**References/Resources**

- November 13, 2015 CMS Memo "Provider Directory Requirements – Update"
- May 26, 2016 CMS Memo "Continued Monitoring of Medicare-Medicaid Provider and Pharmacy Directories"
- September 8, 2016 HPMS E-mail "Follow Up to the MMP Provider and Pharmacy Directory Technical Assistance Webinar"
- January 13, 2017 HPMS E-mail "Release of CMS's Online Provider Directory Report and Supporting Data"
- January 17, 2017 CMS Memo "Provider Directory Policy Updates"

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**Contact information**

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Questions?

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**Getting OCR Audit-Ready in  
7 Steps:**

Kimberly B. Holmes, Esq.  
Senior Vice President & Counsel  
Cyber Insurance, Liability & Emerging  
Risks  
March 28, 2017




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**Remember first of all...** 

Pursuant to the *HIPAA Security Rule provision on Audit Controls*, 45 C.F.R. sec.164.321(b):

- Covered Entities and Business Associates *must implement hardware, software and/or processes that both record and review activity in IT systems containing or using electronic PHI.*

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**Audit Insight from the recent OCR Enforcement Landscape** 

- Among Others in 2016:
  - University of Mississippi Medical Center
  - Oregon Health & Science University
  - \$2.7M CMP imposed against each CE
  - *Failure to act on identified problems/risks*
- Already in 2017:
  - 3 Major CMP Cases
  - Presence Health Network (\$475k), Children’s Hospital of Dallas (\$3.2M CMP imposed), *Memorial Health Care System (\$5.5M)*

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An Audit Roadmap to Learn From...  
Memorial Health Care System (2/16/17)



OCR Findings:

- Impermissible disclosure of PHI in violation of the Privacy Rule
- Failure to implement procedures to *regularly* review records of information system activity such as audit logs
- Failure to implement policies and procedures to *review and modify* users' access to PHI.

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OCR Audit Control Guidance (Jan. 2017)



- Secure Audit Logs & Audit Trails
  - Audit Logs: Records of events based on applications, users, systems (NIST)
  - Audit Trails: Maintain a record of system activity by application and user activity (NIST)
- Use "reasonable and appropriate" tools to collect, monitor and review\* audit controls
  - \* Restrict review access; need-to-know basis only

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OCR Audit Control Guidance (Jan. 2017)  
(Cont'd)



- Lack of access controls and failure to regularly review audit logs enables hackers and wrongdoing insiders to cover their tracks
- Implementing audit controls and reviewing audit logs *regularly*:
  - Facilitates easier recovery from breaches
  - May help prevent them from happening in the first place

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### Types of Audit Trails



#### Application

- Monitors and logs user activities; when data files are opened/closed, created, read, edited or deleted

#### System-level

- Tracks successful/unsuccessful log-on efforts; and what application the user was seeking to access

#### User

- Monitors user activity by tracking events user initiates (log-on attempts, access to files, etc.)

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### 7-Steps to OCR Audit-Readiness



- Gather your Team (in-house, external resources as needed (i.e, Privacy/HIPAA Counsel, Forensics)
- Determine "Reasonable and Appropriate" Audit Controls to be Implemented
- Conduct/Update enterprise-wide Risk Analysis/Risk Assessment of security risks/weaknesses
  - Understand first what PHI and Tech/IT inventory/assets you actually have

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### 7-Steps to OCR Audit-Readiness (Cont'd)



- Implement or Review enterprise-wide Risk Management Plan (to address identified risks/gaps/weaknesses)
  - Implement/Enforce/Test/Revise as Needed
  - Document, Document, Document
  - Rationale for Resource Allocation/Plan for Addressing Non-Compliance where Applicable
- Review/Revise Policies & Procedures As Needed for:
  - Information systems activity review;
  - Establishing, modifying and terminating access
- Provide Workforce Training
- Regularly review ALL of the above in *normal course of business*

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What are "Reasonable and Appropriate" Audit Controls? 

- Consider Your Risk Analysis results as well as current:
  - Infrastructure
  - Hardware and software security capabilities
- Commensurate with available financial and human resources
- What your Policies & Procedures can support

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4-Factor Risk Assessment 

- Identify your risks/vulnerabilities
- Determine remediation steps needed
- Allocate Resources to address; Outline a rationale (and plan) where not currently addressing a particular risk/vulnerability
- TAKE ACTION to address the risks identified
  - Identified risks/vulnerabilities set the FLOOR of remediation responsibility
  - Clock is ticking from this point...until an event occurs
  - Don't wait to address
  - At minimum: document when/what steps will be taken for all identified risks

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Be Aware of OCR's past hot buttons... 

- Implement robust physical safeguards
  - No unrestricted access to unauthorized individuals
  - Implement Access Controls & Device/Media Controls
- Encrypt and password-protect all points of data access
  - Not required, but consider at minimum:
    - Document reasons for current status if not fully encrypted as Risk Analysis/Assessment will likely point to risks of unencrypted PHI
- Implement/Distribute & Enforce a mobile device policy

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# QUESTIONS?

[kimberly.holmes@idexpertscorp.com](mailto:kimberly.holmes@idexpertscorp.com)

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## Get Started

- There are many different types of careers offered by being involved in compliance:
  - Don't be shy; many of these opportunities weren't even available ten to twenty years ago.
  - This is a developing career path. Help the process.
  - Continue the growth by identifying areas of assistance through the compliance process.
  - Healthcare developments and changes offer nothing but prospects for this field.

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## Join a Compliance Organization

- Not only are there national organizations, there are regional, state and local groups that meet officially or unofficially within their geographic area.
- The best way to identify needed information is through meetings and networking. Always confirm the information you receive through anecdotal conversation with official and appropriate documentation.

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## Join a Compliance Organization

- Compliance organizations offer information through:
  - Publications
  - In-person Meetings
  - Webinars
  - Email Blasts
  - Networking Opportunities
  - Job Boards

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### Use the Materials Made Available to You

- There are many areas that compliance professionals can search to improve their knowledge and expertise in any related healthcare topic.
  - The Center for Medicare and Medicaid Services
    - Join the Medicare Learning Network – ongoing emails and updates will keep you on top of changes going on in the industry. Where Medicare goes, the rest of the industry follows.
    - Use the online Medicare manuals: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

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### Use the Materials Made Available to You

- Don't forget to review the PIM (Program Integrity Manual).
- Read the OIG workplans: <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/HHS%20OIG%20Work%20Plan%202017.pdf>
- Review all publications provided to you by the Compliance Organization that you join.
- Access the webinars and save the powerpoint slides.
- Develop your expertise.

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### Use the Job Board

- Whether you are looking for a new job or not, the job board will help you identify:
  - What new types of opportunities are out there;
  - What types of new jobs are being created;
  - If your organization should consider that type of position;
  - What value the new positions would add to the organization.

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## Use the Job Board

- What areas of the country are hiring?
- What is going on in those geographic areas that might affect you in the future?
- Should you reach out to these organizations to find out what types of needs these jobs are going to address?

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## Attend Meetings

- Go to any Compliance Meeting that is available to you.
  - Don't attend based on location but based on the type of education that is being presented. Any National, Regional, State or Local meeting can add value.
  - Identify the needs of your organization that this type of meeting will address.
  - ATTEND THE PRESENTATIONS!
  - Introduce yourself to the person on either side of you.

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## Attend Meetings

- Take your enthusiasm for new ideas and opportunities back to your organization.
- Implement new ideas that will work for your group and keep the balance in the back of your head for future use.
- Encourage others in your organization based on the information you gained at these meetings.
- Have an annual budget that addresses costs and benefits for meeting attendance.

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## Network, Network, Network!

- Make it your goal to meet ten new people at each meeting that you attend (unless there are ten people at the meeting).
- Again, introduce yourself to each person on either side of you at each general or breakout session.
- If you are alone, seek out other individuals who appear to be attending as a single.

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## Network, Network, Network!

- Ask people about themselves:
  - Where are you from?
  - Who do you work for?
  - What's your favorite football team (basketball, baseball, movie, shopkins, etc.)?
- Identify kindred spirits, people who you would like to continue a relationship based on:
  - Like Positions
  - Resource Availability
  - Career Development
  - You Just Like Them

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## Speak and/or Write Articles

- Speaking at a conference gives you the following:
  - Proficiency on the topic for which you are speaking
  - Consideration as an expert on the topic for which you are speaking
  - Enhancement of your expertise for resume building
  - Name Recognition (Getting your name into the organization as someone who is willing to share expertise)

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## Speak and/or Write Articles

- Writing an article can be a rewarding experience:
  - Makes you accountable for the information you are providing;
  - Documents that you have writing and research skills (always important in the compliance field);
  - Adds to your resume and your accomplishments;
  - Increases your expertise in the compliance field;
  - Develops your reputation as a compliance expert.

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## Get Out There

- Set Goals for the Coming Year
  - Develop one new expertise in your area of healthcare for the coming year.
  - Meet at least twenty new compliance individuals in the coming year (you can do that here).
  - Pledge to write at least one article or perform one speaking engagement (live or webinar) in the coming year of 2017, or, if speaking- the first six months of 2018, as speaking engagements are usually booked a minimum of six months early.

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## Get Out There

- Attend at least one local or regional meeting in the coming year (in addition to this one).
- If there is no local or state organization for compliance in your area, start one.
- Share your expertise through networking and getting to know your fellow professionals.

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## Have Fun!

- You have to do this every day.
  - Meet new people
  - Learn new things
  - Go to new places
  - Enjoy Life!

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## Thank You

Cristine M. Miller, CMPE, CCS-P, CHC

Mountjoy Chilton Medley LLP  
**502.882.4341**  
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**CRIS.MILLER@MCMCPA.COM**

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## IRS Circular 230 Disclosure

As a result of perceived abuses, the Treasury has recently promulgated Regulations for practice before the IRS. These Circular 230 regulations require all accountants to provide extensive disclosure when providing certain written tax communications to clients. In order to comply with our obligations under these Regulations, we would like to inform you that any advice given in this presentation, including any attachments, cannot be used to avoid penalties which the IRS might impose, because we have not included all of the information required by Circular 230, nor have we performed services that rise to this level of assurance.

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**LEGISLATIVE  
 CHANGE:  
 CONGRESSIONAL  
 ACTIONS  
 AFFECTING  
 HEALTH CARE  
 PROVIDERS**

**KIMBERLY BRANDT,**  
CHIEF OVERSIGHT COUNSEL, U.S. SENATE COMMITTEE ON FINANCE

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**Today's Presentation**

- A View from Capitol Hill
  - The 115th Congress & The Senate Finance Committee
  - Legislative Process Overview
- Recent Legislative & Policy Changes Affecting Physician Practices
  - Brief Medicaid Overview
  - Medicaid Reform and Per Capita Caps
  - CMS Audits and Appeals Program
  - Stark Law

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**Disclaimer & Fine Print**

The comments expressed by Kimberly Brandt are her own  
 opinions and ideas, and do not reflect the opinions of the  
 Senate Finance Committee  
 or Chairman Orrin G. Hatch

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## A View from Capitol Hill



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### Standing Committees

- Agriculture, Nutrition, and Forestry
- Appropriations
- Armed Services
- Banking, Housing, and Urban Affairs
- Budget
- Commerce, Science, and Transportation
- Energy and Natural Resources
- Environment and Public Works
- Finance**
- Foreign Relations
- Health, Education, Labor, and Pensions
- Homeland Security and Governmental Affairs
- Judiciary
- Rules and Administration
- Small Business and Entrepreneurship
- Veterans' Affairs

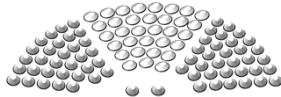
## 115<sup>th</sup> Congress - Senate



52 Republicans

46 Democrats

2 Independents



### Special, Select, and Other

- Indian Affairs
- Select Committee on Ethics
- Select Committee on Intelligence
- Special Committee on Aging

### Joint

- Joint Committee on Printing
- Joint Committee on Taxation
- Joint Committee on the Library
- Joint Economic Committee

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## UNITED STATES SENATE COMMITTEE ON FINANCE

### What is it and What does it do?

#### Finance Committee Jurisdiction:

- Tax matters
- Social Security
- Medicare & Medicaid
- Supplemental security income
- Family welfare programs
- Social services
- Unemployment compensation
- Maternal and child health
- Revenue sharing
- Tariff and trade legislation
- Oversees 50% of Federal Budget

#### History

- During the 14th Congress (1815–1817), the Senate created the Select Committee on Finance to handle some of the proposals set forth in President James Madison's message to Congress
- On December 10, 1816, the Senate established the Committee on Finance as a standing committee of the Senate

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**UNITED STATES SENATE  
COMMITTEE ON FINANCE**

### Committee Leadership



**Chairman Orrin Hatch**

**Ranking Member Ron Wyden**

**Democrats**

- Debbie Stabenow
- Maria Cantwell
- Bill Nelson
- Robert Menendez
- Tom Carper
- Ben Cardin
- Sherrod Brown
- Michael Bennett
- Robert Casey, Jr.
- Mark Warner
- Clare McCaskill

**Republicans**

- Chuck Grassley
- Mike Crapo
- Pat Roberts
- Mike Enzi
- John Cornyn
- John Thune
- Richard Burr
- Johnny Isakson
- Rob Portman
- Pat Toomey
- Dean Heller
- Tim Scott
- Bill Cassidy

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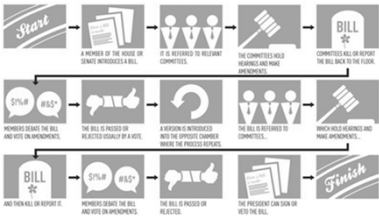
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### How a Bill Becomes a Law - Simplified




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### Recent Legislative & Policy Changes Impacting Health Care Reform




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### Brief Medicaid Overview

- Medicaid is dually-financed by the federal government and states; however, the program is administered by states within the parameters of federal law
- Under the current system, federal Medicaid financing for states is done via an open-ended model that places no caps on the amount of beneficiary spending
- Medicaid provides a guarantee to states for federal matching payments with no predetermined limit. The federal share of Medicaid is determined by a formula set in statute that is based on a state's per capita income
  - Using the current matching formula, the federal government pays an increasingly higher amount to states with larger occurrences of poverty
- The federal matching assistance percentage (FMAP) varies by state from a floor of 50% to a high of 74%

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### Program Eligibility

- Medicaid and the Children's Health Insurance Program (CHIP) cover over 74 million low-income Americans, who fall into four main groups:
  - Infants and children;
  - Pregnant women, parents, and other nonelderly adults;
  - Individuals of all ages with disabilities; and
  - Low-income seniors
- Medicaid covers many—but not all—poverty stricken Americans
  - States can opt to provide Medicaid for children with significant disabilities in higher-income families to fill gaps in private health insurance and limit out-of-pocket burden
- Medicaid assists 1 in 5 Medicare beneficiaries with their Medicare premiums and cost-sharing, and provides many of them with benefits not covered by Medicare (e.g. long-term care, dental care, and vision care)

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### Effect of ACA on Medicaid Enrollment

- Prior to the Affordable Care Act (ACA), most able-bodied low-income adults did not qualify for Medicaid coverage
  - The ACA was established to expand coverage for uninsured, able-bodied Americans with incomes up to 138% of the federal poverty level (FPL). The ACA provided federal funding for the vast majority of the cost of the Medicaid expansion
- As of January 2017, 32 states—including DC—had expanded Medicaid, and 19 states had not. In the non-expansion states, 2.6 million adults with income below 100% FPL have fallen into a "coverage gap" because their income exceeds their state's cutoff for Medicaid
- Since the ACA's expansion, the Medicaid program has become unsustainable and increasingly expensive to maintain

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### Per Enrollee Spending

- Total federal and state Medicaid spending was about \$532 billion in FY 2015 (third-largest domestic program in the federal budget)
- Medicaid is the second-largest item in state budgets, accounting for 18.7% of state general revenue spending and 28.2% of total state general revenue spending
- Although per-enrollee costs are relatively low, total Medicaid costs are high due to a large amount of people in the program and the exceedingly high costs of a minority of beneficiaries
  - Seniors and people with disabilities make up 1 in 4 beneficiaries, but account for almost two-thirds of Medicaid spending
- Medicaid plays a large role in state budgets, states have an interest in cost containment and program integrity

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### Beneficiary Outcomes

- Historically, Medicaid has faced one significant challenge—maintaining physician participation
  - Medicaid beneficiaries reside disproportionately in underserved communities—with a lack of primary care providers—which places stress on the hospital ER's that care for uninsured patients
  - Low provider compensation rates mean that many primary care physicians are unwilling to accept new Medicaid patients, as the costs of care outpace the reimbursement rates
- Factors that contribute to this problem include:
  - Complex program requirements;
  - Payment delays; and
  - Concerns about managing the care of patients with high levels of health and social risk
- Although the ACA expanded coverage to millions of previously uninsured Americans, this didn't translate into better outcomes for beneficiaries

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### Medicaid Program Integrity

- Estimated improper payments totaling more than \$29 billion in fiscal year 2015
- The lack of complete and reliable data on states' spending and financing of the non-federal share of the program hinders federal oversight
- CMS does not have the data needed to understand payments states make to individual providers, nor a standard process for assessing whether payments are economical and efficient as required by law
- There have been cases where the state's Medicaid payments exceeded the hospital's total operating costs
  - States are not required to limit Medicaid payments to Medicaid costs, but payments that greatly exceed Medicaid costs raise questions about whether those payments are economical and efficient, and ultimately used for Medicaid purposes

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## Proposed Medicaid Financing Reform

- The House bill is mainly devoted to reforming the Medicaid program, attempting to take the best elements of the ACA and merge them with an innovative approach to provide essential coverage.
- The American Health Care Act (AHCA) transitions federal Medicaid funding to a per-capita cap basis by 2020, transforming the nature of the Medicaid program
- Amongst other changes, the AHCA will address:
  - State authority to make presumptive eligibility determinations;
  - The ACA's Medicaid expansion by limiting enhanced funding;
  - Incentives for states to re-determine eligibility for Medicaid more often; and
  - Medicaid eligibility issues

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## Senate Reform Efforts

- Prior to the AHCA, the Committee sought guidance from numerous groups and organizations, including:
  - **Governor's Roundtable**—In early January, Republican governors from 11 states were invited to participate in a governor's roundtable. This meeting provided context for the flexibility that many across the nation had been requesting in their state Medicaid programs
  - **1-on-1 Meetings**—Realizing the value of seeking guidance from private organizations, the Senate Finance Committee organized meetings with numerous groups that are responsible for providing care to Medicaid beneficiaries
  - **Letter to Governors**—To inform the Committee of the issues that states face in administering Medicaid programs, a letter was sent to governors to solicit opinions and suggestions for improvements
- States are the best administrators of their Medicaid programs—they know the specific needs of their population. Proactively seeking advice for Medicaid reform from numerous parties has expanded the Committee's understanding of the key issues facing the current system

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## Per Capita Cap Reforms

- What Is a Per Capita Cap?
  - A per capita cap is a limit on per enrollee spending
  - The upper limit on spending is the per capita amount
- Why Does A Per Capita Cap Save Money?
  - This policy saves money because:
    - Growth rate is set as something such as Consumer Price Index Medical (CPI M)
    - Practically, there will also be State incentives to be more efficient
- Why Do States/Governors Prefer A Per Capita Cap Over Block Grant?
  - States receive more money as enrollment grows and less as it falls (large portions of Medicaid enrollment are generally countercyclical to the economy)
  - This policy approach recognizes the difference between different patient populations

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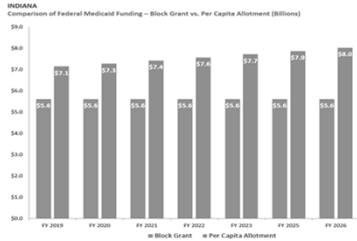
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## Illustrative Impact of PCC vs. Block Grant Approach




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## Per Capita Caps Simplified

- Using a per capita cap with Medicaid there is an upper limit in how much the federal government would reimburse states
  - The cap could be calculated, by a total user or by group population, for a base year
  - Each subsequent year, the per enrollee cap would be adjusted based on a growth rate
  - This would be used to calculate the state's total federal Medicaid funding limit based on the following product:
    - $(\text{base year per capita amount}) \times (\text{growth rate percentage}) \times (\text{enrollment})$
- Through this method of calculating payments to states would reflect changes in enrollment but would simply set an upper limit of funding

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## Understand the Per Capita Cap Approach

### Simplified overview

- Establish the base year for Medicaid enrollees (2016)
- Take the base and grow it by a given inflator (ex. CPI-M)
  - Calculate the 2019 provisional Per Capita Limit
- Calculate the Adjustment Ratio for 2019 Per Capitas
  - Adjust the separate enrollee groups Per Capitas
- Grow the 2019 Adjusted Per Capitas
- Reduce any federal payments for any over spending

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## Audits and Appeals



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## Overview of CMS's Audit Program

### What is it?

- CMS's Audit Program is designed to fight fraud, waste, and abuse by identifying and recovering improper payments made on claims for services provided to Medicare beneficiaries

### History

- The program is the product of a demonstration that ran between 2005 and 2008 and resulted in over \$900 million in overpayments being recovered and returned to the Medicare Trust Fund and nearly \$38 million in underpayments returned to health care providers

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## Recovery *Audit* Contractors (RACs)

### Who are they?

- Four private companies that run Medicare's Recovery Audit Program

### What do they do?

- Identify improper payments from Medicare Part A and B claims
- Analyze claims and review those most likely to contain improper payments, which may include:
  - payment for items or services that do not meet Medicare's coverage and medical necessity criteria;
  - payment for items that are incorrectly coded; and
  - payment for services where the documentation submitted did not support the ordered service
- Request and analyze provider claim documentation to ensure services provided were reasonable and necessary

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## Controversy



### What's the big deal?

- RACs are paid on a contingency-fee basis
- CMS coding standards are complex and constantly changing
- RACs can audit healthcare providers for up to three years

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## Understanding the RACs Appeals Process

### The five-levels of appeal include:

- Redetermination by the Fiscal Intermediary
- Reconsideration by a Qualified Independent Contractor;
- Administrative Law Judge Hearing;
- Medicare Appeals Council Review; and
- Judicial Review in U.S. District Court

### Problems with the process:

- Overloaded system, causing at least a two-year delay at the ALJ level
- High cost of RAC appeals

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## Potential Solutions

### President's Budget Proposal for FY 2016 Includes Several Medicare Appeals Legislative Proposals:

- Provide Office of Medicare Hearings and Appeals and Departmental Appeals Board Authority to Use Recovery Audit Contractor Collections
- Establish a Refundable Filing Fee
- Sample and Consolidate Similar Claims for Administrative Efficiency
- Remand Appeals to the Redetermination Level with the Introduction of New Evidence
- Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review
- Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold
- Expedite Procedures for Claims with No Material Fact in Dispute

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## Audit & Appeal Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM)

- On June 4, 2015, the U.S. Senate Finance Committee passed AFIRM
- The bill was introduced in December 2015
- **Purpose:** Seeks to increase coordination and oversight of government audit contractors while implementing new strategies to address growing number of audit determination appeals that delay taxpayer dollars from reaching the correct source

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## AFIRM Act

### • Proposed Changes—

- Improve oversight capabilities for HHS/CMS that increase the integrity of the Medicare auditors and claims appeals process
- Coordinate efforts between auditors and CMS to ensure that all parties receive transparent data regarding audit practices, improved methodologies, and new incentives/disincentives to improve auditor accuracy
- Establish voluntary alternate dispute resolution process to allow for multiple pending claims with similar issues of law or fact to be settled as a unit, rather than as individual appeals
- Ensure timely and high quality reviews, raise amount in controversy for review by an ALJ to match amount for review by District Court
- Allow for use of sampling and extrapolation, with the appellant's consent, to expedite the appeals process

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## Fraud and Abuse



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## Physician Self-Referral Law (“Stark Law”)

“[If a physician (or an immediate family member of such physician) has a financial relationship with an entity . . . then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made]” under Medicare and to some extent Medicaid

Social Security Act § 1877; 42 U.S.C. § 1395nn

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## Stark Law Problems & Potential Solutions

### PROBLEMS

- Complex and rigid law with difficult exceptions
- Diverged from original intent
- Not aligned with health care delivery reform

### SOLUTIONS

- **H.R. 2914 (2013)** – limiting scope of DHS and narrowing in-office ancillary services exception
- **H.R. 3776 (2013)** – reducing penalties for technical violations
- Expanding Medicare Shared Savings Program Waivers

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## Other Stark Law Proposals

### Legislation:

- **Medicaid Physician Self-Referral Act of 2015** (Rep. McDermott, D-WA)
  - Amends Social Security Act Title XIX to clearly apply Stark-like prohibitions
  - Creates direct False Claims Act liability for Stark Law violations

### Other Changes:

- **Obama Administration Proposed FY 2016 Budget**
  - Excludes radiation therapy, therapy services, advanced imaging, and anatomic pathology services from the in-office ancillary services Stark Law exception unless a practice is “clinically integrated” and demonstrates cost containment

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### Committee Work on Stark Law

- **December 2015** – Senate Finance Committee and House Ways and Means Committee host roundtable to hear from Stark Law experts
- **February 2016** – Reviewing submissions and preparing a white paper on proposed legislative fixes for the law
- **June 2016** – Issued white paper on potential Stark solutions
- **July 2016** – Committee Hearing on issues with Stark law – 3 witnesses, great discussion of issues

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### Physician-Owned Distributorships (PODs)



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### What are PODs?

HHS Office of the Inspector General (OIG), "Special Fraud Alert: Physician-Owned Entities" (2013)

- "Physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs)."

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## Latest POD Developments

- **June 2011** – Senate Finance Committee Report on Physician-Owned Entities
- **March 26, 2013** – OIG Special Fraud Alert on PODs released
- **October 23, 2013** – OIG’s Report on PODs (per Congressional request)

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## POD Developments

- **November 2014** – U.S. DOJ filed two False Claims Act complaints against a Michigan neurosurgeon, a spinal implant company, two of its distributorships, and the companies’ owners
- **May 2015** – A Michigan neurosurgeon, previously involved in a FCA complaint, pleaded guilty to \$11 million in fraud for unneeded surgeries and patient harm
- **November 2015** – Finance Committee PODs hearing examining pros and cons of issue
- **May 2016** – Finance Committee issues updated report on marketplace impact of PODs post OIG fraud alert
- **January 2017** – Surgeon involved in POD sentenced to nearly 20 years in prison for patient harm and unnecessary surgeries.

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## Questions?



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## Contact Information

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 PennState Health 

## Compliance Can Be Ruff A Dog's Approach

Carol Lansford, Executive Director, Valor Service Dogs  
Gabe II, Service Dog and 2016 Dog of the Year  
Kim Lansford, Chief Compliance Officer, Penn State Health

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### Agenda



- Training Principles
- Types of Learners
- Keys to Success

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### Dog-gone Smart! Lessons from a Dog Trainer

Key Principles:

- Be Respectful
- Be Responsible
- Use Positive incentives
- Have Patience
- Have Fun

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## Don't Bark Orders!

### Be Respectful

- Lead by example.
- Expect to be challenged.
- Don't issue too many commands at one time.
- When asking a dog to do something, state it as a matter of fact.
- Your outlook and presentation allows for control, NOT the leash.

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## Don't Bark Orders!

### Be Respectful

- Gain consensus – You should not force the dog to follow commands, the dog has to want to do it.
- If someone respects their trainer, they work as if their trainer is always there.
  - Do the right thing whether you're being watched or not.

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## Don't Go Barking Up the Wrong Tree! Be Responsible

- Dogs are not mind-readers. If you want them to do something, tell them.
- Leave no room for interpretation. The trainer is responsible for communicating expectations.
- While in training, monitor behaviors closely.
- Plan
  - Know what you want the end result to be before you start training. Don't make it up as you go. This leads to confusion and inability to grasp the command.

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## Don't Be A Hound! Give Positive Incentives

- Give words of encouragement whenever the opportunity arises.
- Small accomplishments are still accomplishments – Reward them!
- You can't teach what is right by only teaching what is wrong.
  - Don't use no, no, no.
  - Follow a correction with a positive direction.
- Use a variety of techniques.
- Always end training sessions on a positive note.

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## PAWS! Have Patience

- Don't throw too many commands at one time.
- Don't always expect an immediate response.
- Stepping stones
  - Break a process down to smaller parts.
  - Everything a dog learns is a building block for something else.
- If a dog is not understanding, the problem is usually the direction.
  - Don't repeat yourself over and over.
  - Find a different way.

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## It's a Dog's Life! Have Fun

- Be enthusiastic.
- Be passionate.
- Observe carefully for teaching moments and take advantage of them.



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## Types of Learners



Visual



Auditory



Kinesthetic

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## Visual Learners

Dogs	People
<ul style="list-style-type: none"> <li>• Watch other dogs and learn from them.</li> <li>• Are led by hand/treat movements.</li> <li>• Learn commands with hand signals.</li> </ul>	<ul style="list-style-type: none"> <li>• Combine PowerPoint slides with lectures.</li> <li>• Show videos, movie clips, or online visual media.</li> <li>• Write key words and draw images on a flipchart or whiteboard.</li> <li>• Show and explain diagrams. Ask them to draw a picture.</li> <li>• Include plenty of content in your handouts.</li> <li>• Provide extra material to read after your session.</li> </ul>

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## Auditory Learners

Dogs	People
<ul style="list-style-type: none"> <li>• Verbal commands/sounds.</li> <li>• Eventually all praise becomes verbal.</li> </ul>	<ul style="list-style-type: none"> <li>• Enjoy lectures.</li> <li>• Use lecture, question and answer segments, and discussions.</li> <li>• Play a song to illustrate a point or use background music when appropriate.</li> <li>• Enjoy having breakout groups to discuss the content and hear the perspectives of others.</li> <li>• Allow time at the end of the session to summarize main points and allow for additional questions.</li> </ul>

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## Kinesthetic Learners

### Dogs

- Initially dogs are rewarded with treats.
- Play games to learn more complex commands (tug, retrieve).
- Frequent breaks and quick training sessions.

### People

- Use creative activities that get people out of their chairs and doing something interesting.
- Put Play-Doh, pipe cleaners, stress balls, or other objects at their tables so they can do something with their hands.
- Hold standing discussion groups in the four corners of the room.
- Take frequent stretch breaks, even if you don't leave the room.

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## Keys to Success

1. Know your audience
2. Plan well
3. Manage your "classroom"
  - Be Respectful
  - Be Responsible
  - Use Positive incentives
  - Have Patience
  - Have Fun
4. Inspire your students
5. Continue to improve



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**Helpful Tips for Value Based Payment (VBP) Compliance Programs**

**Greg Radinsky**  
Vice President &  
Chief Corporate Compliance Officer

**Aaron Lund**  
Director of Corporate Compliance &  
Privacy Officer



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**Disclaimer**

The materials and views expressed in this presentation are the views of the presenters and not necessarily the views of Northwell Health



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**VBP Background**



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Health Law Issues 2016

1. **Alternative Payment Models—Moving from Alternative to Mainstream**  
—Robert D. Stone, Alston & Bird LLP

2. **Fraud and Abuse Enforcement**  
—Norman G. Tibbler Jr., Fargue Baker Daniels LLP

Northwell Health™

AHLA Connections February 2016

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### Alternative Payment Model Acceleration

#### U.S. Health Care Payments in APMs

2016 30%

2018 50%

Source: Health Care Payment Learning & Action Network, Alternative Payment Model Framework.  
<https://hcp-lan.org/workproducts/apm-whitepaper.pdf>

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### Commonalities Amongst VBP Programs

Improving Care

Providers/Health Systems

Patient

Care Management

Improving Health Population

Vendors/CBOs

Reducing per capita costs

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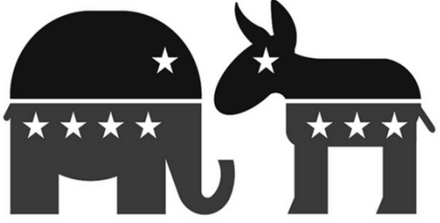
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### The U.S. Election's Impact on VBP



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### Key VBP Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback Statute
- Stark
- Civil Monetary Penalties
  - Gainsharing law
  - Beneficiary inducement



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### FCA Cases Impacting VBP

- False reports or certifications (e.g., quality, annual compliance and data certifications)
- Incorrect information submitted during the performance year must be corrected before the recertification
- Violations of Stark law, AKS, and CMPL
- Failure to return identified overpayments within 60 days
- Subpar "Quality of Care" cases



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### Sampling of Other Risks in VBPs



- Data integrity – P4R
- Funds flow
- Data Use Agreements and privacy
- Antitrust
- Tax exempt
- Fee splitting/Corp. practice of medicine
- Intermediary network entities laws
- Insurance/managed care laws
- New value based contracting models




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### VBP Compliance Nuances


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### Delivery System Reform Incentive Payment (DSRIP) Program

- Authorized through Medicaid Section 1115 waivers
- New York's Program
  - Allows the state to reinvest \$8 billion in federal savings generated by Medicaid Redesign Team (MRT) reforms
  - Specific goal to achieve 25% reduction in avoidable hospital use over 5 years
  - Projects focus on system transformation, clinical improvement, and population health improvement
  - Prescribed compliance program requirements under NY law


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### Bundled Payments for Care Improvement

- Comprised of 4 broadly defined models of care that link payments for the multiple services beneficiaries receive during an episode of care
- Places financial and performance accountability on the organization
- BPCI Awardee Agreement Compliance Program Requirements - Section 111.1.2
  - Designated compliance official or individual who is not legal counsel
  - Mechanisms for identifying and addressing compliance problems
  - Method for anonymous reporting to the compliance official
  - Regular compliance training
  - Requirement to report probable violations of law
- Requires annual certification




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### Accountable Care Organizations (ACOs)



- Why is it called an ACO?
- What is an ACO?
- Commercial ACO vs. Medicare ACO Model?
- What is the Medicare Shared Savings Program?
- Are ACO requirements different from similar government programs?




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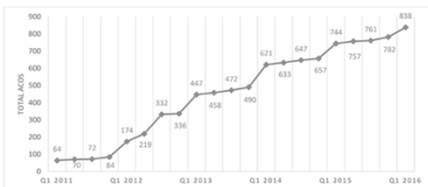
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### ACOs Growth

Figure 1 - ACOs Over Time



Source: HealthAffairs Blog  
<http://healthaffairs.org/blog/2016/04/21/accountable-care-organizations-in-2016-private-and-public-sector-growth-and-dispersion/>




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### MSSP (42 CFR 425.300) v. OIG Compliance Guidance

**MSSP – at least the following:**

- Designated compliance official who is not legal counsel
- Mechanism for identifying and addressing compliance problems
- Mechanism for reporting suspected problems related to ACO
- Compliance training for affected persons
- Reporting of probable violations of law
- Periodic updates to reflect changes in law and regulations

**OIG Compliance Guidance**

- Written policies and procedures
- Designated employee vested with the responsibility for the day-to-day operation of the compliance program
- Training and education
- Communication lines
- Auditing
- Consistency in disciplinary mechanisms
- Responding to compliance matters, including corrective action plans and reporting to government agencies




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### MSSP ACO Compliance Program

- No one size fits all
- Compliance coordination with ACO providers/suppliers
- Integration within a current compliance plan allowed
- Conduct a Compliance Gap Analysis/Assessment Early!
- ACO maintains ultimate responsibility with ACO agreement




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### Prohibition on Certain Required Referrals and Cost Shifting

- Concerns over overutilization of services for Medicare or other federal health programs with respect to care of individuals who are not assigned to the ACO
- Prohibition of an ACO from conditioning participation in the ACO on referrals of non-ACO business
- Increased scrutiny of claims data to detect patterns of cost shifting, including patterns of shifting drug costs
- Prohibition on limiting or restricting referrals of beneficiaries to ACO participants/providers/suppliers within the same ACO, except in limited circumstances
- Beneficiary retains freedom of choice




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### Avoidance of At-Risk Patients

- CMS will monitor the assignment of beneficiaries from the prior year to the current year.
- May result in oversight through a corrective action plan or termination



"Your blood sugar is high, but your salt, pepper, ketchup, mustard and grated cheese levels are fine."




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### Patient Notification

- ACO participants to post signs in their facilities indicating participation in the Shared Savings Program
- ACO participants make available standardized written information developed by CMS to beneficiaries whom they serve
- Required in setting in which beneficiaries are receiving primary care services
- Not required to notify beneficiaries in the event that it terminates participation in the MSSP




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### Beneficiary Inducements

- In general, the ACO prohibited from providing gifts, cash, or other remuneration as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO
- Flexibility to offer beneficiary inducements for healthy behavior
- Must be a reasonable connection between the item or services and the medical care of the beneficiary
- Covers free or below FMV items or services (not cash or cost sharing waivers)
  - Blood pressure cuff for a patient with a history of high blood pressure so that the patient can provide ongoing self-monitoring
- The items or services are in-kind and either are preventative care items or services to advance one or more of the prescribed clinical goals




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### Marketing Materials

- Include those materials and activities used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program
- ACOs may use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all marketing requirements
- ACO must use template language where available
- Materials must be provided in "plain" language
- Materials may not be used in a discriminatory manner or for discriminatory purpose, and must not be inaccurate or misleading
- Applies to social media and websites




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### Documentation Check List

- Documentation of waiver compliance
- Organizational charts
- Background checks
- Compliance training
- Minutes and agendas of committee/leadership meetings
- Provider/supplier lists including removals
- Updated policies and procedures
- TIN/NPI lists
- Conflict of interest reviews and disclosure statements




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### Documentation Check List (cont.)

- Shared savings/loss distribution methodologies and changes
- Approved marketing materials/CMS submissions
- ACO website updates
- Copies of all provider/supplier agreements
- Root cause analysis to address identified compliance issues (CMS likes data!)
- Corrective action plans including disciplinary documentation
- Beneficiary forms and signs (e.g., data opt-out, beneficiary notification requirement)
- Evidence of a culture of compliance (e.g., posters, compliance week, email alerts)




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### Waiver Protections

- ACO Waivers
  - Pre-participation v. Participation Waiver – Stark and AKS
  - Patient Incentive Waiver
  - Self executing but prescriptive requirements to execute
- DSRIP
  - Certificate of Public Advantage (COPA)
  - Application process
- Limitations
  - Will not cover all arrangements (e.g., commercial business)
  - Will not cover activities that are not necessary to carry out the program




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Leveraging your current Compliance Program to meet VBP requirements




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### What are the Compliance Program Requirements?

- Compliance Officer
- Elements – prescribed v. best practice
- Self reporting
- Federal v. state regulations




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### Organizational Structure

- What kind of organization is involved in VBP programs?
  - Existing organization with Compliance Program
  - New entity under a parent organization
  - Consortium
- Who is the governing body?
  - Regulatory requirements (e.g., ACO governance)
  - Audit/Compliance Committees?
- Who is involved in the VBP program?
  - Employed v. community physicians
  - Internal and external resources




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### Compliance Official

- May use existing resources
- Regulatory requirements?
  - ACO requirements
    - Legal counsel and compliance officer must be different people
    - Must report directly to ACO's governing body
  - DSRIP
    - Compliance Officer must be an employee of the PPS Lead and report directly to the PPS's chief executive or other senior administrator and periodically report directly to the governing body
    - May not be legal counsel
  - BPCI
    - May not be legal counsel




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### Policies & Procedures



- Code of Ethical Conduct
- Utilizing current policies
- Distributing/Publishing




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**Reporting Mechanisms**



- Existing reporting mechanisms
  - Helpline
  - Web-based
- Partnering with providers/suppliers' existing compliance programs
- Issues impacting one portion of an organization may also impact the participation in the VBPs




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**Compliance Training**

- Incorporate into current compliance training
- Computer-based training
  - Access
  - Flexibility
- Live training
  - Labor intensive
  - ROI
- Self learning
  - Attestations
- Governing body


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**HIPAA, Data Sharing and Data Use Agreements**

- Covered Entity or Business Associate?
  - BAA
  - State laws regarding protections for special categories of health information (e.g., mental health, substance abuse, HIV)
- Sharing of data amongst partners?
- Data Use Agreement
  - Who can request data?
  - What are the purposes for the data?
  - Minimum necessary
  - Data destruction




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## Engaging participants in the VBP Compliance Program



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### Who is your Audience?

- Board of Directors
- Employees
- Internal and external participants
- Community-Based Organizations



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### Leveraging Partners



- Who are your partners?
  - Health systems
  - Physician practice groups
  - IPAs
- What resources do these partners have to support your compliance program?
- How can you engage these partners to spread the word?
- Participation Agreements



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**Thank You**

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North Shore-LIJ Health System is now **Northwell Health**

# **Helpful Tips for Value Based Payment (VBP) Compliance Programs**

## **Handouts**

**Greg Radinsky**

Vice President & Chief Compliance Officer  
Northwell Health

**Aaron Lund**

Director of Corporate Compliance & Privacy Officer  
Northwell Health

## **Potential Core VBP Compliance Policies/Plan**

1. General ACO Compliance Plan and/or Policy
2. Code of Conduct
3. Notice of Privacy Practices
4. Conflicts of Interest
5. Marketing Materials
6. Patient Incentives
7. Record Retention
8. Reporting of Probable Violations of Law
9. Prohibited Referrals/Ensuring Freedom of Choice
10. Beneficiary Data Sharing Notification
11. Data Access and Use
12. Beneficiary Notification
13. Exclusion Screening
14. Compliance Training
15. Compliance Risk Assessment and Work Plan
16. Compliance Audit and Monitoring
17. Responding to Government Audits, Inquiries and Investigations
18. Investigations Process (including beneficiary and provider complaints)
19. Hotline
20. Compliance Committee Charter
21. Disciplinary Policy/Guidelines

## **Participation Provider Agreements**

### **Screening and Related Requirements**

1. Participant shall not employ or contract with an excluded provider/entity;
2. Participant shall conduct exclusion screenings for all new employees and monthly thereafter for all employees;
3. Participant shall maintain records of exclusion screenings and provide that to the contracting entity upon request;
4. Participant shall immediately notify contracting entity upon identifying an excluded individual; and
5. Participant shall immediately remove the excluded individual from involvement with the project or areas that may receive monies from the federally-funded health care programs.

### **Maintenance of Records and Audits**

1. Participant shall maintain records for any statutorily prescribed period of time under the program;
2. Participant shall provide contracting entity access to these records;
3. Participant shall cooperate with any government source requesting access, audit, evaluate, or inspect records related to the program;
4. Participant shall allow contracting entity access to audit, evaluate and inspect any records related to the program that the Participant is involved with;
5. Participant shall notify the contracting entity if they are contacted by a government source requesting to access, audit, evaluate and inspect records in the connection with the program; and
6. Participant shall allow contracting entity on their premises.


### **Compliance Program and Training**

1. Participant agrees to participate in the Compliance Program
2. Participant agrees to complete any compliance training modules
3. Participant agrees to abide by all contracting entity's compliance policies

## Strategic Considerations in Resolving Voluntary Government Disclosures

Health Care Compliance Association  
Annual Compliance Institute

**Patrick Garcia** – Hall, Render, Killian, Heath, & Lyman, P.C.  
**Kenneth Kraft** – Office of Inspector General, U.S. Department of Health and Human Services



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## Agenda

- Review relevant legal authorities
- Discuss CMS Final Overpayment Rule and obligations
- Review CMS and OIG self-disclosure protocols
- Discuss practical strategies and key considerations for disclosures



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## Determine Potential Liability

**Relevant legal authorities:**

- False Claims Act
- CMS 60-day Overpayment Final Rule
- Civil Monetary Penalties Law (CMP)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral (Stark) Law
- OIG Exclusion



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## False Claims Act

### The False Claims Act imposes liability on one who:

- Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
- Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim.
- Knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the U.S.

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## FCA

### • Knowingly:

- has actual knowledge of the information, OR
- acts in deliberate ignorance of the truth or falsity, OR
- acts in reckless disregard of the truth or falsity.
- no specific proof of intent to defraud is required.



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## Overpayment Statutory Requirements

- In general – If a person has received an overpayment, the person shall –
  - report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
  - notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
    - ACA, Section 6402(a); SSA Section 1128J(d); 42 U.S.C. § 1320a-7k(d)
- An overpayment must be reported and returned by the later of:
  - 60 days after the overpayment is identified, or
  - the date any corresponding cost report is due, if applicable.
- Retained overpayments beyond deadline trigger FCA liability.

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### CMS 60-Day Overpayment Rule

- Final 60-Day Rule published in 2016
  - see 42 C.F.R. § 401.303 et seq
  - Applies to Medicare Parts A & B
  - Established 6-year lookback period
  - Defined when an overpayment is “identified”
  - Clarified standard of investigation required
    - Reasonable diligence



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### CMS 60-Day Overpayment Rule

- A person has “**identified**” an overpayment when the person has or should have, through the exercise of *reasonable diligence*, determined that the person has received an overpayment *and quantified* the amount of the overpayment.
- **Reasonable diligence**
  - Timely, good faith investigation of credible information
  - Completed within **6 months**
    - Except in extraordinary circumstances (i.e. Stark investigations, natural disasters, or states of emergency)
  - Proactive & Reactive

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### 60-Day Clock

- 6 months to conduct reasonable diligence after receiving credible information of a potential overpayment.
- The 60-day clock begins to run:
  - after reasonable diligence identifies an overpayment, OR
  - when credible information was received
    - (if the provider failed to conduct reasonable diligence and in fact received an overpayment)



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### Options for Disclosure

- Refund to Medicare Contractor
- CMS SRDP
- OIG SDP
- State Medicaid Agency
- DOJ



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### Refund to CMS Contractor

- Identified overpayments
- Satisfies report and return obligation
- Simple Process
  - Claims adjustment
  - Credit balance
  - Contractor refund process
- No release



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### CMS Self-Referral Disclosure Protocol (SRDP)

- Actual or potential Stark violations only
- Separate from Advisory Opinion process
- Release of Stark overpayment liability only
- No FCA, CMP, or AKS release
- Stop 60-day clock
- Potential AKS & FCA referral to OIG or DOJ



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### SRDP Recent Developments

- Lookback period changing from 4 to 6 years
  - Revising information collection authority under Paperwork Reduction Act
  - Currently reporting years 5 and 6 is optional
  - Based on date overpayment is identified
- Pervasiveness of noncompliance
  - Quantitative
  - Not certifying other arrangements were compliant

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### SRDP Form

- Optional until approved by OMB
- Required information :
  - disclosing DHS entity
  - referring physicians
  - financial analysis quantifying overpayment
  - certification (hard copy and electronic)
- Cover letter with additional information optional



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### Stark Updates

- Clarification of writing requirement
  - Collection of contemporaneous documents
  - allow reasonable person to verify compliance w/ applicable exception
- Missing signatures (90 days)
- Indefinite holdovers



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## OIG Provider Self-Disclosure Protocol (SDP)



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## OIG/SDP: OIG Administrative Sanctions

- OIG Exclusion Authority
  - § 1128 of the Social Security Act (42 U.S.C. § 1320a-7)
- Civil Monetary Penalties Law (CMP)
  - § 1128A of the Social Security Act (42 U.S.C. § 1320a-7a)



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## OIG/SDP: CMP Case Types

- Billing while excluded
- Kickbacks and Physician self-referral (“Stark”) violations
- False or Fraudulent Claims
- Reporting and Returning of overpayments
- About 40 other OIG CMPs
  - 42 C.F.R. § 1003.102 catalogues available CMPs
  - 42 C.F.R. § 1003.103 catalogues the amount of penalty and assessment available for each CMP

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### OIG/SDP: Background

- Created 1998, Updated 2013
- Receive about 100 submissions a year
- What for? Potential violations of federal criminal, civil, or administrative law for which CMPs are authorized
- Not admitting liability



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### OIG/SDP: Ineligible Submissions

- What is not eligible for OIG's SDP?
  - Errors or overpayments with no potential violation of CMPL
  - Requests for opinion on whether there is a potential violation
  - Stark-only conduct
  - Settlement less than \$10,000 (\$50,000 for AKS)



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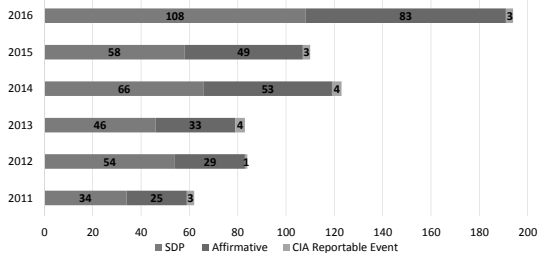
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### OIG/SDP: CMP Settlement Count by Case Type



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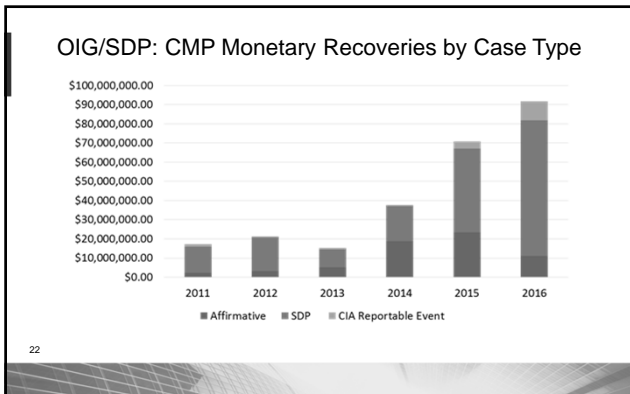
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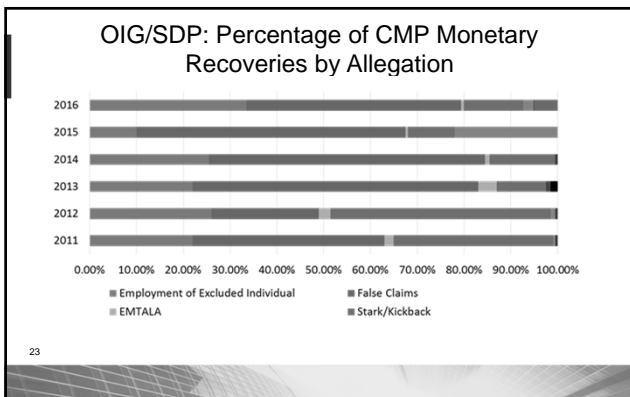
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- ### OIG/SDP: Resolutions
- Benchmark 1.5 multiplier
    - Claims Calculation
      - All claims or statistical sample of 100 claims minimum
      - Use point estimate (not lower bound)
    - Excluded persons – salary and benefits-based
    - AKS – remuneration-based
  - Presumption of no CIA
  - Six-year statute of limitations
  - Tolling of the 60-day period after submission
  - No FCA release, but can help limit exposure, including 60-day issues
  - More predictable process, but DOJ may become involved
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- 24

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### OIG/SDP: Common Mistakes Providers Make

- States in the initial disclosure or at settlement that there is no fraud liability
- Does not identify potential laws violated
- Discloses the conduct too early
- No plan to quantify damages
- Conduct only violates the Stark law
- Refuses to pay a multiplier
- Lack of cooperation
- Argues damages should be calculated in a manner contrary to the revised SDP



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### Key Considerations

- Legal exposure
  - Potential overpayment vs. fraud liability
  - Whistleblower concerns
- Releases
- Amount of repayment
- Timing of resolution
- Finality of resolution
- Optics of conduct and resolution



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### CMS Refund

- Overpayment
- Simple and Fast
- No release
- 6 year lookback period



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### CMS SRDP

- Historically reasonable settlement amounts
- Stark only release (No AKS, CMP, FCA)
- Delayed resolution

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### OIG SDP

- 1.5x multiplier
- CMP and exclusion release (No FCA)
- AKS and Stark (w/ colorable AKS conduct)
  - Remuneration based damages
- 6 year SOL
- Tolls 60-day overpayment clock

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### State Medicaid Agency

- Release of State authorities only
- Uncertain penalty
- Disclosure protocols and procedures vary

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## DOJ

- Broadest release
- No official disclosure protocol
- Uncertain damages calculation and penalty
- Experience may vary widely



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## Summary

Refund	SRDP	SDP	State Agency	U.S. Attorney
<ul style="list-style-type: none"><li>• Simple process/ minimizes legal fees</li><li>• No reduction in amount</li><li>• No release of any kind</li><li>• Six-year lookback period</li></ul>	<ul style="list-style-type: none"><li>• Track record suggests likelihood of reasonable settlement</li><li>• Stark only</li><li>• 1877(g)(1) release</li><li>• <i>De facto</i> six-year lookback period</li></ul>	<ul style="list-style-type: none"><li>• Benchmark 1.5 multiplier</li><li>• Release of CMPL and exclusion</li><li>• Potentially reduce FCA exposure</li><li>• Updated guidelines</li><li>• Six-year SOL</li></ul>	<ul style="list-style-type: none"><li>• Release of State authorities only</li><li>• Uncertainty on posture and penalty amount</li><li>• Experience may vary widely</li><li>• SOL varies</li></ul>	<ul style="list-style-type: none"><li>• Broadest release</li><li>• Uncertainty on posture and penalty amount</li><li>• Experience may vary widely</li><li>• Six-year SOL</li></ul>

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## Practical Takeaways

- Conduct timely investigation
- Determine scope of investigation
- Evaluate potential exposure
- Assess disclosure options
  - Weigh benefits and risks



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[pgarcia@hallrender.com](mailto:pgarcia@hallrender.com)

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202.708.9848  
[kenneth.kraft@oig.hhs.gov](mailto:kenneth.kraft@oig.hhs.gov)

This presentation is solely for educational purposes and the matters presented herein do not constitute legal advice with respect to your particular situation.

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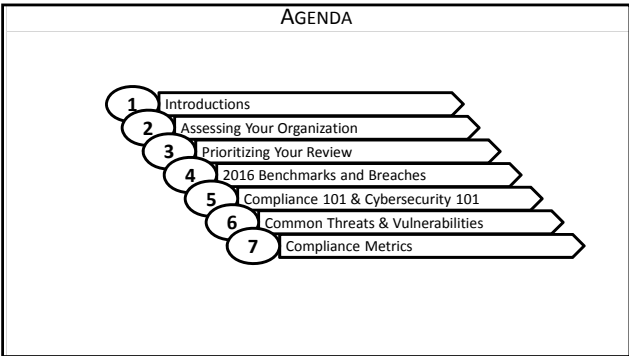
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CYBERSECURITY IN THE POST-ACUTE ARENA

Horizontal lines for notes



Horizontal lines for notes

INTRODUCTIONS
Amy Brantley | Chief Compliance Officer, Reliant Post-Acute Care Solutions
Background: Attorney - 25 years experience, Healthcare - 14 years experience, Healthcare Experience, Reliant Post-Acute Care Solutions (current), Golden Living, Arkansas Children's Hospital
Positions: Chief Compliance Officer & EVP IT, Chief Privacy Officer, Assistant GC Healthcare & VP Compliance, Labor & Employment Counsel

Horizontal lines for notes



INTRODUCTIONS

Lisa Spears | Privacy and Information Security Officer, Reliant Post-Acute Care Solutions

Background	Positions
<ul style="list-style-type: none"> <li>Healthcare – Golden Living - 23 years experience</li> <li><a href="#">Links at Golden Living</a></li> <li>Information Systems Security</li> <li>Process Improvement</li> <li>Project Management (PMP)</li> <li>Information Systems Management (CISM)</li> <li>IT Audit (CISA)</li> </ul>	<ul style="list-style-type: none"> <li>Chief Information Security Officer</li> <li>VP Enterprise Project Management &amp; Internal Controls</li> <li>Director Process Improvement</li> <li>Manager IT Systems Audit</li> </ul>

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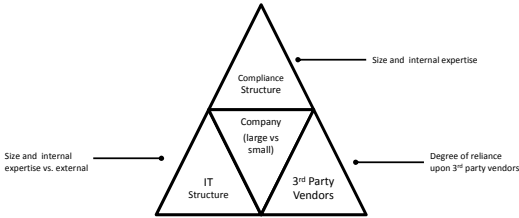
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ASSESSING YOUR ORGANIZATION




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PRIORITIZING YOUR REVIEW

Small Organizations	Large Organizations
<ul style="list-style-type: none"> <li>Third Party Vendors</li> <li>Information Technology</li> <li>Internal Resources</li> </ul>	<ul style="list-style-type: none"> <li>Information Technology</li> <li>Organization Privacy Program</li> <li>Third Party Vendor/BA</li> </ul>

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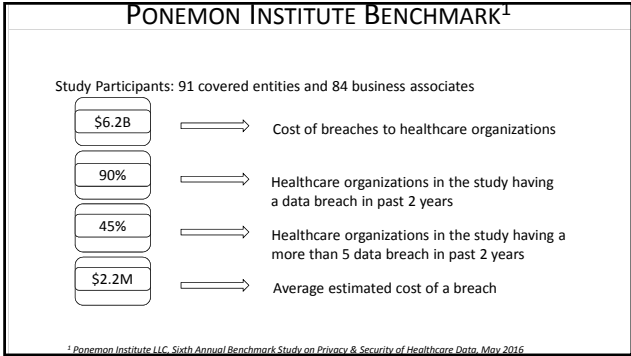
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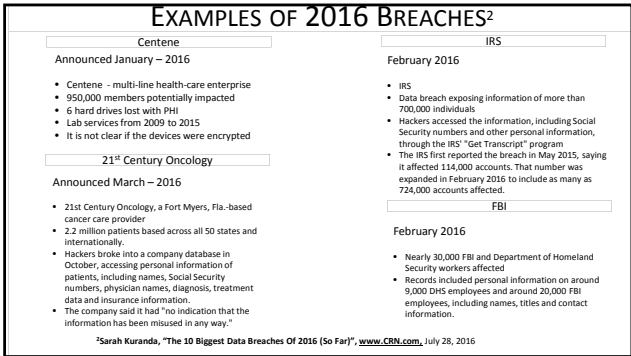
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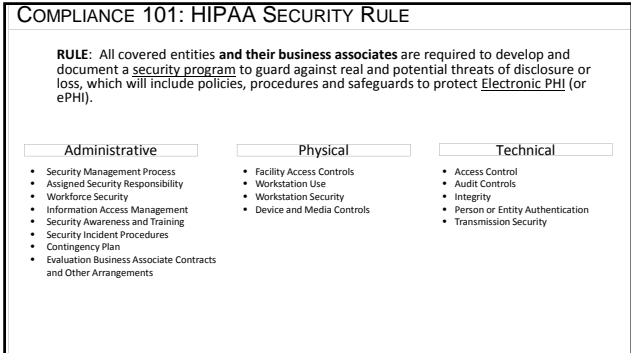
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**COMPLIANCE 101: HIPAA PRIVACY RULE**

**Rule:**  
Protects all "PHI" (protected health information), which includes just about any piece of information that might possibly identify a person, in any form, including oral information

Grants individuals broader rights in their PHI:

- Access
- Amendment
- Disclosure Accounting
- Restrictions
- Confidential Communications

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**COMPLIANCE 101: BUSINESS ASSOCIATE**

**Business Associate (BA)**

**Definition**  
Any entity that "creates, receives, maintains, or transmits" PHI in performing a function, activity, or service on behalf of a covered entity.  

- Examples: billing companies, accountants, insurance agents/brokers, payroll vendors, consultants, law firms, data processing firms...
- Any entity that has access to PHI to do something for a Covered Entity.

**Requirements**  
Covered Entity (CE) cannot release or disclose PHI to business associates unless both parties have a Business Associates Agreement (BAA) in place. BAA is not a Non Disclosure Agreement (NDA). BAA should minimally include:  

- Confidentiality clause
- Breach disclosure requirements and process
- Disposition requirements and process at BAA termination
- Rights of CE to audit the BA

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**COMPLIANCE 101: BUSINESS ASSOCIATE**

**Best Practices for Business Associates Engagement** 

- Select your vendors carefully as they can be jointly or directly liable for security breaches
- Engage all expertise needed (Legal, Procurement, Operations, Security Officer, Privacy Officer) to create a well rounded and all inclusive agreement
- Ask for and review vendor privacy and security policies to get a sense of controls in place
- Make sure basic technical security controls are in place – encryption, patching, anti-virus, password management, etc.

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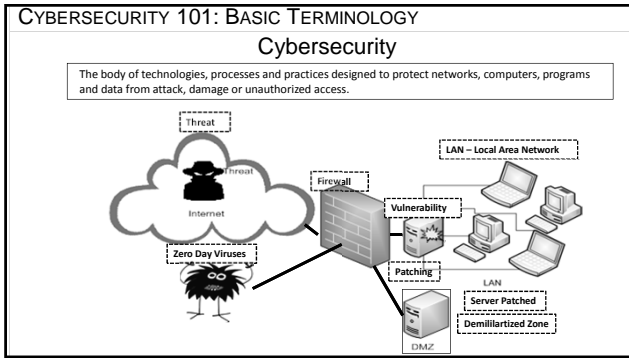
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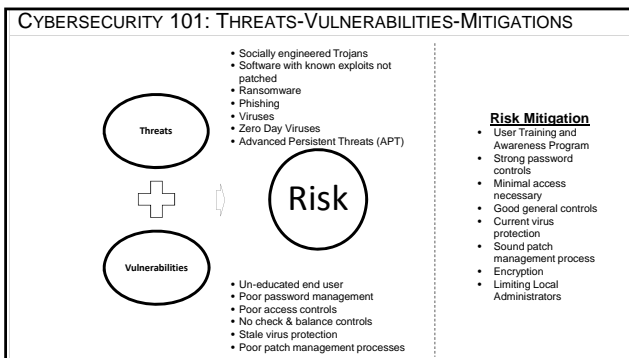
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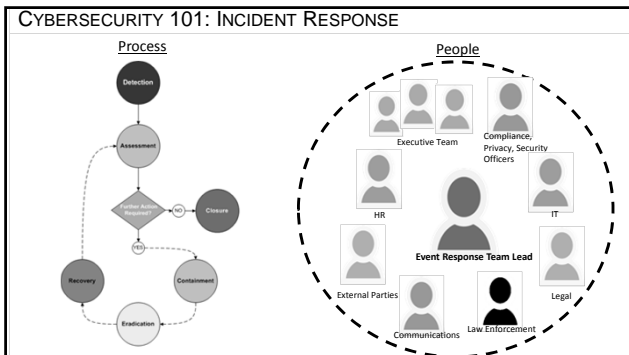
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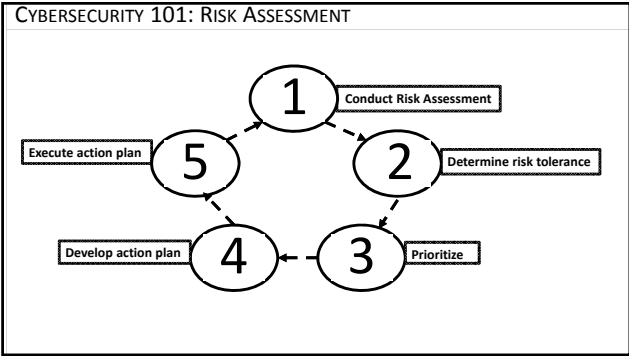
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CYBERSECURITY 101: RISK ASSESSMENT

Risk Tolerance – Business Decision

Risk Tolerance

- Low Tolerance
- Medium Tolerance
- High Tolerance

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COMPLIANCE METRICS: EMAIL

**Current Month Email Stats**

200

**Weekly Heuristics**

Total Submissions for analysis week 4  
**1,024**

Deemed High Risk  
**9**

Submitted to Antivirus scanner for analysis week

**Zero Day Trend**

Outbreak of IRS Phishing emails increased the number of emails blocked and number of emails quarantined & subsequently blocked. No infections encountered.

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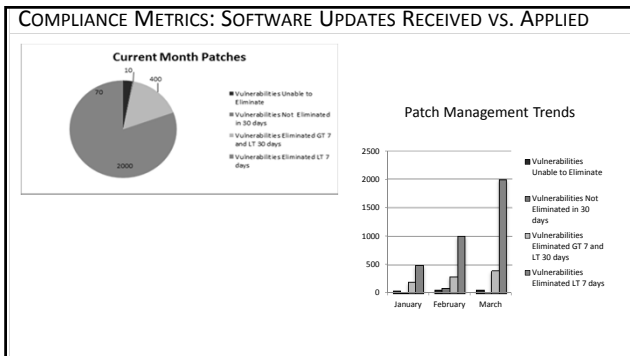
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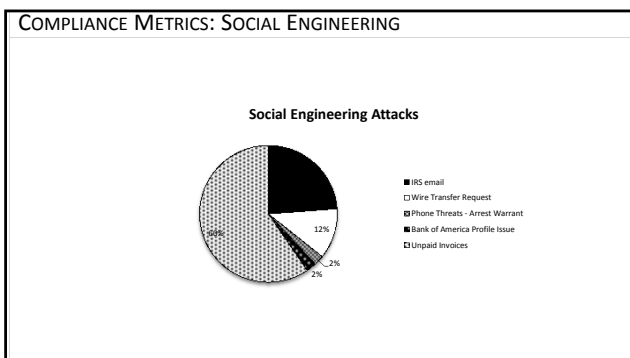
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### COMPLIANCE METRICS: POLICY REVIEW & ATTESTATIONS

Policy Annual Review Status			Policy Employee Attestation Status		
Information Security Policies	Review Date	Review Status	Information Security Policies	Policy Attestation Goal	Policy Attestation Status %
Information Security Policy	1/31/2017	●	Information Security Policy	1000	1000 100%
Access Control Policy	1/31/2017	●	Access Control Policy	1000	1000 100%
Acceptable Use Policy	1/31/2017	●	Acceptable Use Policy	1000	900 90%
Business Continuity Policy	1/31/2017	●	Business Continuity Policy	250	250 100%
Data Classification Policy	1/31/2017	●	Data Classification Policy	1000	900 90%
Encryption Policy	6/30/2017	●	Encryption Policy	100	81 81%
Mobile Devices Policy	1/31/2017	●	Mobile Devices Policy	250	250 100%
Media Handling Policy	6/30/2017	●	Media Handling Policy	1000	1000 100%
Network Security Policy	6/30/2017	●	Network Security Policy	250	225 90%
Physical and Environmental Security Policy	6/30/2017	●	Physical and Environmental Security Policy	1000	1000 100%
Personnel Security Policy	6/30/2017	●	Personnel Security Policy	1000	1000 100%
Risk Assessment & Treatment Policy	12/31/2017	●	Risk Assessment & Treatment Policy	100	100 100%
Remote Access Policy	12/31/2017	●	Remote Access Policy	250	225 90%
Software Development Policy	12/31/2017	●	Software Development Policy	100	100 100%
Security Privacy and Incident Reporting	12/31/2017	●	Security Monitoring and System Auditing	100	100 100%
Communications & Operations Security	12/31/2017	●	Security Privacy and Incident Reporting	1000	1000 100%
			Communications & Operations Security	100	100 100%

● Policy review current  
● Policy review past due

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2/24/2017



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# Bored with Your Board's Involvement with Privacy/Security Program?

Marti Arvin, Cynergistek  
Joseph A. Dickinson, Tucker Ellis



Tucker  
Ellis

March 28, 2017

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## Initial Exercise: CISO Board Update

- Board of Directors/Trustees Monthly Security Program Update



Tucker  
Ellis

March 28, 2017

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Tucker  
Ellis

March 28, 2017

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### Initial Exercise: CISO Board Update

- Engaged?
- Informed?
- Prepared to participate in strategic decision making?

Tucker  
Ellis LLP

March 28, 2017



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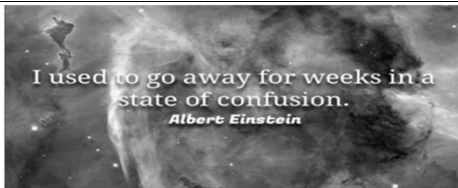
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### Not the Best Result?



*Albert Einstein*

Tucker  
Ellis LLP

March 28, 2017




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### Why the Board needs to be involved?

- Strategic Importance
- Number one concern of senior leaders today
- Most agencies require Board oversight
- Remind Board of the duty of oversight
- Personal Liability
- Significant financial risk/reputational risk

Tucker  
Ellis LLP

March 28, 2017



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### Tone at the Top

- This is nothing new
  - An important basis of a strong compliance program is the support of senior leadership
    - If they don't understand the issues it will be difficult for them to support it
- Cybersecurity issues can be highly technical
  - The presentations to the board must be in layperson's terms
  - A clear understanding of the key factors that put the organization at risk are very important




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### Reflecting the Board's commitment

- The minutes of the BOD meeting or compliance committee meeting should reflect the discussion of cybersecurity
  - The balance between documenting the discussion and not giving away important infrastructure information must be kept in mind – especially in organizations subject to open records laws
  - The minutes should reflect the agreed upon strategy and the Board's involvement in selecting that strategy.




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### Training for the Board members

- The Board does not need to be filled with cybersecurity experts.
  - The questions to ask
    - Does the Board understand the issues?
    - Could the Board articulate the issues in a meaningful fashion to an outside party?
  - The use of analogies that board members can relate to everyday life are a helpful way to get them to relate
- Training for the Board might be different than training for others
  - Be ready to explain why
  - Identify any areas that the Board needs to be more versed in than the average staff member




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### Explaining the cybersecurity and privacy program to the Board

- Providing audit results
  - Continuing theme is to minimize the technical jargon
  - Provide concise easy to understand graphics
  - Provide trends over time
    - Explain why there are increased or decreases
  - Don't bury the lead
    - If there is a system or function that is of more concern than another make sure that is a focus
  - Identify the top three to five points you want to assure the Board's hears




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### WHY IS BOARD INVOLVEMENT SO IMPORTANT?




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### Strategic planning

- IT projects can have a significant impact on the strategic planning of the organization
  - Implementation of a
    - new electronic health record
    - Health information exchange
    - Financial system
    - Telemedicine service




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### Cybersecurity threats are a top concern

- Key threats in healthcare
  - Hacking
  - Ransomware
  - Espionage
- Cybersecurity threats are big business
  - Estimated that in 2016 it was a \$600 billion dollar business
  - Criminals are selling technology to other criminals
    - You don't have to be a computer expert any more to be a cybercriminal




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### Obligations of the governing body

- The Federal Sentencing guidelines specify that the involvement of the governing body is key to an effective compliance program.
- Federal law identifies the obligations of senior leadership and the governing body in a number of cases
- Case law demonstrates the expectation of the fiduciary duty for the governing body and senior leadership.
- New theories of liability may make personal liability of the Board members and the senior leadership more of a




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### Financial and Reputational Risk

- The average cost per record for a breach is \$221 according the the Ponemon study for 2016.
  - The average cost for the healthcare industry is \$402 per record
- Study by Identity Theft Resources Center and CyberScout
  - 1093 data breaches in US in 2016
  - Increase of 40% over 2015
  - Healthcare made up 377 which is 34.5% of the total




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### Financial and Reputational Risk

- The OCR entered resolution agreements for a total of \$23,504,800 in 2016 with the median being \$1,550,000
- Class action lawsuits
  - Even if the organization is successful the cost of defense is still significant
  - State law and federal law cause of action




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### Be the Guide Who Makes The Knowledge Useful

**When a man's knowledge is not in order, the more of it he has the greater will be his confusion. - Herbert Spencer**



March 28, 2017




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### What the Board needs to know and how to provide that knowledge

- Not an IT issue only
  - Legal, HR, Risk, Compliance, Operational Departments
- Cyber Security Program is only part of overall risk management program, but a critical part
  - Technical, Administrative and Physical Safeguards
  - CISO's tend to focus only on technical aspects of security



March 28, 2017




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IT TURNS OUT THAT THE PEOPLE'S BIGGEST FEAR ABOUT CLOUD COMPUTING ISN'T 'DATA SECURITY', IT'S 'WHAT HAPPENS IF THERE'S A THUNDERSTORM?'

© D.Fletcher for CloudTweaks.com

Tucker Ellis LLP

March 28, 2017

CYNERGISTEK

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What the Board needs to know and how to provide that knowledge

- Inform Board of any actual breaches
  - You don't want a board member being blind-sided by inquiries
- Inform Board of any active investigations, complaints or audits
- The Board and C-Suite don't need to know how to configure a barracuda appliance
  - In fact, they do not even need to know that you have one
  - Example – Logging Capabilities

Tucker Ellis LLP

March 28, 2017

CYNERGISTEK

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If everyone is looking at you for the answers you want to have the answers.

Tucker Ellis LLP

March 28, 2017

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### What the Board needs to know and how to provide that knowledge

- Overview of the program
  - Technical, Administrative, Physical
  - Insurance
  - Are we in line with others in the industry?
- Briefly outline the legal requirements and reference how the cyber security program addresses each
- Summarize the assets
- Provide Metrics



March 28, 2017




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### Other Components of Risk Management

- Enable the Board to meet its duty of oversight by:
  - Helping the Board become better acquainted with the Company cyber security posture and risk landscape
  - Enabling the Board to model the effectiveness of the cyber security plan and internal/external controls
  - Enabling the Board to understand the resource needs
- Document the discussions and the Board meetings adequately to reflect that these issues are regularly addressed
- Help the Board understand what they do not know (do they need a Board member with cyber experience?)
- Management incentives based on cyber security risk management



March 28, 2017




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### What the Board needs to know and how to provide that knowledge (continued)

- CISO/CIO Board updates received the lowest rating scores (KPMG)
- The Board is busy/Time is limited
- Seek to incorporate cyber updates as part of the regular Board Update
  - Become a trusted advisor
  - Don't limit interactions with Board members to formal meetings only
  - Identify Board members who are allies



March 28, 2017




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What the Board needs to know and how to provide that knowledge (continued)

- Tie the Cyber Security Program to overall strategies of the organization
  - Engrained as key component
  - Flexibility with who presents
  - Speak their language
  - Avoid technical jargon

In the bottom left corner, there is a logo for "Tucker Ellis LLP" and the date "March 28, 2017". In the bottom right corner, there is a logo for "CYNERGISTEK" and the number "26".

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Questions?

Tucker  
Ellis LLP

March 28, 2017



CYNERGISTEK

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Investigator Documentation of  
**MEDICAL NECESSITY**  
Kelly Willenberg, MBA, BSN, CHC, CHRC

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Kelly Willenberg, DBA, RN, CHC, CHRC, CCRP

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**KELLY WILLENBERG**  
 & ASSOCIATES  
RESEARCH, COMPLIANCE, CONSULTING

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Agenda

- Monitor physicians who are involved in research
- Auditing and monitoring for process improvement
- Leverage expertise

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MEDICAL NECESSITY

*Medical necessity is the reason a given service is covered and payable by Medicare. If the service is deemed "not medically necessary" for any reason, then Medicare will not pay the provider.*

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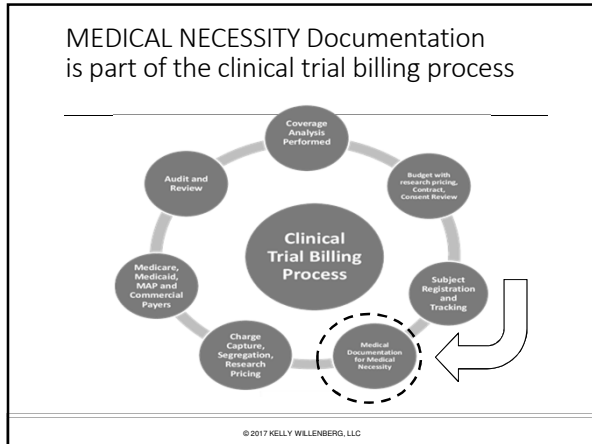
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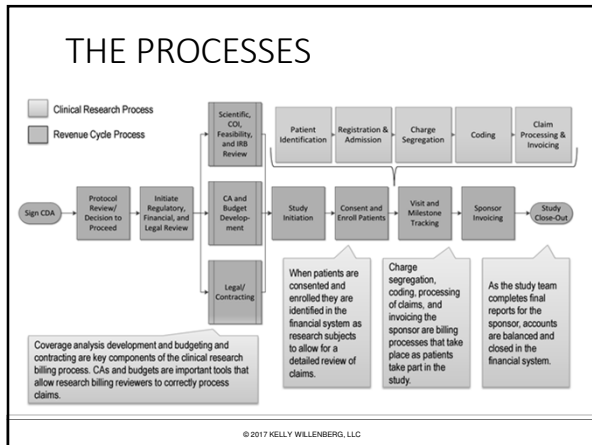
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**COVERAGE ANALYSIS**, billable or not billable

*The Investigator must **APPROVE the Coverage Analysis** to provide assurance that the determinations as to who should pay for the protocol-required procedures have been confirmed.*

**Myth**

Medicare will pay for any item/service designated as "Standard of Care".

**Reality**

"Standard of Care" is not a Medicare concept. Payments for clinical study related items/services are issued by Medicare in accordance with coverage rules and defined terms set by statutes, regulations and local Medicare contractors. To determine which items/services are billable to Medicare, **review the coverage analysis.**

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### COVERAGE ANALYSIS

*Coverage Determinations, Local and National*

*Medicare determines medical necessity in the electronic claims processing world with claim edits.*

- When coverage is restricted by an NCD or LCD, claims processing edits will deny an item or service because the diagnosis code is not listed in the "approved" or "covered" list of codes.
- These coverage determinations should be noted in the line item "Comments" section of the Coverage Analysis

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### INVESTIGATOR

*Coverage Analysis and Medical Documentation*

**COVERAGE ANALYSIS** approval prior to study start up followed by clear and complete **MEDICAL DOCUMENTATION** throughout the study can help with protocol adherence, can help avert provider denials and can help avoid:

- Billing for items or services not supported by:
  - Documentation of study participation, as required
  - Adequate documentation of medical necessity for the item or service
  - A proper, signed order
- Billing without proper codes, modifiers or NCT #
- Waiving/paying/reimbursing subject co-pay or deductible obligations
- Billing for services that were not rendered
- Billing for services that are already paid by the sponsor or promised free in the informed consent
- Billing for services that are for research-purposes only or are part of a non-qualifying clinical trial
- Billing Medicare for device trials without CMS centralized review and approval
- Billing Medicare Advantage Plans (Part C) when claims should be directed to the Medicare Administrative Contractor

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### If Billing to CMS – and Study Is Qualifying...

#### *Compliant billing requirements*

- 1. Modifier Q1**  
*Medically necessary routine patient care  
Treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial.*
- 2. Modifier Q0**  
*Items and services that are being investigated as an objective within the study.*
- 3. Diagnosis code Z00.6**  
*Appended to every bill that includes a Q1 or Q0, in a secondary diagnosis-code position for all participants being treated for a diagnosed disorder; if the participant is a healthy volunteer enrolled in a control group of a diagnostic study, the Z00.6 must be placed in the primary diagnosis-code position*
- 4. Condition Code 30**  
*Appended to every hospital-provider bill (typically, Medicare Part A, if participant is Medicare-insured) whenever a Q1 or Q0 and Z00.6 is required; note that Condition Code 30 is not required for professional billing (e.g. Medicare Part B billing)*
- 5. National Clinical Trial Number (NCT)**  
*When there is a Z00.6 and a condition code 30  
For items and services provided in clinical trials or under CED*

*Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed.*

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## MEDICARE Research Codes and Modifiers

1. **Hospital Inpatient Claims**  
*Research modifiers not currently required*
2. **Hospital Outpatient Claims**  
*Research modifiers required*
3. **Physician Claims**  
*Research modifiers required*
4. **All Government Claims**  
*Clinical Trial Number, 8 digit number*
5. **All Claims**  
*Z00.6 diagnosis code as secondary diagnosis ("examination of participant in clinical trial")*

Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed.

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## CODES & MODIFIERS

Condition Code '30' in Box 18

Value Code 'D4' and 8-digit NCT identifier number in Box 39

Modifier Q1 or Q0 in Box 44

Modifier Code	Description	ICD-10 Code
300	LABORATORY	96419Q1
305	LAB-HEMATOLOGY	85025Q1
335	CHEMOTHERAPY-IV	96413Q1
336	CHEMOTHERAPY-IV	96415Q1
638	INJECTION	96133Q1

ICD-10 code Z00.6 in the secondary position in Box 66

Z04.10 = Chronic lymphoid leukemia

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## CODES & MODIFIERS

8-digit NCT identifier number in Box 19 with "CT" attached. Electronic version 837P does not require "CT"

ICD-10 code Z00.6 in the secondary position in Box 21

Z04.10 = Chronic lymphoid leukemia

Modifier Q1 or Q0 in Box 24.D

Modifier Code	Description	ICD-10 Code
36415	Venipuncture	96415Q1
85025	CBC	85025Q1

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VISITS in which research events occur

- **Mixed visit** - Documentation that occurs on the day of a research required visit that also includes conventional care must include a primary diagnosis other than participation in clinical research and supporting language. Medical documentation should not include language that indicates that the purpose of the visit is to screen or follow the patient for a research study.
- **Research only visit** - If the visit would not be performed per conventional care, no standard billing can occur. Clearly document that the visit is for research purposes only.

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VISITS in which research events occur

*PHYSICIAN'S ORDERS*

- Physician's orders establish medical necessity for the services provided which in turn supports the payment.
- It is the ordering provider's responsibility to order services that are reasonable and necessary according to the patient's clinical condition or signs and symptoms. Provider's documentation in the medical record should support the basis of all orders requested.

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VISITS in which research events occur

*Study Visit Occurs*

- Is the patient registered as a research subject?
- Is the person conducting the visit aware that research related events will occur?
- Is it clearly understood which procedures are protocol required and who is to pay? Are the Coverage Analysis determinations available for review?
- Does the medical record document study participation?
- Does the medical record clearly indicate that the visit and ordered procedures are medically necessary (and billable) or that one or more items is for research purposes only (sponsor to pay)?
- Does the medical record match the billing and coding of events?
- Is Z00.6 used as a secondary or later diagnosis code?

*Why does it matter?*

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### HELPFUL TOOLS TO KEEP YOU ON TRACK

Before Chemo	During Chemo	After Tx Complete
Z01.818 • Encounter for other preprocedural examination • Encounter for examinations prior to antineoplastic chemotherapy	Z79.899 Other long term (current) drug therapy	Z08 Encounter for f/u exam after completed treatment for malignant neoplasm
Additional codes should be used to describe the cancer that they have.	• Z51.0 Encounter for antineoplastic radiation therapy • Z51.11 Encounter for antineoplastic chemo • Z51.12 Encounter for antineoplastic immunotherapy	• Use additional code to identify any acquired absence of organs (Z90) • Use additional code to identify the personal hx of malignant neoplasm (Z85)

*This is an informal guide and does not in any way describe coverage. Code by what is documented in the medical record.*

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### HELPFUL TOOLS TO KEEP YOU ON TRACK

Pre-Operative for CV Procedure	Post CV Procedure	Monitoring Drug (Example- Coumadin)
Z01.810: Encounter for preprocedural cardiovascular examination Z01.811: Encounter for preprocedural respiratory examination Z01.812: Encounter for preprocedural lab examination Z01.818: Encounter for other pre-procedural examination Include the condition requiring the procedure: (Example: Aortic Stenosis, I35.2 Nonrheumatic aortic (valve) stenosis with insufficiency)	Z09 Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm → Code to identify any applicable history of disease code (Z85.- Z87.-) Example: Z86.79 Personal history of other diseases of the circulatory system Example: Z95.2 Presence of prosthetic heart valve	Z51.81 Encounter for therapeutic drug level monitoring Z79.01 Long term (current) use of anticoagulants

*This is an informal guide and does not in any way describe coverage. Code by what is documented in the medical record.*

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### DOCUMENTATION EXAMPLES

#### REASON FOR EXAM

Good	Insufficient
• Cough, fever (ICD-10: R05, R50.81)	• r/o pneumonia (no dx code)
• New onset SOB and chest pain on exertion; s/p 2 cycles doxorubicin for Hodgkin lymphoma (R06.02, R07.89, C81.90, Z79.899)	• r/o cardio toxicity on study drug (Z79.899)

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DOCUMENTATION EXAMPLES

REASON FOR EXAM

Good	Insufficient
<ul style="list-style-type: none"> <li>Newly diagnosed primary CNS lymphoma. He has a dominant mass in the right thalamus/hypothalamus with 2 punctate satellite lesions. Need Chest/abdomen CT to determine whether there is a metastatic source.</li> </ul>	<ul style="list-style-type: none"> <li>Brain tumor</li> </ul>

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DOCUMENTATION EXAMPLES

Good	Insufficient
<ul style="list-style-type: none"> <li>Anemia due to chemo regimen (D64.81)</li> </ul>	<ul style="list-style-type: none"> <li>Anemia (D64.9 )</li> </ul>
<ul style="list-style-type: none"> <li>6-month post chemo surveillance for progression; breast cancer (Z08, Z85.3)</li> </ul>	<ul style="list-style-type: none"> <li>Breast cancer (not clear as to whether this is a new dx or where the patient is on the treatment timeline.)</li> </ul>

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DOCUMENTATION EXAMPLES

NURSING NOTE:

Called Mrs. Smith and told her that, in order to be in the study, her hemoglobin needs to be above 10 and her hgb is 8.6. Dr. Jones says she will need a transfusion to get into the study. Patient agrees. Scheduled for a transfusion tomorrow.

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DIAGNOSIS CODE Z01.818

Encounter for other pre-procedural examination

Applicable To:

- Encounter for pre-procedural examination NOS
- Encounter for examinations prior to antineoplastic chemotherapy

Examination (for) (following) (general) (of) (routine) Z00.00

- pre-chemotherapy (antineoplastic) Z01.818
- prior to chemotherapy (antineoplastic) Z01.818
- pre-procedural (pre-operative); specified NEC Z01.818
- medical (adult) (for) (of) Z00.00; pre-procedural specified NEC Z01.818

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It's All About the \$\$\$\$



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Impact on Revenue Integrity

- Denials not worked
- Appeals – who understands the process for a trial
- Pre-authorizations not performed when necessary
- Write offs unknown to research team
- Stop the bleed.....

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## Claim Denials

*Reminders, this may cause a denial*

- Inadequate process for identifying research studies and study participants
- Inadequate medical documentation or documentation that negates therapeutic intent
- Test ordered using an ICD-10 code with an LCD that prohibits payment
- Un-matching hospital and professional billing claims
- Government codes used on commercial payer claims
- Lack of NCT# when there is a Z00.6 and a condition code 30
- Z00.6 not in the secondary position, it is removed from claim
- Medicare Contractors march to the beat of a different drummer in each region, Sponsor must be willing to work with sites according to region to avoid denials

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## Leverage Expertise

*Research Site Impact*

- More scrutiny with more responsibilities
- Time intensive procedures
- Back end bill hold and review
- Auditing function necessary to ensure compliance

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## Understand Payer Issues When Monitoring Reimbursements

- Covered Medical Benefits
- Covered Drug Benefits
- Network Requirements
- Authorizations Requirements
- Payer Medical Management Policies
- Denials & Appeals
- Improve communication with payers to facilitate authorization and reimbursement
- Facilitate the appeals process if the payers deny coverage

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# Certificate Of Coverage and Evidence Of Coverage

A document given to an insured that describes the benefits, limitations and exclusions of coverage provided by an insurance company.

- **Benefits** - The health care items or services covered under a health insurance plan. Covered benefits and excluded services are defined in the health insurance plan's coverage documents
- **Medical Necessity** - Health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

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# How Do You Train Your Physicians?

- Help them understand the coverage analysis process
- Ensure they document to medical necessity
- Be consistent – establish business rules
- When in doubt, don't bill it and have sponsor cover the costs!

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# Contact Information



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[kelly@kellywillenberg.com](mailto:kelly@kellywillenberg.com)

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**Anti-kickback and Stark Law Developments**

HCCA 21<sup>st</sup> Annual Compliance Institute  
March 28, 2017

**Speakers:**

**Heather Westphal**  
*Senior Counsel, U.S. Dept. of Health & Human Services  
202-619-0335 | heather.westphal@oig.hhs.gov*

**Katherine Lauer**  
*Partner, Latham & Watkins LLP  
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**Charles B. Oppenheim**  
*Principal, Hooper, Lundy & Bookman, PC  
310-551-8110 | coppenheim@health-law.com*

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**Anti-kickback Guidance Update**

2 Heather Westphal

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**Anti-kickback Statute (AKS)**  
Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b))

Criminal penalties for individuals or entities that:

- knowingly and willfully
- offer, pay, solicit, or receive remuneration
- to induce or reward the referral of business reimbursable under Federal health care programs.

Safe Harbors:

- payment or business practices that potentially implicate the AKS, but are not treated as offenses.

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## New Safe Harbors (December 7, 2016)

Section	Brief Summary
1001.952(f)	Technical correction to the referral services safe harbor.
1001.952(k)(3)	Interprets statutory exception to the anti-kickback statute permitting pharmacies to waive cost-sharing based on financial need or failure to collect.
1001.952(k)(4)	Protects certain waivers or reductions of cost-sharing by ambulance providers or suppliers owned and operated by a State or a political subdivision of a state.
1001.952(z)	Protects remuneration between a federally qualified health center (FQHC) and a Medicare Advantage organization pursuant to an agreement related to payment for certain FQHC services.
1001.952(aa)	Protects discounts on the price of certain drugs furnished in connection with the Medicare Coverage Gap Discount Program.
1001.952(bb)	Protects free or discounted local transportation services provided to Federal health care program beneficiaries.

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## Local Transportation Safe Harbor

Protects from AKS sanctions free or discounted local transportation by Eligible Entities to established patients to obtain medically necessary items or services.

- **Local:** within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area
- **Eligible Entity:** any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items
- **Established patient:** a person who has selected and initiated contact to schedule an appointment with a provider or supplier to schedule an appointment, or who previously has attended an appointment with the provider or supplier

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## Local Transportation (cont.)

Some Other Key Requirements:

- No luxury, air, or ambulance
- Uniform policy unrelated to referrals
- No marketing
- Separate protection for “shuttle service” with some requirements the same (e.g., still must be local) but others different (e.g., no “established patient” requirement)

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### Advisory Opinions

#### OIG Advisory Opinion No. 16-10:

- Transportation program sponsored by two local healthcare districts to help get patients to a hospital or clinic in one of the districts
- Jointly hired a transportation coordinator and provided financial assistance for low-income patients to secure certain forms of public transportation

#### OIG Advisory Opinion No. 16-02:

- A state academic medical center (Hospital) that operates regional clinics that provide prenatal care for primarily low-income women to offer aid to qualified patients in the form of mileage reimbursement or fare reimbursement for public transportation to deliver at the Hospital
- Arrangement also had a lodging and meals component that could be included for patients with a physician's order justifying the stay (generally high-risk pregnancy)

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### Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians (June 22, 2016)

- Cautionary alert to home health agencies (HHAs) and physicians who refer to them about direct or indirect payments for referrals
- Must ensure arrangements and the payments under compensation arrangements between HHAs and physicians are fair market value and commercially reasonable in the absence of Federal health care program referrals

[https://oig.hhs.gov/compliance/alerts/guidance/HHA\\_%20Alert2016.pdf](https://oig.hhs.gov/compliance/alerts/guidance/HHA_%20Alert2016.pdf)

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### OIG Self-Disclosure Protocol

- Benchmark 1.5 multiplier
  - Claims Calculation
    - All claims or statistical sample of 100 claims minimum
    - Use point estimate (not lower bound)
  - Excluded persons – salary and benefits-based
  - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- Does not secure FCA release, but can help limit exposure
- More predictable process, but DOJ may become involved

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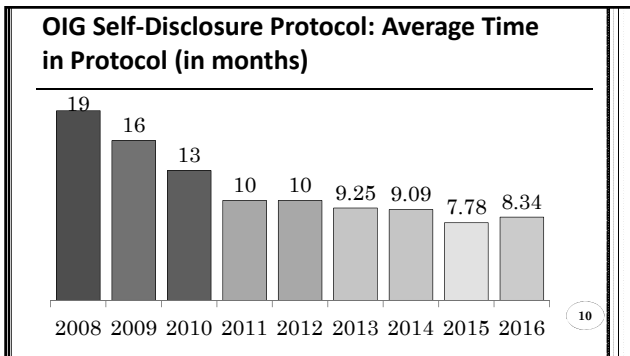
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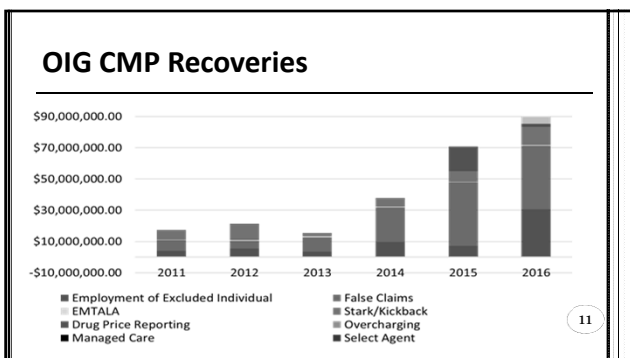
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## Anti-kickback Enforcement Update

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### Significant AKS Settlements

- o 12/15/16: Forest Laboratories LLC
  - \$38 M civil FCA settlement for kickbacks in the form of payments and meals to referring physicians related to speaker programs in exchange for prescriptions of drugs
- o 12/2/16: Vitas Health Corporation Midwest
  - \$200K civil FCA settlement for kickbacks in the form of contributions to cancer charity established by referring physician in exchange for hospice referrals; referring physician pled guilty and sentenced to 45 years
- o 10/3/16: Tenet
  - \$513M criminal and civil FCA settlement for kickbacks in the form of payments for various services to owners and operators of prenatal care clinics serving primarily undocumented Hispanic women in return for the referral of labor and delivery medical services at Tenet hospitals paid for by Medicaid; two individual pleas; one additional hospital executive recently indicted

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### Significant AKS Settlements

- o 3/23/16: Respirationics
  - \$34.8M civil FCA settlement for kickbacks in the form of free call center services to DME suppliers that bought its masks for patients with sleep apnea
- o 3/1/16: Olympus Corp
  - \$623.2M criminal and civil FCA settlement for kickbacks in the form of consulting payments, foreign travel, lavish meals, millions of dollars in grants and free endoscopes to physicians and hospitals

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### AKS Focus on Individuals

- o In recent years, DOJ has prosecuted or settled with a number of executives of healthcare companies in AKS matters:
  - W. Carl Reichel of Warner Chilcott
  - David Bostwick of Botswick Laboratories
  - Edward Novak, along with two other executives of Sacred Heart Hospital

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### AKS Arrangements Under Scrutiny

- o Joint Ventures
- o Discounts
- o Swapping
- o Call Coverage
- o Co-marketing/Practice Support
- o Speaker Payments
- o Grants
- o Entertainment

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### AKS: Are the Stakes Getting Higher?

- o Increased public access to manufacturer payments to referral sources through Sunshine Act data
- o Increasing involvement by Criminal Division
- o Increasing focus on individuals
- o More non-intervened civil FCA cases pursued by Relators
- o More significant collateral consequences
  - Exclusion
  - Enhanced Corporate Integrity Agreement Provisions
  - Monitorships (OIG and DOJ)

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### Stark Regulations Update

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### **New Stark Regulations: Key Changes (October 30, 2015)**

- Leniency on “written agreement” and “one-year term” requirements
- New exception for recruitment of mid-level clinicians
- New exception for timeshare arrangements
- Extensions on permitted “holdover” arrangements
- More latitude on missing signatures

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### **How The Stark Rules Have Changed – Written Agreement/Term**

- Depending on the facts and circumstances, a collection of documents, e.g., e-mails, drafts, invoices, cancelled checks, timesheets, etc. can constitute a “written agreement”
- The “one-year term” requirement can be satisfied if the arrangement lasted one year, even if the written agreement does not specify a term
- These are both “clarifications” of existing law, meaning that they apply retroactively too

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### **How The Stark Rules Have Changed – Recruiting Mid-Levels**

- Previously, there was just a “physician” recruitment exception
- Now, hospitals (and FQHC/RHC) can recruit mid-levels to provide primary care or mental health services to a physician’s practice
- Covers PAs, NPs, clinical nurse, specialists, certified nurse, midwives, LCSWs and psychologists
- Up to 50% of compensation, once every 3 years (and other restrictions apply)
- What about 501(c)(3) hospitals?
- Effective as of January 1, 2016

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### How The Stark Rules Have Changed – Timeshare Arrangements

- Protects certain “timeshare” arrangements (not leases, which are subject to a different exception) between hospital or physician organization and a physician or medical group
- Space, equipment and other items are predominantly for evaluation and management (E/M) visits
- Any equipment is in the same building as E/M visits and used for diagnostic imaging only if incidental to E/M visit, and not used advanced imaging, radiation therapy or clinical laboratory services (other than CLIA-waived tests)
- Could this be used in hospital-licensed or provider-based space?
- Effective as of January 1, 2016

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### How The Stark Rules Have Changed – Holdovers

- The old rule allowed expired leases and personal services arrangements to continue after expiration on the same terms for up to 6 months, if exception otherwise satisfied
- Their new rule extends the 6 months to an unlimited period of time
- But, beware of fair market value issues and changes in services and/or compensation
- Effective as of January 1, 2016

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### How The Stark Rules Have Changed – Signatures

- The old rule allowed arrangements where only a signature was missing, for up to 90 days if inadvertent and 30 days if advertent
- Now, all arrangements are allowed, when only a signature is missing, for up to 90 days
- This grace period is still limited to once per physician every 3 years
- Effective as of January 1, 2016

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**Recent Cases and Settlements**  
How Should Compliance / Legal Respond?

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***U.S. v. Bradford Regional Medical Center***

- Two cardiologists, a hospital and an imaging camera
- The carrot, the stick and the carrot
- The \$6,545/month sublease
- The non-compete
- What did we learn?

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***U.S. v. Tuomey Healthcare System***

- A hospital and its 18 part-time physician employees
- When is compensation fair market value?
- When does compensation take referrals into account?
- What is the moral of the story?

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## U.S. v. Halifax

- Two Big Issues: Oncologists' Bonus Pool Included DHS and neurosurgeons compensation was "off the charts"
- What is the U.S. DOJ saying about physician compensation?
- "Given that each neurosurgeon was paid total compensation that exceeded the collections received for neurosurgical physician services, Defendants could not reasonably have concluded that the compensation arrangements in those contracts were fair market value for the neurosurgical services or were commercially reasonable."
- What does this mean?
- What are the lessons?

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## Losses on Physician Services – OK?

- DOJ asserts that paying physicians more than the professional collections they generate exceeds FMV, is not commercially reasonable, and takes referrals into account.
- But, there is no requirement that providing physician services must be profitable:
  - If compensation is FMV and is not adjusted for referrals, it should satisfy the Stark Law
  - Some service lines have unprofitable payor mixes or low demand
  - CMS recognizes legitimacy of subsidizing physician compensation, e.g. in the Emergency Department
  - Likewise, call coverage and hospitalist services often require subsidies

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## Stark Self-Disclosure

When, Why, How, What?

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### **Stark Law Self-Disclosure Protocol**

- Should be used for “Stark only” self-disclosure
- Tolls the 60-day repayment obligation, but doesn’t permit payment with the self-disclosure!
- Requires detailed submission, including:
  - facts and circumstances of violation
  - legal analysis of why it doesn’t comply
  - calculation of financial damages
- What types of compromise might be available?

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### **Alternatives to Stark SRDP**

- Report and Repay (in full) to Medicare Administrative Contractor (MAC)
- Use OIG Self-Disclosure (if colorable AKS violation)
- Others?
  - AUSA
  - DOJ
- Self-remedy?

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### **Case Studies On SRDP**

- How did we decide there was a Stark violation?
- How did we decide there was no colorable AKS violation?
- Did the physician join the self-disclosure?

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### Case Studies On SRDP (Cont'd)

- What is the settlement timeline?
- What is the settlement process?
  - Offer amount
  - Negotiable?
  - Timing?
  - Financial Distress?

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### Compliance Tips

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### Compliance Tips

- Contract management system, including database for tracking contracts, policies & procedures for entering into, renewing and monitoring contracts, etc.
- Maintain written agreements, signed by parties, and make sure they remain current (consider use of "evergreen" provisions and ways to ensure compensation remains fair market value and set in advance)
- Document the basis for determining FMV at the start of contract term
- Document services performed contemporaneously throughout term

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## Compliance Tips (cont.)

- Document the reasons for the arrangement, especially if losses are anticipated (pre-transaction document)
- Assess potential consequences (cause and effect) and develop mitigation strategy, if applicable
- Document when you say “no” to physician compensation/deals
- Don’t forget to check on physician ownership of vendors/suppliers!
- Don’t forget that a physician’s “immediate family members” financial relationships are attributed to the physician!

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## The Trump Administration: How Will It Impact Kickback and Stark Laws?

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## Questions & Answers

**Speakers:**

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### Risk Assessments and Work Plans- Key Spokes in the Circle of Compliance

Kate Flynn, Compliance Officer  
Al Josephs, Senior Director, Risk Assessments and Culture  
Laura Range, Vice President, Deputy Chief Compliance Officer

March 28, 2017

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### Agenda

- Why risk assessments are essential
- Sample approach to conducting a meaningful risk assessment
- Compiling and reporting results
- Developing remediation activities and Work Plan items to address risk assessment findings



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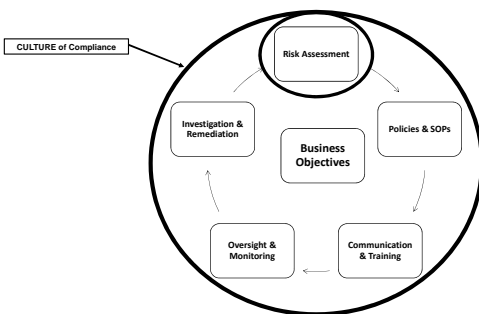
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### Compliance Life Cycle



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### Risk Assessments and Work Plans—An Overview

**Defined:** A Risk Assessment is the identification and evaluation of potential risk within your organization. It involves the analysis of systems and processes against a benchmark, standard, law or regulation along with the determination of the level risk (high, low, or medium) associated with the activity.

**Work Plan:** The purpose of a Work Plan is to address risk identified in the Risk Assessment process that created the greatest exposure to an organization. Components of the Work Plan include: clear description of the risk, identification of current controls and safeguards in place, assignment of accountability for remediation the risk, and due date for completion.

**Reporting:** An effective Work Plan must be communicated to all key stakeholders at the beginning of the process and with periodic updates on the status of the Work Plan. At a minimum it should include Senior Leadership and the Governing Body of the Organization. In addition the Work Plan is a useful tool in promoting compliance to others within the organization.




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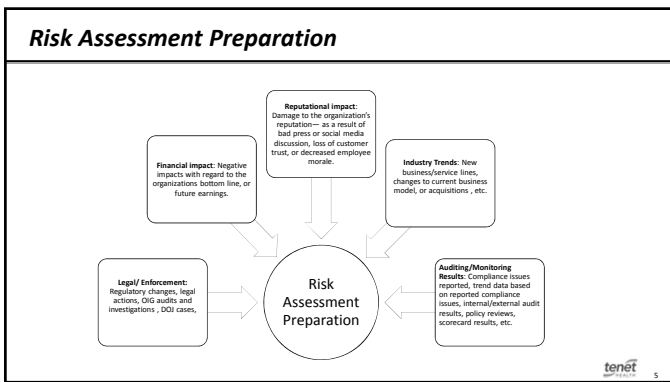
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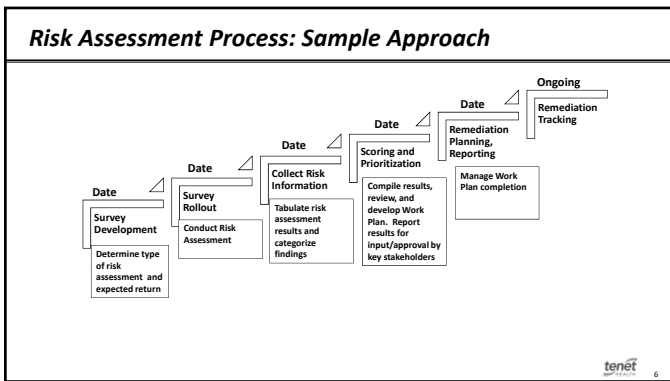
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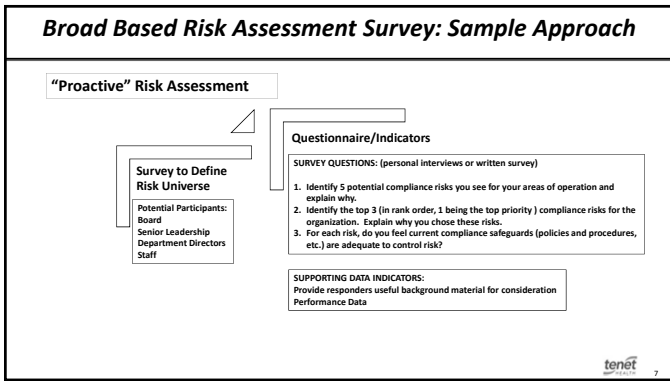
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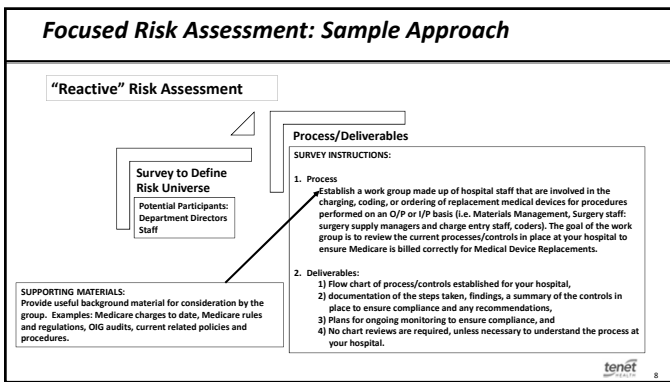
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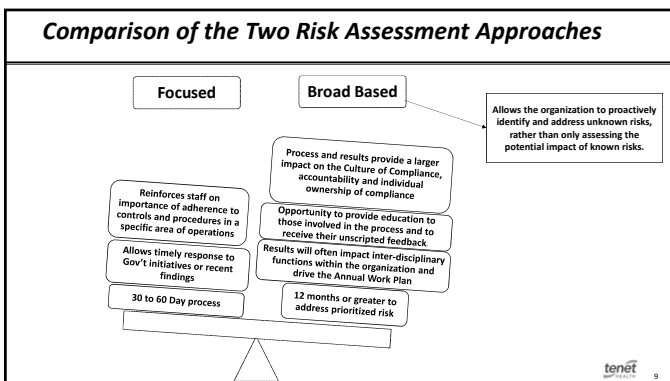
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### Sample Survey

**SECTION II: HOSPITAL RISK IDENTIFICATION**

**COMPLIANCE RISK SURVEY**

Directions: Review the top five Compliance risks for your facility. For each risk select the most significant contributing factor and identify the level of risk. You are also asked to provide an explanation of your selection. (i.e., why did you select this risk?)

Risk Area:

Contributing Factor:

Level of Risk:

Explanation of Risk:

Sample Response:

**SECTION III: SUFFICIENT RISK IDENTIFICATION**

Please identify the top three Compliance risks that represent your facility. List the risk in writing under each of today's heading. For each risk state the level of risk and identify whether or not your facility's safeguards have been implemented. You are also asked to provide an explanation of your selection. If you believe the current safeguards are adequate, leave blank.

Risk Area:

Level of Risk:

Are there sufficient safeguards?

Explanation of your selection:

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### Summary of Key Data Points Resulting from the Survey

**Data Points**

- Risk Area or Category assists in analyzing the overall survey results.
- Primary Contributing Factors help to further understand the reason for the perceived risk.
- Sufficient Safeguards identify if current safeguards are adequate.
- Risk Level assessed as High or Elevated, Medium, Low or alternatively whether it Will Happen, Most Likely to Happen, Might Happen, Likely not to Happen.
- Free Text Comments will contain a wealth of information that may generate additional categories for use in evaluating and tabulating the data.

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### Categorizing Free Text Data: Examples

<b>Regulatory</b>	<b>Physician Management</b>	<b>Hospital Operations</b>
<ul style="list-style-type: none"> <li>Medical Necessity</li> <li>Physician Management</li> <li>Provider Based Entities</li> </ul>	<ul style="list-style-type: none"> <li>Credentialing</li> <li>Medical Staff Management</li> <li>Employed Physicians</li> </ul>	<ul style="list-style-type: none"> <li>Policy Management</li> <li>New Service Lines</li> <li>Leasing Equipment</li> </ul>

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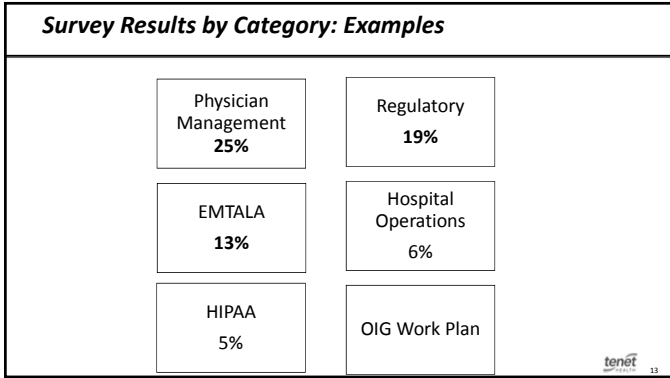
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### Harnessing the Power of Excel Pivot Tables: An Example

Snapshot of Results					
Sample Data					
Category	Elevated	Medium	Low	Total	% of Total
Physician Management	45	78	40	163	25.2%
Regulatory	17	56	52	125	19.3%
EMTALA	11	46	27	84	13.0%
Hospital Operations	2	16	21	39	6.0%
HIPAA	5	24	3	32	4.9%

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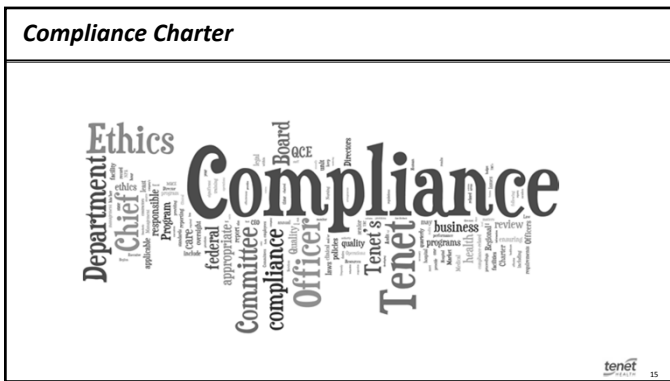
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**Work Plan Design: Sample Approach**

Regulatory

Core Focus Areas

- Physician Relationships
- Provider Based Entities
- Medical Necessity




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**Work Plan Design: Sample Approach**

Regulatory

- Design training for leadership on how to have difficult conversations with physician from a legal, compliance and regulatory perspective **Physician Relationships**
- Evaluate the "Site Neutral Payment" Finals Rules impact on provider based entities **Provider Based Entities**
- Review processes used to determine medical necessity for inpatient status and O/P procedures **Medical Necessity**




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**Work Plan Design: Sample Approach**

Hospital Operations

Core Focus Areas

- New Service Lines
- Joint Venture/Partnership Management




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### Work Plan Design: Sample Approach

Hospital  
Operations

- Design and develop tools for use when exploring and implementing new service lines,
- Evaluate monitoring effectiveness of Joint Ventures/Partnerships

**New Service Lines**

**JV/Partnership Management**



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### Work Plan Design: Additional Risk Considerations

Hospital Operations


DOJ/OIG  
Enforcement Trends

OIG Compliance  
Reviews

Internal  
Investigations Trend

Hotline  
Call Trends

Audit Findings  
(Internal and External)



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### Work Plan Monitoring: Sample Approach

Hospital Operations

2017 Work Plan				Focus Area	
Focus Area	Description	Current Risk/Mitigation	Action Items	Leader(s)	Due Date
Hospital					
Regulatory	Design training for leadership on how to have difficult conversations with physician from a legal, compliance and regulatory perspective				
	Evaluate the "Site Neutral Payment" Final Rules impact on consider based entities				
	Review processes used to determine medical necessity for inpatient stays and O/P procedures				
Hospital Operations					
	Design and develop tools for use when exploring and implementing new service lines				
	Evaluate monitoring effectiveness of Joint Ventures/Partnerships				



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# Questions?



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Al Josephs     Al.Josephs@tenetHealth.com  
Laura Range     Laura.Range@tenethealth.com

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## Slide 23

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**RL14** We should add a slide for Questions?

Range, Laura, 2/14/2017

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## Medicare and Medicaid False Claims Investigations Post *Escobar*

Forward Thinking Healthcare Solutions  
It's What We Do

Joan Feldman, Esq.  
HCCA's 21<sup>st</sup> Annual Compliance Institute – National Harbor, MD  
March 28, 2017

www.shipmangoodwin.com    Greenwich    Hartford    New Haven    New York    Stamford    Washington, DC

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## Anatomy of a False Claim

False Claims laws are the Government's primary tool for combating fraud

Liability occurs where a defendant (i) knowingly presents (or causes to be presented) a false or fraudulent claim for payment; (ii) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (iii) conspires with others to commit a violation of the False Claims Act; (iv) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money or transmit property to the Federal Government

31 U.S.C. §§3729-3733

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## Potential Repercussions of a False Claim

- Civil - damages, penalties per claim, attorneys' fees, exclusion
- Criminal - Prison, fines, forfeiture, exclusion



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**Qui Tam**

- Relator or whistleblower on behalf of Government
- Only if the Government has yet to file FCA lawsuit
- Bounty and attorneys' fees
- Intervention by the Government
- Possible liability without Government intervention



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**Escobar Case**

- Relator argued that violation of regulations constitute false and fraudulent claims to Medicaid
- Claims did not *expressly* certify that the services were performed in compliance with state regulations
- The relator argued that the provider *implied* its regulatory compliance when it submitted the claims (i.e., "implied certification")
- Claim is fraudulent not because of an implicit (vs. actual) representation of regulatory compliance
- Government declined to intervene, district court granted the defendants' motion to dismiss because complaint relied on noncompliance with regulations, rather than conditions of *payment*

U.S. ex rel. Escobar v. Universal Health Servs., Inc., No. 11-CV-1170-DPW, 2014 WL 1271757, at \*7 (D. Mass. Mar. 26, 2014).

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**Escobar Case**

- The US Court of Appeals for the First Circuit reversed, held that conditions of payment, need not be expressly designated
- The supervision regulations at issue did impose conditions of payment, and therefore were "dispositive evidence of materiality"
- Circuit Courts were split on the issue of implied certification

U.S. ex rel. Escobar v Universal Health Servs., Inc., 780 F.3d 504, 512 (1st Cir. 2015).

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### Escobar Case

- The Supreme Court granted *certiorari* to answer whether the implied certification theory was a viable one, and if so, whether it could only apply where a provider violated a legal requirement that the Government had expressly designated as a condition of payment



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### Escobar Case

- Court held that FCA should not be considered a vehicle for "punishing garden-variety breaches of contract or regulatory violations..."
- Court held that a misrepresentation about legal compliance does not become material simply because the Government expressly labeled the legal requirement as a "condition of payment, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision



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### Significance of Escobar

- Implied certification theory may be a basis for FCA liability if allegations satisfy both FCA's materiality and scienter requirements
- The focus going forward will be whether the Government would have actually refused to pay the allegedly false claim if it had known of the information allegedly omitted or misrepresented



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**Escobar Lessons**

- False Claims Act is nuanced and complex
- Implied certification is a valid theory
- Materiality will be closely scrutinized and evaluated on fact specific, case-by-case basis
- React appropriately and promptly to FCA complaints or concerns

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**Conducting the FCA Investigation**



- Getting the investigation started
  - Preserving attorney-client privilege
  - Working with Government attorneys
- Avoiding major pitfalls during an internal investigation

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**Starting the FCA Investigation**

- Document the false claim allegation
- Communicate the allegation to leadership
- Engage legal counsel
- Notice to carrier
- Assign responsibility for the investigation
- Ensure the sphere of communication is limited
- Ensure accountability and follow-up

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### Conducting the FCA Investigation

- Dig deep and uncover every stone
- Don't assume the Government's position is correct
- Advocate your position of facts and law
- Continue to keep the board informed
- Avoid whistleblower retaliation
- Be mindful of collateral effect on employees

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### Planning the FCA Investigation

- Develop investigative plan and timeline
- Decide who must be interviewed
- Place certain employees on leave
- Maintain records of the investigation process, interview notes, and witness log
- Schedule and conduct interviews
- Remind those interviewed of confidentiality

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### Conducting the FCA Investigation

- Attorney conducts investigation or deputizes staff to assist with investigation
- Litigation hold communicated throughout organization
- Document review begins
- Interviews conducted
- Auditors or experts engaged

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### Maintaining the Privilege

- Protecting attorney-client privilege
- Interview witnesses separately
- Document production and create privilege log
- Limit number of individuals in the sphere of knowledge

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### Working with the Government

- Be cooperative and responsive
- Production must be timely
- Understand the issue, the facts and the relevant law
- Don't be intimidated-push back
- Understand the settlement if there is one

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### Mitigating the Risk of a FCA Qui Tam

- Be responsive to all issues raised
- Follow through on investigation
- Circle back to complainant
- Provide assurance that the matter is being appropriately addressed
- Involve counsel, experts and the Government as needed



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## Joan W. Feldman, Partner

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# Strategies for Professionalism When Tantrums Aren't an Option

HCCA Compliance Institute  
March 28, 2017  
Jay P. Anstine  
President  
Bluebird Healthlaw Partners, LLC

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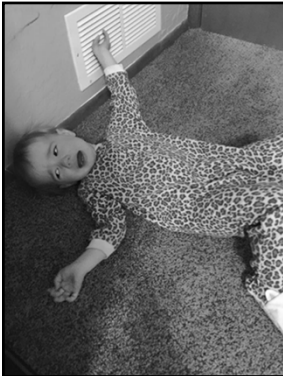
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*"A professional is one who does  
[his/her]  
best work when he/she] feels the least  
like working."  
-Frank Lloyd Wright*

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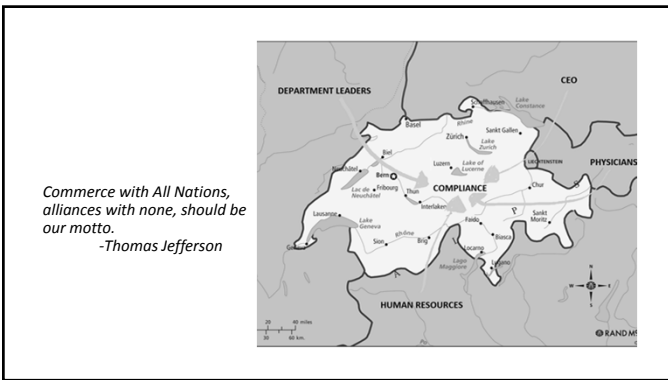
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Know Your Political Landscape

- Identify the leaders in your organization.
- Develop a sense of "political" self-awareness.
- Identify your leaders' political self-interests.

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Build Strong Relationships



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Building Strong Relationships

- Establish Rapport.
- Build and Maintain Trust.
- Support Your Leaders.

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Use Diplomacy to Influence Behavior



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### Use Diplomacy to Influence Behavior

- Know your audience.
- Know how decisions are made in the organization.
- Appeal to their interest, not their position.

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### Challenging Professionalism.



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### Consulting to Defensive Leaders

1. "Are you crazy? You want us to do what?"
2. "We've always done it this way..."
3. "You just don't know operations..."
4. "You're just an obstacle to me getting \_\_\_ done."
5. "Do you know what the \_\_\_ I do for a living?"

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### Overcoming The Defensive

- Be engaged to their business.
- Be empathetic to their challenges and interests.
- Approach your role as a resource and not an obstacle.

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### Investigations & Difficult Witnesses

Common Characteristics:

- Defensive
- Reluctant to speak
- Argumentative

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### Overcoming Difficult Witnesses

- Establish rapport/Identify root cause of difficulty.
- Approach your role as gatherer-of-facts, not interrogator.
- Don't return anger; empathize but don't advise.

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Check-in with  
Thyself.

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*"Stress is the trash of modern life. We all generate it, but if you don't dispose of it properly, it will pile up and overtake your life."*  
-Danae Pace

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What Causes Stress?

**Self-Inflicted Causes:**

- Failing to prioritizing projects;
- Procrastination;
- Not taking the time to plan;
- Failing to delegate tasks to others.

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How are you managing your time?

- Identify your most motivated time to tackle the least motivated tasks.
- Can you leverage technology or communication forms to save time?
- Block time on your calendar and honor it as if it were a meeting.

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How are you managing your workload?

- Create your "to-do" list based on assigned priority levels (A, B, C, ).
- Triage work coming in based on priority level.
- Communicate honestly with others on deadlines/expectations.

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How are you managing stress?

- Are there changes you can make to make life easier on yourself?
- Identify where stress is coming from and schedule time to address it.
- What is your system for disposing of stress?

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### How are you managing work-life balance?

- How are you prioritizing life (be honest)...is it time to reprioritize?
- Schedule in time for you (perspective, relaxation, constructive project).
- Plan out the following day before you go home.

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### Takeaways

- In times of frustration remember we need problems to be employed.
- The real growth in life comes from experiences outside our comfort zones.
- Develop your own support system.

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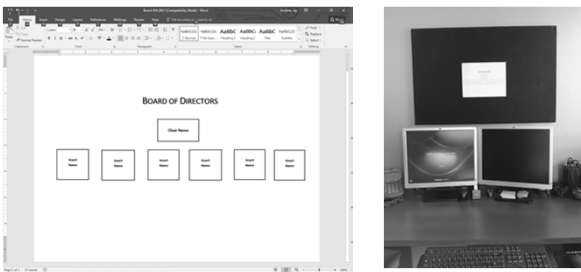
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### Develop Your Own Support System



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Questions?

*Jay P. Anstine, JD*  
*President*  
*Bluebird Healthlaw Partners, LLC*  
*303-910-1583*  
[janstine@bluebirdhealthlaw.com](mailto:janstine@bluebirdhealthlaw.com)

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## Challenges for Academic Medical Centers

Brett Short, CCO, University of Kentucky  
Lisa Taylor, CCO, UC Health

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## We are Unique!

Unique – being the only one of its kind; unlike anything else. Synonyms: distinctive, distinct, individual, special, idiosyncratic

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## Challenges

- Dealing with Teaching Physicians and Residents
- Documentation in the medical record
- How to manage the tri-partite mission

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## Tri-Partite mission

- Education
- Research
- Patient Care




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## Complexity

- Legal Organization – one hybrid, multiple entities
- Physicians – employed vs leased
- Number of Employees
- Collaboration – multiple departments and may supervisors
- Community
- Politics

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## Education

- Colleges – Medical School, Nursing, Pharmacy
- GME – reporting on Cost Report
  - Other Hospitals
  - Outside country
- Moonlighting
- Teaching – Physician Guidelines
- EPIC Issues
  - Automatic
  - Fellows who are also MD's
- Policies – University or AMC

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## Research

- Where does it sit? University or Hospital?
- Contracts
- Privacy laws - HIPAA versus State
- Access to PHI
- Research as healthcare delivery
- FERPA vs. HIPAA

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## Healthcare

- Hospital Based Clinics
- Nurse Practitioners to mid-levels
- Concurrent surgeries
- EPIC Issues/Documentation Issues
- Indigent Care
- Gifts to Patients
- Community versus Teaching Physicians

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## Areas of Focus - Soft Skills

- Relationship Building
- Overcoming Barriers
- Collaboration
- Communication breeds respect
- Find Champions
- Connect people
- Be a partner
- Beware of institutional wear

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**Thank you!**  
**Questions?**

Brett Short, CCO, University of Kentucky  
[Roger.short@uky.edu](mailto:Roger.short@uky.edu)

Lisa Taylor, CCO, UC Health  
[Lisa.taylor@UCHealth.com](mailto:Lisa.taylor@UCHealth.com)

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# Challenges for Academic Medical Centers

## Key Questions to Answer

1. Who are the members of the executive team?
2. How is the organization legally set up?
3. Number of employees, providers, and physicians?
4. Are physicians employed, leased, or community?
5. What is the departmental structure of the organization?
6. How is the organization placed and working with the community?
7. Are there any internal or external politics to be aware of?
8. How is the hospital associated with the academics?
9. What medical colleges are associated with the hospital (i.e. medical, nursing, pharmacy, etc.)?
10. Are you aware of the details of your residency program (how many residents/fellows, how is it reported on the cost report, do they go to any other hospitals or provide time outside of the country, etc.)?
11. Do you allow residents to moonlight? Is there a policy?
12. Are you aware of the CMS Teaching Physician Guidelines and are your providers?
13. Do you have any EPIC issues? Who approves EPIC changes? Is anything automatic? How do you manage fellows who are also physicians?
14. Who has to follow which (University or Hospital or both) policies?
15. Where does your research management sit – university or hospital?
16. Do you have contracts/BAA's where needed? Who manages contract process?
17. Are you aware of federal and any state privacy laws and how they impact all facets of your organization?
18. How do you conduct access to PHI by researchers?
19. Are you aware of the difference between pure research and treatment involving research?
20. Are you aware of the difference between HIPAA and FERPA and how to apply the differences?
21. Do you have physicians or hospital based clinics or both? Do you understand the legal and billing differences?
22. How are your mid-levels employed? Any issues with split-shared billing by physicians using Nurse Practitioners?
23. Do you allow concurrent surgeries? If so, do you have documented policies and procedures? Do clinicians define key and critical portions?
24. Is the research a government or sponsored study?
25. What about research that is performed by someone other than a physician?
26. Where does the IRB sit?
27. How do you handle indigent care? Do you have an appropriate Charity Care policy?
28. How do you deal with gifts to patients?
29. Do you handle community physicians differently than your teaching physicians?



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## Discussion Points

- Health IT
- Security In Healthcare
- Ransomware
- Breach Risk Maturity
- Discussion



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## Delivery of Care Has Transformed

MORE TECHNOLOGY



ENHANCED ACCESS



HIGHER AVAILABILITY



...YET HEALTHCARE IS STILL NOT SECURE

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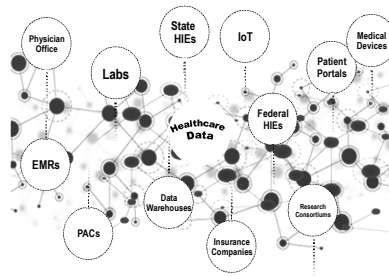
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### Provider / Patient Infrastructure

- Family physician / PCP / GP
- Specialist clinic
- Blood Lab
- X-Ray / Cat Scan provider
- Local hospital
- Rehab facility after hospital discharge
- Online patient portals
- Insurance company (payer)
- Health Information Exchanges
- EMR-to-like-EMR integration
- Data Warehouse(s)
- Data push to patients & other providers
- Push to the State, research consortiums
- Data push of lab results to providers
- Data pull from EMRs for visiting patients (Patient Portals)
- IoT
- Medical Devices



\* Doug Copley data from SecureWorld 2014

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### Transformed Care is a Hotbed for CyberSecurity

- Digitizing patient record
- Sharing patient across HLS ecosystem
- Data-based collaborative care
- Analytics to enhance care
- Electronic registries for population health
- Personalized medicine

**DATA EXPLOSION**  
Unprecedented Security Risk




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“

WHAT THREAT VECTOR IS MOST CONCERNING TO YOU AND WHY.

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### The Next Battleground

**THE NEXT THREAT**  
Forrester Research 2016 Cybersecurity Report – #1 prediction will be ransomware for medical devices or wearables

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### CHANGING HEALTHCARE LANDSCAPE

**646** M&A / DIVESTITURES  
**90%** PROVIDER ORGANIZATIONS ADMITTED A RECENT "SIGNIFICANT SECURITY INCIDENT"  
**\$9.5** BILION  
**#4** 2016 M&A ACTIVITY WITH MORE THAN \$298B IN DEAL VALUE

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“  
HAVE WE BEEN HACKED?  
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## SECURITY INCIDENTS AND BREACHES

329 2016 & 51 2017 REPORTED BREACHES OF 500 OR MORE AFFECTED

16.6MM INDIVIDUALS AFFECTED  
425K INDIVIDUALS AFFECTED

OVER \$20MM IN FINES IN 2016  
OVER \$11MM IN FINES IN 2017

Source: U.S. Department of Health and Human Services  
Office for Civil Rights Breach Portal  
[https://ocrportal.hhs.gov/ocr/breach/breach\\_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf)

BREACH TYPE	AFFECTED ENTITIES	
	2016	2017
HACKING/ IT INCIDENT	113	14
IMPROPER DISPOSAL	7	2
LOST	16	4
THEFT	62	10
UNAUTHORIZED ACCESS/DISCLOSURE	130	21
TYPE NOT DISCLOSED	1	
<b>TOTAL</b>	<b>329</b>	<b>51</b>
BA	20	3
HEALTH PLAN	51	8
HEALTHCARE PROVIDER	256	40
NOT SPECIFIED	2	0
<b>TOTAL</b>	<b>329</b>	<b>51</b>

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## Notable Breaches in 2016

REPORTED: 8/3/16 AFFECTED INDIVIDUALS: 3,620,000 CAUSE: HACKING/ IT INCIDENT	REPORTED: 8/9/16 AFFECTED INDIVIDUALS: 3,486,120 CAUSE: HACKING/ IT INCIDENT	REPORTED: 3/4/16 AFFECTED INDIVIDUALS: 2,213,997 CAUSE: HACKING/ IT INCIDENT	REPORTED: 8/12/16 AFFECTED INDIVIDUALS: 882,990 CAUSE: HACKING/ IT INCIDENT	REPORTED: 12/16/16 AFFECTED INDIVIDUALS: 749,017 CAUSE: HACKING/ IT INCIDENT
REPORTED: 8/12/16 AFFECTED INDIVIDUALS: 651,971 CAUSE: UNAUTHORIZED ACCESS/ DISCLOSURE	REPORTED: 11/18/16 AFFECTED INDIVIDUALS: 531,000 CAUSE: HACKING/ IT INCIDENT	REPORTED: 2/12/16 AFFECTED INDIVIDUALS: 483,063 CAUSE: LOSS	REPORTED: 5/15/16 AFFECTED INDIVIDUALS: 400,000 CAUSE: THEFT	REPORTED: 12/21/16 AFFECTED INDIVIDUALS: 381,504 CAUSE: HACKING/ IT INCIDENT

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## 14 Ransomware Incidents

BECKER'S HEALTH IT & CIO REVIEW Hospitals are hit with 88% of all ransomware attacks

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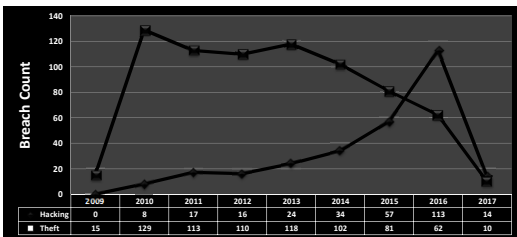
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### THEFT VS HACKING TREND



Source: U.S. Department of Health and Human Services  
Office for Civil Rights Breach Portal  
[https://ocrportal.hhs.gov/ocr/breach/breach\\_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf)

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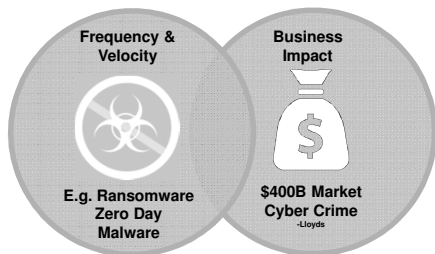
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### Healthcare Industry: Challenges – Cyber Threats




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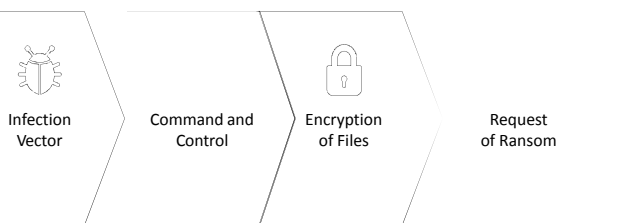
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### Typical Ransomware Infection

Ransomware is malware for data kidnapping, an exploit in which the attacker encrypts the victim's data and demands payment for the decryption key. Ransomware spreads through e-mail attachments, infected programs and compromised websites.




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### Ransomware: Underground Market Place

**1**

**\$39 Only**  
Lifetime License

**2**

**Russian Roulette**

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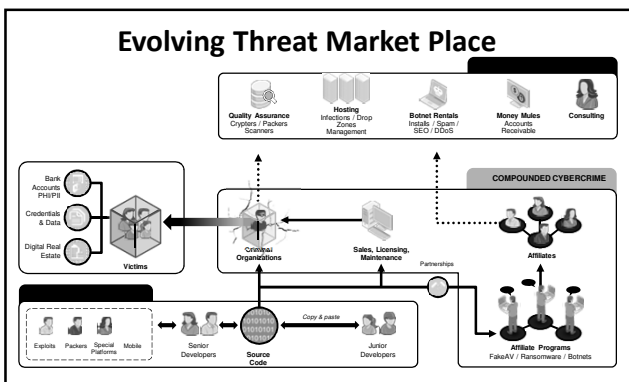
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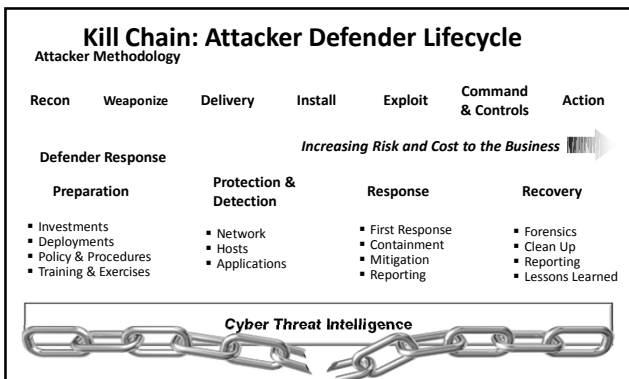
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“

**DISCUSS SOME OF THE WAYS YOU CAN  
BREAK THE KILL CHAIN AND DEFEND  
AGAINST MULTI-VECTOR ATTACKS.**

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**Decrypting a Ransomware Strategy  
SECURE NETWORK THREAT DETECTION & ANALYSIS**

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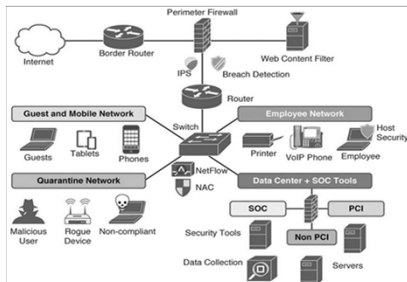
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### Sample Secure Network Topology



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## Segmentation: Not all assets are equal

<p><b>LIFE CRITICAL:</b>                  No Internet -&gt; Connection to Internal; APPS and DC only                  Highly Segmented from the rest of the network                  SEGMENTED NETWORK</p>
<p><b>HIGH PHI/PII/PCI:</b>                  Strong Encryption, 2 Factor Authentication, Whitelist (signed) Apps, DNS Firewalling, Endpoint Protection, Server Side Protection, Proxied Internet Access, MicroSegmentation, App Sandboxing, Email Security, Content Filtering/Inspection</p>
<p><b>Low/Medium:</b>                  DNS Firewalling, Endpoint Protection, Server side Protection, Proxied Internet Access, Content Filtering/Inspection.</p>

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## Security Operations Center




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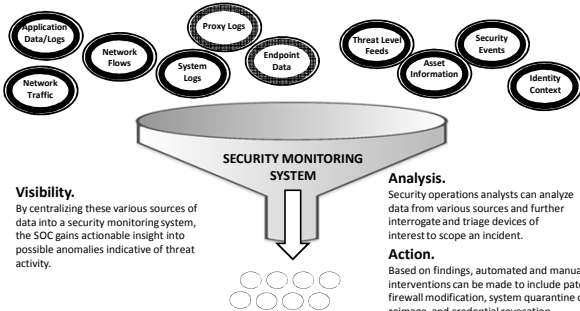
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## SOC: Data Aggregation for Improved Incident Handling




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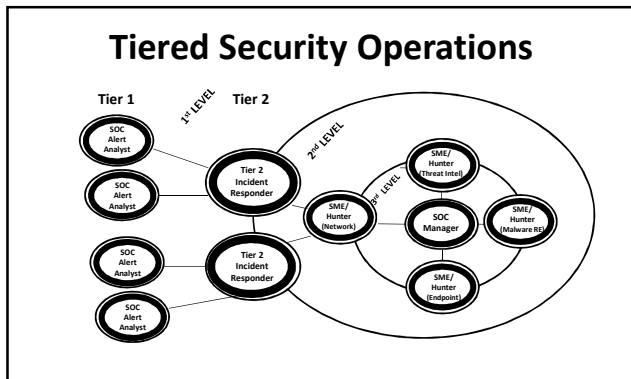
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### Threat Management

- Consolidate functions of incident monitoring, detection, response, coordination, and computer network defense tool engineering, operation, and maintenance under one organization: the Cyber Security Operations Center (CSOC.)
- Achieve balance between size and visibility/agility, so that the CSOC can execute its mission effectively.
- Give the CSOC the authority to do its job through effective organizational placement and appropriate policies and procedures.
- Focus on a few activities that the CSOC practices well and avoid the ones it cannot or should not do.
- Favor staff quality over quantity, employing professionals who are passionate about their jobs, provide a balance of soft and hard skills, and pursue opportunities for growth.
- Realize the full potential of each technology through careful investment and keen awareness of—and compensation for—each tool's limitations.

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### Common Vocabulary

- Attack method : The manner or technique and means an adversary may use in an assault on information or an information system.
- Exfiltration: The unauthorized transfer of information from an information system.
- Attack Vector
- Indicator of Compromise
- C2- command and control
- DPP (Deep Packet Processing) -Deep Packet Processing delivers the ability to inspect, forward, drop, clone, or even modify network traffic, at line rates. With Deep Packet Processing and combinations of policies and/or programming, the lag time from inspection to action drops from minutes or hours or worse, days, to milliseconds.
- EPP (endpoint protection): Including host-based features like firewall, anti-malware, whitelisting and disk encryption
- EVC – Endpoint Visibility and Control
- ETDR – endpoint threat detection and response
- Tactical Threat Intelligence – often referred to as tactics, techniques and procedures (TTPs) and is information about how threat actors are conducting attacks
- TTPs – Tools, Techniques and Processes

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## Threat Intelligence

- **Cyber Intel Collection and Analysis**: Collection, consumption, and analysis of cyber intelligence reports, cyber intrusion reports, and news related to information security, covering new threats, vulnerabilities, products, and research.
- **Cyber Intel Distribution**: Synthesis, summarization, and redistribution of cyber intelligence reports, cyber intrusion reports, and news related to information security to members of the constituency on either a routine basis (such as a weekly or monthly cyber newsletter) or a non-routine basis (such as an emergency patch notice or phishing campaign alert).
- **Cyber Intel Creation**: Primary authorship of new cyber intelligence reporting, such as threat notices or highlights, based on primary research performed by the SOC. For example, analysis of a new threat or vulnerability not previously seen elsewhere. This is usually driven by the SOC's own incidents, forensic analysis, malware analysis, and adversary engagements.
- **Cyber Intel Fusion**: Extracting data from cyber intel and synthesizing it into new signatures, content, and understanding of adversary TTPs, thereby evolving monitoring operations (e.g., new signatures or SIEM content).
- **Trending**: Long-term analysis of event feeds, collected malware, and incident data for evidence of malicious or anomalous activity or to better understand the constituency or adversary TTPs (Tools, Techniques and Processes. This may include unstructured, open-ended, deep-dive analysis on various data feeds, trending and correlation over weeks or months of log data, "low and slow" data analysis, and esoteric anomaly detection methods.
- **Threat Assessment**: Holistic estimation of threats posed by various actors against the constituency, its enclaves, or lines of business, within the cyber realm. This will include leveraging existing resources such as cyber intel feeds and trending, along with the enterprise's architecture and vulnerability status. Often performed in coordination with other cybersecurity stakeholders.

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## Security Outreach

- **Product Assessment**  
Testing the security features of point products being acquired by constituency members. Analogous to miniature vulnerability assessments of one or a few hosts, this testing allows in-depth analysis of a particular product's strengths and weaknesses from a security perspective. This may involve "in-house" testing of products rather than remote assessment of production or preproduction systems.
- **Security Consulting**  
Providing cybersecurity advice to constituents outside the scope of CND; supporting new system design, business continuity, and disaster recovery planning; cybersecurity policy; secure configuration guides; and other efforts.
- **Training and Awareness Building**  
Proactive outreach to constituents supporting general user training, bulletins, and other educational materials that help them understand various cybersecurity issues. The main goals are to help constituents protect themselves from common threats such as phishing/pharming schemes, better secure end systems, raise awareness of the SOC's services, and help constituents correctly report incidents.
- **Situational Awareness**  
Regular, repeatable repackaging and redistribution of the SOC's knowledge of constituency assets, networks, threats, incidents, and vulnerabilities to constituents. This capability goes beyond cyber intel distribution, enhancing constituents' understanding of the cybersecurity posture of the constituency and portions thereof, driving effective decision making at all levels. This information can be delivered automatically through a SOC website, Web portal, or email distribution list.
- **Redistribution of TTPs (Tools, Techniques and Processes)**  
Sustained sharing of SOC internal products to other consumers such as partner or subordinate SOCs, in a more formal, polished, or structured format. This can include almost anything the SOC develops on its own (e.g., tools, cyber intel, signatures, incident reports, and other raw observables). The principle of quid pro quo often applies: information flow between SOCs is bidirectional.
- **Media Relations**  
Direct communication with the news media. The SOC is responsible for disclosing information without impacting the reputation of the constituency or ongoing response

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## Decrypting a Ransomware Strategy

### BREACH SECURITY ASSESSMENT

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### Healthcare Breach Security Assessment Program

- Created by Intel and VMware
- The assessment is free of Cost
- Confidential
- Contact:

Chris Logan  
 Sr. Healthcare Strategist  
 VMware Healthcare  
 clogan@vmware.com




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### Breach Security Assessment How it Works



- One (1) hour assessment
- By conference call or in person
- Priority across 8 breach types
- Presence of 42 breach security capabilities from the maturity model
- Org type, country, size for future comparison with similar peers
- Post assessment and quarterly reports
- Maturity score, priorities and capabilities benchmarked against industry
- Spreadsheet used to gather assessment input
- No personally identifiable information or patient information collected

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### Breach Types Assessed

1. Cybercrime Hacking
2. Ransomware
3. Loss or Theft of Mobile Device or Media
4. Insider Accidents or Workarounds
5. Business Associates
6. Malicious Insiders or Fraud
7. Insider Snooping
8. Improper Disposal




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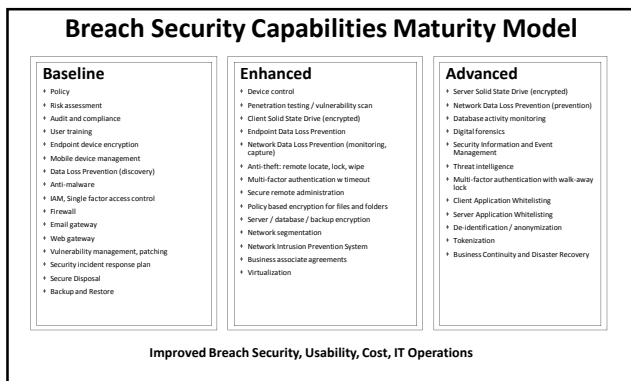
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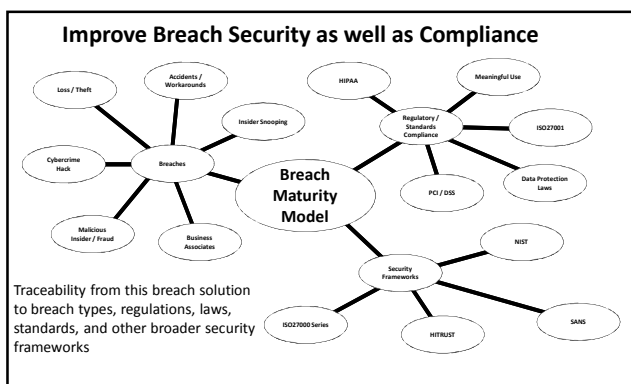
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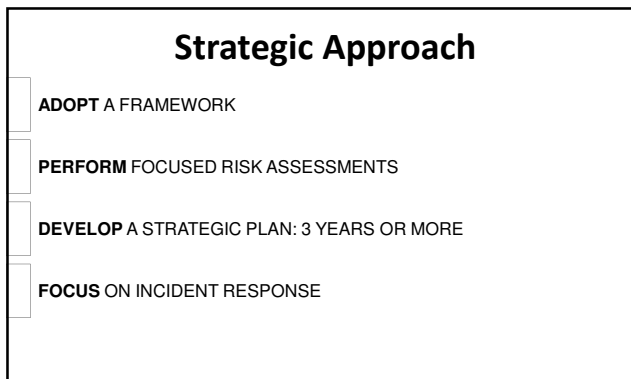
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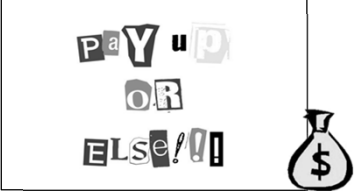
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**RANSOMWARE:  
SHOULD I NOTIFY LAW  
ENFORCEMENT?**

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Common Definitions 

**Ransom:** "A consideration paid or demanded for the release of someone or something from captivity."  
www.merriam-webster.com/dictionary/ransom

**Extortion:** "Obtaining money or property by threat or force."  
criminal.findlaw.com/criminal\_charges/extortion.html

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**Everything Old is New Again**

- Criminals engaged in these illegal activities long before the internet existed
  - Middle Ages knight warfare
  - Pirates
  - Salzburg-Bavaria 30 Years War
  - Kidnapping
- The internet provided a new venue for crime – a networked world of computers
  - Criminals can now commit an extremely lucrative crime from the comfort of their own home
  - \$10 million to \$50 million MONTHLY income for cybercriminals





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Cyber Definitions



**Ransomware:** "A type of malware that prevents or limits users from accessing their system, either by locking the system's screen or by locking the users' files unless a ransom is paid."

www.trendmicro.com/vinfo/us/security/definition/Ransomware



**Crypto-Ransomware:** "More modern ransomware families which encrypt certain file types on infected systems and forces users to pay the ransom through certain online payment methods to get a decrypt key."<sup>14</sup>

- Also referred to as Crypto-Extortion.

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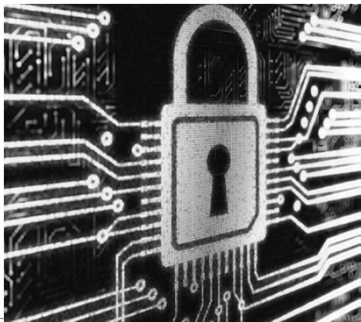
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YOU HAVE BEEN HACKED !



Now what?

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Imagine...



- ❖ No access to email
- ❖ No access to EHR
- ❖ Medical test results cannot be accessed or shared
- ❖ Have to resort to paper records
- ❖ Medical personnel have to talk in person
- ❖ Transfer of high-risk patients to other medical facilities
- ❖ \$3.6 million BitCoin ransom demanded

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This is exactly what happened to Hollywood Presbyterian Medical Center in Los Angeles



Loss per day on CT Scans alone: \$100,000

Ransom paid to decrypt files: \$ 17,000

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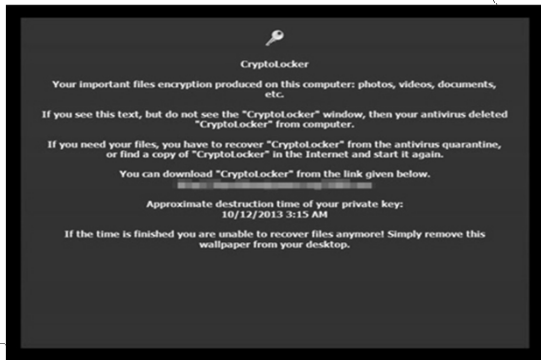
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### The threat



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## The Risk

A recent U.S. Government interagency report indicates that, on average, there have been 4,000 daily ransomware attacks since early 2016.

This represents a 300% increase over the 1,000 daily ransomware attacks reported in 2015.

Source: How to Protect Your Network from Ransomware, US Government Interagency Technical Guidance Document  
file:///data:/new01/roster/Users/Data/warrent/M/2016/documents/Healthcare/Ransomware/technical-document-ransomware-prevention-and-response.pdf

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## The Cost

### MONETARY

2015 - FBI's Internet Crime Complaint Center (IC3) received 2400 ransomware reports

- Losses = \$24 million
- Average Ransom demand: \$10,000

First Quarter 2016

- Ransom Cost: \$209 million
- FBI's forecast for 2016 losses = \$1 billion

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### OTHER COSTS

- Downtime/loss of productivity
- IT services – review systems and data, remove malware, clean data
- Addressing the breach of confidential information
- Damage to reputation

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Which law enforcement agency do you contact?



- Local
- State
- Federal
- International

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### Considerations



- ✓ Jurisdictional issues
- ✓ Computer crimes and forensics training
- ✓ Staffing
- ✓ Special Units
- ✓ Resources

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## State



- State laws vary
- Pennsylvania enacted Hacking and Computer Crimes legislation in February of 2003
- Felony Offenses
- PA State Police established a Computer Crimes Unit
- In 2002, PSP created Regional Computer Crime Task Forces

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## Federal



Hobbs Act, 18 U.S.C. 1951  
interference with commerce by extortion

18 U.S.C. 875  
interstate communication of threat to injure property of another

These laws were not seen as specifically covering computers

Commencing in 1996, Congress began to enact specific legislation to combat computer crime

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## Current Federal Laws

- Computer Fraud and Abuse Act (CFAA) 18 U.S.C. 1030
  - Federal computers
  - Bank computers
  - Computers used in or affecting interstate and foreign commerce
  - only "slight impact" on interstate commerce needed
    - computer that accesses the internet
    - victim and perp can be in same state
- Computers are the victims – not a venue



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- ◉ Identity Theft Enforcement and Restitution Act of 2008
- ◉ Economic Espionage Act 18 U.S.C. 1832 theft of trade secrets
- ◉ Money Laundering 18 U.S.C. 1956 and 1957
- ◉ Wire Fraud 18 U.S.C. 1343 yielded most computer crime convictions
- ◉ 18 U.S.C. 876 mailing threatening communications
- ◉ 18 U.S.C. 877 mailing threatening communications from foreign country
- ◉ 18 U.S.C. 880 receipt of the proceeds of extortion

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### Federal Agencies



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### FBI



- FBI is the lead federal agency for investigating criminal cyberattacks
  - Cyber Division at HQ
  - Cyber Squads at HQ and 56 field offices
  - Cyber Action Teams –mobilize on moment's notice
  - 93 Computer Crimes Task Forces
  - Partnerships with other Federal agencies

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- Leads the National Cyber Investigative Joint Task Force (NCIJTF)  
domestic coordination  
established 2008
- National Cyber Forensics and Training Alliance (NCFTA)
- Partners with private sector through InfraGard and Information Sharing and Analysis Centers (ISACs)  
16 crucial infrastructure sectors  
Includes healthcare and public health



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Internet Crime Complaint Center (IC3)

**www.ic3.gov**



Filing a Report

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Internet Crime Complaint Center (IC3) website screenshot. The page title is 'Filing a Complaint with the IC3'. The main content area explains that the IC3 accepts online Internet crime complaints and lists the required information for filing a complaint: victim's name, address, telephone, and email; financial transaction information; subject's name, address, telephone, email, website, and IP address; specific details on how you were victimized; email header(s); and any other relevant information. A 'File a Complaint' button is visible at the bottom of the main content area. The right sidebar contains 'Site Navigation' links: Alert Archive, FAQs, Disclaimer, Privacy Notice, Internet Crime Prevention Tips, and Internet Crime Schemes. Below that is an 'Annual Report' section with a small image. The browser address bar shows 'https://www.ic3.gov/default.aspx'.

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Q: What details will I be asked to include in my complaint?

- Victim's name, address, telephone, email
- Financial transaction information
- Suspect's name, address, telephone, email, website, IP address
- Date and details on how you were victimized
- Initial entry vector or vulnerability if known
- How detected
- Specific assets impacted
- Email header(s)
- Any other relevant information you believe is necessary to support your complaint




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- Analysts review each report
- Refer to appropriate law enforcement agency for investigation and prosecution
- IC3 database shared through Law Enforcement Enterprise Portal (LEEP) – compare and compile
- Report cannot be withdrawn once submitted

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## Secret Service



- ⊙ Electronic Crimes Task Force
  - national network to prevent, detect and investigate cybercrimes (39 task forces)
- ⊙ Electronic Crimes Special Agent Program
- ⊙ Computer Emergency Response Team
- ⊙ Collaboration with international law enforcement agencies
- ⊙ National Computer Forensics Institute – training for state and local LEO

<https://www.secretservice.gov/investigation/#field>

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- ⊙ Official position: FBI does not support paying ransom
  - Not guaranteed that data will be released
  - Emboldens the cybercriminals
  - Encourages others to engage in cyber-extortion
  - Helps to fund other illegal activities



<https://www.fbi.gov/investigate/cyber>

- ⊙ But, in 2015 a Special Agent speaking at the 2015 Cyber Security Summit said: “pay up”
  - Why? “The ransomware is that good.”



<http://www.businessinsider.com/fbi-recommends-paying-ransom-for-infected-computer-2015-10>

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## International

- ⊙ Budapest Convention on Cybercrime - November 2001
  - first international treaty on computer crimes
  - foundation for global law enforcement of cyberspace
- ⊙ Main objective: Pursue common criminal policy aimed at the protection of society against cybercrime, especially by adopting appropriate legislation and fostering international cooperation
  - 24/7 access and response
  - exchange of information
  - mutual assistance
- ⊙ Russia has not signed or ratified – cites violations of international law and sovereignty claims
- ⊙ US ratified 2006




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### Future



- The growth of the IoT has exponentially increased the range and number of devices which can be attacked
- Medical devices
  - pacemakers
  - defibrillators
  - insulin pumps



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### Why Report to Law Enforcement?

- Access to tools and contacts not available to private citizens
- Location of the stolen data
- Apprehension of the perpetrator
- Creation of a more safe and secure cyberspace
- Compilation of data and trends
- Improvement in future responses
- Prevention of future losses



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### So, where does that leave us?

#### **Be vigilant**

- Prevention
  - up-to-date antivirus and firewalls
  - enable pop-up blockers
  - always backup data
  - be skeptical
  - read FBI and industry alerts
  - educate employees
  - risk analysis
- Business continuity plan



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Reporting helps law enforcement make cyberspace safer for everyone

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References

- <https://www.dhs.gov/sites/default/files/publications/USSS%20Electronic%20Crimes%20Task%20Force.pdf>
- <http://www.riskmanagementmonitor.com/tag/ransomware/>
- <http://www.securityweek.com/ransomware-four-ways-assess-growing-threat-business-risk>
- <https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf>
- <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-61r2.pdf>
- <https://www.justice.gov/criminal-ccips/file/872771/download>
- <http://www.healthcare-informatics.com/news-item/cybersecurity/report-internet-enabled-medical-devices-becoming-bigger-target-ransomware>
- <https://arstechnica.com/security/2015/06/fbi-says-crypto-ransomware-has-raked-in-18-million-for-cybercriminals/>
- <http://tech.firstpost.com/news-analysis/symantec-classifies-ransomware-as-the-most-dangerous-cyber-threat-336688.html>
- <https://www.trendmicro.com/infocenter/definition/Ransomware>
- <https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/0900001680081561>
- <https://www.fbi.gov/file-repository/law-enforcement-cyber-incident-reporting.pdf/view>
- <https://www.justice.gov/usao/priority-areas/cyber-crime>

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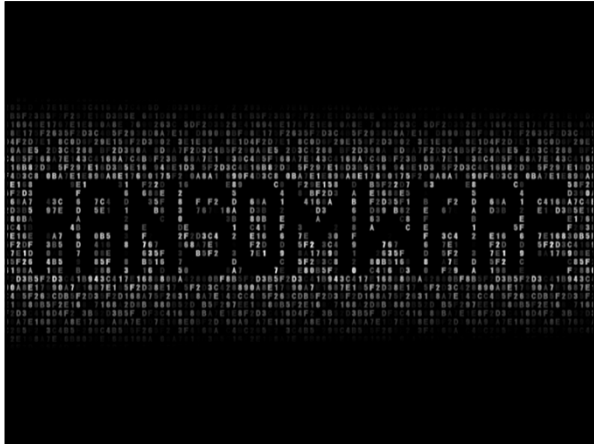
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**Ransomware and HIPAA**

- When talking about how to prepare for and survive a ransomware attack, HIPAA provides a good blueprint
- If you have had a ransomware attack, you probably have also had a HIPAA breach



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**What is HIPAA? What is HITECH?**

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
  - Federal law to improve efficiency of health care industry
  - Privacy Rule (2003) and Security Rule (2005)
- The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009
  - Focused on adoption of EHRs
- Final Omnibus Rule
  - January 2013; effective September 23, 2013 - sweeping changes

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### What is PHI?

Information that relates to:

- (1) an individual's past, present, or future physical or mental health or condition,
- (2) the provision of health care to the individual, OR
- (3) the past, present, or future payment for the provision of health care to the individual



**Covered Entities and Business Associates must vigorously protect against unauthorized use of or access to PHI that they create, receive, maintain, or transmit.**

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### Who Must Comply with HIPAA's Requirements to Safeguard PHI?

- **Covered Entities** - Health plans, (e.g. Medicare or Medicaid) health care clearinghouses, and health care providers (doctors, nursing homes, or clinics) who bill electronically
- **Business Associates** - A person or entity that performs certain functions or activities for or on behalf of a covered entity that requires the person or entity to create, receive, maintain or transmit PHI. For example:
  - Law firms;
  - Billing/collection companies;
  - Financial institutions (other than pure banking services); and
  - Accounting firms
- **Subcontractors of Business Associates**

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### How HIPAA Compliance Can Help You **PREPARE** for and **RESPOND** to a Ransomware Attack – **SECURITY RULE**

- The Security Rule establishes national standards to protect electronic PHI. It requires entities to:
  - Implement security measures; and
  - Implement policies and procedures.

**The HIPAA Security Rule could prevent the introduction of ransomware into your system and can help you respond to a ransomware attack!**

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How HIPAA Compliance Can Help You  
**PREPARE** for and **RESPOND** to a  
Ransomware Attack - **SECURITY RULE**

- **General requirements (45 C.F.R. § 164.306)**
  - Ensure confidentiality, integrity, and availability of electronic PHI created, received, maintained, or transmitted
  - Protect against reasonably anticipated threats or hazards to the security or integrity of such information
  - Protect against reasonably anticipated uses or disclosures of such information that are not permitted by the Security Rule
  - Ensure compliance by workforce
- **The Security Rule requires the implementation of certain safeguards:**
  - (1) administrative (45 C.F.R. § 164.308),
  - (2) physical (45 C.F.R. § 164.319), and
  - (3) technical (45 C.F.R. § 164.312)

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How HIPAA Compliance Can Help You  
**PREPARE** for a Ransomware Attack

- **Security Management Process**  
(Administrative Safeguard)
  - Implement policies and procedures to prevent, detect, contain, and correct security violations
    - Risk Analysis
    - Risk Management Program
    - Sanction Policy
    - Information System Activity Review

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How HIPAA Compliance Can Help You  
**PREPARE** for a Ransomware Attack –  
**RISK ANALYSIS**

- Assess risks and vulnerabilities to your information
- Methodologies vary depending on the size, complexities, and capabilities of your organization
- See HHS guidance regarding elements of a risk analysis:  
<http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>

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How HIPAA Compliance Can Help You  
**PREPARE** for a Ransomware Attack –

**RISK ANALYSIS**

**Elements of a Risk Analysis**

1. Determine scope
2. Data collection
3. Identify and document potential threats and vulnerabilities
4. Assess current security measures
5. Determine the likelihood of threat occurrence
6. Determine the potential impact of threat occurrence
7. Determine the level of risk
8. Identify security measures and finalize documentation
9. Periodic review and updates

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How HIPAA Compliance Can Help You  
**PREPARE** for a Ransomware Attack –

**RISK MANAGEMENT PROGRAM**

- Composed of policies and procedures
- Your management and other key decision makers must be involved
- Prioritize risks that you identify from the risk analysis
- Determine options for mitigating the risks
- Develop a plan for implementing security measures
  - Security measures should guard against and detect malicious software

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How HIPAA Compliance Can Help You  
**PREPARE** for and **RESPOND** to a

Ransomware Attack – **EMPLOYEE**

**TRAINING**

- Employees need to be trained on BOTH:
  - Threat of ransomware; AND
  - Policies/procedures to follow if they receive a ransom demand or believe the system has been infected
- Train and retrain employees
- Use simulated attacks

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### How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **POLICIES**

What type of policies does your organization need?

- What to do when you find out you are being attacked;
- What actions you will take to get your data and your systems back; and
- Comprehensive data protection plan that meets your unique operational needs.

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### How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **SECURITY INCIDENT POLICY**

HIPAA	RANSOMWARE
Identify and respond to suspected or known security incidents	Detect ransomware and conduct an initial analysis
Mitigate, to the extent practicable, the harmful effects of the security incident that are known	<ul style="list-style-type: none"> <li>• Contain the impact and spread of the ransomware</li> <li>• Eradicate the instances of ransomware and remediate vulnerabilities that permitted the ransomware attack</li> <li>• Restore lost data and return to "business as usual" operations</li> </ul>
Document security incidents and their outcomes	<ul style="list-style-type: none"> <li>• Document attack and remediation</li> <li>• Conduct post-incident activities</li> </ul>

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### How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **EMERGENCY RESPONSE POLICY**

- Contact information for critical team members, federal authorities, and outside vendors (e.g. legal counsel and technical forensic investigators)
- Utilize decision trees
- Policies/procedures need to be tested and updated.

A timely response will limit damage.

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How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **CONTINGENCY PLAN**

Elements:

- Data Backup Plan
- Disaster Recovery Plan
- Emergency Mode Operation Plan

All contingency plans need to be tested and revised.

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How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **DATA BACK UP POLICY**

- All entities must have a data backup and recovery plan for all critical information
- Backup plans must include:
  - How often backing up
  - Where backing up
- Test backup plans

Ransomware attacks deny access to data. Maintaining frequent backups and ensuring the ability to recover data from backups is crucial to surviving a ransomware attack.

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How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **DISASTER RECOVERY POLICY**

- Document process to restore lost data and recover computer systems
- Define the resources, actions, tasks, and data required to manage the recovery process

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How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **EMERGENCY MODE OPERATION PLAN**

- Purpose: Enable the continuation of crucial business processes that protect the security of data during and immediately after a crisis situation

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How HIPAA Compliance Can Help You **RESPOND** to a Ransomware Attack – **Security Rule Policies**

- **Workforce Security Policy**
- **Security Awareness and Training Policy**
- **Security Officer Policy**

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**HIPAA Breach**

- Breach = the acquisition, access, use or disclosure of PHI in a manner not permissible under HIPAA which compromises the security or privacy of PHI
- If PHI is encrypted as part of ransomware attack, there has been an unauthorized disclosure
- Rule: An impermissible use or disclosure of PHI is presumed to be a breach, unless there is a *low probability* that the PHI has been compromised



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### Risk Assessment

Factors considered when conducting a risk assessment:

- 1.The nature and extent of the PHI involved;
- 2.The unauthorized person who had access to or used the PHI or to whom the disclosure was made;
- 3.Whether the PHI was actually acquired or viewed; and
- 4.The extent to which the risk to the PHI has been mitigated

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### HIPAA Reporting Requirements

Providing Notification To...	Breach Involved Fewer Than 500 Individuals	Breach Involved 500 or More Individuals
Individuals	No later than 60 days from discovery	No later than 60 days from discovery
U.S. Department of Health and Human Services	Submit a log of all breaches once a year, no later than 60 days after end of calendar year	At the same time as notice to individuals, no later than 60 days from discovery
Media	N/A	No later than 60 days from discovery

Chart comes from CMS Outreach and Education Materials  
<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurityTextOnly.pdf>

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How the "Three Amigos" of a Compliance Program  
Can Work Together to Support and Advance an  
Effective Compliance Program



2017 Health Care Compliance Association  
Compliance Institute 2017  
National Harbor, MD  
March 26-29, 2017

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About the Speakers

Bill Wong, CHC, CHPC, CCS, CPC, CPMA, CDEO  
Sr. Coding & Compliance Educator/Auditor  
Providence Health & Services

Walter Johnson, CHC, CHPC, CCEP, CCEP-I  
Director of Compliance & Ethics  
K-Force Government Solutions

Frank Ruelas  
Facility Compliance Professional  
St. Joseph Hospital & Medical Center

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Objectives



- Assess and identify how Compliance, Legal, and HR play critical roles in several key elements of a compliance program to include those related to policies and procedures, auditing and monitoring, response and investigation, and enforcement

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## Objectives



- Assess and identify how Compliance, Legal, and HR play critical roles in several key elements of a compliance program to include those related to policies and procedures, auditing and monitoring, response and investigation, and enforcement
- Identify and learn how to align the strengths and weaknesses of these three areas so as to optimize their overall, collective contributions to the development of a compliance program.

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## Objectives



- Assess and identify how Compliance, Legal, and HR play critical roles in several key elements of a compliance program to include those related to policies and procedures, auditing and monitoring, response and investigation, and enforcement
- Identify and learn how to align the strengths and weaknesses of these three areas so as to optimize their overall, collective contributions to the development of a compliance program.
- Identify risks to mitigate the potential of sub optimization in the level of collaboration among Compliance, Legal, and HR given their respective duties that support an effective compliance program

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## Objectives



- Assess and identify how Compliance, Legal, and HR play critical roles in several key elements of a compliance program to include those related to policies and procedures, auditing and monitoring, response and investigation, and enforcement
- Identify and learn how to align the strengths and weaknesses of these three areas so as to optimize their overall, collective contributions to the development of a compliance program.
- Identify risks to mitigate the potential of sub optimization in the level of collaboration among Compliance, Legal, and HR given their respective duties that support an effective compliance program

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## Let's meet the Three Amigos!



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### Compliance Officer

- Develop, modify, implement compliance policies and procedures
- Administer compliance activities
- Monitor system wide compliance with the Code of conduct

Source: Health Care Compliance Association  
Job Description: Compliance Officer

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### Compliance Officer (continued)

- Maintain compliance reporting systems
- Evaluate, investigate, and document report of non compliant activities
- Coordinate internal compliance investigations and routine audit

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### Compliance Officer (continued)

- Coordinate internal compliance investigations and routine audit
- Develop and review compliance education program
- Serve as coordinator for external investigations and inquires related to the program
- Report compliance issues and activities on a regular basis to Board of Trustee

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### Human Resources Director (continued)

- Annually reviews and makes recommendations for improvement of the organization's policies, procedures and practices on personnel matters.
- Maintains knowledge of industry trends and employment legislation and ensures organization's compliance.
- Maintains responsibility for organization compliance with federal, state and local legislation pertaining to all personnel matters including AA/EEO compliance and labor relations.

Source: Society for Human Resource Management  
Job Description: Director of Human Resources

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### Human Resources Director (continued)

- Coordinates or conducts exit interviews to determine reasons behind separations.
- Consults with legal counsel as appropriate, or as directed by the CEO, on personnel matters.
- Recommends, evaluates and participates in staff development for the organization.
- Participates on committees and special projects and seeks additional responsibilities.

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### Legal Counsel

- Give accurate and timely counsel to executives in a variety of legal topics (labor law, partnerships, international ventures, corporate finance etc.)
- Collaborate with management to devise efficient defense strategies
- Specify internal governance policies and regularly monitor compliance
- Research and evaluate different risk factors regarding business decisions and operations

Source: Society for Human Resource Management  
Job Description: Director of Human Resources

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### Legal Counsel (continued)

- Apply effective risk management techniques and offer proactive advise on possible legal issues
- Communicate and negotiate with external parties (regulators, external counsel, public authority etc.), creating relations of trust
- Draft and review legal documents to ensure the company's legal rights
- Deal with complex matters with multiple stakeholders

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### Legal Counsel (continued)

- Provide clarification on legal language or specifications to everyone in the organization
- Conduct your work with integrity and responsibility
- Maintain current knowledge of alterations in legislation

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# Scenarios Ours and Yours

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Which Amigo to Involve?

	Compliance	HR	Legal
Who?	✓	✓	✓
What?	✓	✓	✓
Where?	✓	✓	✓
When?	✓	✓	✓
Why?	✓	✓	✓
How?	✓	✓	✓

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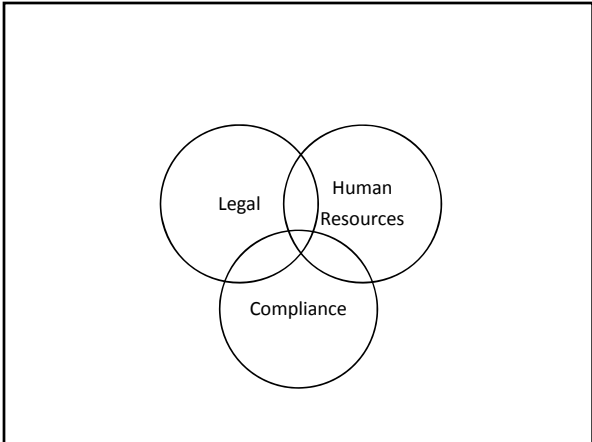
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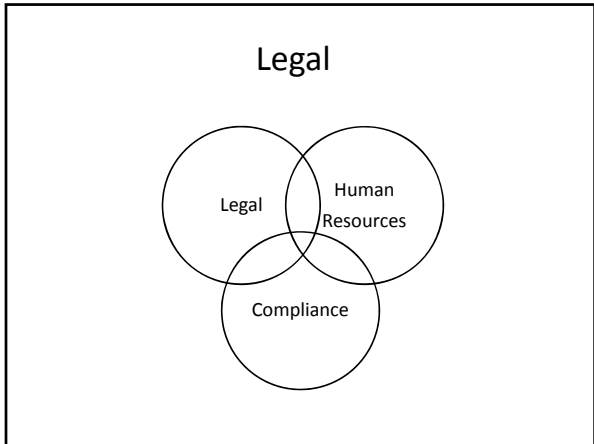
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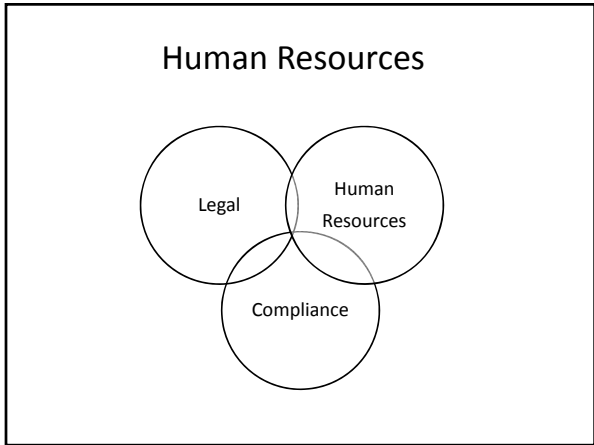
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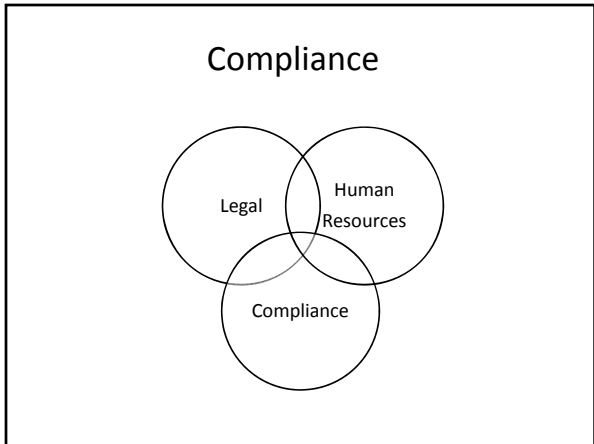
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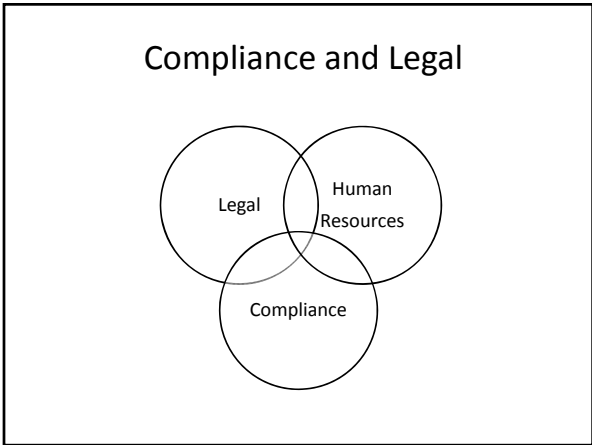
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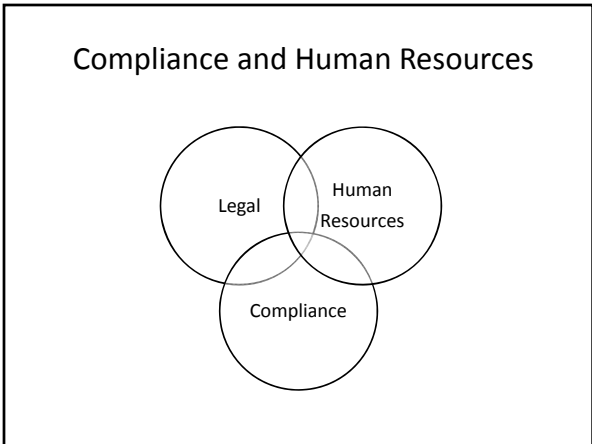
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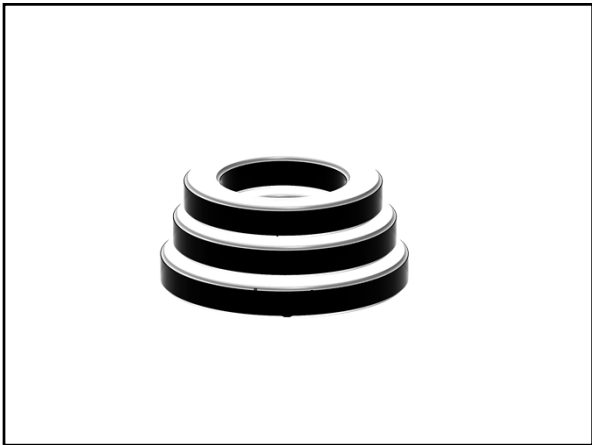
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**W03 -340B Drug Pricing Self-Disclosures and Repayments: Success Stories and Lessons Learned**

Anne Daly  
Karolyn Woo-Miles  
Emily Cook

HCCA Annual Compliance Institute  
March 29, 2017

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**Overview**

- Planning Ahead
  - > 340B Compliance "tool kit"
- Testing the Plan
  - > Evaluating the tools
- Ready for Action
  - > Identification of potential non-compliance
- Go Time!
  - > Submitting self-disclosures and manufacturer notices
- Victory Lap
  - > Follow-up and close out

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**Preparing**

Make sure your Entity understands the purpose of 340B:

**"The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."**

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**Preparing**

Understand your Entity's 340B Program

- How are you eligible?-Understand the implications, for example:
  - > GPO Prohibition—DSH, children's, free-standing cancer center
  - > Orphan Drug Exclusion—CAH, RRC, SCH
  - > Parent, child sites? Contract Pharmacy
  
- What are your State's Medicaid requirements for 340B?
  - > Carve in or carve out status
  - > Billing or identifying 340B drug claims
    - Medicaid Exclusion File? Modifiers?

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**Preparing**

- Who and what are your entity's 340B Program Operators and influences?
  - > Authorizing Official – assess understanding of program and role
    - Registration and recertification on HRSA 340B database
  - > Pharmacy – purchasing, splitting software; replenishment processes
  - > Ordering providers and settings
  - > Vendors, consultants, informal guides
  - > Professional Organization Conferences, articles

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**Planning Ahead**

- Review Policies and Procedures, Program Activities
  - > P&P updates needed?
  - > Auditing or monitoring with effective CAPs?
  
- Ascertain key stakeholders, staff, and program champions
  - > Learn their goals for the program
  - > Assess their understanding of the program

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**Planning Ahead**

- Educate staff beyond their focused duty
  - › Help operators understand constraints on program activity and their effect on others
    - Eligible patient
    - Outpatient only
    - Purchasing/replenishing
  
- Define Material Breach
  - › Guidance available
  - › Consider legal counsel

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**Planning Ahead**

- Anticipate Audits – HRSA, Manufacturer
- Gather, Memorialize, Refine-
  - › Patient Eligibility Process
  - › Document Government Ownership or Control
  - › Inventory Management
  - › Duplicate Discount Prevention
  - › Vendor Change Process
- Identify how Entity structures its program to align with 340B program intent
  - › How is the Entity using the Savings that result?
    - Investing in mission, enhancements, etc.

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**Testing the Plan**

- Test what you have memorialized-
  - › Patient Eligibility Process
    - Pull a 340B replenishment and trace to Entity patient on order of provider with ongoing relationships with the entity?
  - › Inventory Management
    - Show replenishments only of 340B drugs administered to an eligible Entity outpatient?
  - › Material Breach
    - Does the definition yield reasonable results when used to calculate hypothetical breaches?

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### Testing the Plan

- Duplicate Discount Prevention
  - > Pull 340B Medicaid patient bill and consistently find State requirements met?
- 340B Manufacturer or Vendor Information
  - > How are orders, records, contact information retained?
  - > How are is contact information monitored to ensure it is kept current?
  - > How is a manufacturer or vendor change or termination processed?

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### Ready for Action

- How is potential non-compliance discovered?
- What are the next steps to determine if there is a real issue?
- When to handle internally and when to retain outside help

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**DRAFT**

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**DRAFT**

**HRSA Requirements - Oversight of 340B Contract Pharmacies**  
 HRSA requires that covered entities conduct the following oversight activities for their contracted pharmacies.

**Contract Pharmacy Oversight Requirements**

1. Conduct independent annual audits and/or adequate oversight mechanism.
2. Documentation requirements:
  - a. Develop written 340B Program policies and procedures involving contract pharmacy oversight
  - b. Maintain auditable records at both covered entity and contract pharmacy
  - c. Ensure written contract pharmacy agreement lists each contract pharmacy individually and is in place before registering contract pharmacy in 340B Program
  - d. Contract pharmacy may not be utilized for purposes of the 340B Program until it has been registered, certified, and pharmacy is listed on the covered entity's 340B database record
3. Ensure that 340B drugs are only provided to 340B-eligible patients.
4. Carve-out Medicaid at contract pharmacies – or develop an alternative arrangement to work in collaboration with the state Medicaid agency to ensure duplicate discounts do not occur and report this to HRSA.
5. Maintain accurate information in the HRSA 340B database, including covered entity contact information, contract pharmacy information, and Medicaid billing information.

Source: <https://www.hrsa.gov/opa/updates/contractpharmacy02052014.html>  
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**DRAFT**

**Contract Pharmacy Oversight Requirements**

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**DRAFT**

**Example: Threshold Indicators**  
 What are the next steps to determine if there is a real issue?

<i>Percent</i> of noncompliant claims, to total 340B purchases or to any one manufacturer	<i>A fixed dollar</i> amount of noncompliant claims, based upon total outpatient/340B spend	<i>Percent</i> of noncompliant claims, to total 340B inventory (units)
<i>Percent</i> of noncompliant claims, to total review sample	<i>Percent</i> of noncompliant claims, to total prescription volume/prescription sample	Noncompliant claims will not self-correct within <b>*X* months</b>
Total amount of refund due to manufacturers <b>exceeding X%</b> of monthly 340B drug spend for the parent and all child sites		<b>Greater than or equal to X%</b> of total number of approved claims in the same period as the violation

Source: [https://docs.340bvp.com/documents/public/resourcecenter/Establishing\\_Material\\_Breach\\_Threshold.pdf](https://docs.340bvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf)  
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### Go Time!

- Emily Cook
- Next steps after confirming non-compliance
- Disclosures to manufacturers, HRSA or other entities
  - › Requirements and processes

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### Next Steps

- Process may vary depending on the nature of the non-compliance
- Refer to internal processes
  - › Follow established organization reporting procedures
  - › Involve appropriate compliance and legal staff
- Significant or novel issues may require involvement of outside legal counsel

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### Next Steps

- Refer to 340B Policies and Procedures
  - › Policies should include material breach reporting threshold
- Determine whether non-compliance required reporting to HRSA, manufacturer, state or other entity
- Most confirmed non-compliance will require reporting to one or more entities
- "Self-help" corrections require risk analysis and should involve consultation with legal counsel

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### Written Disclosures

- Material breach requires reporting to HRSA and other affected entities
- Non-material non-compliance may also require reporting depending on the nature of the non-compliance
- Evaluate appropriate timing of notices to different affected entities
- Determine appropriate level of detail to include in disclosure letter

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### Victory Lap

- HRSA oversight of disclosures to manufacturers
- Obligations for resolving non-compliance
- Non-responsive manufacturers
- Disagreements regarding resolution

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### HRSA Oversight

- HRSA will monitor corrective actions taken following disclosure of material breach
- Be prepared to make at least two notices to affected manufacturers
- Retain documentation of notices sent, responses received and dates of all communications
- HRSA will request periodic updates until satisfied that the issue is resolved as to manufacturers requesting repayments
- Note- self-disclosures following an audit notice are likely to result in adverse audit findings

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### Obligations for Corrective Action

- Expectation of “good faith” efforts by covered entity and manufacturer to resolve non-compliance
- Typically reasonable process, although can be lengthy
- No required time frame for resolution
  - > Although updates required to HRSA for self-disclosed non-compliance

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### Non-responsive manufacturers

- Two frequent scenarios for non-responsive manufacturers
  - > No response to notices
  - > Become unresponsive after initial contact
- Expectation of two notices
- HRSA has indicated that it is willing to close self-disclosures if covered entity can document that manufacturer has been non-responsive
  - > HRSA currently requires covered entities to agree to work with late-responding manufacturers

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### Disagreements Regarding Resolution

- Disputes as to the appropriate corrective action are unusual, but do occur
- Path forward is not clear
- To-date, HRSA has instructed the covered entity and manufacturer to continue “good faith” efforts
- HRSA has closed self-disclosures with open disputes between covered entities and manufacturers

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# How to Navigate and Survive a Mega Breach

Regina Verde | Compliance and Privacy Officer, University of Virginia Health System (Moderator)  
Nadia Fahim-Koster | Director, IT Risk Management, Medtology Services  
Erin Dunlap | Shareholder, Polsinelli, PC  
Abby Bonjean | Associate, Polsinelli, PC



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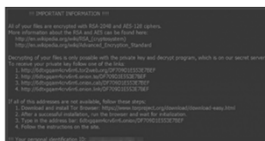
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## Ransomware Attack – Hollywood Presbyterian Medical Center, CA (2016)

- Ransomware virus called Locky
  - Usually spread via email
- An employee must have clicked on the link, activating the virus
- Access to network and data was locked
- Paid 40 Bitcoin (approximately \$17,000) to regain access
- How can we respond to and survive such incidents?



The Locky screen of death

[ 2 ]

Reference: Senko, Chris. "Ransomware Case Studies: Hollywood Presbyterian and The Ottawa Hospitals." InfoSec Resources. <http://www.infosecresources.com/insights/healthcare-informatics/healthcare-ransomware-attack-articles-and-case-studies/ransomware-case-studies-hollywood-presbyterian-and-the-ottawa-hospital.html>

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## Discovery, Investigation, Data Evaluation and Remediation

- What plans does your organization have in place to handle an incident?
- Do you have a Security Incident Response Team (SIRT)?
- Correcting and/or containing the cause of the breach
- Identifying the scope of the breach
  - Consider hiring outside forensic analyst
- Do you have insurance that may cover the data breach?
  - Review scope of coverage and provide proper notice
- Was the breach caused by the act of a third-party vendor?
  - Review applicable contracts
- Should you engage law enforcement?

[ 3 ]

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## Notification Process and Mitigation Strategies

- When do you move from an "IT centric" incident response to notify compliance, legal, public relations...etc.?
- Who to notify and when?
- What to consider when hiring outside vendors?
- What services should you provide affected individuals?
- Sanction workforce member(s) involved
- Retrain all workforce members (or specific department) to reduce likelihood of incident reoccurring
- Review any relevant policies and procedures and revise if necessary
- Cooperate with the various enforcement agencies

[ 4 ]

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## Lessons Learned and Recommendations for Prevention

- Have a post-breach meeting and revise incident response plan, if necessary
- Conduct tabletop exercises
- Establish relationships with vendors (e.g., forensic analysts and notification vendors)
- Obtain cyber liability insurance
- Know where your ePHI is and safeguard it appropriately
- Educate, educate, educate!
  - Remind employees of cybersecurity risks
- Document, document, document!

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## Questions?

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## **DATA BREACHES: HOW TO RESPOND AND WHAT TO EXPECT**

**By: Erin Fleming Dunlap, Esq. and Abby Bonjean, Esq.**

**February 17, 2017**

Reports of a potential data breach can be devastating to any organization. Often times, IT departments are under-staffed or ill-equipped to jump into “incident response” mode and take immediate steps that are necessary to identify, correct and contain the problem. Further, compliance departments do not always have a formal process in place to address the problem quickly from a regulatory and operational perspective, so organizations are scrambling to figure out what to do and when to do it. While we always advise our clients to put in the time and effort to create an incident response team and prepare a formal incident response plan that is tailored to the specific organization (and blessed by senior leadership), this white paper provides a quick overview and some practical tips on how to respond and what to expect following a data breach.

### **I. Reporting/Investigation/Mitigation**

Data breaches and security incidents are triggered in many ways (*e.g.*, phishing attacks, malware, ransomware attacks and system errors). It is critical that employees know how to identify and report a potential data breach. Some organizations have a well-publicized help-desk line or reporting hotline. Employees should know who to call, and they should be instructed not to delay reporting – even if it is only a suspected issue. The quicker the organization learns about an incident, the sooner they can start their incident response process.

When an organization learns of a potential data breach, it should take immediate steps to identify, correct and/or contain the issue. This may require shutting down systems or terminating workforce members’ access to the system. The organization will then need to determine the scope of the breach, including what data is involved and how many individuals have been affected. This may require interviews with workforce members, a thorough review of systems or the use of an outside vendor. Some IT departments are limited in the type or depth of the forensic analysis they can perform. If the issue is big enough, it may be worth spending the money on an outside analyst to take a deeper dive into the system or the data.

Once the issue is corrected and contained, the organization should consider what it can do to mitigate harm to the affected individuals. For example, an organization may choose to contact patients immediately if there is a real risk of identity theft (*e.g.*, credit card information was stolen). The organization should also consider whether to contact law enforcement and whether it has insurance to cover the data breach. If it has insurance, review the scope of coverage and provide proper notice to the carrier.

The organization then needs to consider taking additional mitigation steps – both short term and long term – to minimize the chance of the same type of incident from occurring in the future. These steps can range from sanctioning an employee who acted improperly or negligently to sending organization-wide emails about security/cyber risks to retraining the workforce to reviewing and revising applicable policies and procedures to updating the organization’s risk analysis and risk management plan.

**PRACTICAL TIP:** If the data breach affected more than 500 individuals, your organization will likely be subject to a compliance review by the Office for Civil Rights (OCR), so be sure to maintain thorough documentation of both your internal investigation into the incident and any subsequent mitigation steps. We have found that creating a timeline of the events is helpful and can serve well in preparing a response to OCR’s data request about the incident.

## **II. Breach Analysis/Reporting Under HIPAA**

Once you get through the initial phase of identifying the issue and taking steps to mitigate the harm, you must consider your other legal obligations. Assuming your organization meets the definition of a “Covered Entity” or a “Business Associate” under the Health Insurance Portability and Accountability Act and its implementing regulations (“HIPAA”), you must comply with the HIPAA Breach Notification Rule, 45 C.F.R. §§ 164.400-414.<sup>1</sup> Under the HIPAA Breach Notification Rule, a Covered Entity is required to provide notification following a Breach of Unsecured Protected Health Information (“PHI”).<sup>2</sup>

A Breach is defined as the “*acquisition, access, use or disclosure of PHI in a manner not permitted by the HIPAA Privacy Rule which compromises the security or privacy of such information.*” There are three exceptions to the definition of Breach, but they are limited and rarely apply in the context of a large data breach or cyber-attack.<sup>3</sup>

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<sup>1</sup> Separate from the HIPAA Breach Notification Rule, almost every state has a breach notification law. Those laws should be reviewed in short order, as some of those laws are more stringent than the HIPAA Breach Notification Rule.

<sup>2</sup> “Unsecured PHI” is PHI that has not been rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in guidance (e.g., PHI that has not been encrypted).

<sup>3</sup> The three exceptions to the definition of a Breach are: (i) any unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of a Covered Entity or a Business Associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the HIPAA Privacy Rule; (ii) any inadvertent disclosure by a person who is authorized to access PHI at a Covered Entity or Business Associate to another person authorized to access PHI at the same Covered Entity or Business Associate, or organized health care arrangement in which the Covered Entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Privacy Rule; and (iii) disclosure of PHI where a Covered Entity or Business Associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.



Assuming your organization has had an impermissible acquisition, access, use or disclosure of PHI that does not meet one of the Breach exceptions, the incident is *presumed* to be a Breach requiring notification unless you can demonstrate through a written risk assessment that there is a “low probability that the PHI has been compromised” based on the following four factors:

1. The nature and extent of the PHI involved, including the types of identifiers and likelihood of re-identification;
2. The unauthorized person who used the PHI or to whom the disclosure was made;
3. Whether the PHI was actually acquired or viewed; and
4. The extent to which the risk to the PHI has been mitigated.

A Covered Entity or Business Associate may consider other factors (as appropriate), but the risk assessment must be documented, thorough, completed in good faith and the conclusions reached must be reasonable.

**PRACTICAL TIP:** We have had clients conclude through a written risk assessment that there is a low probability that PHI has been compromised following an impermissible disclosure – often because the type of data exposed posed minimal risk of identity theft or re-identification, but entities should be careful about performing a risk assessment on a large data breach. OCR has issued a fair amount of guidance on the four factors set forth above. Entities should ensure they are staying within that guidance and making reasonable conclusions.<sup>4</sup>

If your organization cannot conclude through a written risk assessment that there is a low probability that the PHI was compromised – you must find that there was a Breach of Unsecured PHI and provide notification of the Breach to: (i) each individual whose PHI has been, or is reasonably believed to have been, accessed, acquired, used, or disclosed as a result of such Breach; (ii) the Secretary of HHS; and (iii) in certain circumstances, the media.

- (i) Notice to Affected Individual(s)

A Covered Entity must provide notice to the affected individuals in written form by first-class mail, or alternatively, by e-mail if the affected individual has agreed to receive such notices

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<sup>4</sup> If the incident involved a ransomware attack, OCR has issued guidance suggesting that entities should consider the following in determining whether there is a low probability that the PHI was compromised: (i) the exact type and variant of malware discovered; (ii) the algorithmic steps undertaken by that type of malware; and (iii) whether there were communications, including exfiltration attempts between the malware propagated to other systems, potentially affecting additional sources of ePHI. According to OCR, by understanding what a particular strain of malware is programmed to do can help determine how or if a particular malware variant may laterally propagate throughout an entity’s enterprise, what types of data the malware is searching for, whether or not the malware may attempt to exfiltrate data, or whether or not the malware deposits hidden malicious software or exploits vulnerabilities to provide future unauthorized access. OCR also suggests that entities should consider: (i) whether there is a high risk of data unavailability or a high risk to data integrity; (ii) whether the ransomware deletes the original data and leaves only the data in encrypted form; (iii) whether or not the data has been exfiltrated.

electronically. ***Individual notifications must be provided without unreasonable delay and in no case later than 60 days following the discovery of a Breach*** and must include, to the extent possible, a description of the Breach, a description of the types of information that were involved in the Breach, the steps affected individuals should take to protect themselves from potential harm, a brief description of what the Covered Entity is doing to investigate the Breach, mitigate the harm, and prevent further Breaches, as well as contact information for the Covered Entity.

If the Covered Entity has insufficient or out-of-date contact information for fewer than 10 individuals, the Covered Entity may provide substitute notice by an alternative form of written, telephone, or other means. If the Covered Entity has insufficient or out-of-date contact information for 10 or more individuals, the Covered Entity must provide substitute individual notice by ***either*** posting the notice on the home page of its web site or by providing the notice in major print or broadcast media where the affected individuals likely reside. If a Covered Entity chooses to provide substitute notice on its web site, it may provide all the information described at § 164.404(c) directly on its home page (“home page” includes the home page for visitors to the covered entity’s web site and the landing page or login page for existing account holders) or may provide a prominent hyperlink on its home page to the notice containing such information. Additionally, for substitute notice provided via web posting or major print or broadcast media, the notification must include a toll-free number for individuals to contact the Covered Entity to determine if their PHI was involved in the Breach.

(ii) Notice to Secretary

In addition to notifying the affected individuals, a Covered Entity must notify the Secretary of HHS of a Breach of Unsecured PHI. A Covered Entity must notify the Secretary by visiting the HHS web site and filling out and electronically submitting a Breach report form: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html>. If a Breach affects fewer than 500 individuals, the Covered Entity may notify the Secretary on an annual basis – but no later than 60 days after the end of the calendar year in which the Breach occurred. ***If a Breach affects 500 or more individuals, the Covered Entity must notify the Secretary without unreasonable delay and in no case later than 60 days following the discovery of a Breach.***

(iii) Notice to Media

A Covered Entity that experiences a Breach affecting more than 500 Individuals of a State or jurisdiction is also required to provide notice to prominent media outlets serving the State or jurisdiction. Covered Entities will likely provide this notification in the form of a press release to appropriate media outlets serving the affected area. The media notification obligation is met when notice to the media is provided; it does not matter whether or not the media outlet chooses to report on the notification. ***The media notification, if required, must be provided without unreasonable delay and in no case later than 60 days following the discovery of a Breach and must include the same information required for the individual notice. Notices to the media should be provided contemporaneously with those to the affected individuals.***

**PRACTICAL TIP:** As soon as you have determined the discovery date, make a timeline for your incident response team and determine as soon as possible if substitute notice or media notice is required. If you decide to use an outside vendor to handle the notification process, build in sufficient time to engage the vendor and get the patient list and documentation in final form (*e.g.*, several vendors require 3-5 business days after the patient list is uploaded and the breach template letters are finalized to send the notifications).

### **III. Preparing for OCR Compliance Review**

After you report a Breach, OCR may perform a compliance review. Due to a new intake process at OCR, it could be handled by any regional office.

For each Breach report involving 500 or more affected individuals, OCR automatically opens a compliance review. In August 2016, OCR announced that it was also going to begin investigating breaches affecting under 500 individuals (“Under 500 Breaches”). As part of this new initiative, we understand that each of OCR’s regional offices has been instructed to investigate a certain number of Under 500 Breaches, and it appears those investigations have begun. Over the past few months, some of our clients have received data requests about Under 500 Breaches they reported in 2015, and OCR seems to be using these investigations to perform “compliance checks” – delving into HIPAA compliance areas unrelated to the areas/issues that caused or relate to the Under 500 Breaches that triggered the review. According to OCR, when determining whether to investigate Under 500 Breaches, it may consider the number of individuals affected by the breach; the amount and type of PHI involved; breaches caused by theft or improper disposal of PHI; hacking incidents; or entities that have filed numerous Under 500 Breaches involving the same types of issues. Thus, we believe any entity that reported Under 500 Breaches that fit or highlight these focus areas should be prepared for an OCR compliance review. An OCR compliance review may also be opened after receiving a complaint from an affected patient or another third-party, such as the media.

Once a compliance review is opened, a Covered Entity or Business Associate (specifically, the individual identified on the OCR breach report) usually receives an initial call from an OCR investigator within two weeks (or, in some cases, within a day or two) of submitting the report. The purpose of this call is to ensure that the information submitted in the initial report is accurate. Following the call, OCR will send the entity a letter and document request list to initiate the formal investigation. The timing may vary, but OCR tends to send the letter and document request list within two weeks of the initial call. The investigator on the initial call may offer specific information as to when an entity can expect the formal investigation letter and document request.

Although OCR’s document requests vary depending on the type of incident at issue, be prepared to submit the following:

- Position statement regarding the incident
- Risk analysis
- Risk management plan

- Evidence of implemented security measures (e.g., configuration settings, invoices, screenshots, etc.)
- Evidence of training (e.g., copies of training materials and attendance records)
- Relevant policies and procedures (e.g., sanction, security incident, facility access controls, device and media controls, access control, breach notification, etc.)
- Evidence of sanctions imposed on the responsible employee(s), if applicable
- Security incident report
- Copies of notices to individuals and the media
- Business Associate Agreements, if applicable

**PRACTICAL TIP:** Organizations facing a compliance review should also review the “corrective action obligations” in the Corrective Action Plans (that correspond to the Resolution Agreements) on OCR’s website: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>. These can serve as great “roadmaps” for what types of corrective action OCR expects an entity to take following a breach or security incident.

**IV. Potential Penalties/Resolution Agreement**

If an entity is found to have violated HIPAA, OCR and States’ Attorneys General may impose sanctions, including civil monetary penalties (“CMPs”) ranging from \$100 to \$50,000 per HIPAA violation – but the maximum CMPs that can be applied for additional violations of the same regulation in any one year are within a range of \$25,000 to \$1,500,000. HHS is required to impose a CMP if a violation is found to constitute willful neglect of the law. The chart below shows the tiered penalties based on the entity’s culpability:

<b>Violation Category</b>	<b>Each Violation</b>	<b>All Such Violations of an Identical provision in Calendar Year</b>
Did Not Know	\$100-\$50,000	\$1.5 million
Reasonable Cause	\$1,000-\$50,000	\$1.5 million
Willful Neglect, Corrected within 30 Days	\$10,000-\$50,000	\$1.5 million
Willful Neglect, Not Corrected within 30 Days	\$50,000	\$1.5 million

HHS will not impose the maximum penalty amount in all cases, but will instead determine the penalty based on: (i) the nature and extent of the violation; (ii) the resulting harm (e.g., the number of individuals affected, reputational harm, etc.); (iii) the entity’s history of prior offenses or compliance; (iv) the financial condition of the entity; and (v) any other factor that justice may require be considered. HHS also retains the ability to waive a CMP, in whole or in part, and to settle any issue or case or to compromise the amount of a CMP.

However, a *large majority* of OCR compliance reviews do not end with the imposition of CMPs. Rather, OCR may close the matter with suggested action items for the entity or, in more egregious cases, OCR will enter into a Resolution Agreement, in which the entity agrees to pay a settlement amount and enter into a corrective action plan. The latter type of OCR enforcement continues to increase. In 2016, OCR announced that it had entered into 12 settlements and imposed 1 CMP – the most enforcement actions in a given calendar year. Those settlements included the first involving a Business Associate as well as the largest settlement to date, which totaled \$5.5 million. We are seeing similar enforcement activity in 2017. As of the date of this publication, OCR has entered into 3 Resolution Agreements and imposed a CMP of \$3.2 million.

## V. Conclusion

Data breaches are a scary subject for most organizations. In our experience, however, the more an organization does at the front end – the less likely it is to make missteps and the better it fares in a subsequent government investigation. Preparation, education and documentation are essential. If your organization has not prepared an incident response plan, it should. Consider adding “incident response plan” to the next compliance committee meeting agenda. If your employees have not been educated about the current cyber threats and security risks, they should be – through multiple communication channels. Finally, if you are not documenting all of your efforts, then you will have a hard time showing the government that you took the necessary and appropriate steps to address the problem. Now is the time.

## **DATA BREACH CHECKLIST**

### **Breach Prevention and Preparation**

- Obtain cyber liability insurance
- Establish relationships with external parties (*e.g.*, patient notification, call center services, credit monitoring, IT forensics and counsel)<sup>1</sup>
- Identify **ALL** ePHI your organization creates, receives, maintains or transmits
- Conduct a risk analysis and develop a risk management plan
- Implement, and maintain documentation of, appropriate security measures (*e.g.*, encryption, firewalls and intrusion detection systems)
- Implement policies and procedures that address the requirements of the HIPAA Privacy, Security and Breach Notification Rules
- Create an incident response team and define team member role and responsibilities
- Create and test an incident response plan
- Train workforce members on how to identify and report security incidents

### **Breach Response**

- Notify cyber insurance carrier
- Engage external parties (*e.g.*, patient notification, call center services, credit monitoring, IT forensics and counsel)
- Contain breach source, if necessary
- Consider notifying law enforcement
- Determine who and what was affected
- Notify necessary parties and agencies within applicable timeframes
- Sanction responsible workforce member(s), if applicable
- Document all mitigation steps taken
- Prepare for and respond to inquiries from government agencies

### **Post-Breach**



- Update your risk analysis and risk management plan
- Revise policies and procedures, as necessary
- Retrain workforce members
- Evaluate incident response plan and revise as necessary

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<sup>1</sup> Your cyber insurance carrier may have preferred vendors.

**HCCA'S 21<sup>ST</sup> ANNUAL COMPLIANCE INSTITUTE**

LESSONS LEARNED: HOW RECENT ENFORCEMENT CASES PROVIDE INSIGHT INTO EFFECTIVE COMPLIANCE PROGRAMS FOR FAIR MARKET VALUE AND COMMERCIAL REASONABLENESS


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**PRESENTERS**




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**SESSION LEARNING OBJECTIVES**



- Learn What Fair Market Value (FMV) and Commercial Reasonableness (CR) Issues Are Driving Recent Enforcement Activity for Hospital-physician Arrangements and Transactions.
- Use Lessons Learned from Recent Cases to Analyze Organizational Processes, Practices, and Outcomes and Identify High-risk FMV/CR Compliance Risk Areas.
- Develop Improved Organizational Structures and Processes to Manage and Reduce Real World FMV/CR Compliance Risk.


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**DISCLAIMER**

- This program is a general discussion of regulatory and business issues; it should not be relied upon as legal, valuation, business, financial, compliance, or other professional advice.
- The panelists will provide their own views and not those of their current or past employers or clients.
- Not all slides will be covered in detail. Some are for reference only.
- The slides are the result of the collaboration of the panelists and reflect their individual and collective thoughts and observations.
- This presentation may include a discussion of hypothetical scenarios. Any hypothetical scenarios are intended to elicit thoughtful and lively discussion, but do not represent actual events.
- This program may include a discussion of certain ongoing or settled *qui tam* or other lawsuits. The discussion is based on publicly available documents and allegations in the lawsuits. We wish to remind participants that allegations are allegations only. We also wish to remind participants that the list of cases and related issues we discuss may not be comprehensive.

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**FMV AND CR ISSUES THAT DRIVE RECENT ENFORCEMENT ACTIVITY FOR HOSPITAL-PHYSICIAN ARRANGEMENTS AND TRANSACTIONS**

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**THE HIGH RISK OF PHYSICIAN ARRANGEMENTS**

- "Arrangements with physicians are the highest compliance risk area in 2017,"<sup>1</sup> according to Richard Kusserow, former Inspector General. The most significant source for identifying Stark violative contracts remains whistleblowers. "The number one enforcement priority for both the OIG and DOJ will continue to be any arrangement that implicates the Anti-Kickback Statute and Stark Law."

<sup>1</sup>Kusserow, Richard, "Kickback Cases Remain Top DOJ and OIG Priority in 2017", Strategic Management Services, LLC. Jan. 2017, accessed Feb. 11, 2017.

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RECENT MAJOR SETTLEMENTS WITH DOJ INVOLVING PHYSICIAN ARRANGEMENTS

- Tuomey - \$72.4 million \*
- Halifax - \$85 million
- Citizens' Medical - \$21.8 million Business Valuation:
- Columbus Regional - \$35 million • DaVita - \$389 million (total)
- North Broward - \$69.5 million
- Adventist - \$118.7 million

\* Negotiated settlement from \$237 million jury verdict

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U.S. *ex. rel.* DRAKEFORD v. TUOMEY HEALTHCARE SYSTEM, INC

- Things You Didn't Know about *Tuomey*, But Should Have Known
  - DOJ's closing argument (both trials) began with painting the physician arrangements as a vehicle for Tuomey to retain lucrative HOPD surgery revenues instead of allowing lower cost ASC rates into the market.
  - "Instead, ladies and gentlemen, this was a scheme by a hospital to lock in all the outpatient referrals in town once competition cropped up. And the way the hospital did that, ladies and gentlemen, was to pay doctors more than they could ever possibly make working on their own." (Tuomey 1 Trial – Closing Argument)

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U.S. *ex. rel.* DRAKEFORD v. TUOMEY HEALTHCARE SYSTEM, INC

- DOJ fact-checked Tuomey's claims about community need
  - Depositions showed physicians were not a risk to leave the community
  - Deposition showed no real issues over call coverage
  - Tuomey medical staff had grown substantially prior to physician deals
- **75<sup>th</sup> percentile is NOT FMV based on this case!**
  - DOJ's expert said median compensation ratios (per wRVU and % of collections) is the FMV level
  - In unique circumstances, 75<sup>th</sup> percentile rates can be FMV

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*U.S. ex. rel. DRAKEFORD v. TUOMEY HEALTHCARE SYSTEM, INC*

- Tuomey's practice losses were an indication of payment for referrals
  - Used in DOJ's closing arguments (both trials)
    - "And, finally, just use your common sense. The only reason that it makes sense to [pay] these doctors a million and a half dollars a year is to save the eight to \$12 million a year in referrals. And even Paul Johnson, the Tuomey's CFO, acknowledged on cross-examination or, excuse me, on direct examination that really, yeah, the hospital was getting back for all that money was referrals." (Tuomey 2 Trial – Closing Argument)
  - DOJ's valuation expert testified the losses were an indication the arrangements were not commercially reasonable
    - Losses are justified in some cases, but not Tuomey's

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- Halifax Hospital Medical Center
  - County/taxing district hospital in Volusia County, Florida, with 678 beds
- *Qui tam* relator - hospital compliance officer
- Case issues
  - Compensating oncologists based on HOPD profits
  - Compensating neurosurgeons above FMV
- DOJ won summary judgment on oncologists compensation.
- Halifax settled after losing summary judgment.

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- Neurosurgeons (3 FTEs)
  - Compensation formula
    - Base salary
    - Bonus: 100% of collections above base salary
    - Specific collection rates set for certain types of patients or payers
  - Halifax lost motion for summary judgment on neurosurgeons.
  - DOJ and Halifax hired valuation experts and their reports were included in pleadings for case.

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- DOJ's Expert: Reported wRVUs Unreliable
  - Reported wRVUs were materially above the 90<sup>th</sup> percentile: 2x 90<sup>th</sup> in many cases.
  - Material inconsistency from year-to-year
  - Collections per wRVU below the median, but hospital had favorable payer mix.
  - Internal compliance reviews showed major billing and coding problems, including RNs performing patient visits.

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- DOJ's Expert: Reported wRVUs Unreliable (cont'd)
  - Time analysis
    - E&M comparison: at or well above FP median wRVUs
    - Consultant found docs hours equivalent to 6,900 to 8,700
  - *Rejected use of comp/wRVU for FMV analysis*

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- DOJ's Expert FMV Analysis: Comp Not FMV
  - 75<sup>th</sup> percentile rates used as FMV due to data issues; "benefit of doubt to hospital"
  - Comp to pro collections ratio used
  - Neurosurgeons comp ratios above 75<sup>th</sup> percentile
  - Compensation and professional collections benchmarking not correlate
  - One neurosurgeon given 67% pay increase upon employment

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- DOJ's Expert CR Analysis: Contracts Not CR
  - Favorable treatment in comparison to other employed physicians: car allowance, set collection rates, others
  - Compensation model allowed docs to receive 100% of collections.
  - Practice would **always** incur a loss
  - **Material financial losses on practice, but internal report netted referrals against losses**

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*U.S. ex. rel. BAKLID-KUNZ v. HALIFAX HOSPITAL MEDICAL CENTER*

- Government intervened in case
- Case settles with DOJ for **\$85,000,000**
- Qui tam relator to receive \$20,800,000 from settlement

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*U.S. ex. rel. PARIKH v. CITIZENS MEDICAL CENTER*

- Citizens Medical Center (CMC)
  - County hospital in Victoria, TX, with 296 beds
- FCA / *qui tam* claim filed by 3 local cardiologists who were at odds with CMC; prior lawsuit between parties
- Allegations of multiple issues including kickback, billing, others
- Significant allegations about referral patterns and requirements for cardiac surgeries and cardiology privileges
  - Cardiologists to refer to CMC's exclusive cardiac surgeon and perform services at CMC

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U.S. *ex. rel.* PARIKH v. CITIZENS MEDICAL CENTER

- Alleged collective compensation levels of 3 employed cardiologists went from \$630,000 (pre-employment) to \$1,400,000 (post-employment).
  - Higher than private practice mentioned 10 times in complaint
  - No FMV studies prepared; just board approval
- Practice losses: 2008 = \$400,000 / 2009 = \$1 million
- Referrals alleged to be reason for incurring practice losses
  - Not commercially reasonable to lose money continually

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U.S. *ex. rel.* PARIKH v. CITIZENS MEDICAL CENTER

- CMC responses in pleadings
  - Employed cardiologists made around the national median
  - Legitimate reasons for comp to go up under employment
    - *More charity care in private practice*
  - One doctor had competing offers.
  - Employment offered for physician retention purposes
  - Employed cardiologists made less than the *qui tam* relator cardiologists

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U.S. *ex. rel.* PARIKH v. CITIZENS MEDICAL CENTER

- Judge's Ruling on Motion to Dismiss:
 

*"Relators have made several allegations that, if true, provide a strong inference of the existence of a kickback scheme. Particularly, the Court notes Relators' allegations that the cardiologists' income more than doubled after they joined Citizens, even while their own practices were costing Citizens between \$400,000 and \$1,000,000 per year in net losses. Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens is sufficient to allow an inference that they were receiving improper remuneration. This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals."*

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U.S. *ex. rel.* PARIKH v. CITIZENS MEDICAL CENTER

- Government intervened in case.
- Case settles with DOJ for **\$21,750,000.**
- Qui tam relators to receive \$5,981,250 collectively from settlement

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- Columbus Regional Healthcare System
  - Nonprofit hospital in Georgia and Alabama
  - Case involved HOPD cancer center for one of its hospitals
- *Qui tam* relator: former administrator of cancer center (2011-13)
- Focus on compensation and billing for Andrew W. Pippas, M.D.
  - Employed medical oncologist since 2003
  - Center's medical director
  - Paid based on wRVUs plus stipends for directorships

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- Total compensation for Dr. Pippas (in \$ millions):

2007	2008	2009	2010	2011	2012	2013
\$1.742	\$1.698	\$1.635	1.564	\$1.508	\$1.500	\$1.500

- Compensation per wRVU rate:
  - \$113.67 through 2008 / \$90 thereafter
- Directorship compensation per year
  - Cancer center = \$200,000
  - Clinical research = \$100,000

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- FMV opinions
  - Late 2008: high but OK
  - Early 2009: too high (different firm); cut rate to \$90/wRVU
  - Early 2013: too high due to being credited for wRVUs of another physician and an NP
- *Qui tam* relator findings circa 2011
  - Billed for work of another physician
  - Paid for wRVUs of other physician and APPs

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- *Qui tam* relator findings circa 2011
  - Billing and payment for other providers' wRVUs not stopped until April 2013, despite 2007 outside audit and internal audits beginning in 2008
  - Upcoding for E&M codes reported in late 2008; also not corrected until April 2013
- Other issues with Dr. Pippas
  - Working less than 5 days per week
  - Not working expected hours on directorships

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- Other issues with physician relationships at hospital
  - Overlapping medical directorships / too many directorships
  - Internal audit found other compliance issues
- Key themes in complaint
  - Excessive comp because at or above 90<sup>th</sup> percentile (5x)
  - No commercial reasonableness analyses for deals
  - Paid in excess of collections by significant amounts
  - 2013 FMV opinion should have been applied retroactively due to practice of crediting wRVUs from other providers.

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- CRHS purchase of Tidwell Cancer Treatment Center (TCTC)
  - Relator allegations
    - Price paid in excess of FMV
    - Not commercially reasonable in the absence of referrals because purchase was defensive and not in response to community need
  - Purchased July 15, 2010, for \$10.7 million from radiation oncologist
  - Draft valuation used for transaction
    - Prepared for competing health system used to support FMV
    - FMV = \$9.1 million based on DCF only
  - Relator hired own valuation experts

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- Relator expert's CR analysis of purchase of TCTC
  - CRHS's purchase strategy was purely defensive, and not for community need.
  - Equipment at TCTC was outdated.
  - Dr. Tidwell's competence and ability to practice medicine to the standard of accepted care was identified as an ongoing issue with other CRHS oncologists.
  - CRHS did not appear to support the TCTC's operational and strategic efforts.
  - \$10.67 million purchase price was in excess of FMV.
  - CRHS pulled together its letter of intent and marched to the July 15, 2010 close without typical due diligence.
  - CRHS did not obtain a final FMV Opinion.
  - CRHS's market for new radiation therapy patients was mostly stagnant.

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U.S. *ex. rel.* BARKER v. COLUMBUS REGIONAL

- Government intervened in case
- Settlement with DOJ
  - Columbus - **\$25,000,000** plus up to **\$10,000,000** in contingency payments
  - Dr. Pippas - **\$425,000**

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U.S. *ex. rel.* REILLY v. NORTH BROWARD HOSPITAL DISTRICT

- North Broward Hospital District
  - Nonprofit health system with 30 facilities in South Florida
- *Qui tam* relator: Michael Reilly, M.D.
  - Local orthopedic surgeon
  - Offered employment by North Broward, but declined
  - *Appears* to have obtained inside financial documents to assist in case
  - Press interviews: not happy with what Broward was doing

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U.S. *ex. rel.* REILLY v. NORTH BROWARD HOSPITAL DISTRICT

- Compliant: Broward losses millions on its employed physicians
  - \$150 million between 2004 and 2011
  - Loses are due to overcompensating its physicians.
  - Compensates physicians in excess of collections.
  - *Keeps internal reports showing IP and OP contribution margin for each physician.*
  - Broward offsets practice losses by IP/OP contribution margin.
  - Losses only financially sustainable and CR is consider referrals.

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U.S. *ex. rel.* REILLY v. NORTH BROWARD HOSPITAL DISTRICT

- Highly detailed complaint full of alleged data on Broward's physician practices
  - Orthopedic surgeons
    - \$24 million total loss since 2004
    - CEO tells *qui tam* relator making money due to referrals
    - Pressure to refer ancillaries
  - 2011 review for major physician groups
  - 2009 losses by hospital
  - References various contribution margin reports

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U.S. *ex. rel.* REILLY v. NORTH BROWARD HOSPITAL DISTRICT

- Highly detailed complaint (cont'd)
  - Physicians paid over 90<sup>th</sup> percentile; some with low production
  - Low charity care: not cause of low collections
  - Planned and budgeted for losses
- **Key theme: practice losses**
  - Mentioned 77 times in the body of complaint (74 pages)
  - Practice losses show compensation not FMV

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U.S. *ex. rel.* REILLY v. NORTH BROWARD HOSPITAL DISTRICT

- Government intervened in case
- Broward settles with DOJ for **\$69,000,000**
- *Qui tam* relator to receive \$12,045,655 from settlement

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U.S. *ex. rel.* PAYNE, et al. v. ADVENTIST HEALTH SYSTEM

- Adventist Health System
  - Nonprofit health system
  - Case involved physician relationships at facilities in Florida, Illinois, North Carolina, Tennessee, and Texas
    - These states joined with U.S.
- *Qui tam* relators: all worked at Park Ridge Health hospital
  - Michael Payne: Risk Manager
  - Melissa Church: Executive Director of Physician Services
  - Gloria Pryor: Compliance Officer for Physician Offices

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U.S. *ex rel.* PAYNE, et al. v. ADVENTIST HEALTH SYSTEM

- Physician cost center accounting
  - Revenues included professional and HOPD facility fees
  - Costs: physician comp, support staff, facility costs, and hospital overhead
- Tracking of hospital contribution margin by physician
  - Reported hospital-side profits by physician
  - Management used to justify practice losses and comp levels
  - Report limited to senior management
  - *Relators accidentally given report*

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U.S. *ex rel.* PAYNE, et al. v. ADVENTIST HEALTH SYSTEM

- Contract compensation caps related to losses were not enforced
- Physicians paid various perks
- Bonuses paid from revenues that included HOPD amounts
  - "Part A" payments
  - Management regularly spoke to physicians about being paid from HOPD revenues
  - Practice losses, despite inclusion of HOPD facility fees
  - High bonus amounts for little work
  - Total compensation exceeded collections

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U.S. *ex rel.* PAYNE, et al. v. ADVENTIST HEALTH SYSTEM

- Management became concerned about compensation levels.
  - Internal review
    - 50 physicians over MGMA 90<sup>th</sup> percentile
    - Many had production below median
  - Concerns over bonus plan: "Part A" payments
  - Hospitals told to stop "Part A" payments but did not
  - No self-reporting due to fear of high penalties
  - *Changed comp plan to RVU model, but total compensation remained the same*

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U.S. *ex rel.* DORSEY v. ADVENTIST HEALTH SYSTEM

- Adventist Health System (AHS)
  - For physician relationships at facilities in Florida, Illinois, North Carolina, and Texas
    - These states joined with U.S.
- *Qui tam* relator
  - Sherry Dorsey: COO of Physician Enterprise AHS
    - Reported to senior executives
    - Began work 7/12/12
    - AHS notified Dorsey was a witness on 5/23/13

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U.S. *ex rel.* DORSEY v. ADVENTIST HEALTH SYSTEM

- Complaint provides chronicle of Dorsey's meetings with senior AHS executives and operators.
- Complaint allegations
  - Compensation based on DHS referrals / HOPD revenues
  - 85 physicians paid over MGMA 90<sup>th</sup> percentile, many over \$1 million per, and some between \$2-3 million
  - Expressed incredulity to senior management about compensation and production levels
  - Recommended coding audit

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U.S. *ex rel.* DORSEY v. ADVENTIST HEALTH SYSTEM

- Complaint allegations (cont'd)
  - Compensation model to convert to wRVUs but total compensation to remain same
  - Senior management ignored her concerns
    - Required to return over 90<sup>th</sup> percentile report
    - Warned not to raise major concerns
  - Provides information on specific physicians

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U.S. *ex rel.* PAYNE, et al. v. ADVENTIST HEALTH SYSTEM  
 U.S. *ex rel.* DORSEY v. ADVENTIST HEALTH SYSTEM

- Government intervened in both cases
- AHS settles with DOJ for **\$115,000,000**

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U.S. *ex rel.* HAMMETT v. LEXINGTON COUNTY HEALTH SERVICES DISTRICT

- Lexington Medical Center (LMC)
  - 428-bed county hospital in West Columbia, South Carolina
  - Over 600 physicians and 70 medical practices
- *Qui tam* relator: David Hammett, MD
  - Neurologist who LMC employed and later terminated
  - Part of a 7-doc internal medicine group LMC acquired (not a owner in the group)
  - Group had significant imaging ancillaries, including an MRI

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U.S. *ex rel.* HAMMETT v. LEXINGTON COUNTY HEALTH SERVICES DISTRICT

- Employment termination lawsuit provided information used in whistleblower case.
- Key allegations
  - Buying access to patients via acquiring physician practices
  - Paying commercially unreasonable compensation
  - Mandating referrals by employed physicians and punishing those who do not refer
  - Paying for referrals through high compensation levels

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U.S. *ex rel.* HAMMETT v. LEXINGTON COUNTY HEALTH SERVICES DISTRICT

- Employment offers to group: all physicians except one would receive higher compensation
- Hammett's compensation plan
  - Base salary of \$318,758, up from \$250,000 pre-employment
  - Bonus: tiered comp/wRVU rates: \$50, \$74, \$98
  - Earned on average about \$600,000 per year
- Alleged other physicians had median productivity but compensated in excess of MGMA 90<sup>th</sup> percentile

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U.S. *ex rel.* HAMMETT v. LEXINGTON COUNTY HEALTH SERVICES DISTRICT

- Alleged physicians told high comp in exchange for referrals
- Purchase price for practice: \$1.5 million, and made post-deal payments to owners not in purchase agreement
- Practice loses money post-acquisition.
  - Hammett told losing money due to higher compensation and reduced ancillary profits
- LMC tracks imaging referrals, which declined post acquisition.
- Alleged physicians instructed to increase ancillaries.

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U.S. *ex rel.* HAMMETT v. LEXINGTON COUNTY HEALTH SERVICES DISTRICT

- Hammett continues to refer outside ancillaries, as he did pre-employment; alleged he was pressured about referrals
- LMC terminates Hammett.
- Government intervened in case.
- LMC settles with DOJ for **\$17 million.**
- Hammett receives **\$4.5 million.**

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U.S. *ex. rel.* ELISABETH MARKLEY v. SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC.

- Spartanburg Regional Healthcare System (SRHS)
  - South Carolina governmental health system (self-funded)
  - Multiple hospitals and facilities
  - Services counties in South and North Carolina
  - 300 physicians in Medical Group of the Carolinas (MGC)
- *Qui tam* relator: Elisabeth Markley
  - Former physician compensation coordinator
  - Worked on physician contracting

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U.S. *ex. rel.* ELISABETH MARKLEY v. SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC.

- Alleged she raised issues about compensation but was told to “shut up” about them
- Alleged she was promised promotions, but not given
- Terminated due to restructuring
- Case filed in September 2015 and unsealed in October 2016
- DOJ is investigating, but has not intervened in the case.

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U.S. *ex. rel.* ELISABETH MARKLEY v. SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC.

- Key allegations
  - Practices losses due to compensation in excess of FMV and not CR; practices always projected to lose money
  - Make up for losses with referrals
  - Meetings about hiring new physicians would include discussions of how much referral revenue they would bring
  - Avoiding outside FMVs by excluding compensation
  - Paying for services not actually provided
  - Acquiring practices to get referrals

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U.S. *ex rel.* ELISABETH MARKLEY v. SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC.

- Practice losses
  - 97 MGC groups operated at a loss; 11 made a profit
  - Total losses in FY15 = **(\$40,569,674)**
  - Losses never projected to turnaround
- High compensation for certain physicians; above 75<sup>th</sup> percentile
- Example of oncologist deal
  - Discussed downstream revenue of \$30-\$40 million per year
  - Paid \$600,000 in total comp
  - Projected to lose \$589,000 per year

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U.S. *ex rel.* ELISABETH MARKLEY v. SPARTANBURG REGIONAL HEALTH SERVICES DISTRICT, INC.

- Circumventing of outside FMV process
  - Policy to obtain outside FMV if comp over 75<sup>th</sup> percentile
  - Markley told to exclude comp items to keep under 75<sup>th</sup>
  - Pay employed physicians on 1099 basis for certain services
- Payment for services not provided
  - Management of practice groups
  - Quality outcomes
  - Administrative services
  - Supervision of NPs

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U.S. *ex rel.* DAVID BARBETTA v. DAVITA, INC. AND TOTAL RENAL CARE, INC.

- DaVita, Inc.
  - Publicly traded dialysis center provider
- *Qui tam* relator: David Barbetta – senior financial analyst in M&A
- Dialysis center transaction allegations
  - Sales of shares of existing dialysis centers below FMV
  - Purchases of physician-owned dialysis centers above FMV
  - *De novo* joint ventures that made little to no economic sense apart from referrals

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U.S. *ex rel.* DAVID BARBETTA v. DAVITA, INC. AND TOTAL RENAL CARE, INC.

- Allegations regarding DaVita's buy/sell strategies
  - Manipulation of financial models used by analysts and provided to outside appraiser to value dialysis centers
    - *Ad hoc* adjustments to financial models
    - Application of non-standard formulas and algorithms
  - "Gaming" revenue and cost assumptions given to the valuation firm
  - Only obtained a valuation when purchasing 100 percent of a partner's interest in a jointly-owned center

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U.S. *ex rel.* DAVID BARBETTA v. DAVITA, INC. AND TOTAL RENAL CARE, INC.

- Government intervened in case.
- DaVita settles with DOJ for **\$389 million**.

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KEY FMV/CR ISSUES IN ENFORCEMENT CASES

- **Losses, losses, losses, losses, and more losses**
  - Losses presented as definitive indication that compensation is above FMV
  - Losses are only justifiable and rational by taking into account referrals.
- Physicians paid over the MGMA 90<sup>th</sup> percentile are suspect and probably being paid for referrals.
- Making more money under hospital employment than in private practice is suspect.
- Tracking referrals and offsetting practice losses with profits on referrals
- Compensation in excess of collections

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KEY FMV/CR ISSUES IN ENFORCEMENT CASES

- Discussions and analyses of physician referrals as part of deals
- Paying physicians for the production of another provider
- Billing and coding issues
- Valuation issues
  - No valuation
  - Using old valuations or draft valuations
  - Manipulation of the valuation process or data

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KEY FMV/CR ISSUES IN ENFORCEMENT CASES

- High levels of wRVUs that are questionable
- Payments for services not provided
- Rationale and explanations that don't square with the facts
- Defenses that have little impact
  - Nonprofit status
  - Community need – sole provider or safety net hospital
  - Median compensation
  - "Hospitals all lose money on their physician practices" (made by Tuomey in closing arguments)

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KEY FMV/CR ISSUES IN ENFORCEMENT CASES

- What's Not a Key Issue
  - Matching compensation and production (percentile matching) is occasionally used to indicate excessive compensation.
    - Example: 65<sup>th</sup> percentile wRVUs warrants 65<sup>th</sup> percentile total compensation
  - Practice losses are by far the more broadly used economic indicator of compensation in excess of FMV.
  - Industry's exclusive focus on surveys and percentile matching is out of sync with current enforcement trends.

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USING LESSONS LEARNED FROM RECENT CASES TO ANALYZE ORGANIZATIONAL PROCESSES, PRACTICES, AND OUTCOMES AND IDENTIFY HIGH-RISK FMV/CR COMPLIANCE RISK AREAS

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THE CURRENT ENFORCEMENT ENVIRONMENT

- In a Post- *Tuomey* World, Providers Are Settling Cases Rather Than Litigating Them Through Trial.
  - FMV and CR issues will not be fully litigated based on the merits or technical arguments.
  - Unlikely pretrial motions can prevail based on expert opinions outside of trial process.
  - Settlement context changes the playing field: must meet regulators based on their worldview
    - Did you do wrong?
    - Are you a good actor or bad actor?

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THE CURRENT ENFORCEMENT ENVIRONMENT

- Investigations are Emerging Due to *Qui Tam* Relator Cases (Whistleblowers)
  - Based on deal "insiders" with access to insider information
  - Often not based on front-end FMV/CR issues, but about administration of contracts and contract outcomes
- Government responses to *qui tam* relator filings
  - Join the suit?
  - If join, how large of a fine to pursue under FCA?

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**AVOIDING BADGES OF FRAUD**

- How Do Prosecutors Think about a Case?
  - Lying
  - Cheating
  - Stealing
- These are the real themes put to the jury, rather than technical arguments
- Avoid practices that are considered "badges of fraud"

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**AVOIDING BADGES OF FRAUD**

- Reports and analyses offsetting practice losses against hospital referral profits
- Hospital operators talking about how practice losses are offset by hospital profits from referrals
- Physician compensation based on outpatient or other hospital service line profits
- Practice losses combined with high compensation and other "bad facts" indicating an offset between losses and referral profits
- Compensation models that essentially force losses (i.e., the compensation formula affords no chance for the practice to breakeven or make money)
- Lack of legitimate business reasons for losses (e.g., charity care, startup of a business, or needed coverage for necessary hospital service line such as trauma)
- Practice losses on arrangements where significant hospital profits are made as a result of the arrangements or can be tied indirectly to the arrangements

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**THE CURRENT ENFORCEMENT ENVIRONMENT**

- Settlements Based on DOJ's Perception of the Compliance-Orientation of the Organization
  - Existence and effectiveness of compliance programs and systems
    - Organizations should effectively establish a compliance orientation
    - Previously tainted organizations face the need to rehabilitate
  - Organizational systems to promote compliance

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THE CURRENT ENFORCEMENT ENVIRONMENT

- Settlements Based on DOJ's Perception (cont'd)
  - Outcomes of transactions and arrangements
    - Compensation levels
    - Practice losses
    - Contract terms and conditions
  - Review of real facts and circumstances rather than purported or perceived facts and circumstances

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FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK

- Failed Deal Development Processes
  - Executives aggressively promoting deals while manipulating financial data and models
  - Insufficient controls to prevent bad actors from violating the one-purpose test
- Absence of Adequate Segregation of Duties
  - Executives with access to internal analysts and data provided to external valuation firms

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FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK

- Flawed Process for Establishing and Documenting FMV
  - Lack of documented, defensible conclusions of FMV
    - Deals move forward without FMV support
    - Deals are based on incomplete external analysis performed for another party or another purpose
    - Conclusion or documentation is technically unsupported
  - Lack of independent review or quality control processes
    - Unchecked manipulation of internal data and financial models
  - Haste to close the deal is the greatest driving force

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**FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK**

- Inadequate Process for Use of Outside Valuation Consultants
  - Blatant manipulation of data furnished to outside valuator
  - Suppression of undesired valuations, opinion shopping
  - Selective use of valuator for limited transactions (i.e., buy-only)
  - Inadequate valuator qualification and monitoring process, resulting in plug-and-play valuations
  - Reliance on incomplete analysis obtained for another party or purpose

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**FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK**

- Deficient Process for Establishing and Documenting CR
  - Defensive or anti-competitive decisions for unnecessary services are allowed to take precedence over legitimate business reasons
    - Buying a business of little strategic or community benefit other than referrals
    - Buying redundant, used, or outdated equipment
    - Employing providers with questionable standards of care
    - Entering a stagnant market or service line
  - Lack of compliance training and monitoring

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**FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK**

- Process and Organizational Issues
  - Lack of adequate FMV and CR review process
  - Lack of segregation of duties or "separation of powers"
    - Hospital operators driving physician deals
    - No independent compliance functions with institutional power
    - Comparing physician practice losses to hospital contribution margin reports
  - Involvement of hospital management in the administration of physician contracts

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**FAILED PROCESSES CONTRIBUTING TO COMPLIANCE RISK**

- **Process and Organizational Issues**
  - Lack of organizational compliance structures
    - Problems identified but not resolved
    - Instructions to change compensation not followed
    - Compensation not based on contract terms
    - Attribution of wRVUs from other providers
    - Ignoring concerns of employees who raise legitimate compliance issues
  - Compliance training
  - Legal oversight?

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**DEVELOPING IMPROVED ORGANIZATIONAL STRUCTURES AND PROCESSES TO MANAGE AND REDUCE REAL WORLD FMV/CR COMPLIANCE RISK**

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**ENTERPRISE RISK MANAGEMENT (ERM) FOR FMV/CR**

- **New Compliance Paradigm**
  - Mitigate risks for FMV/CR compliance based on enforcement environment
    - Focus not only on technical, regulation-oriented compliance
    - Prevent *qui tam* relators from emerging
    - Reduce settlement amounts in case of compliance "fumble"
  - Foster compliance orientation through organizational structures and systems

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FOUR CRITICAL RISK AREAS



- **Process Risk**
  - Industry compliance paradigm: get FMV and legal review on front-end of deal
    - "Check the box" orientation
    - Often, focus on issues not at issue in enforcement actions
  - Pre-transactional systems and processes have weaknesses in ensuring front-end and *long-term* FMV/CR compliance.
  - Executives incorrectly believe the transaction or arrangement falls outside the purview of the Stark law.

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FOUR CRITICAL RISK AREAS

- **Implementation/Administration Risk**
  - Deals are not operationalized consistent with expert opinions or internal approvals.
  - Contracts are not administered as approved or according to the written terms.
  - Contracts not administered according to the valuation opinions or internal approvals.

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FOUR CRITICAL RISK AREAS

- **Circumstantial Risk**
  - Facts and circumstances have changed from when the deal was originally approved.
- **Outcomes Risk**
  - Arrangements result in high risk outcomes or "red flags" based on current enforcement trends.

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**FMV/CR PROCESS BEST PRACTICES**

- Health System Narrative to Reduce Potential Compliance/Enforcement Risk
  - The health system must provide a broader analysis based on a pre-transactional study in which an individual physician transaction is viewed in the context of an overall long term fiscal strategy and not a singular compensation arrangement.
  - Create a plenary omnibus financial, clinical, and legal strategy for the health system addressing as a part of that strategy its short and long term physician acquisition goals to satisfy prospective market conditions, including value based programs, bundled payments, joint venture, and ACO models.
  - Creation of an omnibus pre-transactional document broadly articulating the integration strategy with forecast of potential hospital losses over a transition term serves to replace the government's view physician loss equals payment for referrals.

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**FMV/CR PROCESS BEST PRACTICES**

- Health System Narrative to Reduce Potential Compliance/Enforcement Risk
  - Issues to address in the strategy document
    - How does the health system intend to effectuate clinical alignment to address the clinical and financial challenges with its business lines?
    - Do the proposed clinical services contribute to the development or operation of a clinical service line?
    - Are the financial and clinical purposes of the proposed arrangement specifically addressed based on FMV and CR, as well as related to the overall financial and clinical integration goals of the health system?

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**FMV/CR PROCESS BEST PRACTICES**

- CR Involves a Financial and Contractual Analysis
  - Compensation relative to collections
  - Bonus structure based on revenue minus expenses, rather than first dollar earned
  - Assessment of certain contractual terms
  - Immateriality of the belief that many hospital-based physician practices lose money

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FMV/CR PROCESS BEST PRACTICES

- Remedy Deficient Organizational Compliance Mindset
  - In several *qui tam* actions, employees were ignored or retaliated against when raising legitimate compliance issues.
  - Implement controls to prevent bad actors from violating the one-purpose test.
  - Engage in FMV/CR compliance training and monitoring.
- Establish Organizational Risk Parameters and Tolerance Thresholds Around the Four Corridors of FMV/CR Risk.

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FMV/CR PROCESS BEST PRACTICES

- Process Risk
  - Deal development process
  - Approval process
  - Contracting process
  - Payment process
  - Process for establishing FMV
  - Process for establishing CR
  - Process for using outside valuation consultants
  - Internal process compliance testing

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FMV/CR PROCESS BEST PRACTICES

- Implementation/Administration Risk
  - Process for implementing contracts
  - Process for contract administration
- Circumstantial Risk
  - Process for implementing facts and circumstances review
  - Process for periodic review of facts and circumstances

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FMV/CR PROCESS BEST PRACTICES

- Outcomes Risk
  - Review of internal and external valuations
  - Review of deal file documentation
  - Review of contract administration
  - Review of facts and circumstances
  - Financial outcomes analysis
    - Physician clinical compensation benchmarks
    - Analysis of practice losses
  - Process compliance auditing

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FMV/CR PROCESS BEST PRACTICES

- Address Real-world Enforcement Risk in the Context of an Organization's Goals, Values, and Available Resources
- Be Prepared for a Compliance Emergency: Optimum Defense for a *Qui Tam* Relator Filing
- "Stress Test" Processes and Outcomes to Find Weaknesses and Address Them

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KEY TAKEAWAYS FOR FMV/CR ERM

- A Well-Managed Contract Database Serves as a Platform to Support Ongoing Management and Compliance Reviews
- The Government's Decision to Intervene and the Size of the FCA Damage Assessment is Based in Large Part on the Compliance-Orientation of the Organization and the Existence and Effectiveness of Compliance Programs and System
- FMV and CR are Not a One-and-Done, Check-the-Box Activity, but Must Contemplate that Facts and Circumstances Change Over Time

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**THE GOVERNMENT'S VIEW OF PRACTICE LOSSES**

- "And, finally, just use your common sense. The only reason that it makes sense to [pay] these doctors a million and a half dollars a year is to save the eight to \$12 million a year in referrals. And even Paul Johnson, the Tuomey's CFO, acknowledged on cross-examination or, excuse me, on direct examination that really, yeah, the hospital was getting back for all that money was referrals."
- "Would the hospital have done this, would the hospital have entered into these contracts if it weren't for the referrals? Well, the evidence showed that the only way that deal made any sense is if there were referrals. The hospital is losing one-and-a-half million dollars a year, was losing one-and-a-half million dollars per year, and it raises the question why."

Tuomey 2 Trial - government counsel closing argument.

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- The Government's View on Practice Losses
  - Losses are a definitive indication that compensation is above FMV
  - Losses are only justifiable and rational by taking into account referrals
- In Reality, Hospital Losses on Physician Practices Are Driven by:
  - Local market conditions
  - Health system strategies and decision-making
  - Business decisions driven by physicians
  - Physician practice entity revenues
  - Practice overhead
  - Provider contracting

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Local Market Conditions Affecting Physician Practice Profits
  - Local market economy and industry conditions
  - Community physician need and medical staff development plan
  - Payer policies and local market reimbursement implications
  - Payer mix implications of local conditions
  - Hospital charity care policies
  - Local practice consolidation and hospital employment trends

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Health System Strategies and Decision-Making Affecting Practice Profits
  - Defensive or anti-competitive decisions for unnecessary services allowed to take precedence over legitimate business reasons
    - Buying a business of little strategic or community benefit other than referrals
    - Buying redundant, used, or outdated equipment
    - Entering a stagnant market or service line
  - Deferred decisions on practice divestitures

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Health System Strategies and Decision-Making Affecting Practice Profits (cont'd)
  - Health system profitability focus over professional practice profits
  - Physician leadership engagement level
  - Practice management resources
    - Executive leadership
    - Practice management personnel
    - Technology resources

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Physician-Driven Business Decisions Affecting Practice Profits
  - Hospital-physician ventures and arrangements
  - Incentive compensation structure
  - Location, facilities, equipment, and service offerings
  - Supplier relationships
  - Personnel

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Physician Practice Entity Revenue Implications for Practice Profitability
  - Acquisitions in which ancillaries are stripped out and converted to HOPD
  - Managed care contract provisions and negotiation
  - Declining fee-for-service reimbursement
  - Revenue cycle policies and processes
  - Collection lag for startup practices
  - Low or declining physician professional productivity

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Practice Overhead Implications for Practice Profitability
  - System-wide accounting and budgeting practices
  - Non-provider personnel compensation and benefit policies
  - Non-physician personnel staffing levels

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**THE ANATOMY OF PHYSICIAN PRACTICE LOSSES**

- Provider Contracting Implications for Practice Profitability
  - Outdated and inconsistent physician contracts and compensation provisions
  - Physician and non-physician provider compensation in excess of FMV
  - Extravagant fringe benefit offerings

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THANK YOU.

<p>TIMOTHY SMITH, CPA/ABV <i>Ankura Consulting</i> <i>tim.smith@ankuraconsulting.com</i> (214) 200-3693</p>	<p>GREGORY D. ANDERSON, CPA/ABV, CVA <i>HORNE LLP</i> <i>greg.anderson@hornellp.com</i> (601) 620-5101</p>
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Legal Standards -AKS

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- **Anti-Kickback Statute** prohibits knowingly & willfully paying, offering, soliciting or receiving remuneration in return for referral
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, sale of practice, bona fide employment, physician recruitment, etc.)
- “One Purpose” rule

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Legal Standards - Stark Law

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- **Stark law:** If physician (or immediate family member) has financial relationship with entity (e.g. hospital), physician may not make referral to entity for designated health service (“DHS”) and entity may not submit claims for such services.
- “Designated Health Services” = Lab services, therapy services, radiology/imaging, DME, prosthetics & orthotics, home health services, outpatient Rx drugs, inpatient & outpatient hospital services.
- “Financial relationship” under Stark? Any ownership or investment interest; Any compensation arrangement (defined as “any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity” with certain very limited exceptions..
- “Referral” is defined very broadly, and includes: A request for, or ordering of, DHS; Establishment of a plan of care, etc.
- Safe Harbors and Exceptions: Rental of office space & equipment, Bona fide employment, Personal service arrangements, Physician recruitment, Isolated Transactions, Remuneration unrelated to DHS, etc.

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Legal Standards - FCA

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- **False Claims Act** prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - Retention of overpayment
    - 60-day rule
- *Qui tam* actions

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Role of Compliance, In-House  
and Outside Counsel to Company

- Whistleblowers work with government to identify and prosecute cases
- Does the entity have an effective compliance program?
- Will it be necessary to conduct employee interviews?
- Who will handle them?
- How will interviews be memorialized?
- Will the company retain counsel for employees if requested?
- How will the company handle a refusal to cooperate?

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Investigation

- Take every complaint and allegation seriously.
- What are the issues?
- What is the applicable legal standard?
- Who at company/entity decides whether compliance will conduct initial investigation?
- What are the risks of compliance acting without direction of counsel?
- Making yourself a witness/accomplice/co-conspirator.
- Cost of outside counsel vs. cost of foregoing outside counsel.
- Pitfalls: waived privileges, binding admissions, payment suspension, loss of licenses or privileges, penalties, imprisonment, and government-wide exclusion.

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Questions

Kirk Ogrosky  
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Anna Grizzle  
(615) 742-7732

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**Analytics: Enhancing Your Hospital Compliance Program**



Kate Conklin, B.A., CPMSM, CPHQ, Chief Compliance Officer  
Trissi Gray, MBA, CHRC, Assistant Director, Health System Compliance

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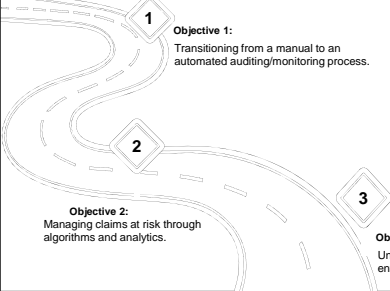
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**Today's Session**



**1 Objective 1:**  
Transitioning from a manual to an automated auditing/monitoring process.

**2 Objective 2:**  
Managing claims at risk through algorithms and analytics.

**3 Objective 3:**  
Understanding the role that the enterprise plays in compliance.

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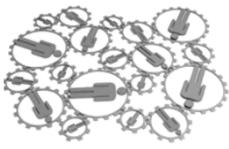
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**Polling Question: What is Your Role in Compliance?**

- A. Compliance Officer
- B. Legal Counsel
- C. Compliance Administrator/Specialist
- D. Billing/ Coding Compliance
- E. Other



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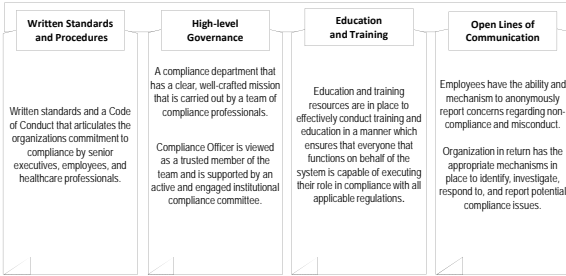
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**Compliance: Roles and Responsibilities**



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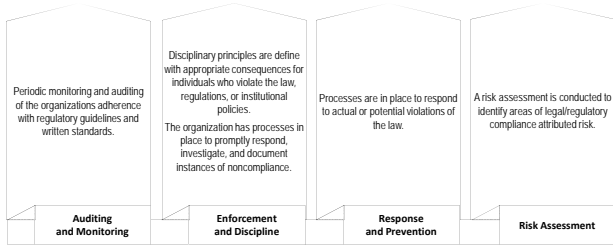
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**Roles and Responsibilities (continued)**



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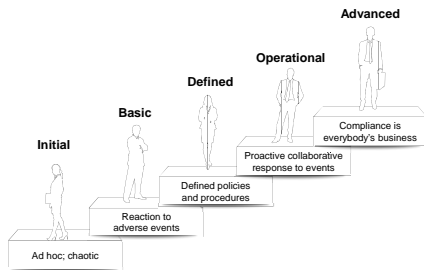
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**Optimizing Resources: Program Maturity**



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**Polling Question: Organization Compliance Program Maturity**

Compliance Program:

- A. Ad Hoc
- B. Fragmented
- C. Defined
- D. Operational
- E. Advanced



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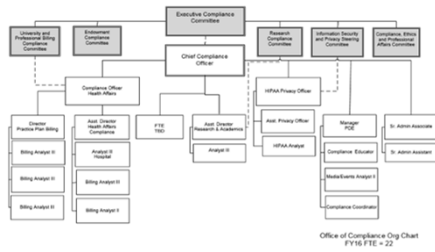
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**Compliance Program Infrastructure**



Office of Compliance Org Chart  
FY16 FTE = 22

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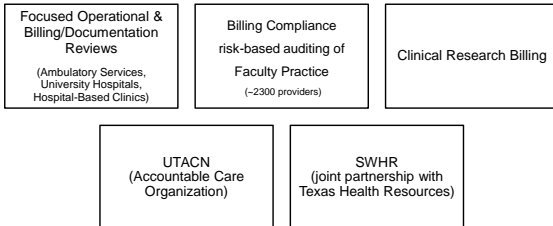
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**Program Responsibility: Health System Compliance**

Compliance program monitoring and advisory engagement includes:



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**Compliance: Auditing and Monitoring**

*Element of an effective compliance program is to conduct periodic auditing and monitoring of the organization's adherence with regulatory guidance and established written standards.*

Audit and Review Types:

Baseline	• High level review
Probe	• Determine whether a compliance issue exists
Routine	• Evaluate ongoing compliance
Expanded	• Enlarge sample based on error rates identified during a routine audit
Focused	• For cause review

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**Risk Identification: Organizational Strategic Initiatives**

The slide displays a central diagram of concentric circles representing risk levels, with 'Strategic Risks' at the outer edge and 'Operational Risks' at the inner core. To the left is a bar chart showing data trends. To the right is a table with columns for 'Risk Area', 'Risk Level', and 'Risk Status'. The text 'Page 1' is visible in the bottom right of the slide content.

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**Auditing and Monitoring: Compliance Risk Areas**

- Inpatient Rehabilitation Facility
- Cochlear Implants: Recalls
- Bariatric Surgery
- Overlapping Surgeries
- High Dollar Chemotherapy Drugs
- Sleep Testing
- Major Joint Replacements: Hip and Knee
- Hyperbaric Oxygen Therapy and Skin Substitutes
- Short Stays: 2 Midnight Rule




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**Polling Question: Does your facility use analytical software to conduct compliance reviews/audits?**

- A. Yes
- B. No



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**Compliance Monitoring: Manual Process**

- Identifying most recent claims
- Risk universe
- Gross charges vs. net charges
- Claim reports (4 systems) prior to centralization
- Manual Spreadsheet
- Reporting
- Audit Retention



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**New Age Compliance: Using Analytics to Identify and Audit Risk**

- Standardized solution for inpatient and outpatient data, that utilizes claims data (835/837s)
- Daily evaluation of compliance-attributed risk and coding outliers
- Leverage Medicare and Medicaid audit rules as well as, MEDPAR and PEPPER benchmarks.
- Data mining and proactively identify compliance risk
- Robust workflow to manage deadlines, additional documentation requests and external audit request.



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**Compliance Program: Mission, Vision and Value**

*Each day our patients, students, and the public count on us to deliver the very best in patient care, state-of-the-art research, and outstanding medical education. As a University, we strive to meet and exceed these goals. By fostering a culture of compliance with established policies and standards, we reassure the community of our commitment to adhering to all applicable laws, rules, and policies.*

Daniel K. Podolsky, M.D.  
President, UT Southwestern Medical Center

Source: UT Southwestern Medical Center, Standards of Conduct (2013)

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**Rules of Engagement: Executive Trust**

- Finding ways to connect with the CEO, CFO, COO and CNO
  - Tone at the Top: Culture of Ethics and Compliance
  - Executive Leadership Team Compliance Rounding
  - Executive Leadership Team- Dedicated Quarterly Meetings for Compliance
  - Meaningful Data: Compliance Dashboards, Real-time Auditing and Monitoring
  
- Compliance - Valued Addition to Operations
  - Accreditation and Patient Safety
  - Revenue Cycle Operations (HB and PB)
  - Clinical Research
  - Hospital and Ambulatory Services-Operations



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**Compliance: The Change Agent**



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### Understanding the Marriage: Operations vs. Compliance



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### Rules of Engagement: Collaboration and Transparency

- Culture: Embedding a "just culture mindset" is key.
- Communication: clear, concise and engaging discussions regarding strategic initiatives, organizational risks (appetites) and risk mitigation.
- Cross-Functional Risk-Management Approach: Eliminating silos and amplifying change agent teams to mitigate risk.
- Report, Report, Report: Establish KPIs and benchmark against organizations and other academic medical centers.
- Continuous Process Improvement: Plan, Do, Study, Act



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Contact Information:



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[kate.conklin@utsouthwestern.edu](mailto:kate.conklin@utsouthwestern.edu)

Trissi Gray, MBA, CHRC, Assistant Director, Health System Compliance  
[trissi.gray@utsouthwestern.edu](mailto:trissi.gray@utsouthwestern.edu)

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## Monitoring & Auditing HIPAA Compliance

Donald A. Sinko,  
Chief Integrity Officer

Vicki R. Bokar,  
Sr. Director Corporate Compliance  
Cleveland Clinic

March 29, 2017

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## Agenda

- Overview of Cleveland Clinic Health System and Compliance structure
- Where HIPAA fit into our Compliance Program
- Where adjustments were needed
- Effectively auditing and monitoring for HIPAA compliance

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## About Cleveland Clinic



- 7.1M Outpatient Visits
- 161,664 Acute Admissions
- 3,584 Physicians & Scientists
- 51,487 Employed Caregivers
- 28.5M sq. ft. Facility Space
- 10 Regional Hospitals
- 150+ Northern Ohio Outpatient Locations
- Staff physicians are salaried; on one year contracts

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### National & International Locations



- Canada – Executive Health, Sports Health and Rehabilitation
- Nevada – Lou Ruvo Center for Brain Health, Glickman Urological & Kidney Institute
- Florida – Integrated Medical Campus in Weston; Outpatient Locations in West Palm Beach
- Abu Dhabi - Partnership with Mubadala Development Co.
- London – In Progress

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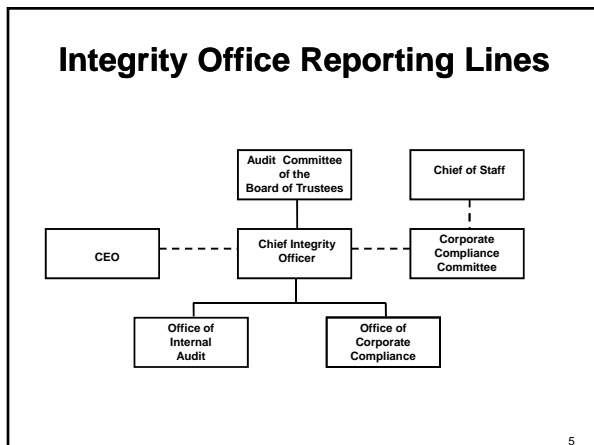
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### Internal Audit

- Focuses on all risks to the organization (not just regulatory risks)
- Tests effectiveness of new or existing internal controls, including those that affect the compliance program
- Audit work is formerly governed by professional audit standards
- Typically does not have operational responsibilities

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### Internal Control

- A process or action that is designed to prevent misconduct or minimally identify and detect it in a timely manner
- Typically include policies, procedures, SOPs, technology (e.g. access controls, audit logs)
- Monitoring itself may be an internal control. So can education & training

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### Corporate Compliance

- Department or Office that focuses on regulatory risk
- Creates, administers and monitors the entity's Compliance & Ethics Program
- Has an advisory and educational role
- Some operational responsibilities (especially for HIPAA)

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### Integrity Office & HIPAA

- Compliance Office
  - Administrative Requirements (§164.530 et seq.)
  - Breach Notification & Reporting (§164.400 et seq.)
- Internal Audit (IT Section)
  - Various Security Rule Standards
- Internal Audit (Research Section)
  - Research Uses & Disclosures (§164.512)

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### **Compliance & Ethics Program**

- A formal system of policies, procedures and other strategies designed to assure organizational compliance with applicable laws and standards governing the organization, including HIPAA

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### **Cleveland Clinic's Corporate Compliance Program**

1. Compliance Committee
2. Written Standards (Code of Conduct), policies and procedures
3. Open Lines of Communication (e.g. encourage reporting, including anonymous options)
4. Training and Education
5. *Auditing and Monitoring Plans*
6. Response to Detected Deficiencies
7. Consistent Enforcement of Disciplinary Standards
8. *Annual Risk Assessment*

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### **HIPAA Assessment is Mandatory**

- All Institutes, Hospitals and Divisions required to evaluate HIPAA compliance as part of their annual risk assessment
  - Review incident trends, root causes, effectiveness of safeguards, breach data, enforcement actions, patient complaints, PHI inventory
- Risks must be mitigated via their annual compliance work plan

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### **It Seemed Like a Great Process**

- Everyone was talking about HIPAA and there was a genuine desire to comply
- Numerous resources were focused on HIPAA compliance
- Loads of education was provided
- HIPAA concerns were increasingly being reported and addressed
- We were monitoring system activity and auditing access
- HIPAA “Walk-Throughs” were ongoing

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### **But Something Was Missing**

- We became really good at detecting, but wanted to do more preventing
- We felt that “snooping” and mis-mailings could not be our only risk to PHI
- We were being consulted regularly about new business operations and strategies involving PHI (e.g. Information Exchanges, ACOs, Health Reform, Telemedicine)
- We wondered whether auditing and monitoring plans could be more effective

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*Not everything that counts can be counted . . .*

*Not everything that can be counted, counts!*

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### An Important Clue

- “Compliance” & “Audit” have multiple meanings
- “Compliance” can also refer to the entity’s responsibility to comply with laws, regulations, an employee’s conduct or a patient’s adherence
- Audit is not just a department or office. “Audit” can refer to system activity logs, access reports, simple chart reviews, or a government audit
- We needed to educate our people

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### Auditing

- Usually retrospective and limited in time and scope
- Typically performed by independent party (internal or external auditors)
- Reviews compliance against a set of standards, such as statutes and regulations or internal policies, used as base measures
- Validates the effectiveness of policies, procedures and other controls in reducing risk

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### Monitoring

- Monitoring is an ongoing daily event which includes conducting analyses and tracking trends to correct issues in “real time” at the lowest level of detection
- It occurs during regular operations as a check to see if procedures are working (Abridged CMS Definition)

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### HIPAA Monitoring & Auditing

- The ultimate goal is to correct and prevent noncompliance *that could lead to* compromise of PHI
- The effectiveness of auditing and monitoring is directly dependent on the effectiveness of the risk assessment
- Why was this so challenging for people to grasp?
- We had to go back to the risk assessment

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### Another Clue

- “Risk assessment” means different things to different audiences!
  - Breach risk assessments
  - Annual compliance risk assessments
  - Internal Audit risk assessments
  - Assessments under the Security Management Process standard (*Risk Analysis*)
  - Enterprise Risk Management process
  - Joint Commission requirements

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### Integrity Office First Steps

- We learned to use terminology consistently
- HIPAA was common ground for collaboration between Audit and Compliance
- We shared observations, internal trends, patterns and other findings
- We looked at enforcement actions and national trends

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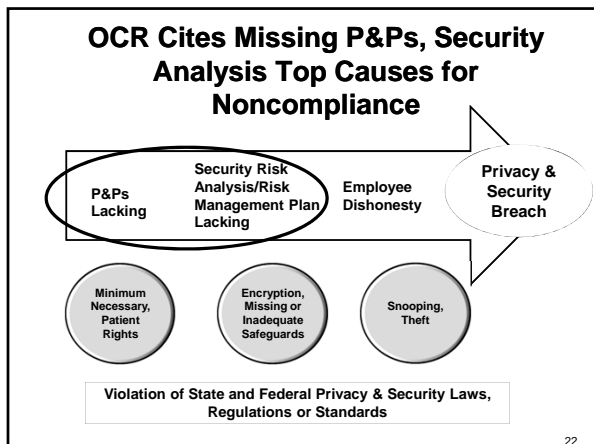
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### The OCR's Expectation

**“Organizations must complete a comprehensive risk analysis and establish strong policies and procedures to protect patients’ health information.”**

**“Further, proper encryption of mobile devices and electronic media reduces the likelihood of a breach of protected health information.”**

Jocelyn Samuels, Director  
OCR Press Release  
September 2, 2015

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### We Partnered with IT Security

- The Information Technology’s Security Department was a trusted advisor to both Audit and Compliance on individual projects and investigations
- We relied on their constant vigilance and they relied on our support
- We looked at our own auditing and monitoring activities

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## We Focused on Existing Silos



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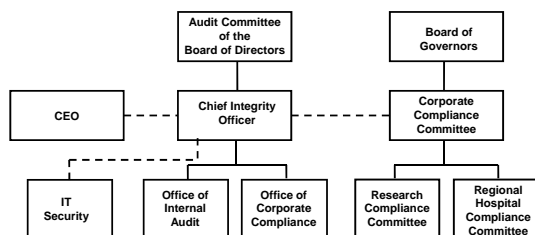
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## Removing Silos Improved Effectiveness



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## We Did More Homework

- We studied our own data (investigation trends, root causes, audit findings, security incidents etc.)
- We identified and prioritized our top risks
- We identified technological solutions that could facilitate more effective prevention and detection across the organization
- We came up with a compelling business case for the Senior Management

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### The Integrity Officer's Role

- **Communication and Education**
  - Senior Management
  - Clinical Leaders
  - Board Support
- **The Ask: Data Loss Prevention (DLP)**
  - Capital
  - Software
  - FTEs

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### What We Needed

- Software to identify and prevent malware (this was timely)
- Software to identify where PHI exists and where it flows
- Software to monitor for inappropriate activities
- Hardware to support it
- FTE's to manage it

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### Using the Tools

- Data at rest
- Data in motion
- Establishing baseline user behavior
- Additional forensic examination
- The tools were also useful for other organizational objectives:
  - PCI compliance
  - Fraud detection

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### Applying the Findings

- We identified specific departments that needed closer monitoring
- We found ePHI that was expired (per our retention policy) and could be sanitized
- We implemented technology to identify and automatically encrypt emails containing PHI and PII
- We developed a response plan for alerts that were triggered

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### You Don't Need Sophisticated Technology

- Track & trend root causes of incidents and breaches
- Patient complaints r/t individual privacy rights, incidental disclosures etc.
- Do a policy & procedure "crosswalk"
- Track and trend disciplinary actions
- Monitor effectiveness of corrective actions (process redesign, SOPs, training). Are incidents decreasing?

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### Other Monitoring Ideas

- Inventory all medical devices that store PHI (networked or not)
- Medical Device "rounds" can confirm appropriate safeguards
- Review training completion rates and notify management if action required
- Survey or test random workforce members to assess comprehension and correct application of P&Ps

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### Other Ideas

- Audit a sample of Business Associate contracts
  - Are they compliant?
- “Secret shopper” site visits
  - Is verification of ID occurring?
  - Are safeguards in place to minimize incidental disclosures?
  - Are NPPs on display?
  - Do they know where to refer privacy complaints?

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### What About Your Ideas?

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STRESS makes you Distracted,  
Distraught,  
Dumb,  
and Dead

Debi Johnson, MBA, RRT, CFC, EHP, CCEP, CHRC  
Compliance Content Developer  
HCCS/Healthstream  
Chief Research &  
Associate Compliance Officer  
Columbus Regional Health

Albert H. Eaton, Ph.D., M.Div.  
Director of Behavioral Science  
Family Medicine Residency  
Columbus, Georgia

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**What is my role in this presentation?**

I'm here as the real life "example" of what stress does to you ...

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**My Personality ...**

Myers-Briggs personality type: ISTJ  
"POLAR BEAR"  
Motto: *I'll work it out myself*  
"Perfection" is typically my goal.  
Type "A": competitive, outgoing, ambitious, impatient, high-strung, hard-driving, control freak ...

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**My Personality ...**

As a child,

- Intense & serious, very mature
- Attracted to interest requiring precision & skill
- Learned best by doing
- Valued routine and structure
- Liked to research and become an "expert"

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**My Personality ...**

As a young person,

- Often more adult than the adults!
- Valued independence, privacy & personal space
- Dependable, loyal & responsible.

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**My Personality ...**

As a partner,

- Practical
- Loyal & sensible
- Do not like spontaneity

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### **My Personality ...**

At work,

- A task finisher
- Good at understanding & applying the RULES
- Over-represented in accountancy, law, uniformed services, surveying, business administration, management & COMPLIANCE!

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STRESS **still** makes you  
Distracted,  
Distraught,  
Dumb,  
and Dead

### **Who Manages You?**

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### **What is Stress?**

- Threat of job change or loss
- Job deadlines or difficult boss
- Your spouse demands more time
- Your child suffers a loss
- Your parent dies
- You get promoted/demoted
- You win the lottery
- A new administration

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**What distresses you?**

- Talking to a psychologist
- Talking to an administrator
- Talking to a physician
- Talking to a patient
- Talking to a judge
- Public speaking

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**Real Stressors!**

- Our "Customers"
  - External/Internal
  - Rules, Regulations, Interpretations
- Threat of ...
  - Mistakes
  - Ambiguity

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**Real Stressors!**

- Our Physical Environment
  - Traffic, Physical threat
  - Economics – food, shelter, water
  - Weather and landscape
- Our Social Environment
  - Family
  - Work
  - Community

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**Real Stressors!**

- Ourselves
  - Biology
  - Behavioral patterns
  - Thoughts
  - Feelings

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**Stress & It's Effects ...**

*Back to the Compliance Professional's Story*

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**Stress...**

*If your personality is anything like mine,  
Think about all the things that irritate you, that cause you  
stress...  
Now,  
Think about the various health events in your life.*

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**Stress...**

*Compliance Officer for around 20 years...  
High anxiety – Creating Compliance Programs from the ground up, several Qui Tam litigations, 1<sup>st</sup> OCR Security Audit.*

*Sudden death of my father.  
... Panic attack on an airplane.  
... Panic attacks in traffic.*

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**Stress & It's Effects ...**

*May '13 New Job – immediate Qui Tam  
Feb '14 - Hospitalized: Vestibular Dysfunction  
Sep '14– Hospitalized: Heart Attack  
Nov '14 – Hospitalized: ?? Stroke  
Mar '15 – Diagnosed: Hypoglycemia*

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**The Effects of Stress**



*I'd like to introduce you to my 36 year old daughter, Kimberly who was diagnosed with Takotsubo Cardiomyopathy*

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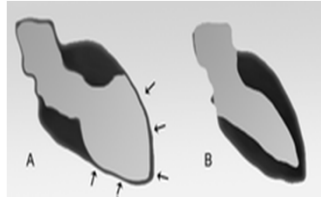
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## The Effects of Stress

Takotsubo  
cardio-  
myopathy



Normal  
heart

Resulting in Acute Congestive Heart Failure

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## The Effects of Stress



... sudden onset of congestive heart failure associated with ECG changes mimicking a myocardial infarction of the anterior wall ...

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## The Effects of Stress

Takotsubo cardiomyopathy...

Stress is the main factor in takotsubo cardiomyopathy, over 85% of cases are set in motion by either a physically or emotionally stressful event that prefaces the start of symptoms. Examples of emotional stressors may include grief from the death of a loved one, fear from public speaking, arguing with a spouse, relationship disagreements, betrayal or financial problems. Acute asthma, surgery, chemotherapy, and stroke are examples of physical stressors.

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**The Effects of Stress**

*October 30, 2015*

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**The Effects of Stress**

December 28, 2015

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**Sorry, It's Not Entirely the Event**

- It is our PERCEPTION of the Event
- What is "stressful"??
- Perception is your reality!
- What you **think** you are going through and
- What you are actually going through

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### **Stress and Distress**

- Some **Stress** is **normal/desirable**
  - Effective homeostasis
  - Coping = return to baseline
- **Distress** is a **problem**
  - Ineffective homeostasis
  - Dumb
  - Dead

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### **Psychobiology**

- Data
  - 5 senses
  - emotions
  - memory
- Outside of consciousness
- Mediated by thoughts

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### **Perception**

- My reality
- Biases my future perceptions
- An internal process
  - Senses
  - Emotion
  - Memory
  - Schemas, models, frames
- Unconscious and Conscious

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## Biology

- Hypothalamic-Pituitary-Adrenal Axis
  - ACTH
  - Cortisol
  - Epinephrine
  - Norepinephrine
- Increased arousal
- Freeze – overwhelmed arousal

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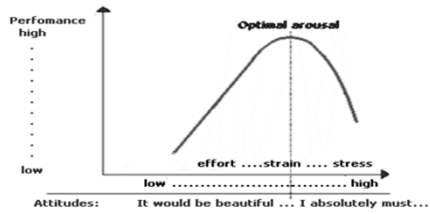
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## DUMB

### Yerkes-Dodson Law



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## Biological responses (short list)

- ↑ Heart Rate
- ↑ Respiration
- ↑ Blood Pressure
- ↑ Sweating
- ↑ Muscle tension
- ↑ Blood to Big Muscles
- ↑ Blood Glucose

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### Biological responses (short list)

- ↓ Blood to gut and gut motility
- ↓ Immune Response over time
- ↓ Heart rate variability (HRV)
- ↓ Cellular repair
- ↓ Hippocampal cells (memory)
- ↓ Frontal lobe functioning
- ↓ Shortens telomeres
- ↓ Inhibits collagen formation

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### The Consequences

- Pain, indigestion, muscle tension
- Difficulty sleeping
- Anxiety/worry
- Distraction/poor awareness
- Loss of Pleasure
- Diabetes risk
- Heart attack risk

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### The Consequences

- Cancer risk
- Difficulty making decisions - judgment
- Impulsivity
- Diabetes risk
- Heart attack risk
- Shorter Life

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### Questions?



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### Thinking

- What you think counts
- Determines perception
  - Threat
  - Challenge
  - Opportunity
- Can lead to physical arousal

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### The Consequences

# DENIAL

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### Dysfunctional Coping

- Alcohol (more than 1-2 drinks)
- Food (especially high fat and sweet)
- Sad or mad
- Sleep (more than 9 hours)
- Work (loss of balance)
- Exercise (dominating your life)
- Sex (overindulgence)
- Avoidance

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### Coping

- Eat better
- Exercise
- Recreate
- Relax
- Good social connections
- Change your thinking
- Change your thinking (What?!)

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### Negative Cognitions

- I can't do this ...
- He always ...
- I never ...
- This will be a disaster
- I can't
  - Cope
  - Change
- Your own negative self-talk

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### Thought Stopping

- Changing patterns
- Recognize negative attributions
- STOP!
- The illusion of "Don't"
- Change thoughts to ...

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### Optimistic Cognitions

- This is an opportunity
- I can really grow through this
- A novel solution will present itself
- I will find help where I least expect it
- How can I see this from another angle
- I will do better if I relax

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### Questions?



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## Feeling



- Let yourself feel!
- What do you feel?
- Do Feelings fit Reality?

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## Memory

- How do your memories
  - affect your perception?
  - influence your mood?
  - guide your perception?
- Memory changes
  - Expectation
  - Satisfaction

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## Physiologically

- How relaxed are you?
- How tense are you?

**DO YOU KNOW ?**

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## Breathing



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## Writing

- Keep a Journal
  - Activities
  - Thoughts
  - Feelings
- A Fifty-word story
  - Great for a specific event
  - Beginning, middle, and end

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## Long-Term Strategies

- Regular Exercise
- Healthy food
- Yoga
- Tai Chi
- Meditation
- Develop relationships

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Questions?



**Thank  
You**

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## Driving Quality of Care Through Culture Change Strategies

Identifying culture challenges, collecting data to show value for change, and creating culture change by demonstrating "what's in it for me?"

HCCA'S 21ST ANNUAL COMPLIANCE INSTITUTE  
MARCH 29, 2017

Jalal Josh Clemens  
Compliance Program Manager  
Stanford University

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### DISCLAIMER



JALAL CLEMENS

WHILE I DO WORK FOR STANFORD UNIVERSITY, ALL THE VIEWS, OPINIONS, AND COMMENTS EXPRESSED IN THIS PRESENTATION ARE MY OWN AND MAY DIFFER FROM STANFORD UNIVERSITY AND OTHER ASSOCIATED ENTITIES.



DR. ROTRUCK  
PEDIATRIC OPHTHALMOLOGY FELLOW  
DUKE UNIVERSITY

**NOTE: I WORK FOR STANFORD UNIVERSITY NOT STANFORD HEALTHCARE WHICH ADMINISTERS ALL THE STANFORD BRANDED HOSPITALS.**

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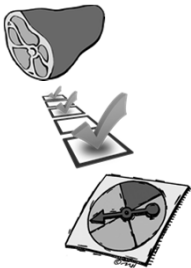
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### TODAY'S TOPICS



- UNDERSTANDING THE EXISTING CULTURE, INDIVIDUAL PSYCHOLOGY AND CREATING CULTURE AND CHANGE CHAMPIONS BY LEVERAGING THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) QUALITY STRATEGY, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) NATIONAL QUALITY STRATEGY AND OTHER GUIDELINES.
- DESIGNING, COLLECTING, AND COMPARING DATA STATISTICS AND SURVEY RESULTS ON QUALITY OF CARE TO PINPOINT STAGNATION OR POTENTIAL CULTURAL BARRIERS TO IMPROVING QUALITY OF CARE WITHIN YOUR ORGANIZATION.
- EXAMPLES AND DISCUSSIONS OF INEXPENSIVE PROGRAMS, FRIENDLY COMPETITIONS, AND OTHER TOOLS THAT CAN BE USED TO DRIVE TARGETED CHANGES IN QUALITY OF CARE WITHIN ORGANIZATIONS.

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LOOKING THROUGH ALL LENSES

- ADMINISTRATIVE BACK OFFICE
- PATIENT AND FAMILY
- CAREGIVER
- COMMUNITY
- PAYER (GOVERNMENT, INSURANCE AND SELF PAY)



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Culture [kuhl-cher]

1. The **behaviors and beliefs** characteristic of a particular social, ethnic, or age group.
2. A particular form or stage of civilization, as that of a certain nation or period.
3. Development or improvement of the mind by education or training.

culture. (n.) Dictionary.com Unabridged. Retrieved October 18, 2016 from Dictionary.com website: <http://www.dictionary.com/browse/culture>

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Organizational Culture

The customs, rituals, and **values** shared by the members of an organization that have to be accepted by new members.

organizational culture. (n.) Collins English Dictionary - Complete & Unabridged 10th Edition. Retrieved October 18, 2016 from Dictionary.com website: <http://www.dictionary.com/browse/organizational-culture>

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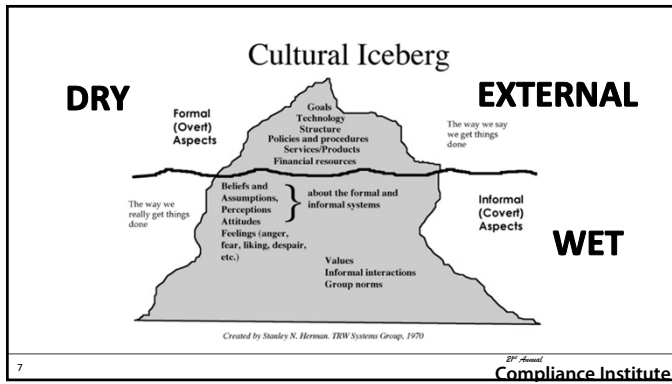
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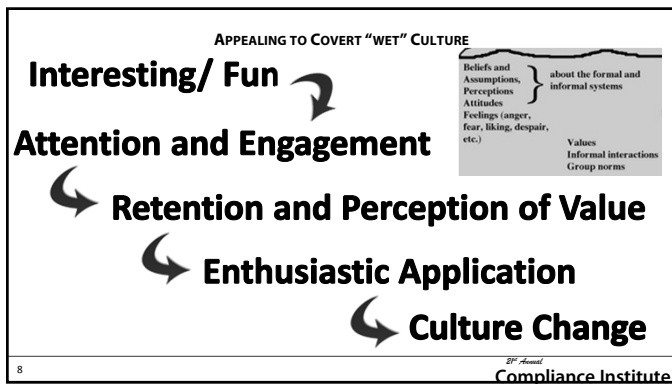
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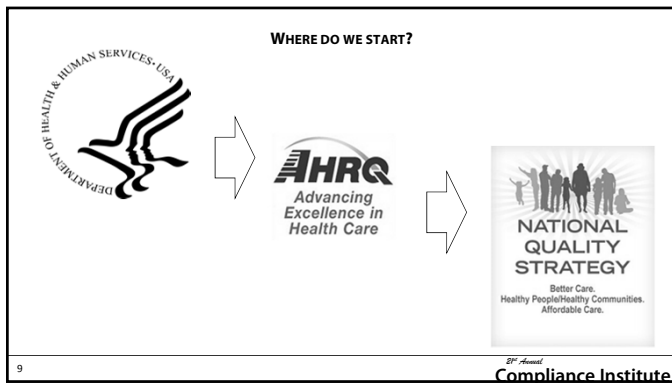
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**WHAT'S THE MEAT OF THE NATIONAL QUALITY STRATEGY (NQS)?**  
**THREE OVERARCHING AIMS**



Patient-centered  
 Accessible  
 Reliable  
 Safe

BP Assured  
**Compliance Institute**

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**WHAT'S THE MEAT OF THE NATIONAL QUALITY STRATEGY (NQS)?**  
**FOUNDATIONAL PRINCIPALS**



**Foundational Principles**

- Eliminate Racial & Ethnic Disparities
- Strengthen Infrastructure & Data Systems
- Enable Local Innovations
- Foster Learning Organizations

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**Compliance Institute**

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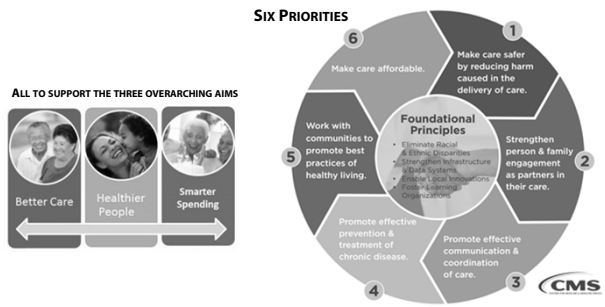
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**WHAT'S THE MEAT OF THE NATIONAL QUALITY STRATEGY (NQS)?**  
**SIX PRIORITIES**

ALL TO SUPPORT THE THREE OVERARCHING AIMS



Better Care    Healthier People    Smarter Spending

**Foundational Principles**

- 1. Make care safer by reducing harm caused in the delivery of care.
- 2. Strengthen person & family engagement as partners in their care.
- 3. Promote effective communication & coordination of care.
- 4. Promote effective prevention & treatment of chronic disease.
- 5. Work with communities to promote best practices of healthy living.
- 6. Make care affordable.

BP Assured  
**Compliance Institute**

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**WHAT'S THE MEAT OF THE NATIONAL QUALITY STRATEGY (NQS)?  
NINE LEVERS**

- MEASUREMENT AND FEEDBACK
- PUBLIC REPORTING
- LEARNING AND TECHNICAL ASSISTANCE
- CERTIFICATION, ACCREDITATION, AND REGULATION
- CONSUMER INCENTIVES AND BENEFIT DESIGN
- PAYMENT
- HEALTH INFORMATION TECHNOLOGY
- INNOVATION AND DIFFUSION
- WORKFORCE DEVELOPMENT



<http://www.ahrq.gov/workingforquality/reports.htm>

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**2016 CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)  
QUALITY STRATEGY**

"... envisions health and care that is person-centered, provides incentives for the right outcomes, is sustainable, emphasizes coordinated care and shared decision-making, and relies on transparency of quality and cost information."<sup>1</sup>

- REFLECTS THE HHS NATIONAL QUALITY STRATEGY
- SET GOALS FOR VALUE-BASED PAYMENTS WITHIN FEE-FOR-SERVICE
- FOUR FOUNDATIONAL PRINCIPLES
- UPDATES ON ACTION TAKEN TO ACHIEVE GOALS RELATED TO NQS SIX PRIORITIES

<sup>1</sup> Centers For Medicare & Medicaid Services. 2016 CMS Quality Strategy (2016). n. pag. 2016 CMS Quality Strategy. 2016 CMS Quality Strategy. Web: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiative/downloads/CMS-Quality-Strategy.pdf>

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**OTHER MATERIALS HELPFUL TO QUALITY STRATEGY**

- **QUALITY OF CARE – 2006 WORLD HEALTH ORGANIZATION**
  - Big picture thoughts on healthcare quality analysis, strategy and implementation  
[http://www.who.int/management/quality/assurance/QualityCare\\_B.Def.pdf](http://www.who.int/management/quality/assurance/QualityCare_B.Def.pdf)
- **STATE HEALTH OFFICIAL LETTER – CMS 2013**
  - Titled: Quality Considerations for Medicaid and CHIP Programs
  - High-level technical assistance to states regarding a framework for quality improvement and measurement  
<https://www.medicaid.gov/federal-policy-guidance/downloads/sho-13-007.pdf>
- **NQS REPORTS AND ANNUAL UPDATES**
  - More detailed focus and status updates on the NQS  
<http://www.ahrq.gov/workingforquality/reports.htm>

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LET'S WAKE UP

You have 30 seconds  
How many As do you count in the below paragraph?

READY?

"You don't need to memorize all these policies. I obviously have not. What you can do is think about the comprehensive picture and then take the policies piece by piece, methodically thinking about what you are doing now to meet them – what you will find is sometimes you don't know what you are doing or why you are doing it. That is fine its ok to cut corners. Find the right contact or start putting that information together."

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LET'S WAKE UP

How many As did you count?

Perception and Focus

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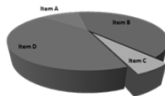
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**START AT THE BEGINNING...**

➤ **UNDERSTANDING WHAT DATA YOU HAVE**

- Key Performance Indicators (KPI), Dashboards, Reporting
- Informal feedback and observation
- Surveys and interviews



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**So much information!**

**Remember:**  
We are looking at this through the frame of **pinpointing** stagnation or potential cultural barriers to improving quality of care within your organization.



Don't miss the: "its ok to cut corners"

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**NINE LEVERS OF THE NATIONAL QUALITY STRATEGY**

➤ **DOES YOUR INFORMATION AND REPORTING COVER THE LEVERS?**

- MEASUREMENT AND FEEDBACK
- PUBLIC REPORTING
- LEARNING AND TECHNICAL ASSISTANCE
- CERTIFICATION, ACCREDITATION, AND REGULATION
- CONSUMER INCENTIVES AND BENEFIT DESIGN
- PAYMENT
- HEALTH INFORMATION TECHNOLOGY
- INNOVATION AND DIFFUSION
- WORKFORCE DEVELOPMENT



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**ASKING THE RIGHT QUESTIONS**

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**HOW TO GET INFORMATION**

- **EXISTING DATA**
  - Encrypted minimum necessary
  - Validate the data
  - Cleanup the data
- **SURVEYS**
  - Use a tool that provides easy analysis
  - Keep information secure, and anonymous if appropriate
  - Ease of access and use for the target
  - Ease of data manipulation/extract
  - Be willing to pay a small fee for the extra features

**.txt .csv**

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**BONUS: HOW TO GET PARTICIPATION**

- **EASE OF USE FOR CONTRIBUTOR**
- **TIMELINESS OF FEEDBACK**
- **SINCERE THANK YOU NOTES**

**Short + Sweet**

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QUICK CHECK – WHERE ARE WE?



- 1. IDENTIFIED REFERENCE GUIDES TO BUILD ON.
- 2. ANALYZED INDIVIDUAL PARTS OF OUR QUALITY OF CARE PROGRAM AND CULTURE AGAINST REFERENCE GUIDES LISTS.
- 3. UNDERSTOOD BROADLY WHAT INFORMATION IS AVAILABLE IN OUR ORGANIZATION RELATED TO QUALITY OF CARE.
- 4. STARTED THINKING ABOUT WHAT THE RIGHT QUESTIONS ARE BY UNDERSTANDING GAPS IDENTIFIED IN #2 AND #3.

What has not occurred yet?

**CHANGE**

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TODAY'S TOPICS

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**CHANGE**

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CHANGE SUCCESS GETTING BUY-IN



- BUILD RELATIONSHIPS BEFORE CHANGE ASK
- UNDERSTAND THE POLITICS AND CULTURE OF THE ORGANIZATION
- IDENTIFY **CHAMPIONS** IN LEADERSHIP
- MEET WITH DETRACTORS AND TALK THROUGH THEIR CONCERNS
- CONVERT THE LOUDEST/MOST OPINIONATED TO YOUR SIDE

THIS CAN TAKE ... **Months**




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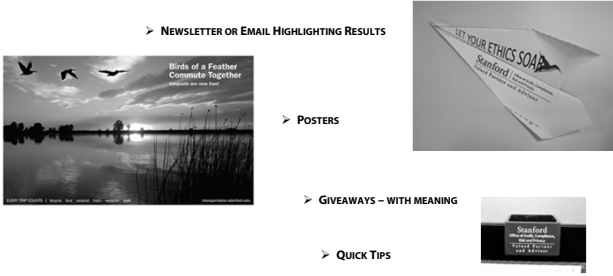
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**THINKING INSIDE THE BOX . . . SORT OF**

- NEWSLETTER OR EMAIL HIGHLIGHTING RESULTS
- POSTERS
- GIVEAWAYS – WITH MEANING
- QUICK TIPS



28 *8th Annual*  
**Compliance Institute**

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**THINKING OUTSIDE THE BOX**

- SCAVENGER HUNT
- NOMINATIONS OR COMPETITION WITH AWARDS FOR CHAMPIONS
- GAMES WITH PRIZES
- ...

**Beware the Pitfall:**  
**If it is optional and  
 requires time and effort  
 outside of work,  
 even if it is fun,  
People may not come.**

29 *8th Annual*  
**Compliance Institute**

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**WHAT MIGHT NOT SPEAK TO THE MASSES**

- FORMAL MEMOS
- GROUP MEETINGS – ESPECIALLY IF ATTENDANCE IS MANDATED
- POLICY UPDATE EMAIL BLASTS
- REPORTS WITHOUT ANY TEETH OR FOLLOW-UP
- SYSTEM UPDATES WITHOUT APPROPRIATELY BROAD COMMUNICATION



30 *8th Annual*  
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FINAL THOUGHTS

- ALWAYS GET A SENIOR LEADERSHIP SPONSOR AND CHAMPION – IDEALLY THE PERSON(S) MOST RESISTANT TO CHANGE IN THE FIRST PLACE OR SOMEONE WITH REFERENT POWER (INFLUENCE)
- HAVING AN ESTABLISHED POSITIVE RELATIONSHIP BUILDS CREDIBILITY
- A PERSONAL ONE-ON-ONE TOUCH MAKES A BIG DIFFERENCE IN RETENTION
- FOLLOWING UP REINFORCES AN IDEA MORE THAN YOU MIGHT THINK
- ASSOCIATING CHANGE WITH A POSITIVE EXPERIENCE REDUCES RESISTANCE.



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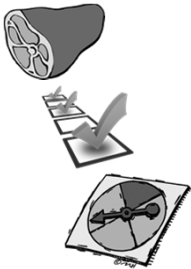
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TODAY'S TOPICS



- UNDERSTANDING THE EXISTING CULTURE, INDIVIDUAL PSYCHOLOGY AND CREATING CULTURE AND CHANGE CHAMPIONS BY LEVERAGING THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) QUALITY STRATEGY, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) NATIONAL QUALITY STRATEGY AND OTHER GUIDELINES.
- DESIGNING, COLLECTING, AND COMPARING DATA STATISTICS AND SURVEY RESULTS ON QUALITY OF CARE TO PINPOINT STAGNATION OR POTENTIAL CULTURAL BARRIERS TO IMPROVING QUALITY OF CARE WITHIN YOUR ORGANIZATION.
- EXAMPLES AND DISCUSSIONS OF INEXPENSIVE PROGRAMS, FRIENDLY COMPETITIONS, AND OTHER TOOLS THAT CAN BE USED TO DRIVE TARGETED CHANGES IN QUALITY OF CARE WITHIN ORGANIZATIONS.

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MAIN TAKEAWAYS



1. LEVERAGE THE QUALITY OF CARE FRAMEWORK TO ANALYZE YOUR PROGRAMS.

2. BE THOUGHTFUL AND PRECISE ABOUT WHAT YOU NEED TO KNOW AND HOW TO GET IT WITH THE MINIMUM INTERRUPTION TO PEOPLE'S LIVES.



3. CLEARLY COMMUNICATE VALUE - DEFINE THE REASON FOR THE CHANGE, THE POSITIVE RESULTS, AND BE CREATIVE IN COMMUNICATING THE NEEDED CHANGE.

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**DISCUSSION/QUESTIONS?**

**Jalal Josh Clemens, CIA, CCEP, CRMA**  
Compliance Program Manager, Office of Compliance and Ethics  
Stanford University Office of Audit, Compliance, Risk and Privacy  
616 Serra Street, Room 10 | Stanford, CA 94305  
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# BUILDING YOUR TOOLBOX TO MANAGE CONFLICT OF INTEREST: SUNSHINE, OPEN PAYMENTS, AND INVESTIGATIONS

2017 HCCA Compliance Institute, National Harbor, MD

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## Presented by

CJ Wolf, MD, CHC, CCEP, CIA, COC, CPC  
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## Agenda

- Explore the key points of the Sunshine Act
- Explain Industry's approach to "Sunshine" reporting and the Open Payments lifecycle
- Leverage your resources to conduct meaningful investigations when data doesn't match

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# SUNSHINE ACT

Key Points

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## Purpose

- Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Created by the Affordable Care Act

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## Mandate

- Manufacturers of a drug, device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient (i.e., physicians and teaching hospitals)
- Applies only to manufacturers
- Transactions reported involve teaching hospitals and physicians

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## Reporting

- Manufacturers must annually register and submit reports to the Centers for Medicare & Medicaid Services (CMS) by 90 days after calendar year end
- Separate reports for general transfers of value and research transfers of value
- Annual reports cover transfers of value made in the preceding calendar year

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## Review Process

- Manufacturers *and* covered recipients have 45 days to review information through secure website prior to public disclosure
  - Covered recipients register to review manufacturer submissions
- Reviewers may indicate agreement/disagreement with information posted
- CMS will not arbitrate disputes between manufacturers and covered entities
- If dispute not resolved, CMS will post information as reported by manufacturer but note that information is in dispute

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## Penalties for Non-Compliance

- Failure to Report: Civil money penalty from \$1,000 to \$10,000 for each unreported transfer of value up to \$150,000
- Knowing Failure to Report: Civil money penalty from \$10,000 to \$100,000 for each unreported transfer of value up to \$1,000,000

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## Corrections

- Manufacturers must report discovered errors or omissions in information submitted immediately
- CMS notifies affected covered recipients and updates website posting annually
- CMS may undertake interim "refreshes" of data posted

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## Documentation

- Manufacturers must maintain all records sufficient to enable audit of compliance with reporting requirement
- Records mentioned for at least 5 years from date that transfer of value is publicly posted not date that transfer of value is reported

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## Covered Recipients

- Physicians
  - Licensed physician, osteopath, dentist, dental surgeon, podiatrist, optometrist, or chiropractor
    - Legally authorized to practice medicine
    - U.S. or U.S. territory (Puerto Rico, Virgin Islands, Guam and American Samoa) even if living abroad
- Excludes:
  - Employee of manufacturer
  - Residents
- Teaching Hospitals
  - Any institution receiving Medicare direct or indirect graduate medical education payments
  - CMS posts list annually on Open Payments website and manufacturers may rely on that list...or can they?

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## Types of Reporting Requirements

Research Payments	Payments or other transfers of value if (1) made in connection with "research" and (2) protocol or written agreement
General Payments	All other transfers of value

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## Research Transfers of Value

- Manufacturers must track and report the following information for research transfers of value related to clinical research:
  - Name of individual/entity directly receiving the transfer of value
    - Physician: Name, business and email addresses, National Provider Identifier (NPI), state license number and state, specialty (as per the taxonomy and code in National Plan and Provider Enumeration System (NPPES)) and type of medicine practiced (M.D., D.O., D.P.M., O.D., or D.C.P.)
    - Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
    - Other Third Party: Name and business and email addresses

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## Data Elements

- Total amount, date and form of research payment
- Name of research study
- Whether the product is a Covered Product, a non-Covered Product, a combination, or neither
  - Covered Product: Prescription drug or medical device if premarket approval by or premarket notification to the FDA is required and payment is available under Medicare, Medicaid or the Children's Health Insurance Program
- Name of related covered product(s)
- Information on physician principal investigators (same as for physicians above)

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### More Data Elements

- Manufacturers must track and report the following abbreviated information for research transfers of value related to pre-clinical research:
- Name of individual/entity receiving the transfer of value
  - Physician: Name, business and email addresses, NPI, state license number and state, specialty and type of medicine practiced
  - Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
  - Other Third Party: Name, business and email addresses
- Total amount, date and form of the transfer of value
- Information on physician principal investigators

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### Research-Related Transfers of Value

- Reported under general transfers of value
  - Protocol development consultation
  - Data monitoring committee service
  - Steering committee service
  - Meals and travel for investigators not covered in clinical trial agreement

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### General Transfers of Value

Consulting fees	Speaker fees
Honoraria	Gifts
Entertainment	Food & Beverage
Travel & Lodging	Courses & Textbooks
Charitable Contributions	Royalties & Licenses
Investment Interest (or potential)	"Grants" (non-research)

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INDUSTRY'S APPROACH TO "SUNSHINE"  
REPORTING

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THE OPEN PAYMENTS LIFECYCLE

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2017 OIG Work Plan: Data Brief on Open Payments Program 



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**Sunshine Data Helps Feds Uncover Fraud**  
Aug 26, 2016 By Jill Wechsler  
The \$7.5 billion in "transfers of value" made in 2015 by pharma companies to physicians and hospitals through the federal Open Payments program has caught the attention of the Department of Justice (DoJ) and federal and state prosecutors investigating fraud throughout the health care system. Enforcement agencies see this wealth of industry data as a ready resource for uncovering unusual arrangements or heavy spending to certain providers that

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2017 OIG Work Plan: Data Brief on Open Payments Program 

New: Data Brief on Financial Interests Reported Under the Open Payments Program

- ACA § 6002 requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals.
- Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians.




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## 2017 OIG Work Plan: Data Brief on Open Payments Program



OIG will also determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations.



OIG will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.

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## Settlements



JUSTICE NEWS

Department of Justice  
Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Tuesday, March 11, 2014

### Pharmaceutical Company to Pay \$27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs

Pharmaceutical manufacturer Teva Pharmaceuticals USA Inc. and a subsidiary, IVAX LLC, have agreed to pay the government and the state of Illinois \$27.6 million for allegedly violating the False Claims Act by making payments to induce prescriptions of an anti-psychotic drug for Medicare and Medicaid beneficiaries. Teva Pharmaceuticals USA is located in North Wales, Pa., and IVAX LLC is a Florida company.

Pharma Company:  
March 2014

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## Settlements



JUSTICE NEWS

Department of Justice  
Office of Public Affairs

SHARE

FOR IMMEDIATE RELEASE

Friday, February 13, 2015

### Illinois Physician Pleads Guilty to Taking Kickbacks from Pharmaceutical Company and Agrees to Pay \$3.79 Million to Settle Civil False Claims Act Case

The Department of Justice announced today that an Illinois physician, Dr. Michael J. Reinstein, pleaded guilty to a federal crime for receiving illegal kickbacks and benefits totaling nearly \$600,000 from two pharmaceutical companies in exchange for regularly prescribing an anti-psychotic drug — clozapine — to his patients. Reinstein also agreed to pay the United States and the state of Illinois \$3.79 million to settle a parallel civil lawsuit alleging that, by prescribing clozapine in exchange for kickbacks, Reinstein caused the submission of false claims to Medicare and Medicaid for the clozapine he prescribed for thousands of elderly and indigent patients in at least 30 Chicago-area nursing homes and other facilities.

Physician: February 2015

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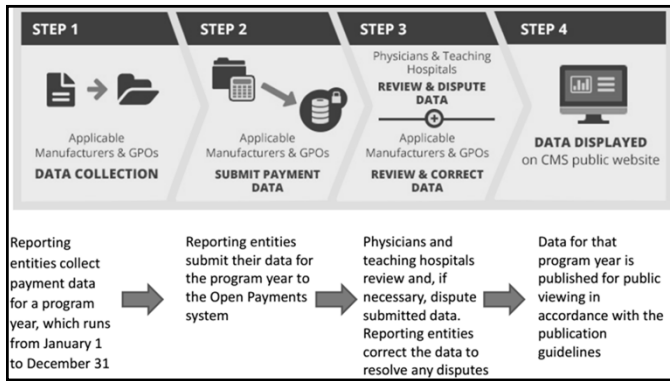
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### Payments Categories

- Consulting Fee
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and Lodging
- Education
- Charitable Contribution
- Royalty or License
- Grant
- Research
- Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program;
- Current or prospective ownership or investment interest;
- Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program;
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program;
- Space rental or facility fees (teaching hospital only);

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[http://phrma-docs.phrma.org/sites/default/files/pdf/phrma\\_marketing\\_code\\_2008.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf)




<http://www.advamed.org/issues/code-ethics/code-ethics>

**MDMA**  
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[http://cvmcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA\\_Code\\_July09.pdf?hSearchTerms=%22code%22](http://cvmcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA_Code_July09.pdf?hSearchTerms=%22code%22)

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**COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES**

<b>ADVAMED MEMBER COMPANIES</b>		<b>NON-MEMBER COMPANIES</b>	
<p><b>3M Health Care</b>      Maureen Harris (Infection Prevention Division and Skin &amp; Wound Care Division)      mharris@mm.com</p> <p><b>Abbott Laboratories</b>      Hotline: 1-855-294-4564 United States Medical      Website: spwslup.abbott.com Products Divisions</p> <p><b>ABIOMED, Inc.</b>      Hotline: 855.475.6376 Stephan McEvoy      978.646.1819 (phone) smcevoy@abiomed.com</p> <p><b>Accurant, Inc.</b>      Susan Clarke</p>	<p><b>AccelSPINE</b>      Sheetal Patel 214.545.5852 (phone) compliance@accelspine.com</p> <p><b>AccuVein, Inc.</b>      Sue Vallejo 631.367.0393 (phone) sue@accuvein.com</p> <p><b>Accumed LLC</b>      Ed Boehmer 503.627.9957 x1293 (phone) eboehmer@accumed.net</p>		

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701 Pennsylvania Avenue, NW  
Suite 500  
Washington, D.C. 20004-2664  
Tel: 302 253 8200  
Fax: 302 253 8220  
www.AdvaMed.org

September 1, 2016

**Via Overnight Mail**

Erin Skinner, Esq.  
Centers for Medicare & Medicaid Services  
U.S. Department of Health & Human Services  
Attention: CMS-1654-P - Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: CMS-1654-P: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Reports of Payments or Other Transfers of Value to Covered Recipients**

Dear Ms. Skinner:

On behalf of the members of the Advanced Medical Technology Association ("AdvaMed"), we write in response to the Department of Health and Human Services, Centers

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## LEVERAGE YOUR RESOURCES TO CONDUCT MEANINGFUL INVESTIGATIONS

WHEN DATA DOESN'T MATCH

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## Conflict of Interest Reporting – Develop Your Program

- Appoint a Conflict Manager to oversee day-to-day monitoring plan
  - Reviewing disclosed potential conflicts
  - Conducting investigations
  - Creating management plans
- Create well-defined policies
  - Determine reporting limits
    - How much outside activity is too much?
  - Provide faculty with clear expectations and definitions
    - "What is honoraria?"

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## Conflict of Interest Reporting – Develop Your Program

- Determine the frequency of reporting
  - Annual? Biannual? Continuous?
  - Update existing disclosure? Provide new disclosure for each new conflict?
- Construct an effective questionnaire
  - Broad questions vs specific inquiries
  - Revise!!
- Decide on a management tool
  - Electronic vs paper
  - Databases vs spreadsheets
  - What can be simplified using the proper tool?

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### COI Technology Enablement

Electronic COI management systems can be used to simplify the COI reporting process – and ultimately the investigation process – for managers and researchers.

- Electronic conflict reporting options
- Centralization of management processes
- Integration with publicly reported databases

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### Monitoring Conflicts – Am I getting the whole story?

An effective COI management program will examine information that is reported AND look for what wasn't reported

- Conduct audits of faculty reporting no conflicts
- Check information against CMS databases
- What should raise a red flag?
  - High dollar amounts vs frequency of outside activity – what is your institution's limit?

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### Monitoring Conflicts – Am I getting the whole story?

Example: Dr. A reports \$10,000 in consulting fees with ABC Pharmaceuticals

- Matches what is publicly reported
- Potential conflict of interest?
- Create a management plan?
- High dollar amounts might trigger further investigation
  - Nature of the relationship between the doctor and the company?

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## Monitoring Conflicts – Am I getting the whole story?

Example: Dr. B reports small payments for meals and travel from several outside medical device companies

- What is the potential for conflict of interest vs conflict of commitment?
  - Impact to the institution and faculty member's institutional responsibilities
- Management plans can help provide guidelines for what is acceptable outside activity

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## Monitoring Conflicts – Am I getting the whole story?

Example: Dr. C reports no conflicts, but public database shows consulting and travel payments to ABC Pharmaceuticals

- Time to conduct an investigation
  - Follow up with the doctor
    - Oversight?
    - Permitted by institutional leadership?
    - Public data incorrectly reported?
- Gather information from other sources

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## Conducting Investigations

Sometimes the most obvious resources are the best

- Ask the Googles!
- Industry websites
  - Dr. C and ABC Pharmaceuticals
    - What do they do?
    - How does it relate to Dr. C's research or specialty?
    - Has Dr. C spoken on their behalf? Mentioned them in lectures?

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## Conducting Investigations

- Doctor's history, research and publications
  - What are the recurring themes and how do they relate to outside interests?
  - Who has the doctor worked with in the past? How might they be involved?
- Institutional records
  - Is there a record of the doctor being granted permission for the work they're doing?
  - Do we have other business agreements in place and how do they relate?

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## Reporting

- Once investigations are concluded, how do you share the information?
- Who is the audience?
- What is the frequency?
- Where at your institution does the management plan "live"?

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## Questions?

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Andrew Hill  
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**Criminal and Civil Enforcement Trends: Focus on Federal Enforcement of Fraud and Abuse Involving Hospice Programs and Opioid Abuse**

*HCCA 21<sup>st</sup> Annual Compliance Institute  
Gaylord National  
National Harbor, MD  
Wednesday, March 29, 2017 10:00-11:45 am*

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**Speakers**

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**Christine Anusbigian, MBA - Specialist Leader**  
• Deloitte & Touche LLP

**Sean Bosack, JD**  
• Godfrey & Kahn, S.C.

**Michelle Frazier, JD, SVP Chief Compliance Officer**  
• Aurora Health Care

**Stacy Gerber Ward, JD**  
• von Briesen & Roper, S.C.  
• Former Assistant United States Attorney

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**Outline**

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- **Background**
  - HCF Statutes
  - Hospice care in the U.S.
  - Opioid abuse in the U.S.
- **Agency involvement and enforcement tools**
- **Fraud Schemes and cases**
- **Compliance/audit recommendations**

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Health Care Fraud Statute: 18 U.S.C. § 1347

- Punishes anyone who knowingly and willfully executes or attempts to execute any scheme to defraud “any health care benefit program,” in connection with delivery of or payment for health care benefits, items or services, or anyone who uses or attempts to use false or fraudulent pretenses, representations, or promises in connection with delivery of or payment for health care benefits, items, or services to gain control of any money or property owned by “any health care benefit program.”

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Health Care Fraud Statute Penalties

- Violators shall be fined and/or imprisoned for up to **10 years**.
- If serious bodily injury results, the violator shall be fined and/or imprisoned for **up to 20 years**.
- If death results, the violator shall be fined or imprisoned for **any term of years or for life**.
- Actual knowledge of the statute or specific intent to violate is *not required*.
- Applies to both government-sponsored programs *and* private insurance.

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False Claims Act 31 U.S.C. § 3729

- Federal law that imposes liability on people who defraud governmental programs like Medicare and Medicaid.
- Violators are subject to civil monetary penalties of \$10,500 to \$20,000 per false claim and three times the actual damages the government sustains due to the fraud.
- **Providers have been sued under the False Claims Act for issuing medically unnecessary prescriptions.**

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Federal Program Exclusion Statute: 42 U.S.C. § 1320a-7

- The "Exclusion Statute" requires that physicians convicted of crimes related to federal healthcare programs, neglect or abuse of patients, or felony violations relating to controlled substances be excluded from participation in federal health care programs.



- Physicians may also be excluded if convicted of a misdemeanor related to a controlled substance, subject to suspension or revocation of license.

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Yates Memorandum: Individual and Corporate Liability

*September 9, 2015:*

- U.S. Deputy Attorney General issued to all DOJ attorneys policy changes regarding treatment of corporate civil and criminal prosecutions.
- **Reason** ...too many individuals escaped punishment for wrongdoing associated with the financial crisis.
- **Outcome** ...an enhanced focus on pursuing civil and criminal cases against individuals.

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Yates Memorandum: Health Care Providers

- Reference to the False Claims Act is one of the DOJ's primary tools.
- Providers and systems need to monitor the conduct of physicians, nurses and mid-levels.
- Commit to updating compliance policies and procedures.
- Commit to educating individuals on best practices to mitigate institutional and individual risk.

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# Hospice care in the U.S.

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### Increasing Scrutiny of Hospice Care

**Why Focus on Hospice?**

- In 2013, Medicare paid **\$15.1 billion** for hospice care for 1.3 million beneficiaries.
- Between 2005 and 2009, hospice payments **increased 53%**.
- Payments for hospice care in nursing facilities rose even faster: nearly a **70% increase** over the same years.

**What is the Medicare Hospice Benefit?**

To be eligible for Medicare hospice care, a beneficiary must be:

- Entitled to Part A of Medicare
- Certified as having a terminal illness with a life expectancy of 6 months or less.
- Care may be provided in various settings, including the home or a nursing facility.

Source: <https://oig.hhs.gov>

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### Increasing Scrutiny of Hospice Care (cont'd)

Hospice care has been a focus of the Office of Inspector General (OIG), United States Department of Health and Human Services (DHHS).

OIG Work Plan 2017	OIG Reports
<ul style="list-style-type: none"> <li>• Medicare Hospice Benefit Vulnerabilities and Recommendations for Improvement: A Portfolio</li> <li>• Review of Hospices' Compliance with Medicare Requirements</li> <li>• Hospice Home Care — Frequency of Nurse On-Site Visits to Assess Quality of Care and Services</li> </ul>	<ul style="list-style-type: none"> <li>• Hospices Should Improve their Election Statements and Certifications of Terminal Illness (September 2016)</li> <li>• Hospices Inappropriately Billed Medicare Over \$250 million for General Inpatient Care (March 2016)</li> <li>• Medicare Hospice Care For Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements (September 2009)</li> </ul>

Source: <https://oig.hhs.gov>

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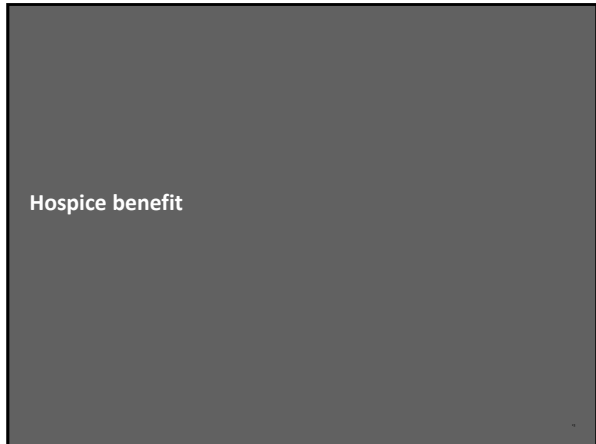
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Hospice benefit

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**The Medicare Hospice Benefit**

- Medicare pays for health services for palliative care that is related to a terminal illness.
- Terminal Illness: One in which the patient's life expectancy is 6 months or less if the terminal illness runs its normal course. 42C.F.R. § 418.3.
- Palliative care is designed to relieve the pain, symptoms, or stress of terminal illness. 42CFR § 418.3.
- Palliative care does not treat the underlying condition.

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**Medicare Hospice Conditions**

- Beneficiary must be terminally ill.
- The treating physician and hospice medical director must both sign the initial certification of terminal illness (90 days).
  - Subsequent certifications must only be signed by one physician.
- Beneficiary must sign an election form.
- A plan of care must be established by the hospice.

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### Care Related to Patient's Terminal Illness

- By signing the election form, the beneficiary waives his/her rights to other Medicare benefits (i.e., curative care) related to the terminal illness.
- Electing the hospice benefit will not alter traditional Medicare benefits for medical conditions not related to his/her terminal illness.

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### Physician Certifications

- For the initial certification period of 90 days, two physicians – the treating physician and the hospice medical director – must certify that the patient has a prognosis of less than 6 months. 42 C.F.R. § 418.20.
- The certification must be accompanied by clinical information and other documentation that support the medical prognosis of less than 6 months. 42 C.F.R. § 418.22.
- “A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare.” 70 Fed. Reg. 70,532, 70,534-35 (Nov. 22, 2005).

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### Hospice Levels of Care

#### Routine Care

- Paid on a daily rate.
- Paid for every day when the beneficiary is on the service, regardless of whether a service was rendered on a particular day.
- Same rate no matter how many disciplines provided care.
- Not paid if another level of hospice care is provided.

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**Hospice Levels of Care (cont'd)**

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**Continuous Care**

- Paid on an hourly basis.
- Beneficiary experiences an acute medical crisis requiring more intensive hospice care.
- Care provided with the intent to maintain the beneficiary at home.
- Minimum of 8 hours of care a day required.
- At least half the hours of care must be provided by a nurse (RN or LPN).

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**Hospice Levels of Care (cont'd)**

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**General Inpatient Care**

- Inpatient hospitalization specifically to address care related to the terminal illness.
  - Pain control/symptom management.
  - Breakdown of caregiver support system.

**Respite Care**

- Short-term inpatient care specifically to relieve caregivers.
- Expected to be provided on an occasional basis.
- Duration is limited to 5 days.

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**Hospice Levels of Care (cont'd)**

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Rev. Code	Level of Care	2016 Reimbursement
651	Routine Home Care (days 1-60)	\$186.85/day
651	Routine Home Care (days 61+)	\$146.83/day
652	Continuous Care	\$944.79 (\$39.37/hour)
655	Inpatient Respite Care	\$167.45/day
656	General Inpatient Care	\$720.11/day

Source: Medicare Learning Network Matters No. MM9301 (9/4/15)

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### Hospice Cap

- There is a cap on the amount that a hospice can be paid annually.
- The cap amount for 2016 was **\$27,820.75**.
- To determine a hospice's aggregate cap, multiply the number of Medicare beneficiaries by the hospice cap amount.
- So, if a hospice has 100 beneficiaries, the aggregate cap calculation is:
  - $100 \times \$27,820.75 = \$2,782,000$
- If the hospice has received more than that amount from Medicare during the year, the hospice must pay back the overage.

Source: CMS Fact Sheet, Final Fiscal Year 2017 Payment and Policy Changes for the Medicare Hospice Benefit (CMS-1652-F).

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### Hospice fraud schemes

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### Hospice Fraud Schemes

- Admitting and retaining beneficiaries that do not have a prognosis of 6 months or less.
  - Local Coverage Determinations (LCDs) are used to determine prognosis.
- Red Flags
  - High percentage of beneficiaries with "suspect" diagnosis such as dementia and failure to thrive.
  - High percentage of beneficiaries that have long lengths of stay (more than one year).
  - Discharging beneficiaries to avoid "cap exposure."

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**Hospice Fraud Schemes**

- Billing for a higher level of care than necessary
  - Billing for general inpatient care or continuous care when the patient does not need elevated levels of care.
- DOJ complaint against national hospice company:
  - The company marketed crisis care services to patients and their families as “intensive comfort care” services, without mentioning that, in order to bill Medicare for these services at the higher rates, a patient had to be experiencing a short-term crisis and have acute medical symptoms.
  - One company nurse stated that, on more than one occasion, when the company sent her to the homes of patients whom she was told needed crisis care, she arrived only to find that the patients were at church, playing bingo, or having their hair done, and not in crisis.

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**Hospice Fraud Schemes**

- Discharging beneficiaries for hospital care related to terminal illness and then readmitting them.
- Hiring medical directors who also serve as medical directors for nursing homes in an effort to obtain referrals.
- Offering kickbacks to nursing homes for referrals.
  - Hospice nursing staff providing care to non-hospice residents.
  - Supplying the nursing home with equipment allegedly for the residents on hospice.

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**Hospice Cases**

Hospice care has been a focus of the OIG and the DHHS.

- SouthernCare Inc. <sup>17</sup>, an Alabama-based company, and its shareholders allegedly submitted false claims to the Government for hospice patients who were not eligible for such care. In 2009, SouthernCare Inc. agreed to pay a total of \$24.7 million to settle allegations and enter into a corporate integrity agreement (CIA) with OIG.
-  Roberto Ruiz, M.D., and his company, Southwest Internal Medicine Group, P.C., entered into an integrity agreement with OIG in 2009 to resolve charges of submitting false claims to Medicare for hospice services. The agreement requires written policies, employee education, and annual audits. He also paid \$525,000 to resolve his civil liability.
- In 2008, Solaris Hospice, Inc. <sup>18</sup>, formerly Home Hospice of North Texas, and its two owners agreed to pay \$500,000 plus interest to resolve allegations that Solaris submitted improper claims for hospice-related items and services. The improper claims included, for example, alleged misrepresentation to Medicare of the medical conditions of patients to ensure that they would be or continue to be hospice patients. Also, Solaris Healthcare, the parent company of Solaris, agreed to enter a 5-year CIA with OIG.

[http://oig.dhs.gov/newroom/news\\_releases/2011/hospice.asp](http://oig.dhs.gov/newroom/news_releases/2011/hospice.asp)

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## Hospice compliance assessment

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### Hospice Claims Assessment

The following activities are completed during a hospice medical record assessment:

1. Confirm sampling parameters	2. Obtain data & select samples	3. Obtain records
<ul style="list-style-type: none"> <li>Confirm the sampling parameters such as:                             <ul style="list-style-type: none"> <li>Sample size,</li> <li>Number of hospice claims,</li> <li>Payor mix (e.g., Medicare, Medicaid, and commercial payors),</li> <li>Dates of service,</li> <li>Random or focused sample, and</li> <li>A focused sample may include selections based on certain facilities, geographies or potential high risk claims.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Obtain a report of claims billed for the specified period of time.</li> <li>Based on the agreed upon criteria select a sample.</li> </ul>	<ul style="list-style-type: none"> <li>Claim form</li> <li>Remittance advice.</li> <li>Physician certification and/or recertification that the beneficiary meets the hospice criteria of a terminal prognosis.</li> <li>Documentation of face-to-face encounters.</li> <li>Completion of the hospice election notices.</li> <li>Other                             <ul style="list-style-type: none"> <li>Billing documents (AOB, MSP, ABN, contract notes etc.)</li> <li>Licensure</li> </ul> </li> </ul>

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### Hospice Claims Assessments (cont'd)

The following activities are completed during a hospice claims assessment:

#### 4. Evaluate Claims & Medical Records

- Compare each record to the payor billing requirements at the time of service.
- Hospice claims and medical records are evaluated for the following:
  - A preliminary assessment and/or plan of care was developed and signed within 48 hours of admission
  - If the physician certification / recertification that the beneficiary meets the hospice criteria of a terminal prognosis was completed within the required timeframes, and that appropriate signature and dates are present
  - If the patient's clinical documentation meets LCD criteria
  - If the physician's "face-to-face" requirement was met as required for recertification of the terminal illness prior to 180th day recertification period and each subsequent recertification period thereafter. Whether the document was signed by the physician and the narrative contains a summary of patient's continual eligibility for hospice
  - If the appropriate level of service, as supported by the documentation, was charged and reported on the claim
  - If the hospice election forms were completed within the required time frame and whether the election forms contain the content required by Medicare.

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### Hospice Claims Assessments

Compliance with the following guidelines are assessed during hospice claims assessments:

**Guidelines**

- CMS Pub 100-4 Chapter 11
- CMS Pub 100-2 Chapter 9
- Title 42, Part 418
- Medicare LCDs - These policies contain clinical criteria that should be documented by the physician to demonstrate the terminal status of the patient.
  - Home health & hospice Medicare Administrative Contractors:
    - National Government Services, Inc.
    - CGS Administrators, LLC
    - Palmetto GBA
- OIG Compliance Program Guidance Hospices – published 1999

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### Hospice Claims Assessments (cont'd)

CMS Published an example election statement in December 2016.

N/A N Matters Number: N/A N Related Change Request Number: N/A

Medicare Hospice Election Statement

I, \_\_\_\_\_ (Print Name) \_\_\_\_\_, choose to elect the Medicare hospice benefit and receive hospice services from \_\_\_\_\_ (Hospice Agency).

**Hospice Philosophy:**  
I understand that I have been given a full explanation and have an understanding of the purpose of hospice care. Hospice care is a voluntary plan and other options related to my terminal illness and related conditions and such care will not be deemed to be curative. The focus of hospice care is to provide comfort and support to both me and my family members.

**Effect of a Medicare Hospice Election:**  
I understand that by choosing hospice care under the Medicare Hospice Benefit, I am waiving (giving up) all rights to Medicare payments for services related to my terminal illness and related conditions and I understand that while this election is in force, Medicare will make payments for care related to my terminal illness and related conditions only to the designated hospice and attending physician that have entered a statement that services not related to my terminal illness or related conditions will accept to be eligible for coverage by Medicare.

**Right to choose an attending physician:**  
I understand that I have rights to choose an attending physician to create my care. My attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions.

I do not wish to choose an attending physician.

I understand that my choice for an attending physician is: \_\_\_\_\_ (Print Name) \_\_\_\_\_  
Physician full name: \_\_\_\_\_ (Print Name) \_\_\_\_\_  
Office Address: \_\_\_\_\_  
I understand and understand the above, and authorize Medicare hospice coverage to be provided by \_\_\_\_\_ to begin on \_\_\_\_\_ (Effective Date of Election).

Note: The effective date of the election, which may be the first day of hospice care or a later date, but may be earlier than the date of the election statement. An individual may not designate an effective date that is retroactive.

Signature of Beneficiary/Representative \_\_\_\_\_ (Date) \_\_\_\_\_  
 Beneficiary or surrogee to sign.  
Name: \_\_\_\_\_  
Witness signature \_\_\_\_\_ (Date) \_\_\_\_\_

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE07p.pdf>

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### Hospice Claims Assessments (cont'd)

The following illustrative examples display the tools that can be utilized when conducting a hospice claims assessment:

Requirement of Hospice	Completed	N/A	Continue care
1. US-24 Claim Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Membership Certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Assignment Certificate of Payment (Assigned to Patient/Proxy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. D-01 or Assignment Provider/Designated Beneficiary Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Data processing authorization to Access/Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Form of care determination form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Request for Review Information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Data processing authorization, Proxy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Data processing authorization, Proxy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Category	Item	Completed	N/A	Continue care
Medicare	Medicare Number	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Medicare Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Medicare Enrollment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Medicare Assignment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient/Proxy	Signature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Witness Signature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Witness Date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hospice	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Request for Review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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### Hospice Claims Assessments (cont'd)

During a hospice claims assessment, it is important to consider additional review areas:

**Other Review Areas:**

- Hospice cap
- Quality reporting
  - 2% reduction in payment for not reporting
- Potential data analytic examples:
  - Referral patterns
  - Diagnoses
  - Utilization / length of stay

**Interviews:**

- Interview and other document review to assess both controls in place and improper practices, for example:
  - Processes for auditing and monitoring and/or quality assurance checks
  - Systems, tools or prompts that serve as checklists and/or reminders to complete required tasks
  - Inappropriate referrals
  - Selection of patients that are lower cost and longer term

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### Hospice Claims Assessments (cont'd)

Look for risks identified in OIG Compliance Program Guidance specifically for hospice care.

- Uninformed consent to elect the Medicare Hospice Benefit.
- Admitting patients to hospice care who are not terminally ill.
- Arrangement with another health care provider who a hospice knows is submitting claims for services already covered by the Medicare Hospice Benefit.
- Under-utilization.
- Falsified medical records or plans of care.
- Untimely and/ or forged physician certifications on plans of care.
- Inadequate or incomplete services rendered by the interdisciplinary Group.
- Insufficient oversight of patients, in particular, those patients receiving more than six consecutive months of hospice care.
- Hospice incentives to actual or potential referral sources (e.g., physicians, nursing homes, hospitals, patients, etc.) that may violate the anti-kickback statute or other similar Federal or State statute or regulation including improper arrangements with nursing homes.
- Overlap in the services that a nursing home provides, which results in insufficient care provided by a hospice to a nursing home resident.
- Improper relinquishment of care services and professional management responsibilities to nursing homes, volunteers and privately-paid professionals.
- Providing hospice services in a nursing home before a written agreement has been finalized, if required.
- Billing for a higher level of care than was necessary.
- Knowingly billing for inadequate or substandard care.
- Pressure on a patient to revoke the Medicare Hospice Benefit when the patient is still eligible for and desires care, but the care has become too expensive for the hospice to deliver.
- Billing for hospice care provided by unqualified or unlicensed clinical personnel.
- False dating of amendments to medical records.
- High-pressure marketing of hospice care to ineligible beneficiaries.
- Improper patient solicitation activities, such as "patient charting".
- Inadequate management and oversight of subcontracted services, which results in improper billing.
- Sales commissions based up on length of stay in hospice.
- Deficient coordination of volunteers.
- Improper indication of the location where hospice services were delivered.
- Failure to comply with applicable requirements for verbal orders for hospice services.
- Non-response to late hospice referrals by physicians.
- Knowing misuse of provider certification numbers, which results in improper billing.
- Failure to adhere to hospice licensing requirements and Medicare conditions of participation.

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## Opioid abuse in the U.S.

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### Opioid Overdoses the United States (2000-2014)



- From 2000 to 2014 nearly half a million people died from drug overdoses.
- Since 1999, the number of overdose deaths involving opioids nearly quadrupled.

At least **HALF** of all opioid overdose deaths involve a **prescription opioid.**

Centers for Disease Control and Prevention. [Opioids in Drug and Opioid Overdose Deaths - United States, 2000-2014. MMWR 2014; 63\(10\):201-204.](#)

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### Opioid Overdose Deaths in the U.S.

In 2014, opioids were involved in 47,000 deaths in the U.S.

Approximately 129 people die every day from drug poisoning, 61% of them are pharmaceutical opioids or heroin related.



Side effects may include death!

SOURCE: Office of the Attorney General Memorandum, September 21, 2016. Subject: Department of Justice Strategy to Combat Opioid Epidemic

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### Economic Impact of the Opioid Epidemic

- \$55 billion in health and social costs related to prescription opioid abuse each year.
- \$20 billion in emergency department and inpatient care for opioid poisonings.



Each day, more than **1,000** PEOPLE are treated in emergency departments for not using prescription opioids as directed.

Source: Pain Med. 2013;22(4):657-67. doi:10.1016/j.painmed.2013.03.014

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### 3 Pillars of Engagement Memo

#### From the Office of Attorney General (9/2016)

**Prevention**

- Strengthen prescription drug monitoring programs (PDMPs).
- Ensure safe drug disposal.
- Prevent overdose deaths with naloxone.

**Enforcement**

- Investigate & prosecute high-impact cases.
- Enhance regulatory enforcement.
- Encourage information sharing.
- Fund enforcement related research.

**Treatment**

- Share best practices for early intervention.
- Support medication-assisted treatment.
- Promote treatment options throughout the criminal justice system.

Source: OAG Memo distributed 9/21/2016 - Subject: Department of Justice Strategy to Combat Opioid Epidemic

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### HHS - New Actions to Combat Opioid Epidemic

- A proposal to eliminate any potential financial incentive for doctors to prescribe opioids based on patient experience.
- Expanding access to buprenorphine.
- Launch of more than a dozen new research studies on opioid misuse and pain treatment.
- A requirement for Indian Health Service prescribers and pharmacists to check state PDMP databases before prescribing or dispensing opioids.

Source: Burwell, S. (7/2016) "HHS announces new actions to combat opioid epidemic." HHS.gov.

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### Prescription Drug Monitoring Programs (PDMPs)

PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients, to monitor for suspected abuse or diversion.

Source: Centers for Disease Control and Prevention, (3/23/2016) Injury Prevention & Control: Opioid Overdose. Available at: <https://www.cdc.gov/overdose/pdmp/index.html>

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**PDMPs (cont'd)**

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- 29 states are receiving funding through the *Prevention for States* program.
- Through 2019, CDC plans to give selected states annual awards between \$750,000 and \$1 million to advance prevention in four key areas.
- PDMPs continue to be among the most promising state-level interventions to improve painkiller prescribing, inform clinical practice, and protect patients at risk.

Source: Centers for Disease Control and Prevention, (8/30/2016) National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. Prevention for States, Available at: [https://www.cdc.gov/drugoverdose/states/state\\_prevention.html](https://www.cdc.gov/drugoverdose/states/state_prevention.html)

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**Federal enforcement tools**

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**Controlled Substances Act (CSA)**  
 21 U.S.C. § 801, *et seq.*

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- The CSA is the framework through which the federal government regulates the lawful production and distribution of controlled substances.
- The CSA places certain drugs and chemicals into one of five schedules.
- Schedule 1 has no accepted medical use.
- Schedules 2 through 5 include substances that have accepted medical uses and the schedules reflect substances that are progressively less dangerous and addictive.

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### Controlled Substances Act (cont'd)

- The CSA requires that any person or entity who handles a controlled substance must register with the Drug Enforcement Administration (DEA).
- The CSA requires registrants to maintain accurate records of all transactions involving controlled substances and accurate inventories.
- The CSA provides criminal sanctions for the illicit possession, manufacture, or distribution of controlled substances.
- The CSA also contains civil penalties for violations, including violations of the record keeping provisions.

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### Controlled Substance Act Enforcement

Schedule	Example	Prison Time	Fines
II	Oxycodone Fentanyl	Up to 20 Yrs.	Up to \$1M
III	Tylenol w/Codeine Ketamine	Up to 10 Yrs.	Up to \$500,000
IV	Valium Ambien Darvocet	Up to 5 Yrs.	Up to \$250,000

- Prison terms and fines double for distribution to persons under 21.
- Persons convicted can be subject to forfeiture of personal property and real estate

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### DEA Registration & Licensure Actions



- Under 21 U.S.C. § 822, Physicians must register in order to prescribe or dispense controlled substances.
- Medical licensure loss or limitation and loss of DEA registration often go hand-in-hand.

- Where physicians are charged with prescription-related criminal violations or civil violations, voluntary surrender of DEA registration is often part of a plea or settlement.

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### Civil Enforcement of the CSA

- *U.S. ex rel. Denk v. PharMerica Corp.*, E.D. Wisconsin
- PharMerica is a closed-door pharmacy that provides pharmaceuticals to long-term care facilities.
- The relator was a pharmacy manager in the Wisconsin pharmacy.
- Initially reported to the DEA that the pharmacy was not obtaining prescriptions for controlled substances dispensed to nursing homes.
  - Staff contacted the pharmacy and asked that a drug be dispensed for the resident.
  - Pharmacy dispensed the drug and simultaneously created a document with some of the information necessary for a prescription and faxed it to the resident's physician.

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### Civil Enforcement of the CSA (cont'd)

- CSA requires that Schedule II drugs (narcotics) be dispensed only after receiving an original written prescription (21 C.F.R. § 1306.11(a)).
- The CII written prescription requirement has two exceptions:
  - Prescriptions for nursing home residents can be faxed.
  - In an emergency situation, the practitioner may give an oral prescription to the pharmacy, followed within 7 days by a written prescription.
  - 21 C.F.R. § 1306.11(d) and (f)
- Schedule II prescriptions cannot be "refilled" – a new prescription must be given (21 C.F.R. § 1306.12(a)).

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### Civil Enforcement of the CSA (cont'd)

- The DEA executed administrative warrants at several PharMerica pharmacies.
- Concluded that PharMerica dispensed Schedule II narcotics without first having an original written prescription and, in some instances, never received a prescription.

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**Civil Enforcement of CSA (cont'd)**

- The relator alleged that many of these inappropriately filled medication requests were reimbursed by the Medicare Part D program and, therefore, the claims for these drugs to Part D were false and violated the False Claims Act.
- The United States intervened and filed a complaint (Case No. 09-CV-720, E.D. Wisconsin).
- Case settled for \$31.5 million to resolve both violations of the CSA and the FCA.

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**Mass General Hospital (Civil case)**

**Time Frame:** From October 2011 to April 2015

**Issue:** Lax controls and procedures to guard against theft and diversion of controlled substances.

**Examples:** 2 nurses stole +17,000 pills from automated drug-dispensing machines. MGH failed to report to DEA.

A 2-month audit (2013) found +25,000 missing or extra pills at the inpatient and outpatient pharmacies.

Medical personnel often took controlled substances with them to lunch at the on-site hospital cafeteria.

**Outcome:** \$2.3M violations of the Controlled Substance Act (21 C.F.R.).

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**Potential fraud schemes**

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**Courting Disaster**

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**Physician Behavior that Invites Liability and Investigation:**

- Operating like a "Pill Mill"
  - High-volume pain clinics that prescribe large quantities of painkillers to people who don't need them medically.
  - Investigators are on the lookout for high-turnover practices.
- Failure to "trust but verify"
  - Failure to physically examine patients.
  - Failure to notice drug dependence.
  - Prescribing drugs without legitimate medical need.
  - Failure to monitor patients on state PDMPs.
  - Failure to adhere to pain contracts.
  - Failure to require urine testing where appropriate.

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**Fraud Schemes**

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Examples of opioid fraud schemes:

- Diversion through automated drug-dispensing machine
- Forged prescriptions
- Bedside diversion
- Operating room diversion
- Prescribing professionals – "pill mill"

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**Supporting compliance**

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### Centers for Disease Control Guidelines for Prescribing Opioids

Encourage providers to implement leading practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1. Identify and treat the cause of the pain, use non-opioid therapies.
2. Start low and go slow.
3. Close follow-up.
4. Conduct a physical exam, pain history, past medical history, and family/social history.



Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

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### CDC Guidelines to Avoid Liability (cont'd)

5. Conduct urine drug test.
6. Consider all treatment options.
7. Implement pain treatment agreements.
8. Monitor progress with documentation.
9. Use safe and effective methods of discontinuing opioids.
10. Use PDMP data to identify past and present opioid prescriptions throughout treatment.



Source: CDC Guidelines for Prescribing Opioids for Chronic Pain, 2016

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### Compliance Assessment - Diversion Prevention Program

- Create Diversion Prevention Program
  - Overseen by multidisciplinary Steering Committee that includes Medical Staff, Pharmacy, Nursing, Loss Prevention/Security, Human Resources, Compliance, Patient Safety/Clinical Risk Management, Legal Services, Operations.
- Develop control standards
  - Include comprehensive background investigations of employment candidates & mandatory pre-employment and periodic drug testing.
- Solidify incident response and reporting processes.
- Ensure effective and consistent training for signs of diversion and drug-seeking behavior.
- Automated drug-dispensing machine/Pyxis – location – in sight of other professionals or camera.

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### Compliance Assessment - Regular Auditing

- Conduct risk assessment through Diversion Prevention Committee to prioritize audits, including scope and location/department.
- Review storage and security processes to ensure that controlled substances and prescription pads/paper are secured.
- Identify high risk areas where waste diversion may occur (i.e., surgical, anesthesia, procedural) and develop regular audit process to monitor these areas.
- Ensure effective investigation and reporting processes are in place to address suspected diversions.

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### Compliance Assessment Using Analytics To Detect Diversion

#### Opioid Data Mining Project

- Identify prescribing time period (ex. April 11, 2016 - April 17, 2016).
- Develop filter protocol to identify common indicators of improper prescribing:
  - 10 or more prescriptions for opioids within a week,
  - prescriptions with a count of 60 or more pills,
  - immediate releasing, including 20-30 mg IR opioids and all medications with Oxycodone, Methadone and Fentanyl in title.
- Run opioid prescribing report out of Epic (or other system) and filter as described above.
- Based on results, work with leadership to review physician prescribing practices.
- Develop opioid prescribing tool kit and other materials to facilitate discussion.
- Coordinate with leadership and Human Resources to develop corrective action plan, as appropriate.

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### Thank You

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## **Health Care Compliance Association: 21<sup>st</sup> Annual Compliance Institute**

**March 26 – 29, 2017**

### **Criminal and Civil Enforcement Trends: Focus on Federal Enforcement of Fraud and Abuse Involving Hospice Programs and Opioid Abuse**

#### **A Funny Thing Happened on the Way to the Compliance Institute**

For the past five years, Sally Smith has served as the Director of Nursing at Live Longer Hospice, which is part of a large hospice chain in Wisconsin. Two years ago, Live Longer was purchased by a private equity company, and there has been a push from corporate ever since to obtain patients that reside in nursing homes.

As Director of Nursing, Sally manages the nurses who do assessments of patients for admission to hospice and for continuation of the hospice benefit. Sally also participates in the interdisciplinary team (IDT) meetings where patients are evaluated for certification and recertification for hospice. The Executive Director (ED) of Live Longer is Sally's boss and does not have any healthcare background, except that she was previously a pharmaceutical sales representative. The ED supervises the marketing staff, and Sally occasionally interacts with the sales staff to coordinate admissions visits for potential patients.

Many of Live Longer patients reside in local nursing homes and its Medical Director, Dr. Small, also serves as the medical director for two of these nursing homes. Dr. Small also is the primary care physician for many of the patients and writes prescriptions for these patients, including narcotic prescriptions for pain control. The drugs are then administered to patients by the hospice nurses, who have access to the automated dispensing machines (ADMs) used by the nursing homes.

Sally is aware that, in addition to having access to the ADMs, the hospice nurses have been asked by nursing homes to contact the closed door pharmacy that they use when the nurses notice that one of the hospice patients have run out of pain medication so that the pharmacy can start the process of refilling the prescription. The medical director recently commented that she's noticed that she often signs prescriptions provided to her by the nursing home's pharmacy several weeks after she believes the drugs to have been dispensed. She assumes that the DEA has blessed this process for nursing home and hospice patients.

Last week, Sally called me because two of her nurses complained that they feel pressured to admit patients to hospice when they don't think the patient qualifies for the Medicare benefit. For example, at recent IDT meetings, the ED questioned why there were patients that the nurses were not recommending for admission. The ED suggested that another nurse evaluate all patients who were not recommended for admission. The ED also suggested that, for patients that were being recommended for discharge, the nurses were being "too positive" in their notes.

That same day, the nursing home called Sally to let her know that it was discovered in a controlled substance audit that they were short 50 80mg Oxycotin pills from the ADM and would be conducting an investigation of possible diversion of those pills.

When I talked with Sally, I asked whether these issues have come up before, and she indicated that Live Longer has a compliance program that audits medical records for each office annually. Over the last 5 years, 30% of the programs have had audit findings that patients receiving services didn't qualify for the Medicare hospice benefit. Findings are referred back to the ED to be addressed. Sally can't recall what happens to those audits after they are sent back to the ED. The compliance program does not address controlled substances.

Sally also mentioned that, when she approached the ED about these concerns, she responded that corporate is directing that they "look carefully" at all prospective clients. The ED also told Sally that, by the way, she can only take 2 weeks of maternity leave when her baby is due next week.

## Medicare Overpayment 60-Day Rule

What Your Compliance and Auditing  
Departments Need to Know



**POWERS**  
POWERS PYLES SUTTER & VERVILLE PC  
ATTORNEYS AT LAW



**ROC** HEALTHCARE  
ADVISORS

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## Objectives

- Review the key legal, operational and technical takeaways from the ACA 60-Day Report and Repay Statute.
- Discuss the implications of “reasonable diligence” and “credible information” as defined in the clarified rule.
- Review strategies for proactive compliance activities that will reduce risk of overpayments and limit exposure of provider.

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## Key Legal, Operational and Technical Takeaways

- Key provisions of the 60-Day Rule
- The 60-day “clock”
- Credible information of an overpayment
- Duty to investigate and quantify
- Reasonable diligence—proactive and reactive
- The six-year “lookback” period
- Reporting and refund process
  - Impact of contractor audits
  - Appeals
- Pre-payment probe audits

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## Statutory Requirement to Report & Repay

- Congress created the new 60-day repayment provision through Section 6402(a) of the Affordable Care Act
- Added section 1128J(d) to the Social Security Act, now codified at 42 U.S.C. 1320a-7k (d)
- Became law March 23, 2010
- CMS asserts that the law has been enforceable since that date, despite the absence of regulations until now, and court decisions support that position

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## Final 60-Day Rule

- Final rule applies **only to overpayments under Parts A and B of Medicare**
  - CMS issued a separate rule for Parts C and D of Medicare (May 23, 2014)
  - No rulemaking yet for Medicaid but statute in effect
- Requires providers to investigate with reasonable diligence if credible evidence exists of a potential overpayment
- If an overpayment is identified, the provider has 60 days to report and repay

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## Definition of "Overpayment"

- An "overpayment" means any funds a **person** has received or retained to which the **person is not entitled**
  - This has nothing to do with **causation or fault**
  - Human error, system error, fraud, contractor error or "otherwise," it can still be funds to which you are not entitled
  - The amount of the overpayment can be:
    - A portion of the paid claim (e.g., upcoded claims)
    - The whole claim (e.g., medically unnecessary or uncovered service)

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## Consequences

- Failure to report and repay creates an **“obligation”** equal to the retained overpayment
- Failure to satisfy an “obligation” is a violation of the False Claims Act
- The FCA is **enforceable by the government and whistleblowers**, potentially exposing the provider to **liability vastly larger** than the amount of the overpayment
- Also, violates the Civil Monetary Penalties Law

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## Identification

- Under the rule, an overpayment is **identified** when the recipient **has, or should have**, through **reasonable diligence**:
  - > **Determined that it received** an overpayment,  
and
  - > **Quantified the amount** of the overpayment

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## Credible Information

- CMS: “We believe credible information **includes** information that supports a **reasonable belief** that an overpayment **may** have been received.”
- Examples of when discovery of credible information triggers a duty to investigate:
  - > Discovery of unlicensed or excluded individual
  - > Certain hotline complaints
  - > Local or national coverage policy
  - > Contractor audits
  - > Internal reviews
  - > Unexplained increase in revenue from Medicare

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## Duty to Investigate & Quantify

- Even a **single overpaid claim** may create a duty to look further with respect to **similar claims**
  - Scope of further inquiry depends on nature of the isolated claim
  - Do a **“probe”** sample, and if that finds more overpayments, then a broader sample
- Only make repayment at conclusion of investigation
- Extrapolation or claim-by-claim review is permissible

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## Reasonable Diligence

- CMS says that reasonable diligence includes both
  - **“Proactive compliance activities”** to monitor for receipt of overpayments, and
  - Investigations **in response to “credible information”** of a potential overpayments
- Facts and circumstances determine
  - Whether the compliance efforts are “reasonable,” and
  - What rises to the level of “credible information”
- Investigation is expected to take no longer than six months, absent exceptional circumstances

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## The “Lookback” Period

- Must return overpayments identified within six years of receipt of the funds
  - Originally proposed 10 years
  - Consistent with CMP statute of limitations
- Reopening regulations allow contractors to reopen for only four years (with good cause)
- Final 60-Day Rule extends window for provider-initiated reopenings to six years

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## The 60-Day Clock

- Under the rule, 60 days begins to run **after “identification”**
- Identification occurs after reasonable diligence
- **Except**, if provider **has** credible information
  - Does **not** exercise reasonable diligence
  - And there **is** an overpayment
  - Then you are late after 60 days, not eight months

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## The Clock (cont.)

- The deadline for refunding overpayments is **suspended**:
  - If the **OIG** has accepted a voluntary disclosure under its Self-Disclosure Protocol (kickback cases)
  - If **CMS** has accepted a voluntary disclosure under its Voluntary Self-Referral Disclosure Protocol (Stark cases)
  - An **extended repayment schedule** is requested

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## The Reporting & Refund Process

- Final rule defers to existing refund processes:
  - Claims adjustment
  - Credit balance
  - Voluntary refund to contractor
  - Disclosures through CMS or OIG
- Method of repayment chosen will be based on facts and circumstances of overpayment (e.g., amount, culpability)
- Chosen method may dictate the details necessary for the report

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## Reporting & Refund (cont.)

- CMS permits and maybe even encourages sampling and extrapolation as part of quantifying overpayments
  - But only the specific claims identified in the sample will get adjusted on the contractor's books
  - Only those claims specifically identified are appealable
- Reporting and repaying does not insulate provider against future audits

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## Impact of Contractor Audits

- Results of contractor audits can create duty to investigate further
- Contractors limited to four-year reopening period but providers may have duty to go back additional two years
- CMS allows providers who disagree with results of audit to pursue appeals first before exercising reasonable diligence in investigating additional overpayments

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## Appeals

- 60-Day Rule does not eliminate appeal rights, even for self-identified overpayments
- Providers may not "game the system" by appealing a subset of claims identified as overpaid to avoid duty to fully investigate or make full repayment
- Appeals of extrapolated amounts are difficult but not impossible

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Reducing Risk of Overpayments and Limiting Exposure of Provider

## COMPLIANCE AND AUDIT ACTIVITIES

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## Reasonable Diligence



A provider's compliance with the new rule will require **proactive compliance activities** in addition to **reactive investigations** once "credible information" of an overpayment is received. "Minimal compliance activities" may "expose the provider or supplier to liability," because it may be considered "failure to exercise reasonable diligence."

A "react and respond" approach will no longer be enough.

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## Proactive Compliance Activities

- Review compliance plan and assure that the plan is effective in being able to identify, investigate and calculate overpayments for 6 year period
- Ensure monitoring efforts (i.e., self-audits, internal statistical analysis, etc.) are well documented. Potential areas to be monitored:
  - Coding
  - Claim accuracy
  - Secondary payer
  - Medical Necessity documentation
- Assessing 3<sup>rd</sup> Party Risk (e.g., billing companies, coders, etc.)
- Update policies and systems to handle overpayments
- Ensure that all business units understand the law

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## Compliance Program Checklist



- Internal process for collecting data on areas that could trigger overpayments - routine billing errors to deliberate Fraud, Waste and Abuse issues.
- Guidelines for investigating potential overpayments - legal involvement, determining look-back period, how to scope audit.
- Tracking system of potential overpayments- date of determination and repayment timelines.
- Regular audits/review (recommend monthly or quarterly) of potential overpayment issues and decisions.
- Procedure for evaluating potential overpayments and who will be the ultimate decision maker for determining if an overpayment has been received.

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## "PRACTICAL APPLICATION OF 60 DAY RULE THROUGH CASE EXAMPLES- INTERACTIVE DISCUSSION"

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## Thank You! – Any Questions?



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## How to Overcome Growing Pains by Maturing your Compliance Program from the Wonder Years to the Golden Years: Physician-Hospital Arrangements

**Presented by:**

R. Ross Burris, III, Shareholder, Polsinelli  
Tynan P. Olechny, Principal, PYA  
Valerie G. Rock, Senior Manager, PYA



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## Objectives

### The Wonder Years



- Understand common legal and regulatory compliance pitfalls in new and maturing physician-hospital relationships

### Coming of Age



- Learn to successfully implement key operational and compliance success factors and instill a culture of compliance post-transaction to ensure long term success

### Gray Zone



- Present best practices in handling complex and subjective government guidance to protect your investment, including critical planning steps and key considerations in contract renewals

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## The Wonder Years

### The Wonder Years



- Identifying potential alignment options
- Numerous legal and regulatory considerations
- Careful planning required
- Coding and compliance considerations
- Financial and operational due diligence
- Valuation documentation

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## Identifying Potential Alignment Options

Independent Physician and Independent Medical Staff Privileges	Cooperation through Professional Services Contract	Direct Employment Employment through Affiliates	Purchase Physician Practice and Employ Physicians	Clinical and Contractual Joint Ventures Ambulatory Surgery Center Imaging Modality PHO Management Services Service Line Co-Management Agreements	CIN PHO ACO
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## Numerous Regulatory and Legal Issues

- State and federal fraud and abuse
- Anti-trust
- Provider-based requirements
- Physician/provider credentialing
- Licensure/CLIA/Pharmacy
- Change of ownership documentation/notification
- Group purchasing organization purchasing/340B pricing
- Commercial reasonableness (i.e., need for services, financial viability, etc.)

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## It's All About the Plan

- Understand the Complex Regulatory Environment
- Understand the Forces Driving Integration
- Be Aware of Recent Compliance Trends
- Know the High Cost of Poor Planning




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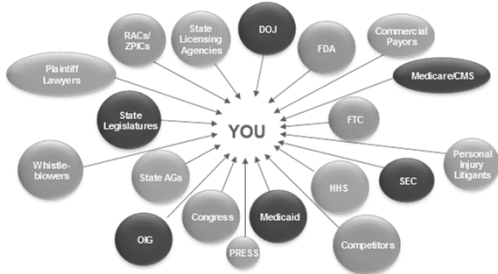
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## They're all watching you




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## The Intricate Compliance Web

- State and Federal Agencies
  - Carrying out
- State and Federal Laws
  - In partnership with
- Private and Public Organizations




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## State and Federal Laws & Regulations

Laws	Regulations
<ul style="list-style-type: none"> <li>▪ Affordable Care Act (ACA)</li> <li>▪ Anti-kickback Statute (AKS)</li> <li>▪ Stark Law</li> <li>▪ Civil Monetary Penalties (CMP)</li> <li>▪ False Claims Act (FCA)</li> <li>▪ Social Security Act (SSA)</li> <li>▪ HIPAA &amp; HITECH</li> <li>▪ State Physician Self-Referral (Baby Stark)</li> <li>▪ CON</li> <li>▪ CPOM &amp; Fee Splitting</li> </ul>	<ul style="list-style-type: none"> <li>▪ Conditions of Participation</li> <li>▪ Enrollment &amp; Recertification</li> <li>▪ Reimbursement</li> <li>▪ Licensure</li> <li>▪ Assignment</li> <li>▪ Suspension and Exclusion</li> <li>▪ Antitrust</li> </ul>

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The Bad Boys of Healthcare Justice -  
Ft. Anti-Kickback Statute (AKS)

- Prohibits the "knowing" and "willful" offer, payment, solicitation, receipt or facilitation of remuneration— i.e., both sides of any kickback
  - Intent Required
- "Remuneration" defined broadly as anything of value including cash, discounts, rebates and even free goods
- Applies to arrangements involving items or services reimbursed in whole OR in part by a Federal Healthcare Program
- Virtually any type of marketing program or marketing relationship with a physician, long term care facility, or other provider can implicate the AKS
- Applies to virtually any financial relationship with any party in a position to refer or recommend business

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AKS (cont.)

- Regulated by the Office of Inspector General (OIG) and the Department of Justice (DOJ)
- Criminal + Civil penalties - fines, imprisonment, potential Medicare/Medicaid exclusion, potential "bootstrapped" False Claims Act claims:
  - **5 year prison or \$25K per violation**
  - **Up to 5-year exclusion**
  - **3x remuneration offered + 50K per violation**
- "Safe Harbors" are "voluntary", but if met, immunize the arrangement from prosecution
- "Safe Harbors" are narrowly drawn and there is no "marketing" safe harbor

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The Bad Boys of Healthcare Justice –  
Ft. Physician Self-Referral Act (Stark)

- "a physician [or their immediate family member] who has a direct or indirect financial relationship with [a DHS] entity, may not make a referral for the furnishing of DHS for which payment otherwise may be made under Medicare."
  - Strict Liability – NO INTENT REQUIRED
- An entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral

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Stark (cont.)

- DHS is a defined term (e.g., DME equipment and supplies, home health, prosthetics)
- Physician is a defined term
- Financial Relationship is...a defined term
- ONLY applies to "Physicians" (and those that the physician deals with) and "Medicare" BUT
- Applies to referrals between any third-party DHS entities AND even the physician's own practice entity
  - UNLESS AN EXCEPTION IS MET

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The Bad Boys of Healthcare Justice –  
Ft. False Claims Act (FCA)

**FCA 101**

Treble damages and fines for knowingly:

- ✓ Filing a false claim with the Federal government, or *causing* the filing of a false claim
- ✓ Creating a false record in order to get a claim paid
- ✓ Conspiring to get a false claim paid, or
- ✓ Concealing an obligation to repay monies owed to the Federal government

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FCA (cont.)

- **Bootstrapping to AKS Claims**
  - ACA allows the government to "bootstrap" an FCA claim to an AKS claim, arguing, in essence that the kickback relationship made the claim false.
- **Qui Tam Relators**
  - FCA allows individuals to bring suit against companies as qui tam relators.
- **Sixty Day Rule**
  - Failing to return "identified" overpayment within 60 days.
- **Bottom Line**
  - Violating AKS, the Stark Law or failing to return overpayments 60 days after identifying may create FCA liability even with an indirect seller of goods or services.

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The Bad Boys of Healthcare Justice –  
Ft. HIPAA & HITECH

- The Health Insurance Portability and Accountability Act (HIPAA) and the related Health Information Technology for Economic and Clinical Health (HITECH)
- HIPAA requires Covered Entities and their Business Associates to protect Private Health Information (PHI)
- HITECH has specific security standards for PHI and requires mandatory disclosure when a data breach has occurred

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HIPAA & HITECH (cont.)

- Further requirements:
  - Covered Entities must conduct security assessments to identify vulnerabilities
  - Business Associates are also subject to audit & investigation
  - Covered Entities must report Business Associate breaches of unsecured PHI
  - OCR may open a compliance review to investigate any reported breach of unsecured PHI
  - Covered Entities have greater liability if Business Associate is acting as “agent”
    - Unclear how OCR is interpreting this term

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Careful Planning Required

- Initiate confidentiality and non-solicitation agreements
- Assemble the “engagement team”
  - Board of Directors, administration (C-suite), legal, compliance, finance, operations, human resources, internal audit
  - Outside counsel
  - Appraisers to conduct business and compensation valuations
- Execute letter of intent (LOI) or term sheet

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### Careful Planning Required (cont.)

- Identify assets to be acquired
  - Permits/licenses/certifications/government approvals
  - Rights under contracts (vendors, suppliers, software, etc.)
  - All tangible and personal property (FFE)
  - Inventories of supplies, purchased goods, drugs, etc.
  - Intellectual property
  - Rights under leases
  - Prepaids; security deposits
  - Patient records
  - EHR
  - Personnel

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### Careful Planning Required (cont.)

- Other "up front" considerations
  - Length of agreement
  - Minimum period of time that party cannot terminate "without cause"
  - Compensation structure
    - Minimum guaranteed base salary plus productivity bonus
    - Compensation or collections/wRVU (for PSA)
    - Incorporation of quality component
  - Specific reference to modifier adjusted, personally performed wRVUs
  - Consistent compensation terms, subject to existing practice metrics

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### Careful Planning Required (cont.)

- Other "up front" considerations (cont.)
  - Inclusion of clause that expects the provider to bill according to government and commercial payer requirements
  - Renegotiating leverage tied to individual performance
  - Compensation at all times must be subject to fair market value and commercial reasonableness requirements
  - Include clause for assessing contract if a specific % shift in coding or wRVU totals occurs from year to year
  - Any obvious unbundled codes to be excluded at true up
  - Noncompetes – duration, scope of services, geographic scope
  - Unwind provisions

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### Coding and Compliance Considerations

- Detailed analysis of data and assessment of risk
  - Internal
  - External
- Anticipate practice changes

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### Data Analysis & Risk Assessment: Internal Data

- Benchmark and Review:
  - Evaluation and Management (E/M) services
  - Procedures (high use of at-risk procedures)
  - Use of modifiers
  - wRVUs (productivity)
  - Quality metrics

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### Data Analysis & Risk Assessment: External Data

- Publically reported data
  - Highest utilizers of codes or modifiers are targets for audits
- OIG, CMS, CERT, RAC audit activity
- Recent CIAs

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## Data Analysis and Risk Assessment: Tip

- Be careful of exposing issues
  - Once exposed, issues must be addressed
  - Ensure due diligence is only as aggressive as the hospital's ability to react to potential issues

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## Anticipate Practice Changes

- Practice pattern changes once employed that impact the data:
  - Shift to provider-based,
  - Physician and nonphysician provider (NPP) services/utilization,
  - Shift of ancillary services to the hospital

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## Due Diligence

- Traditional Purpose: obtain information about what is material to the Seller's business and identify items that may need additional attention and analysis.
- Typical requests include information regarding:
  - Corporate Documents
  - Accounting and Financial Statements
  - Assets and Liens
  - Material Contracts and Payor Agreements
  - Real Property – Owned/Leased
  - Intellectual Property
  - Insurance
  - Legal Issues and Govt. Investigations
  - Licensure and Certifications
  - Compliance Program and Training
  - Privacy and Security
  - Employees / Independent Contractors
  - Medical Staff
  - Environmental

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### The Due Diligence Balancing Act

- Educate C-Suite on importance of including Compliance ON THE FRONT END of deals
- Have Due Diligence Plan
  - Clearly Define Goals
  - Select tools (interviews, document review, etc.)
  - Stay within parameters
- 60 Day Rule = Due Diligence Balancing Act

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### Financial and Operational Due Diligence

- Historical compensation and production
- Historical billing and collections activities
- Overhead expenses
  - Staff
  - Rent
  - Malpractice insurance
  - Physician and staff benefits

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### Financial and Operational Due Diligence (cont.)

- Staffing complement and ratios
- Payer mix
- Credentialing considerations
  - Medicare/Medicaid processing times can be lengthy
- Future billing and collection activities
  - Who will conduct?
- Financial analysis to estimate potential practice losses/gains

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## Valuation Documentation

- Documenting and validating supporting documentation for physician compensation
  - Physician needs assessment
- Documenting calculation of designated health services
- Be cognizant of any "special" arrangements for physicians (e.g., anything that differentiates one physician's contract from the general provisions of other physician contracts)
- Obtain fair market valuation and commercial reasonableness opinions, as appropriate, to support physician compensation arrangements

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## Finally...

- Before closing, prepare a post-closing checklist noting action items for issues identified during due diligence. Don't let issues identified during diligence get lost in the shuffle!
- Addressing issues as soon after closing as possible assists in risk reduction.
- Compile a post-integration multi-disciplinary team and assign responsibilities for post-closing projects.
- If possible, schedule post-close plan kickoff call and regular team meetings to discuss the status of post-close projects.

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## Coming of Age



- Most parties go into the relationship with the intention of being "in it for the long haul"
- Post-integration process may take longer than the planning/negotiation, due diligence, and transaction closing steps combined
- The length and complexity of the post-integration process will vary depending on the type of transaction entered
- Thorough due diligence on the front end will help ensure a carefree coming of age period

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## Coming of Age "To Dos"

- Monitor physician behavior changes
- Continually audit, track and communicate
- Create or confirm audit and disciplinary policies are clear and enforceable/enforced

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## Coming of Age Catastrophes

- *Successor Liability for Overpayments*
  - United States v. Vernon Home Health, Inc., 21 F.3d 693, 5th Cir. 1994 (Nursing home successor liable for predecessor's overpayments in asset purchase b/c federal law preempts state corporate law and provider number was assigned)
- *Antitrust*
  - Federal Trade Commission v. St. Luke's Health System, Ltd., Case No. 1:12-CV-00560-BLW and 1:13-CV-00116-BLW (D. Idaho 2014) (Merger would result in anticompetitive pricing that could not be overcome by efficiencies and ordered divestiture)

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## Coming of Age Catastrophes

- *Fraud and Abuse/Physician Compensation*
  - U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc., Case No. 3:05-2858-MBS (D. S.C. 2013) (M.D. contracts based on referrals result in \$237.5M fines & damages)
  - U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, Case No. 6:09-cv-1002-Orl-31 TBS (M.D. Fla. 2014) (M.D. bonus compensation not based on personally performed services violates Stark)
- *Provider-Based Status*
  - Mission Regional Hospital Medical Center v. Centers for Medicare and Medicaid Services, Dec. No. CR2458 (November 2, 2011) (Hospital acquired in asset purchase deal could not be added as inpatient remote location and had to undergo full survey before it could bill Medicare for services)

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## Coming of Age Catastrophes

- *Fraud and Abuse/Physician Compensation and Leasing Issues*
  - Intermountain Health Care, Inc., Settlement Agreement (2013)
  - U.S. ex rel. Osheroff v. Tenet Healthcare, Case No. 09-22253-CIV-HUCK/O'SULLIVAN (S.D. Fla 2013)
  - U.S. ex rel. Schubert v. All Children's Health System, Inc., Case No. 8:11-cv-1687-T-27-EAJ (M.D. Fla 2013)
  - U.S. ex rel. Hector Luque v. Adventist Health, Case No. 2:08-01272 (E.D. Cal. 2013)
- *60 Day Rule*
  - Kane v. Healthfirst Inc. et al. and U.S. v. Continuum Health Partners Inc. et al., Case No. 1:11-cv-02325, (S.D.N.Y. 2015)

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## Triggers for Physician Behavior Changes

- Compensation based on wRVUs
- Provider education
- Changes in what drives the physician's compensation

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## Common Behavior Changes – Compensation based on wRVUs

- Upcoding E/M services
- Use of NPPs/Residents for increased volume
- Unbundling E/M services
  - Minor vs. major global periods
- Unbundling surgeries
- Tip:
  - If billing departments are not monitoring for correct coding the claim can be submitted with more codes than are paid or correct
  - If compliance departments are not monitoring for correct coding compared to documentation, there is increased risk for overpayment

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### Commonly Audited Modifiers

- **25** - Separate E/M on the same day as a Minor Procedure
- **57** - Separate E/M on the same day or day before as a Major Procedure
- **58** - Staged or Related Procedure During a Global
- **59** - Distinct Procedural Service
- **78** - Unplanned Return to the OR/Related Procedure
- **79** - Unrelated Procedure During the Global Period

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### Modifier 25

#### **Modifier 25: Significant, Separately Identifiable E/M Service by the Same Physician on the Same Day of the Procedure or Other Service.**

- If a procedure has a global period of 000 or 010 days, it is defined as a minor surgical procedure
- The decision to perform a minor surgical procedure is included in the payment for the minor procedure and should NOT be reported separately
- If a significant and separately identifiable E/M service is performed, and it is unrelated to the decision to perform the procedure, then it can be separately reported

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### Time: Risk

- Using time as a work-around to documenting
- Combining E/M time with the time spent performing other procedures/services
  - Psychiatric codes
- Not documenting time
  - Assuming time captured in EHR
  - Too difficult to keep up with

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**Tip**

- Billing and compliance staff should be educated on:
  - Place of service requirements,
  - Modifiers to identify provider-based,
  - If a practice is provider-based or just a specific location is,
  - How to bill for NPPs in order to identify personally performed services vs NPP services and correct billing to Medicare and Medicaid

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**Common Behavior Changes:  
Provider Education**

- Education and close monitoring can correct physician coding to be more accurate which can increase or decrease wRVUs
  - limited prospective reviews
  - shadowing
  - and lots of education initially
  - limit exposure on new providers
- Lack of education and monitoring can lead to physician manipulation of the system

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**Common Behavior Changes:  
Changes in What Drives Physician Compensation**

- Change in practice patterns due to NPPs not being included in the calculation
  - Shift in work flow
  - Tip: Confirm omission of NPP services
- Ancillary services no longer directly related
  - Orders may decrease
  - Do not forget to include supervision for services physicians can no longer directly bill for (e.g., infusion supervision)

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## Continually Audit, Monitor, and Track

- Conduct regular billing and coding audits
  - Annual with follow-up, quarterly
- Conduct periodic operational assessments to ensure best practices are in place
- Provide feedback to physicians routinely
  - Production
  - Quality metrics
  - Financial performance

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## Gray Zone



- Timing of contract renewals
- Commit to fair market value and commercial reasonableness compliance reviews
- Special considerations

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## In the Gray Zone

- Conduct thorough review of contracts to identify the contracts to keep and which contracts to terminate or renegotiate
- Many contracts require 30 to 90 days to terminate without cause
- Plan accordingly especially if anticipate significant changes to agreement terms, arrangement structures, defined quality metrics, etc.

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### Commit to FMV and CR Reviews

- Even if agreement is for multiple years, may still need to evaluate for compliance with fair market value and commercial reasonableness
  - Valuation period may be for only 1 year or 2 years when agreement is for 3 years
  - Survey benchmarks and reimbursement changes annually
  - Quality metrics re-evaluation to ensure robustness
  - Impacts of behavior changes

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### Special Considerations

- Administration of contract
  - Appropriate calculation of wRVUs
  - Modifier adjusted and personally performed
  - Bonus calculated based on correct threshold
  - Achievement of quality metrics appropriately tracked and recorded
  - Medical director time sheets completed

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### Special Considerations (cont.)

- Contract mitigation based on audit results
  - Compliance rate impact on bonus
  - Deduction of overpayments to bonus
- Need for self-disclosure?
- Evolving payment models
- "Volume to value"

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**Privacy Officer Roundtable  
HCCA Compliance Institute  
March 29, 2017**

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Marti Arvin  
VP Audit Strategy  
CynergisTek, Inc.

Adam Greene  
Partner  
Davis Wright Tremaine LLP

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**Potential Hot Topics**

- Recent OCR Guidance
  - Right of access questions
  - Guidance on allowing third parties (e.g., media) into treatment areas
  - Ransomware
- Relationship between Privacy Officer and Security Officer
- Thoughts on Recent OCR Enforcement Trends
- Should HIPAA Be Repealed or Changed?

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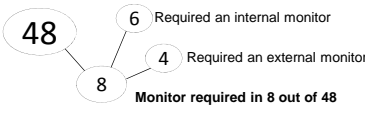
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**Enforcement Highlights**

<b>45</b>	OCR Settlements	<b>3</b>	Civil Monetary Penalty Actions
<b>\$58,455,200</b>		<b>\$1,299,004</b>	
In settlements and CMPs		Average settlement amount	

<b>31 of 48</b>	
enforcement actions arose from breach reports to HHS	
<b>Monitor required in 8 out of 48</b>	

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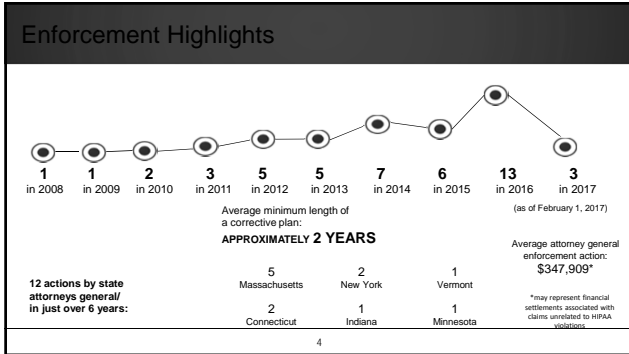
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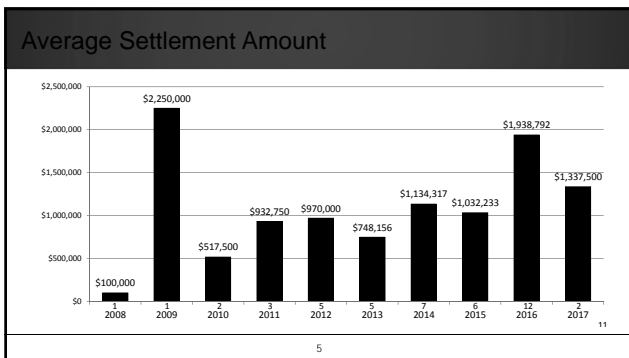
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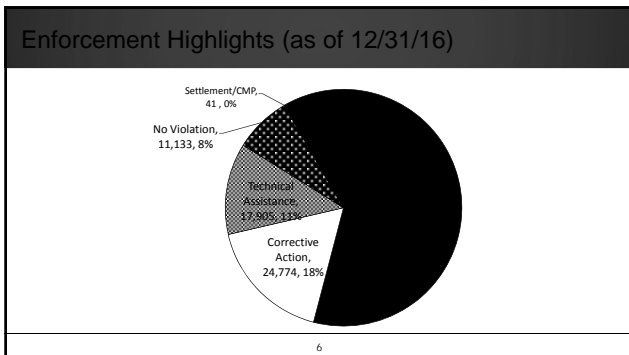
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Adam Greene Davis Wright Tremaine LLP <u>AdamGreene@dwt.com</u> (202) 973-4213
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 **NUANCE**

**Pay for Performance:  
Live at a Physician Practice Near You!!!**

Catherine Gorman-Klug RN, MSN  
Director Quality Service Line  
Tony Oliva D.O  
CMO

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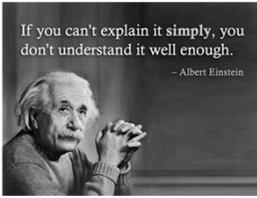
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**MACRA 101**

 If you can't explain it simply, you don't understand it well enough.  
— Albert Einstein

 **NUANCE**

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**Agenda**

- Why you need to know about MACRA
- What is MACRA?
- Who is eligible to participate
- Coding Considerations for MACRA
- Resources

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## The Impact

- Far Reaching
- Not Just Physicians
- Not Just Physician Practices
- Success will take a village:
  - Keys to Success
    - Documentation Improvement Teams
    - Coding Teams



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<b>Hospital-Based</b>	<b>MIPS eligible clinician who furnishes 75 percent or more of covered professional services in an inpatient hospital, on-campus outpatient hospital or emergency room setting in the year preceding the performance period</b>
Non-Patient Facing	<ul style="list-style-type: none"> <li>• Individual MIPS eligible clinician who bills 100 or fewer patient-facing encounters (including Medicare telehealth services) during the non-patient facing determination period.</li> <li>• A group where more than 75% of the NPIs billing under the group's TIN meet the definition of a non-patient facing individual MIPS eligible clinician during the non-patient facing determination period.</li> </ul>



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### 42 CFR Parts 414 and 495 [CMS-5517-FC]

Medicare Program; Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models



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*Physicians and their care teams are the most vital resource a patient has. As we implement the Quality Payment Program under MACRA, we cannot do it without making a sustained, long-term commitment to take a holistic view on the demands on the physician and clinician workforce." The new initiative will launch a nationwide effort to work with the clinician community to improve Medicare regulations, policies, and interaction points to address issues and to help get physicians back to the most important thing they do – taking care of patients."*

Andy Slavitt, acting Administrator of CMS



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### What's New?

- MACRA (Medicare Access and Chip Reauthorization Act) repeals the Medicare Sustainable Growth Rate methodology for physician payment
- Creates a new methodology:
  - The Quality Payment Program



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MACRA  
Group Registry Bonus MIPS  
CMS Improve ACO Population Health Quality  
APM Individual EHR  
PSO CAP Public Health  
Pick your Pace CostACO  
Measure Advancing Care Information



Advancing Care Information

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### Goals of the New Rule

- Introduce more flexible reporting options in year one
- Adjusts low volume threshold for small practices
- Establishes Advanced Alternative Payment Models (APM)
- Simplify the all or nothing EHR requirement
- Establish the medical home to improve care coordination



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### The Quality Payment Program

- Rewards the Delivery of High Quality Patient Care
- Creates two models:
  - Advanced Alternative Payment Models
  - Merit Based Incentive Payment System
- Will affect more than 600,000 eligible providers, according to CMS
- 60 day comment period in flight



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### Fast Fact

Clinicians participating in Medicare serve more than 55 million of the country's seniors and individuals with disabilities, according to CMS



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### Who Qualifies?

- Providers:
  - Physicians, Physicians Assistants
  - Nurse Practitioners, CRNAs, Clinical Nurse Specialists
- Who:
  - Bill Medicare more than \$30,000 annually
  - OR
  - Provide care for at least 100 Medicare patients annually



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### Deciding which program to pick...

- This is not an option
- Providers may only participate in the program for which they qualify



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### Alternative Advanced Payment Models



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
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**Advanced Alternative Payment Models**

- Payment Approaches provide added incentives to deliver high quality and cost efficient care
- Can apply to:
  - A specific condition
  - A care episode
  - A population
- Designed for Practitioners in specific value based care models
- CMS estimated that between 70,000 and 120,000 clinicians in 2017 will participate in and qualify for incentive payments under the APM path

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
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**What qualifies as an advanced APM in 2017?**

- The final rule identifies the following as advanced APMs for 2017:
  - Comprehensive End Stage Renal Disease Care Model
  - Comprehensive Primary Care Plus Model
  - Medicare Shared Savings Program Tracks 2 and 3
  - Next Generation ACO Model

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
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**Associated APM Rewards**

- Providers who:
  - receive 25% payment through Medicare payments or:
  - see 20% of their Medicare patients through an Advanced APM in 2017
- Will earn a 5% incentive payment in 2019

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
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**Merit-based Incentive Payment System**



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
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**Merit Based Incentive Payment System**

- A new program for *certain* Medicare enrolled practitioners:
  - those participating in traditional fee for service Medicare
- Consolidates and sunsets components of 3 existing programs:
  - Physician Quality Reporting System
  - Physician Value Based Payment Modifier
  - Medicare EHR Incentive Program for Eligible Professionals
- CMS estimated that about 500,000 clinicians will be eligible to participate in MIPS in its first year



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**MIPS' Focus**

- A cohesive program that emphasizes:
  - Quality
  - Cost
  - Use of certified electronic technology
  - Avoidance of redundancies



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### MIPS Scoring

- Quality 60 %
- Advancing Care Information 25 %
- Improvement Activities 15%



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### MIPS Overall Payment Model

- Payment adjustments in the first year will be neutral, positive or negative up to 4 percent
- This will grow to 9 percent by 2022



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### Pick your Pace Implementation



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### When does the Program start?

- Several options are provided:
  - If prepared providers can begin collecting data on January 1<sup>st</sup> 2017
  - May also elect to begin collecting data anytime between January 1<sup>st</sup> and October 2<sup>nd</sup>
- Data for either option is due to CMS no later than March 31<sup>st</sup>, 2018
- Will determine payment adjustments beginning January 1<sup>st</sup> 2019



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### MIPS Reporting Options



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### MIPS Overall Requirements

- Report on up to 6 quality measures, including at least one outcomes measure, for a minimum of 90 days within the attestation window
- Groups will need to report on 15 quality measures for a full year
- Attest to completing up to 4 quality improvement activities for a minimum of 90 days
- Complete the security risk analysis and attest to the ability to conduct e-Prescribing, provide patient access to data, send summaries of care, and request/accept summaries of care



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### Individual Reporting

- May report as an individual provider based upon NPI number
- Individual data for each of the MIPS categories to be submitted through any of the following methods:
  - a certified electronic health record
  - A qualified clinical data registry,
  - routine Medicare claims processing



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### Group Reporting

- A group is defined as
  - a set of clinicians (identified by their NPIs) sharing a common Tax Identification Number
  - no matter the specialty or practice site
- MIPS data submitted as a group, will get one payment adjustment
- based on the group's overall performance
- Group data for each of the MIPS categories to be submitted through any of the following methods:
  - Through the CMS web interface
    - **To submit data through the CMS web interface, you must register as a group by June 30, 2017**
  - a third-party data-submission service such as a certified EHR
  - registry
  - a qualified clinical data registry



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### Selecting Measures to Report

- At a minimum, the following factors should be considered when selecting measures for reporting:
  - Clinical conditions usually treated
  - Types of care typically provided – e.g., preventive, chronic, acute
  - Settings where care is usually delivered – e.g., office, emergency department (ED), surgical suite
  - Quality improvement goals for 2016
  - Other quality reporting programs in use or being considered



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### Quality Measure Selection

- 271 Available
- Review and select measures that best fit your practice.
- Add up to six measures from the list below, including one outcome measure. You can use the search and filters to help find the measures that meet your needs or specialty.
- If an outcome measure is not available that is applicable to your specialty or practice, choose another high priority measure.



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### “Advancing Care Information” Replaces MU in MIPS

- Total Number of required measures reduced to 5:
  - Security risk analysis
  - E-prescribing;
  - Provide patient access
  - Send summary of care
  - Request/accept summary of care
- Optional Measures will be available to increase score



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### Advancing Care Information

- 2 options:
- In 2017, there are two measure set options for reporting. The option you use to submit your data is based on your electronic health record edition.
- **Option 1:** Advancing Care Information Objectives and Measures-15 available
- **Option 2:** 2017 Advancing Care Information Transition Objectives and Measures-11 available



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### Improvement Activities

- **Most participants:** Attest that you completed up to 4 improvement activities for a minimum of 90 days.
- **Groups with fewer than 15 participants or if you are in a rural or health professional shortage area:** Attest that you completed up to 2 activities for a minimum of 90 days.
- **Participants in certified patient-centered medical homes, comparable specialty practices, or an APM designated as a Medical Home Model:** You will automatically earn full credit.
- **Participants in certain APMs under the APM scoring standard, such as Shared Savings Program Track 1 or the Oncology Care Model:** You will automatically be scored based on the requirements of participating in the APM. For all current APMs under the APM scoring standard, this assigned score will be full credit. For all future APMs under the APM scoring standard, the assigned score will be at least half credit.
- **Participants in any other APMs:** You will automatically earn half credit and may report additional activities to increase your score



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### Transition Year Bonuses

- Improvement Activities including:
  - Utilizing Certified EHR technology
  - Reporting to Public Health Agencies
  - Reporting to Clinical Data Registries
- A 5 percent bonus credit will be awarded to providers who report on public health measures and participate in a clinical data registry reporting program



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### Are small practices able to participate?

- Providers who fall below the requirements of at least \$30,000 Medicare charges or 100 Medicare patients are exempt from participating in 2017
- CMS estimates this represents 32.5 percent of clinicians, accounting for only 5 percent of Medicare spending
- CMS is offering an option for small practices and solo physicians to join together in virtual groups and submit combined MIPS data
- The final rule also allots \$20 million a year for five years for training and education of physicians in practices of 15 or fewer and those who work in underserved areas



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## Compliance Considerations for MACRA

- Significant focus on ICD 10 Specificity and associated documentation
- Increased emphasis on specialty specific measure selection
- Laser focus on physicians participating in ACOs applying to participate in MIPS
- Focus on HCCs especially for APMs
- Physician Documentation will need increased specificity and clarity
- Coders can assist by taking a lead in assisting physicians and office staff's understanding of the codes required for the various selected measures



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## Resources

- CMS MACRA Website:
  - <https://qpp.cms.gov/>
  - <https://qpp.cms.gov/resources/education>
  - [https://qpp.cms.gov/docs/QPP\\_Where\\_to\\_Go\\_for\\_Help.pdf](https://qpp.cms.gov/docs/QPP_Where_to_Go_for_Help.pdf)
- AAPC:
  - <https://www.aapc.com/blog/34697-clinicians-know-about-macra-mips-apms/>



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Thank you

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## Compound Pharmacy Prosecutions: Past Lessons and Future Trends

March 29, 2017  
National Harbor, MD

Health Care Compliance Association  
21<sup>st</sup> Annual Compliance Institute

Elizabeth D. Shaw  
RezLegal, LLC  
Jacksonville, FL

Jason Mehta  
Assistant U.S. Attorney  
Jacksonville, FL

Ryan Stumphauer  
Stumphauer & Stoman  
Miami, FL

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## The Compound Drug Scheme

- Compounded Medicine: Allegedly Custom -Tailored to Unique Health Needs of Individual Patients
- Targeted TRICARE and Government Retirement Programs
- In the first 9 months of 2015, Tricare paid \$1.7 billion, or 20% of their total prescription drug budget, on compounded drugs.
- Compared to just \$23 million in 2010, a 7,291% increase
- In two years, TRICARE's average cost for a compound drug jumped from \$192 to \$2,595



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## The Compound Drug Scheme

- Pain creams, scar creams, wound creams, hormone replacement
- Some egregious cases have involved compounded drugs ranging from \$5,000 to \$40,000 per script
- Defense Health Agency had to Seek Additional Funding to Cover \$2 Billion Budget Hole
- Intense Media Scrutiny - CBS Nightly News and Wall Street Journal
- DOJ, DOD, OPM dedicate substantial resources to "clean up"



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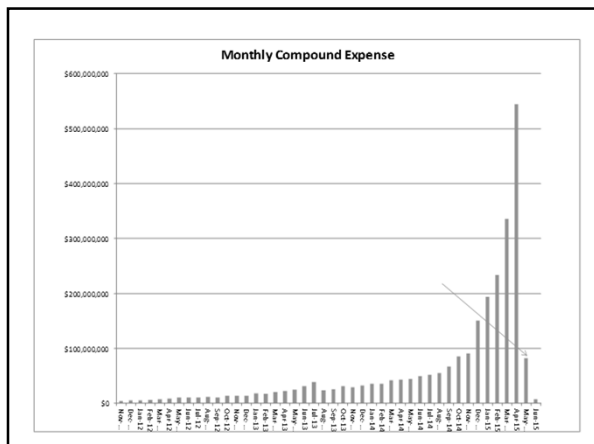
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### Compounding Pharmacy Fraud: Fact Patterns & Trends

- **Physician Kickback Schemes:**
  - Research Studies
  - Medical Director Positions
  - Providing High Salary Jobs to Spouses, Family Members
  - “Evaluation” or “Encounter” Fees for TeleMed Docs
- **Marketer Kickback Schemes**
  - % Based Compensation to Marketer; Commissions as High as \$8,000 per script
  - Concealed as Hourly Fees for Lead Generation, Consulting, Patient Screening, Patient Verification




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### Compounding Pharmacy Fraud: Fact Patterns & Trends

- **Patient Kickback Schemes:**
  - Co-Pay Assistance
  - Research Participation Fees
  - % Payments and Untraceable Gift Cards
- **Other Schemes**
  - Identity Theft: Unsolicited Deliveries to TRICARE Beneficiaries
  - Targeted Phone Solicitations, Phishing Schemes
  - Doctors and Patients in Different States; No Physician Evaluation = No Bona Fide Patient-Physician Relationship
  - Changing Formulas to Maximize Reimbursement




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### Data Mining & Target Selection

- Historically, civil enforcement actions generated by whistleblowers
- Now, TRICARE Data Mining is Used to Identify Targets
- Data Doesn't Lie; Signs of Trouble:
  - Rapid billing spikes for compounds drugs from 2013 to May 2015
  - Claims Attributable to a Small Number of High Volume Prescribing Physicians
  - Doctors and Patients in Different States
  - Multiple Compounds for Each Patient
  - Identical Compounds for Each Patient



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### Government Enforcement Tools

- **Civil Enforcement Proceedings:** False Claims Act
- **Criminal Enforcements:** Indictment in Florida, Texas, California
  - Prosecutors using traditional tools including search warrants, phone recordings, body recorders and surveillance.
- **Administrative Sanctions**
  - Exclusion Proceedings
  - Recoupment of Overpayment
  - Corporate Integrity Agreements
- **Other Remedies**



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### Other Consequences

- State Licensure & Disciplinary Issues for Medical and Pharmacy Professionals
- Loss of Privileges at Hospitals
- Adverse Employment Actions
- Loss of Professional Opportunities
- Termination of Payor Contracts
- On-Site Inspections and Audits
- Public Shaming

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**TRICARE Rules:  
What You May Not Know**

- Reimbursements Come from Private PBMs: Express Scripts and CVS Caremark.
  - Don't be fooled; it is still government money
- Stark Law Not Applicable
- 60 Day Report and Refund Not Applicable
- Administrative Definitions (32 CFR 199.9)




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**Advice of Counsel Defense**

- Very common in compounding pharmacy cases
- Many pharmacies sought legal advice regarding physician relationships and marketing relationships
- Gut-Wrenching Decisions for the Defense
  - Waiving Privilege
  - Exposing Advice, Good and Bad, to the Government
  - Exposing Attorneys to Interviews
  - Did your client tell attorney *everything*?
  - Did the client *really* follow the advice?
- Possible malpractice claims against Attorneys

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**The Yates Memo:  
A Check May Not Solve the Problem**

- To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the **individuals** involved in corporate misconduct.
- Both criminal and civil corporate investigations should **focus on individuals** from the inception of the investigation.
- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another. Every whistleblower case is evaluated by criminal.
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires.
- Civil attorneys should **consistently focus on individuals** as well as the company. Focus is on accountability and deterrence, not just money




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**Compliance for Compound Pharmacies  
& Lessons Learned**

- Hire a Compliance Officer
- Develop and Implement an Effective Compliance Program
- Conduct internal and coordinate external billing audits
- Develop and implement corrective action plans
- Train staff and providers to address compliance issues

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**What's Next?  
Future Enforcement Trends**

- Continued prosecutions – both civilly and criminally
- Expanded focus nationally
- Focus on pharmacies, doctors, marketers and others
- Other agencies getting involved
- Emerging growth of Department of Defense fraud investigators

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**Questions?**

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**Effective Auditing Programs for  
Managed Care Plans**

**Health Care Compliance Institute**  
**March 29, 2017**

<p>Nicole S. Huff, DHA, MBA, CHC, CHSP Chief Compliance Officer &amp; Privacy Officer St. Luke's University Health Network Bethlehem, PA</p>	<p>Deborah M. Johnson, MS, MHA, PhD Senior Director, Compliance and Internal Audit Peach State Health Plan Atlanta, Georgia</p>
<p>Andrea J. Hundley Director, Compliance Care Source Health Plan Atlanta, Georgia</p>	

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**Disclaimer**

The views and opinions expressed during this presentation are those solely of the presenters and not those of any company or entity with which they may be associated.

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**Today's Goals**

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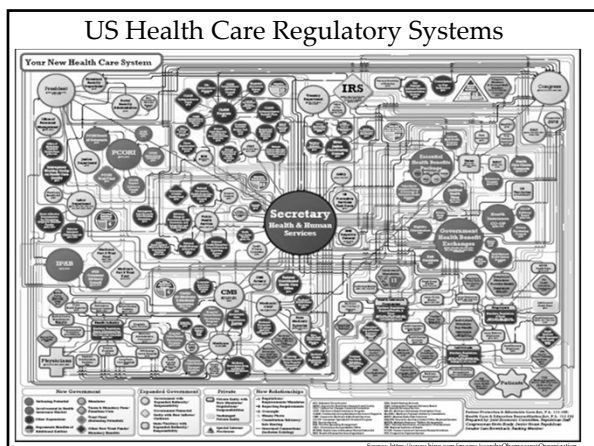
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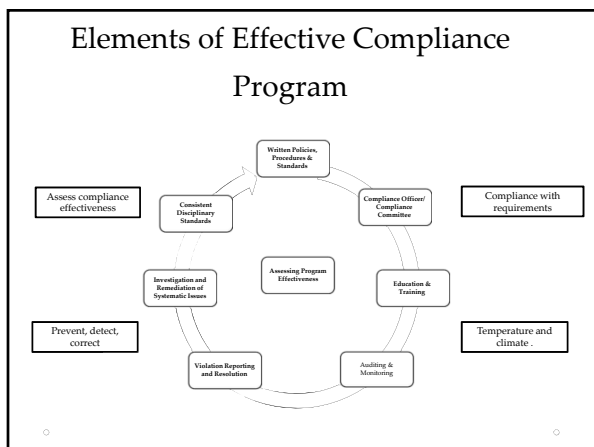
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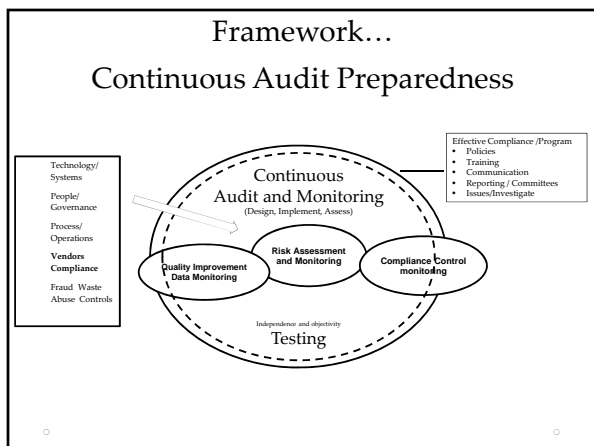
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## Effective Audit And Monitoring Program

- **Audit Program, Oversight and Stakeholders**

- o Audit Program Description and reporting structure
- o Audit Program Work plan (annual)
- o Governance and executive management oversight
- o Programs Internal resource(s), teams and stakeholder

- **The Audit Committees**

- o Audit Committee Charter
- o Internal audit program's purpose, design and implementation process.
- o Audit Committee core membership

- **Key Stakeholder to involve in the Internal Audit Program Activities**

- o Operational executive leaders and manager from anchor business units
- o Internal work teams Subject Matter Experts (SME) assist with auditing monitoring compliance controls.
- o Vendors champions

*Note: External auditors and regulators test adherence to compliance requirements.*




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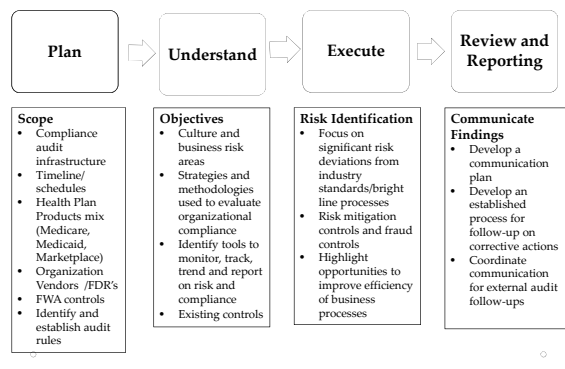
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## Set Goals, Objectives, Process and Reporting Procedures




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## Building An Effective Annual Audit Plan

### Outline Product Mix

- o **Medicare (Part C and D Participation)**
  - Medicare Advantage
  - Medicare Medicaid Plans
  - Institutional Special Needs Plans
  - Dual Special Needs Plans (dual eligible)
  - Prescription Drug Plan /Drug Rebate Programs
- o **Medicaid (State Contract)**
  - Health Services (Population)
  - Technology /Telehealth
  - Reporting
- o **Federally Funded "MarketPlace"**
  - Exchange/ Health Marketplace Products
    - o (State and Federal)
- o **Accrediting bodies**
- o **Vendors**
- o **Fraud Waste Abuse**




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### Consider Your Product Mix

- Collaboratively develop project scope, sample, size, timeline and communications.
- Current policies and procedures, product risk profiles and previously identified issues.
- Attend and observe scheduled event/activity, collect relevant materials and information.
- Clarify, confirm and categorize observations. Provide individual program, summary update and immediate action reports.
- Each potential compliance observation is initially documented, reviewed and reported as an independent unique occurrence.
- Patterns and trends are analyzed to determine if compliance observations are the result of more systemic compliance gaps.

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### Develop a Comprehensive Annual Audit Plan

**CMS Audit Protocols**

- o Comments and Responses
- o Past Published Medicare Program Audit Performance

**DHHS / CMS HPMS Memoranda**

- o Compliance Program Effectiveness Requirements
- o Seven Elements

**Past Audits Findings and Corrective Actions**

- o All Products
  - Performance Outcomes / Risk Areas
  - Quality Improvement / Case Management
  - Risk Assessment Findings
  - Vendor /FDR Findings
  - Leadership and Governance Reporting

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### Case Scenario # 1

The management team instructs the Compliance Officer to report all audit risk findings quarterly to the team. The report should only be reviewed with the management team and should not exceed ten minutes because the organization cannot afford to pay employees for non-productive time. "And the Compliance Report is always too long!"

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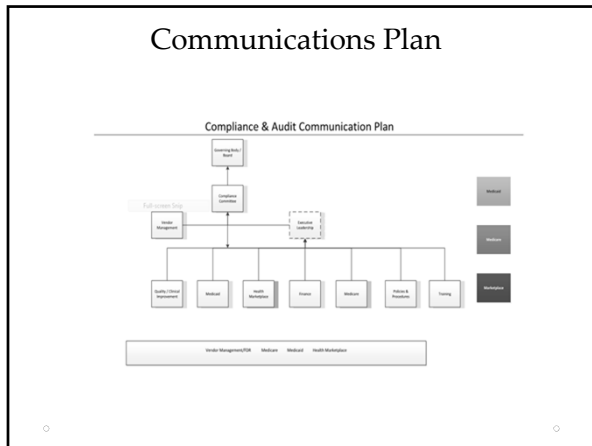
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### Reporting Tracking and Trending Risks

- Board and Compliance Committee reports on Internal Audit work plan
- Overview of current compliance risks
- Status report of new or revised policies & procedures
- Summary of identified key FWA issues
- HIPAA program audit updates & risks monthly/ quarterly/annual
- Compliance Program assessment results/ risks and corrective action plan
- Vendor performance / compliance monitoring / identified risks
- Communicate updated State contract requirements/risks
- Monitoring and review of compliance departments responsibilities to ensure resource dedication to core compliance requirements
- Use dashboards, data, and surveillance tools to demonstrate monitoring results

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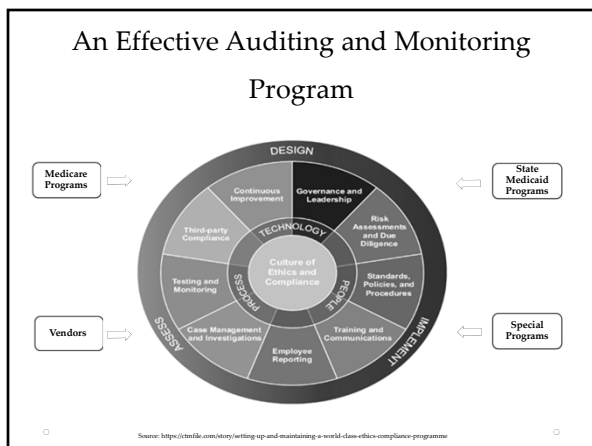
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## Auditing & Monitoring – Medicaid Managed Care

- Program Structure
  - Foundational to the auditing & monitoring process
- Program Focus
  - What is being audited & monitored
- Program Reporting
  - Key stakeholders

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## Auditing & Monitoring Medicaid Health Plan

An effective Compliance Program will include a robust methodology to audit and monitor all functional areas in an organization against the following:

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## State and Federal Regulatory Requirements

- Federal Regulations
  - Health Insurance Portability & Accountability Act (HIPAA)
  - Member Rights & Responsibilities
  - Early, Periodic Screening, Diagnostic & Treatment (EPSDT) Services
- State Statutes
  - Primarily an extension of federal regulations
  - State Plan Amendments
  - Physician contracts (Georgia Code§ 33-20A-61 - Physician contracts)
- Recently Passed Legislation
  - House Bills
  - Senate Bills

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## State Medicaid Contract Requirements

### State Contract Requirements

- o Service Level Agreements
- o Turnaround Times
- o Committee Structures
- o Reporting
- o Vendor Responsibilities
- o Remedial Actions
- o Corrective Action Processes




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## Historical Findings

### Internal /External Audit Review Findings

- o External Quality Review (EQRO) Audits
- o Internal Audits / Risk Assessments
- o Statements on Standards for Attestation Engagements (SSAE)
- o Accrediting Body
  - National Committee for Quality Assurance (NCQA)
  - Utilization Review Accreditation Commission (URAC)




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## Seven Elements

- Written policies and procedures
- Designation of a Compliance Officer & Compliance Committee
- Effective training and education
- Effective lines of communication
- Internal auditing and monitoring
- Enforcing standards through well-established guidelines
- Responding to identified problems and taking appropriate corrective action
- Assessing Program Effectiveness




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## Case Scenario #2

The operation manager recently received your SSAE-16 report that must be submitted to your State agency. Is there anything else you need to do with the report findings other than send the report to the State agency?




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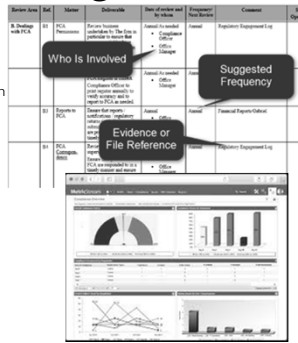
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## The Monitoring Process

- Monitoring is:
- An ongoing event
  - Conducting analyses and tracking trends to correct issues in "real time"
  - Continuously validating risk assessments
  - Performed at the lowest level of detection
  - Completed regularly during normal operations
  - Recording and reporting incidents of non-compliance
  - Communicating potential risks




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## Monitoring Process




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# The Audit Process

Auditing is

- o Formal retrospective review
- o Methodical
- o Includes sampling
- o Performed periodically (i.e., annually)
- o Performed by un-biased auditors




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# Auditing Process

### Identify Risks

- Internal controls questionnaire
- Audit scope
- Objectives

### Audit Risk Areas

- Fieldwork
- Evaluation
- Testing controls

### Review Audit Results

- Assess results
- Communicate findings to stakeholders

### Take Corrective Action

- Issue corrective actions for remediation
- Monitor remediation

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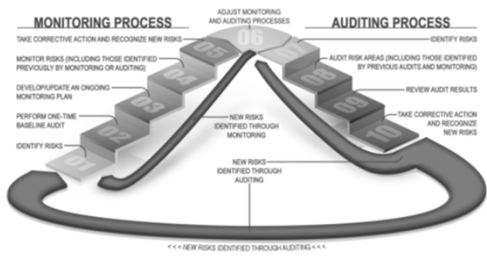
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# Relationship Between Auditing & Monitoring



Source: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/vhi-internal-monitoring-j20aid.pdf>

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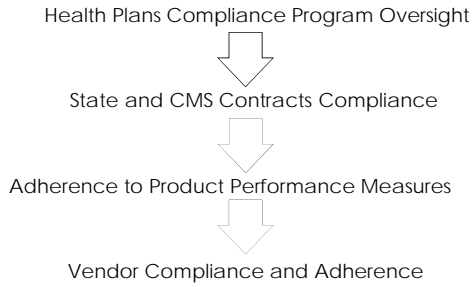
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### Comprehensive Auditing and Monitoring




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### Case Scenario #3

The Compliance Officer received an anonymous call that an executed agreement with a network of providers expired. The agreement was for the Medicare Advantage and Part D plans. However, capitated payments were still being made to the providers.




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### What's Next?

- Obtain a list of all contracts
- Randomly select and test sample contracts
- Trace payments from accounts payable ledger to agreements and vice versa
- Review authorization and payment process
- Interview staff
- Review previous audits for similar findings
- Summarize findings in a report with recommendations
- Collaborate with the responsible manager to develop a corrective action plan
- Communicate results of audit report with those responsible for contract management and other leaders within organization

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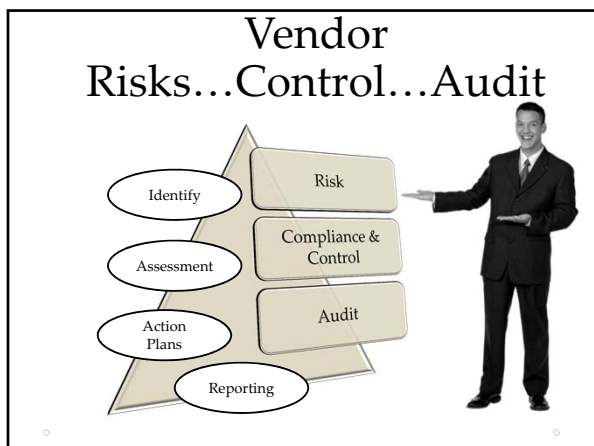
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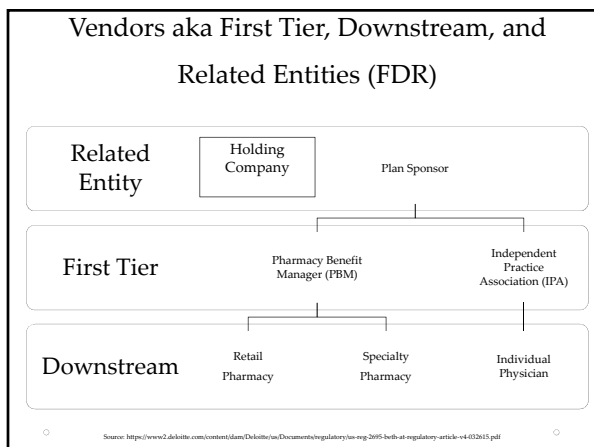
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- ## Compliance Risks
- Lack of coordinated compliance oversight
  - Incomplete list identifying all vendors and FDRs
  - No written agreement with vendor to include CMS expectations for FDR oversight
  - Not meeting quality care measurements
  - Not performing exclusionary checks
  - Poor utilization management
  - Lack care coordination
  - No credentialing process
  - Payment inaccuracies
  - Billing errors
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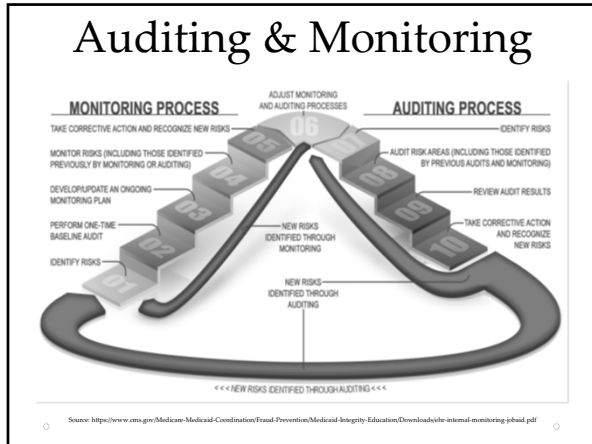
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- ## Auditing & Monitoring
- Prompt assignment of a qualified person to vendor oversight
  - Verify and validate that executed and current contracts exist
  - Ensure FDR specific CMS requirements are met
  - Perform due diligence pre-contractual audits
  - Monitor exclusion screenings and credentialing
  - Develop audit plan to include performance audits & corrections
  - Conduct claim data mining and credentialing evaluations
  - Follow up on external/internal audit results and recommendations to ensure compliance with FWA
  - Annually evaluate FDRs

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- ## Evaluation and Performance
- Annually evaluate FDRs
    - Desk and onsite visits
    - Adherence to plan and regulatory requirements
    - Validate FDRs compliance program
  - Performance Maintenance
    - Review contractual established performance metrics
    - Review new state guidance
    - Set rules for downstream
    - Focus on FWA compliance
    - Corrective action plan for non-compliance including contract termination
  - Document results in a written report

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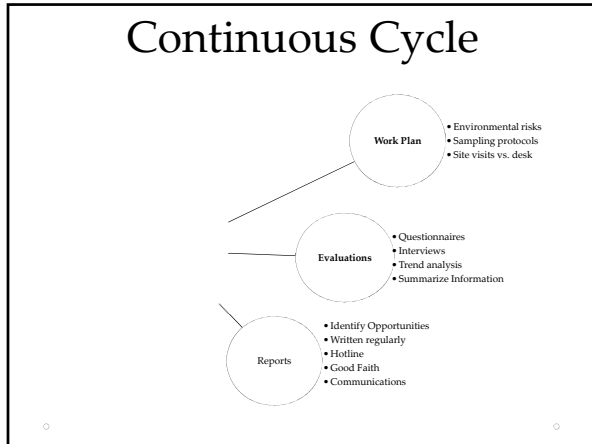
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### Board, Physicians and Staff Training

- Be brief and detailed
- Use data, trends and performance measures
- Financial data and risks
- Demonstrate any potential risk impact on business operations
- Use examples that are relevant to the audience
- Responsibilities and obligations
- Questions and answers

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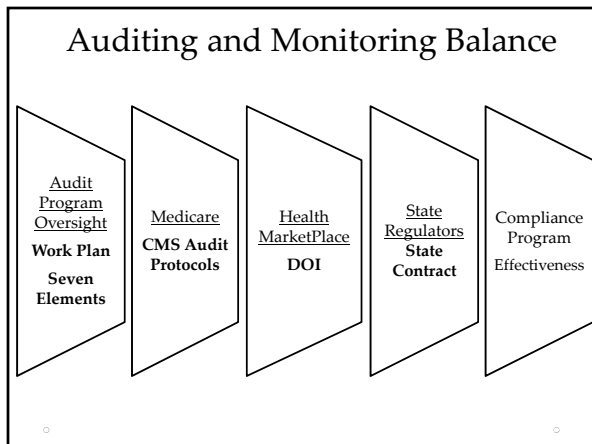
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**Medical Mutual**<sup>SM</sup>  
PROTECTING OUR PROFESSION

*MIPS, APMS, QRUR, and CMS Data:  
How Do Your Physicians Compare?*

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**Auditing Quality: The Quality Payment Program**

- ◇ Quality Payment Program 2017 - and beyond
- ◇ Audit Points: QPP Implementation
- ◇ Big Data and Doctors On-Line
- ◇ Malpractice and Quality
- ◇ Conclusions

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**Speaker's CME Disclosure**

- Michelle Moses Chaitt, J.D. and D. Scott Jones, CHC, have no financial conflicts to disclose.
- Attendees are not charged for this presentation, it is provided as a service.
- This presentation is not offering medical, legal, accounting, regulatory compliance or reimbursement advice or attempting to establish a Standard of Care. Please consult professionals in these areas if you have related concerns.

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*Quality and Value  
Healthcare –  
2017 and Beyond*

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**The Future of MACRA Payment Reform**

- In 2015, MACRA passed 92-8 in Senate and 392-37 in House.
- MACRA repealed the unsustainable “Sustainable Growth Rate” or SGR formula, which could have resulted in a 21% Physician Fee Schedule reduction in 2015.
- 2017 is the MACRA transition year and programs are in place to shift provider payments to the Quality Payment Program.

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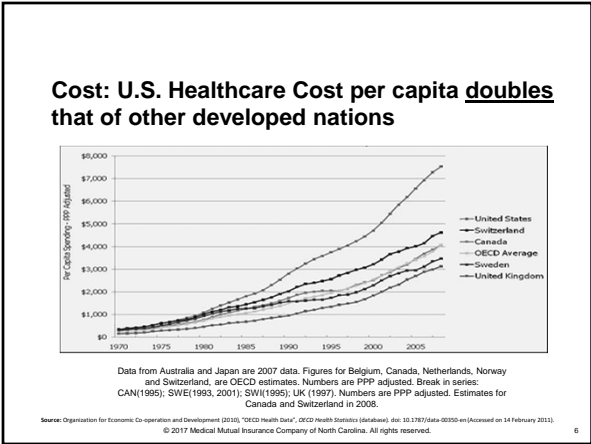
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**2017: The Quality Payment Program (QPP)**

- **Rulemaking enacted by CMS under MACRA**
- **MACRA Repealed** the Sustainable Growth Rate (SGR) Formula
- **Streamlines** multiple quality reporting programs into the new Merit-based Incentive Payment System (MIPS):
  - Physician Quality Reporting Program (PQRS)
  - Value Based Modifier (VM)
  - Medicare Electronic Health Records (EHR) Incentive Program
- **Provides incentive payments for participation in Advanced Alternative Payment Models (APMs)**

• <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Quality-Payment-Program-MACRA-NPRM-Slides.pdf>

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**QPP Participation**

- Not participating in the QPP in CY 2017 will result in a negative -4% payment adjustment to the Physician Fee Schedule in CY 2019.
- Physicians should:
  - Determine if they wish to report by joining an Advanced Alternative Payment Model (APM) program, such as an ACO, or report independently through the Merit Based Incentive Program (MIPS).
  - Determine if they wish to report through a clinical data registry.
  - Consult with their current EMR vendor to determine what registries and MIPS reports are supported.

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**Individual or Group Reporting**

- Physicians may report individually on quality measures -
- Or, Groups may report as a group under one Tax ID number (TIN).
- Note that individual physicians will receive a group score rating. High performers or low performers may be positively or negatively affected by the group score.

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**Audit Points:**

- Reporting: MIPS or APMS?
- Reporting: Clinical Data Registry or Data Submission by Practice?
- EMR: What Registries and MIPS or APMS will the current EMR vendor support?
- Reporting: Individual or Group?
- Comparing Scores:
  - Which reporters achieve a better score as an individual?
  - Which reporters are low achievers?

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**Who Participates in MIPS?**

- Medicare Part B clinicians (paid under the Medicare Physician Fee Schedule, PFS) billing more than \$30,000 a year and providing care for more than 100 Medicare patients a year.
- These clinicians include:
  - Physicians
  - Physician Assistants
  - Nurse Practitioners
  - Clinical Nurse Specialists
  - Certified Registered Nurse Anesthetists

• <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Quality-Payment-Program-webinar-slides-10-26-16.pdf>

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**Who is Excluded from MIPS?**

- Newly-enrolled Medicare clinicians
  - Clinicians who enroll in Medicare for the first time during a performance period are exempt from reporting on measures and activities for MIPS until the following performance year.
- Clinicians below the low-volume threshold
  - Medicare Part B allowed charges less than or equal to \$30,000, or who treat 100 or fewer Medicare Part B patients
- Clinicians significantly participating in Advanced APMs.
- Health Professional Shortage Area (HPSA) exceptions
  - Rural Health Clinics, Federally Qualified Health Centers, Critical Access Hospital may have an exception.

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**Audit Points:**

- Identify and exclude new clinicians enrolled in Medicare for the first time.
- Establish a MIPS or APMS training process for those doctors, so they can achieve maximum scores when they start reporting. Identify reporting start dates.
- Identify clinicians who do not meet the low-volume thresholds. Monitor changes to ensure they begin reporting if they exceed the low volume limits.

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**MIPS Scoring**

- Providers may attain a 100% score when reporting under MIPS. 2017 data will impact 2019 reimbursement.
- Four measurement categories include:
  - **Quality** (60% for 2017)
  - **Advancing Care Information** (ACI, renamed from Meaningful Use) (25% for 2017)
  - **Clinical Improvement Activities** (CPIA) (15% for 2017)
  - **Cost** (0% for 2017, but will be weighted for 2018 and beyond)

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**APM's Explained**

- Exempt from MIPS reporting.
- Includes payment models managed by CMS:
  - CMS Innovation Center Model (other than a Health Care Innovation Award)
  - Medicare Shared Savings Program Accountable Care Organizations (MSSP ACOs)
  - Demonstration under the Health Care Quality Demonstration Program
  - Demonstration required by federal law

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### Advanced APM's

- A subset of APM's, which also:
  - Require participants to use certified EHR technology
  - Bases payment on quality measures, comparable to those in the MIPS Quality performance category
  - APM members bear more than nominal financial risk for monetary losses
  - Or, the APM is a Medical Home Model expanded by the CMS Innovation Center
- APM's and Advanced APM's may earn a +5% annual bonus

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### How does the Payment Adjustment work?

- Data submitted affects payment two years later. 2017 data affects 2019 payment.
- CMS sets a performance threshold number of points that must be earned through MIPS reporting (maximum=100)
- Each point above the Performance Threshold (PT) = higher incentive payments.
- Each point below the PT = lower payments.
- Physician scores will be posted on sites like Physician Compare and are downloadable by the public.

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### What is the Projected PT Range of Payments?

- 2017 Transition Year Range (3 to 70 points)
  - -4% (no participation)
  - +5%
- 2018 Projected Range (0 to 100 points)
  - -5%
  - +10%
  - Additional +5% bonus for a final score of 100
- 2020 Projected Range (0 to 100 points)
  - -5%
  - +9%
  - Additional +10% bonus for a final score of 100

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**Budget Neutrality**

- MIPS penalties assessed to poor performers will be used to pay incentives to positive performers.
- MACRA calls for the QPP to be budget – neutral (does not increase the overall CMS budget).

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**Audit Points:**

- Physician MIPS Points
- Percentage of payment increase or decrease, by physician
- APM Reporting criteria and performance

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**Quality Payment Program Home Page**

- CMS provides a comprehensive Home Page for QPP information.
- <https://qpp.cms.gov/>

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*QPP Implementation*

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**Transitional Year 2017: Pick Your Pace**

- Reporting under MIPS or APMS began January 1, 2017.
- APM models will have individual program deadlines. Consult your APM reporting standards.
- For MIPS, physicians have three choices:
  - **Test Pace: Report some data.** Expect a 0 or small negative payment adjustment for 2017.
  - **Partial Year: Report for a 90 day period.** Expect a small positive payment for successful reporting. Last date: October 2, 2017.
  - **Full Year: Full participation and reporting** can result in a modest positive payment adjustment.
- No participation: Negative - 4% payment adjustment.  
<https://blog.cms.gov/2016/09/08/qualitypaymentprogram-pickyourpace/>

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**Group Practice Reporting Option (GPRO)**

- Physicians must decide if they wish to report independently, or as a group.
- If physicians choose the Group Practice Reporting Option, this must be declared to CMS by June 30, 2017.
- Physicians must declare only if they use the CMS GPRO Web Interface (Physician Quality Reporting Portal), or if they use the CAHPS for MIPS survey process.  
[https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/GPRO\\_Web\\_Interface.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/GPRO_Web_Interface.html)

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### Reporting Due Date

- Data Submission date for 2017:
- March 31, 2018
- Data submission dates for subsequent years will also fall on March 31 of the year after the performance measure year.

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### Earning Positive Adjustment

- Positive adjustments are determined by the actual performance data submitted, NOT the:
  - Amount of data
  - Length of time submitted
- Best performance can occur by participating fully, and submitting data on all MIPS performance categories.

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### Audit Points:

- Which Reporting Pace?
  - **Test Pace: Report some data.** 0 or small negative payment adjustment for 2017.
  - **Partial Year: Report for a 90 day period.** Small positive payment for successful reporting. Last date to choose this option: October 2, 2017.
  - **Full Year: Full participation and reporting:** 2017 modest positive payment adjustment.
- Individual or Group Reporting?
- Quality of Data Submitted?

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**Audit Points: Pick Quality Reporting Measures**

- Physicians: Pick up to 6 reporting measures, including an outcome measure, for at least 90 days.
- Groups: report 15 quality measures, for a full year.
- Groups in APM's: Report through APM.
- Quality Measures list and selection tool are available at:
- <https://qpp.cms.gov/measures/quality>

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**Audit Points: Attest to Improvement Activities**

- Physicians and most Groups: Attest completion of up to 4 improvement activities for a minimum of 90 days.
- Groups <15 participants or in rural or HPSA: Attest completion of 2 activities for a minimum of 90 days.
- Groups in APM's: Full Credit is given based on APM requirements.
- Improvement Activities list and selection tool are available at:
- <https://qpp.cms.gov/measures/ia>

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**Audit Points: Advancing Care Information**

- For a minimum of 90 days, complete:
  - Security Risk Analysis
  - E-Prescribing
  - Providing Patient Access
  - Sending Summary of Care
  - Requesting / Accepting Summary of Care
- For additional credit, choose up to 9 measures for 90 days
- For bonus credit, report public health or clinical data registry reporting measures, or use Certified EHR technology for improvement activities.
- <https://qpp.cms.gov/measures/aci>

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**Audit Points: Cost**

- Cost data is calculated by CMS using actual Medicare claims submissions.
- Focus on:
  - Avoiding unnecessary tests services, referrals, hospitalizations
  - Reduce clinical variability by using approved Clinical Practice Guidelines (CPG's)
  - Improve cost containment measures in the practice
- <https://qpp.cms.gov/measures/performance>

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**QPP: MIPS and APM Educational Resources**

- Visit the Educational Resources section of the QPP home pages to view the official rules, MACRA legislation, webinars, educational programs, video libraries, documents and downloads:
- <https://qpp.cms.gov/resources/education>
- View a comprehensive list of APM's operated by CMS, and learn more about Advanced APM's:
- [https://qpp.cms.gov/docs/QPP\\_Advanced\\_APMs\\_in\\_2017.pdf](https://qpp.cms.gov/docs/QPP_Advanced_APMs_in_2017.pdf)

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*Big Data  
Doctors On-Line*

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**Audit Points: Physician Compare**

- JAMA: 65% of consumers are aware of online physician rating sites. 36% of consumers have used a ratings site at least once.
- Patients are seeking more transparency in physician quality and cost.
- Poor MIPS scoring and quality data (reported online by CMS) may take years to improve or reverse.
- Positive quality data reported online can be a competitive advantage.

• JAMA, 2014; 311(7):734-735.

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**Audit Points: MIPS Scores Follow Physicians**

- CMS ties MIPS score to the reporting physician for each performance year.
- If the physician changes organizations before the associated payment year (two years after the performance year), the MIPS score and associated payment adjustment follow to the new organization.
- Check MIPS scores for physician recruiting, credentialing, contracting, and compensation plans.
- MIPS scores are part of a physician's profile and public reputation for the succeeding two years after that score is earned.

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**Audit Points: Reporting MIPS Quality**

- MIPS uses quality measure and reporting from the Physician Quality Reporting System (PQRS) and the Value Based Purchasing programs.
- Report on 6 measures.
- Report on one outcome or high priority measure.
- Each measure assigned 10 possible points.
- Bonus points available for certain quality reporting
  - High priority measures (up to 10%)
  - End to end electronic reporting (up to 10%)

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**Audit Points: Advancing Care Information (ACI)**

- ACI was previously known as Meaningful Use.
- Now is a scoring system where meaningful use measure rates are compared to benchmarks, as in MIPS quality.
- 131 ACI Performance Points:
  - Base Score of 50 points for select measures from MU Stage II or Stage III measure sets
  - Performance Score up to 90 points for performance on 8 measures
  - Bonus Points up to 15 points for reporting to a public health registry and joining the CMS Clinical Practice Improvement Activities (CPIA) measurement study

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**Audit Points: Improvement Activities (IA)**

- IA can earn 20 to 40 points (depending on size, location)
  - Small practices, <15 physicians, rural or HPSA must earn 20 points to obtain full credits
  - All other MIPS eligible physicians must earn 40 points to obtain full credits
- IA Reports can include:
  - Combination of medium and high-weight activities (10-20 each)
  - Certain APM's receive 40 points credit (Shared Savings, Oncology Track)
  - Other APM's receive 50% credit, and may report additional activities to gain a full score

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**Audit Points: Measuring and Considering Cost**

- 2017 Cost weighting = 0, to prevent penalties during the transition year.
- 2018 Cost weighting = 10%.
- CMS rates physicians, based on 40+ cost measures, based on claims submitted to CMS.
- Cost data is taken from actual Medicare Claims.
- Accurate, careful consideration must be given to all services provided beneficiaries. Physicians are now incentivized to avoid unnecessary tests, admissions, or services.

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**A MIPS Final Score Calculation - Example**

- Quality: 42 of 60 points x 60% weight x 100
- = 42 points
- ACI: 50 of 100 points x 25% weight x 100
- = 12.5 points
- IA: 30 of 40 points x 15% weight x 100
- = 11.25 points (rounds up to 11.3)
- Cost: 14 of 20 points x 0% weight (in 2017 only) x 100
- = 0 points
- Total MIPS Points 2017:  $42+2.5+11.25+0 = 65.8$

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*Malpractice and Quality*

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**CPG's and the National Institutes of Health**

- "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (*Institute of Medicine, 1990*)
- NIH Website provides:
  - Standards for Developing Guidelines
  - Specialty Specific Guidelines
- <https://nccih.nih.gov/health/providers/clinicalpractice.htm>

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**Clinical Practice Guidelines (CPG's)**

- Agency for Healthcare Research and Quality (AHRQ) maintains the National Guidelines Clearinghouse.
- Evidence-based CPG's are a means of reducing clinical variability and improving clinical outcomes.
- Designed to improve safety, quality, and accessibility of healthcare.
- Specialty specific for all medical specialties:
- <https://www.guideline.gov/>

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**Quality Payment Program and Medical Negligence Concerns: CPG's**

- The role of CPG's:
  - Not yet considered a Standard of Care
  - May be used as evidence by medical experts in testimony
  - Rapidly increasing number of CPG's
  - Widely accepted use
  - Promoted by medical specialty societies, the National Institutes of Health, and Agency for Healthcare Research and Quality
  - Evidence based analysis supports the concept that reducing clinical variability can improve clinical outcomes in many cases.

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**Quality Payment Program and Medical Negligence Concerns: Reputational Risk**

- By 2019, all physicians may expect to see actual individual QPP 0-100 quality rating scores on public internet sites, such as Physician Compare.
- Physicians face reputational risk by not participating in QPP, or participating and earning low scores.
- Quality scores will become increasingly used by the public, and may become a quality reference in medical negligence suits.
- Physicians reporting in groups will have scores only as good as the group score.

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### Physician Compare

- All Physicians enrolled with CMS have a Physician Compare web page.
- 900,000 physicians listed
- 140,000 hits/day
- Online quality reports on every physician
- CMS must allow reasonable opportunity to review results – may challenge
- 30 day annual preview period for all measurement data



Source: [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Updating\\_and\\_Editing\\_Data\\_on\\_Physician\\_Compare.html](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Updating_and_Editing_Data_on_Physician_Compare.html)  
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### CMS Billing Data

- Billing data for all physicians is available to the public, on line from CMS.
- Provider name, gender, address
- NPI
- Medical Specialty
- HCPCS Code for Procedures Performed
- HCPCS Code Description
- Service Count
- Beneficiary Date Service Count (Number of procedures per Beneficiary)
- Medicare Allowed Amount
- Submitted Amount
- Medicare Paid Amount (Sum to determine totals)
- Are you an unusual or high billing provider?

Source: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicare-provider-charge-data/outpatient.html>  
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### Compliance and Quality of Care Investigation



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**Quality of Care Investigation**

- St. Josephs' Medical Center, Baltimore, MD opens new, state of the art Cardiac Catheterization Laboratory in 2008.
- 1/2008: Retains leading NE area interventional cardiologist, Mark Midei, MD as Director.
- Cath Lab quickly becomes the "go to" facility for difficult cases and stent placement.
- Stent utilization exceeds all manufacturer's prior records, according to e-mail messages by manufacturer later discovered during investigation → over 1000 stents are placed in 2008.

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**Quality of Care Investigation**

- 11/08 & 4/09: In two letters, staff complain to the State Board of Physicians of 36 & 41 patients with "unnecessary stents."
- 4/09: Hospital employee who had a stent placed files a *qui tam* complaint with the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) complaining he/she received a stent that was not medically necessary. DHHS joins suit.
- 6/09: OIG begins a civil investigation.

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**Quality of Care Investigation**

- 4/09 to 6/09: 658 stent placements are reviewed as "not medically necessary."
- 4/09 to 6/09: Hospital relieves Dr. Midei, and eventually the CEO, CFO & other administrative staff.
- 10/09 to 2/10: Letters are sent advising patients to consult with their Cardiologist, because of unnecessary stents.
- Extensive advertising by the plaintiff's bar ensues, including Super Bowl ads.

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**Quality of Care Investigation**

- 2/10: Dr. Midei is the subject of a highly publicized U.S. Senate Finance Committee investigation.
- 11/10: Hospital settles the OIG's charges for \$22M and enters a Corporate Integrity Agreement (CIA).
- 7/11: Dr. Midei's license to practice medicine is revoked by the State Board of Medicine on the basis of four medical records.
- Hundreds of medical malpractice lawsuits filed against Dr. Midei and the hospital.

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**Quality of Care Investigation**

- A media frenzy is ignited, with repetitive, negative news stories about Dr. Midei, the hospital, and parent company, Catholic Health Initiatives (CHI).
- 3/12: St. Josephs' Hospital announces sale to the University of Maryland Medical System. Patient utilization is at record lows. The Cath Lab is virtually closed.
- 2013: The first 21 "unnecessary stent" suits to reach court were consolidated into a single trial.... Rather than face future consolidated trials, defendants settled a group of over 200 cases for approximately \$36M.

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**Quality of Care Investigation**

- 2014: Weinberg v. St. Joseph's Medical Center, Dr. Mark Midei. Plaintiff claims Mr. Weinberg quit his casino development job and lost \$50M after stent placement.
- Phase I Trial: Jury deadlocked on negligence, eventually finds Dr. Midei guilty of medical negligence.
- Phase II Trial: Jury deadlocked on damages. Mistrial. Finding of negligence vacated with prejudice.
- Plaintiff's agreed prior to mistrial to accept a high/low arbitration of \$500K to \$15M. Mistrial payment: \$500K.

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**Quality of Care Investigation**

- Remaining stent claims all settled without trial.
- Estimated total indemnity cost: \$100 Million.
- Hospital almost closed, and was sold by its' parent company.
- Physician lost license.
- 658 patients were affected.
- Over 600 medical malpractice suits were filed.
- Could a quality audit have identified unusual utilization?

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**Quality Payment Program and Medical Negligence Concerns: Administrative Burden**

- QPP has a stated intent of reducing administrative burdens for clinicians.
- However, it is a significant program, requiring administrative attention to quality reporting measures, performance scores, and their effect on reimbursement.
- Physicians should be supported by strong administrators who understand and can implement the program, monitor results, and guide practices.

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*Conclusions*  
*Q&A*

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**QPP Service and Information Center**



- Quality Payment Program Service Center
- 1-866-288-8292
- TTY: 1-877-715-6222
- Monday-Friday, 8 a.m. – 8 p.m., EST
- You may also subscribe to automatic e-mail updates at [www.qpp.cms.gov](http://www.qpp.cms.gov)
- Or, e-mail the QPP at [QPP@cms.hhs.gov](mailto:QPP@cms.hhs.gov)

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**Speaker Contact Information**

**Michelle Moses-Chaitt, J.D.**

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**Speaker Contact Information**

**D. Scott Jones, CHC**



- MMIC Healthcare Compliance and Risk Consultant
- MMIC and HPIX serve 13000 providers in 21 states
- Former medical practice & hospital administrator
- Board Certified Healthcare Compliance Officer (CHC)
- Author, on quality, practice management, compliance
- Frequent speaker to state, regional and national organizations
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- Tel: 717.237.5503 (office); 904. 294.5633 (cell)

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HEALTHCARE COMPLIANCE  
and RISK MANAGEMENT?

Yes...we do that.



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# Mergers & Acquisitions

For the Compliance Professional



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## Presentation Topics

- Healthcare Merger and Acquisition Overview
- Due Diligence Phase
- Pre-Acquisition Planning Phase
- Post-Acquisition Integration Phase
- The Consequences

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## Healthcare Merger and Acquisition Overview



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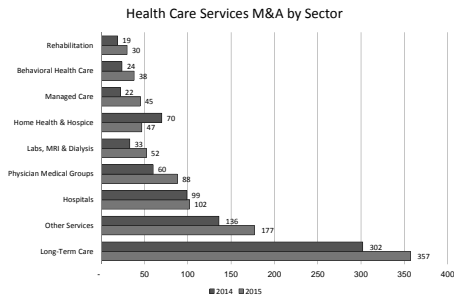
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## Current Market Dynamics



Source: The Health Care Acquisition Report, Twenty-Second Edition, 2016 by Irving Levin Associates, Inc.

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## Common Healthcare Transaction Structures

- Asset Acquisition – only assume agreed assets and liabilities
- Stock Acquisition
- Merger
- Member Substitution




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## Transaction Risks

The main risks are:

1. Acquiring a company that is tainted by corruption, and therefore assuming criminal and civil liability;
2. Paying too much for the acquired company or business, to the extent that part of the revenue and/or profit is based on corrupt behavior, and is therefore not sustainable; and
3. Risk to reputation of the buyer. In addition, there is the risk associated with the drain on management of resolving any issue along these lines that does show up. It can be expensive, time consuming, and distracting.

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## Different Perspectives

Attorneys and Valuation professionals look at what's there.

Compliance looks at what should be there (unanticipated regulatory liabilities).

The Goal of due diligence for an *acquisition* team is to be fully advised of all the legal (and compliance) risks of the *target*. This is rarely possible.

Additional protection in the form of *warranties*: can cover the compliance program and areas of regulatory risk specific to the target.

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## Due Diligence Phase



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## What is Due Diligence?

The purpose of due diligence:

- Assess the risks
- Adjust the value and terms of the agreement
- Decide how much to hold in reserve
- Amount of Due Diligence depends on the size of the acquired company and the risk

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## Due Diligence Considerations - Legal

- The Legal Perspective
  - Contracts
  - Evaluating relationships with "health care professions" – processes involving focused arrangements
  - Labor issues - HR/Employee matters including benefits, contractors
  - Any allegations of violation of law and the resolution
  - Ongoing litigation
  - Government investigations
  - Liens on assets
  - Conditions of assets
  - Licensure and certification
  - Representations and warranties
  - Indemnification

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## Due Diligence Considerations - Valuation

- The Valuation Perspective
  - Structure of the Transaction (asset vs. equity, what is included?)
  - Historical and ongoing risks
  - Historical and forecasted financial statements (income statements, balance sheets, etc.)
  - Tax returns and other IRS documents
  - Payor mix data
  - Assets
  - Indebtedness
  - Regulatory issues, refunds, etc.
  - Volume/production reports
  - Referral sources
  - Current and go-forward agreements
  - Potential problem areas such as goodwill, non-competes and other intangibles

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## Fair Market Value Standard(s) of Value

**Fair Market Value** Tax Purposes, Seller Advisory, Management Decision-Making

• "...the price at which the property would change hands between a willing seller and a willing buyer neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts." Revenue Ruling 59-60

**Fair Market Value** Regulatory Stark and Anti-Kickback Statute Requirements

• "means the value in arm's-length transactions, consistent with the general market value. General market value means "the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party on the date of acquisition of the asset or at the time of the service agreement." § 411.351-42 CFR

**Fair Value** Financial Reporting

• "Price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." ASC 820 (aka SFAS 157)

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## Fair Market Value - Business Analysis

ATTRIBUTE	RELEVANT COMPONENTS
Reimbursement	(A) Reimbursement Status, (B) Fee for service vs. Capitation or Other Bundled Payment, (C) Payor Mix, (D) Governmental Reimbursement and (E) Other Reimbursement
Volume	(A) Specialty, (B) Competition, (C) Capacity of Facility and Equipment and (D) Status of Physicians
Expenses	(A) Physician Compensation, (B) Other outsourced agreements and (C) Fixed/Variable
Risk	(A) Coding, (B) Relationships with Physicians, (C) Diversification, (D) Existence of non-competes and (E) Competition
Other	Working Capital and Capital Expenditures

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## Due Diligence Considerations - Compliance

- The Compliance Perspective
  - o Document review of Policy and Procedure differences to determine integration changes
  - o Billing Reviews
  - o Training documentation
  - o Review Coding, denials, audits, payor mix
  - o Relationships with health care professionals (*focused arrangements* – those in position to influence the volume and/or value of business for the target)
- Assessing the Target's Compliance Program

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## Focus of Compliance Due Diligence

Regardless of the deal structure, "compliance" review needs to focus on:

- Identification of the underlying risks inherent in the type of business conducted by the target
- Review and assessment of the effectiveness of the target's compliance program as a tool to prevent and detect misconduct in those risk areas.

Regulatory due diligence more complicated in health care

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## Hui Chen's Four "Factors"

DOJ Criminal Division Compliance Counsel and Fraud Section Chief recommends review of the following when assessing the effectiveness of a compliance program:

1. Does the compliance program demonstrate thoughtful design?
2. How operational is the program (not a paper program)?
3. How well do stakeholders communicate with each other?
4. How well is the program resourced?

<https://www.youtube.com/watch?v=pRTGZmmbc5o&feature=youtu.be>

(November 13, 2015, NYU School of Law)

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## Steps to Assess the Compliance Program

- Review the oversight and operational structure of the compliance program
- Review the actual operation of the compliance program
- Review the periodic evaluation of the compliance program's effectiveness




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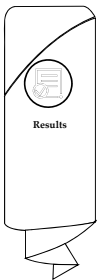
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## Summary of (effectiveness) results



- Striving to fulfill its mission of detecting, deterring, and preventing instances of fraud, waste, and abuse, the [Company Name] Compliance Department, the Executive Compliance Committee and the Board of Directors, continues to evaluate and improve the performance of its Compliance Program.
- **[Reviewer] concluded that [Company]'s Compliance Program would likely be determined "effective," if reviewed by [the DOJ or other governmental agencies].**
- The program would likely qualify as a mitigating factor, reducing culpability in the sanction or penalty phase of a government action associated with an area in which the Compliance Program is demonstratively providing coverage/oversight.

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## Pre-Acquisition Planning Phase



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## Pre-Acquisition - Legal

- Require pre-transaction cure of identified issues, if possible



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## Pre-Acquisition – Valuation

- Review go-forward compensation and any other services agreements (i.e. management agreements), if applicable. Make any necessary changes to valuation analysis.
- Final review of agreements
- Evaluate commercial reasonableness
- Finalize valuation

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## Commercial Reasonableness

- Evaluation of Commercial Reasonableness
  - In 1998, the Center for Medicare Services ("CMS"), in its Stark proposed rule, clarified "commercially reasonable" to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.<sup>13</sup> In the preamble to the Stark Phase II interim final rule, CMS further stated that "an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential designated health services ("DHS") referrals."<sup>14</sup>
  - In determining whether a financial transaction is commercially reasonable, it is important to understand whether the relationship will allow the organization to accomplish its strategic operational, and/or financial objectives. Whereas a fair market value analysis may focus on the compensation components of the transaction, a commercial reasonableness analysis must be larger in scope, to include the overall terms and circumstances of the arrangement. When determining commercial reasonableness, one should ask whether the overall deal makes sense to the purchaser of services (in the absence of referrals) and whether there is a legitimate business propose for the arrangement.

<sup>13</sup>1998 Reg. 401.1.1002, at 1100.  
<sup>14</sup>1998 Reg. 401.1.1002, at 1099.

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## Pre-Acquisition - Compliance

- Map out who will lead process changes and train project managers on what is needed
- Develop tools to map processes against regulations, policies, procedures.
- Rank risks into high, med, low
- Determine resources needed to drive integration




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## Post-Acquisition Integration Phase




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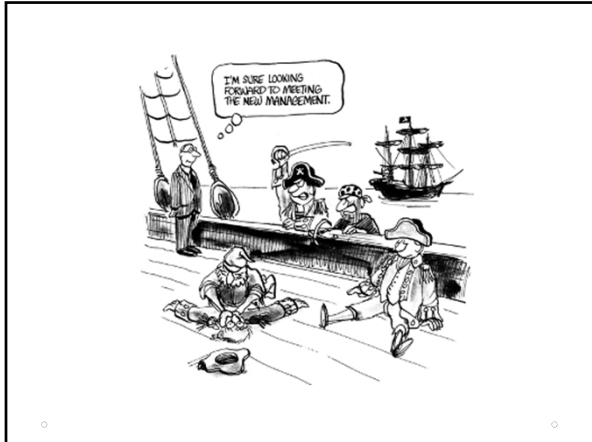
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## Post-Acquisition - Legal

- Successor liability – liability for obligations not specifically assumed
- Contractual
- Medicare
- Common Law
- Statutory
- Stock transactions – liability for obligations intended to be excluded

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## Successor Liability

Medicare Standards and Certifications

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) What constitutes change of ownership -

(1) Partnership. In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) Unincorporated sole proprietorship. Transfer of title and property to another party constitutes change of ownership.

(3) Corporation. The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) Leasing. The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) Notice to CMS. A provider who is contemplating or negotiating a change of ownership must notify CMS.

(c) Assignment of agreement. When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

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## Successor Liability

Change of ownership ("CHOW") - CHOWs "are officially defined and governed by 42 C.F.R. § 489.18 and State Operations Manual (Pub. 100-07), Chapter 3, §§ 3210-3210.5.C. The Regional Office generally makes the final determination as to whether a CHOW has in fact occurred." Medicare Program Integrity Manual (Pub. 100-08), Chapter 15, § 15.7.7.1, ( Rev. 423, Issued: 6-01-12, Effective: 07-02-12, Implementation: 07-02-12).

For program participants that have Health Benefit Agreements or Provider Agreements with the Medicare program (hospital, SNF, HHA, hospice, CORF, OTPT/SP providers and CMHC), a CHOW is important because it must be determined who the responsible party is under the agreement.

CMS has similar concerns with respect to participating suppliers that have category-specific agreements with the Secretary (RHC, ASC, and FQHCs) or that must file cost reports (e.g., ESRD facilities).

For other supplier types (i.e., supplier types without agreements or cost report requirements (e.g., PXR)), the CHOW process is generally to ensure compliance with the statutory requirement for ownership disclosure and to ensure that the program has current, accurate records regarding such participants.

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## Successor Liability

CHOW and 42 CFR 18(d)

(d) Conditions that apply to assigned agreements. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

- (1) Any existing plan of correction.
- (2) Compliance with applicable health and safety standards.
- (3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.
- (4) Compliance with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

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## Successor Liability

What does that mean?

Medicare sanctions and penalties are assigned to the new owner unless the following applies:

- The new owner is not responsible for money owed to the Federal Government due to a determination that the previous owner is personally guilty of fraud as long as the purchase is incorporated as a new and separate corporation.



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## Relying on Representations and Warranties

Regardless of deal structure, the basic transaction documents typically contain representations and warranties of the buyer and the seller to one another, which set forth the basic assurances of a party that certain facts are true and may be relied upon when entering into the transaction.

Seller representations and warranties will usually address the following substantive areas:

- Due organization of the seller and its legal authority to consummate the transaction
- Compliance with laws and permits
- Good and marketable title to the seller's assets, free and clear of liens
- Any required third-party consents to consummate the transaction
- The physical condition of the fixed assets and the overall adequacy of the assets to run the business
- The liabilities of the seller
- Accounts receivable, inventory, and other current assets
- The accuracy of the seller's financial statements and its financial condition
- Tax, intellectual property, environmental, ERISA, and employment matters
- Litigation matters
- Material contracts
- Real property matters
- Broker's fees

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## Post-Acquisition - Valuation

- Conduct purchase price allocation, if requested
- Periodic review of service agreements



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## Post-Acquisition - Compliance

- Set up weekly calls with each department or functional group
- Look for best practices between the organizations
- Use tools to track discussions on process changes
- Expect a loss of expertise and history
- Look at manual and automated processes
- Document discussions, corrective actions needed, barriers and timelines
- Determine risks/exposure, overpayments
- Standardize policies, procedures, training through integration
- Standardize disciplinary actions and other processes that involve other functional departments
- Develop an ongoing audit work plan that looks at focus arrangements and coding/billing

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# The Consequences




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## *qui tam* Court Case: US vs. Bradford Regional Medical Center and V&S, LLC

<p><b>Background</b></p> <ul style="list-style-type: none"> <li>• Lease Agreement between Hospital and Physician-owned LLC.</li> <li>• Valuation of Lease Payment included Non-compete</li> <li>• Other cross-payment arrangements (Billing, etc.)</li> </ul>	<p><b>Issues</b></p> <ul style="list-style-type: none"> <li>• Original Appraiser not involved in case</li> <li>• Appraisal was not deemed credible by the court</li> <li>• Court determined the Non-compete value included referrals and therefore was a Stark violation</li> <li>• Lack of adherence to the agreement</li> <li>• Lengthy negotiations and changing deal structure</li> </ul>
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On November 2010, Bradford was ordered to pay \$2.75 million plus \$600,00 in relator attorney fees to settle claims it violated the Stark Law.

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## *qui tam* Court Case: US vs. Tuomey

<p><b>Background</b></p> <ul style="list-style-type: none"> <li>• Exclusive, 10 yr. term w/ a 3-year non-compete</li> <li>• Base Salary + Productivity Bonus + Incentive Bonus based upon qualitative factors + other payments</li> <li>• Total comp exceeded collections</li> <li>• Full-time benefits for part-time services</li> </ul>	<p><b>Issues</b></p> <ul style="list-style-type: none"> <li>• Opinion Shopping</li> <li>• Blind reliance on valuation opinion</li> <li>• Submitted a total of 21,730 tainted Medicare claims</li> </ul>
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On October 3, 2013, Tuomey was ordered to pay \$237 million in fines for violations of the False Claims Act. On October 16, 2015, the Department of Justice announced a settlement in the amount of \$72.4 million.

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### qui tam Court Case: Barbetta vs. DaVita

#### Background

- Sales of shares of existing dialysis centers below FMV
- Purchases of physician-owned dialysis centers above FMV
- De novo joint ventures that made little to no economic sense apart from the purchase of the physician's patient referrals

#### Issues

- Manipulation of financial models by analysts that were provided to outside appraisers
- Only obtained valuations when purchasing 100 percent of a partner's interest in a jointly-owned center
- Requirement of medical director agreements with non-compete provisions to secure referrals
- Suppression of valuation not supporting deal price

On October 22, 2014, the Department of Justice announced a settlement in the amount of \$350 million to resolve claims that DaVita violated the False Claims Act.

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### qui tam Court Case: Simmons v. Meridian

#### Background

- Relator alleged Meridian violated anti-kickback statute by paying physicians for referrals to Treasure Coast Surgery Center, LLC.
- Relator alleged Meridian paid existing physician owners above FMV for its 60% ownership but charged referring physicians a discounted amount to purchase minority interests
- Relator was the former office manager of Treasure Coast.

#### Issues

- Recruiting efforts and ownership offers appeared in part to be based on physicians' case volume.
- Appearance of conflict of interest throughout the negotiations between Meridian and physicians
- Medical directors were hired despite lack of need

In September 2014, Treasure Coast agreed to a settlement to pay \$5.1 million to resolve claims that it had violated the False Claims Act.

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### qui tam Court Case: Barker v. Columbus Regional and Tidwell

#### Background

- Columbus Regional Health System purchased Tidwell Cancer Treatment Center July 15, 2010.
- Relator alleged purchase price was in excess of fair market value and was not commercially reasonable in the absence of referrals.
- Relator alleged purchase was not in response to a community need.
- Case brought by an individual, Richard Barker, who was the top administrator at John B. Amos Cancer Center.

#### Issues

- Valuation analysis was only a DCF calculation titled "Discussion Documents" identified as preliminary draft. No narrative was provided.
- Report completed for St. Francis, not Columbus Regional Health System
- Analysis did not account for the known outdated equipment in DCF CapEx
- Physician competence and ability to practice medicine at an acceptable level had been identified as an issue by Columbus Regional oncologists.
- Market for new radiation therapy patients was mostly stagnant

In September 2015, Columbus Regional agreed to a settlement to pay up to \$35 million to resolve claims that it had violated the False Claims Act. In addition, the medical director, Dr. Andrew Pippas, agreed to pay \$425,000 to settle claims against him.

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Questions?

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### References

Due Diligence in Health Care

- Compliance Issues in M&A: Performing Diligence on the Target's Ethics and Compliance Program, by M. Mannix and D. Black. *The Complete Compliance and Ethics Manual* (2017), Society of Corporate Compliance and Ethics.
- Mergers and Acquisitions Due Diligence in Health Care, by R. Kusserow. *Journal of Health Care Compliance* (November – December 2013). CCH and Aspen Publishers.
- What Every Compliance Officer Should Know About M&A Due Diligence, by G. Brock, J. Gilbertson, V. Griggley, T. Kraemer, and K. Woo. *Compliance Today* (December 2008), Health Care Compliance Association.

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### References, continued

Compliance Program Effectiveness

- *Compliance Metrics Handbook*, Convercent (2016).
- *Ethics and Compliance Program Effectiveness Report*, LRN, (2016).
- *Principles and Practices of High-Quality Ethics and Compliance Programs*, Ethics & Compliance Initiative (2016).
- How Do I Prove My E&C Program is Effective? The Art & Science of Effectiveness Measurement (Webinar), Navex Global (2016).
- Measuring the Intangible? To Really Improve Corporate Culture and Compliance Effectiveness, it Must be Measurable, by J. Tabuena. *Compliance Week* (August 2016).

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Powered by Pride

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Don't Face the Risk Apocalypse:  
Practical Approaches to Implementing and Integrating ERM and Compliance  
with Quality

HCCA Compliance Institute - March 29, 2017

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Quality and Compliance Starts with the  
Patient Experience!  Centered in Care  
Powered by Pride



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We are the Patient Experience!  Centered in Care  
Powered by Pride



Ron Skillens, CPA, CHC, CHPC  
SVP, ERM and Chief  
Compliance Officer  
JPS Health Network



Frank Rosinia, M.D.  
Chief Quality Officer  
JPS Health Network

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Agenda



- About JPS Health Network
- JPS Organizational Culture
- Our ERM Journey
- The JPS Quality and Patient Safety Program
- Combining ERM and Quality
- Questions

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About JPS Health Network

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**JPS Health Network is...**

- Tarrant County's only Level 1 Trauma Center
  - 2.3 million square feet of facility space
  - 6,500 team members
  - 11 residency and fellowship programs
  - 573 bed acute care hospital
  - More than 40 primary, specialty and school-based health centers
  - Tarrant County's only Psychiatric Emergency Center

223 emergency visits per day in 2009   
 312 emergency visits per day in 2015 

**JPS medical staff credentials**  
as of 2014

- 650 MDs
- 109 DOs
- 17 DDS
- 3 PhDs
- 4 DPMs
- 1 DMD

all physicians with privileges

**As our community grows**  
 and industry standards, regulations, academic requirements and new technology emerge, JPS too must evolve to meet the demands.

Get the latest update at [www.jpshhealthnet.org/bonds](http://www.jpshhealthnet.org/bonds)

- \$1.7 billion in economic activity generated by JPS in 2014
- 14,489 genetic patients cared for in 2015
- 54 languages can be heard in the halls of JPS on any given day
- 58 police officers in the Tarrant County Hospital District police department
- 9th largest employer in the county

**5,000 BABIES** are born at JPS in Tarrant County EVERY YEAR

**20,000 PATIENTS** seen at the Psychiatric Emergency Center each year

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Organizational Culture: Tone at the Top  Centered in Care  
Powered by Pride

**JPS Rules of the Road**  
**Own It**  
**Seek Joy**  
**Don't be a Jerk**



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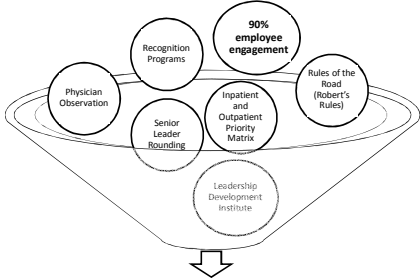
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Elements of culture leading to improved Quality and ERM programs  Centered in Care  
Powered by Pride



JPS Culture

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 Centered in Care  
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**Our ERM Journey**

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**ERM Helps Manage Reputational Risk**  Centered in Care  
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**ERM Timeline**  Centered in Care  
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- SVP, ERM and Chief Compliance Officer position created in 2015 reporting directly to both the Board and CEO
- 9 JPS Board members appointed by the 5 elected County Commissioners
- Board meetings open to public and streamed live on the Internet
- Board wanted to develop an ERM program to give them more visibility on organization-wide risks. Board did not have a good understanding of ERM
- First ERM risk assessment conducted from September 2015 – January 2016
- Met with executive leaders and Board to prioritize top 10 ERM risks
- Currently building risk profiles for each of the top ERM risks and implementing GRC software
- Implementing ERM communication plan and reporting

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**Overcoming ERM Organizational Barriers**  Centered in Care  
Powered by Pride

Barriers	Solutions
<p>Why ERM?</p> <ul style="list-style-type: none"> <li>Not "real" work</li> <li>Lack of support</li> <li>Flavor of the month</li> <li>Too academic</li> <li>Too many risks to focus on</li> <li>Too confusing</li> </ul>	<ul style="list-style-type: none"> <li>✓ Establish board and leadership support at the beginning</li> <li>✓ Educate key stakeholders</li> <li>✓ Define goals and value proposition</li> <li>✓ Keep it simple</li> <li>✓ Get quick wins to gain support</li> <li>✓ Identify a few key ERM risks</li> <li>✓ Practice telling the ERM story</li> <li>✓ Align ERM to key organizational goals and quantify</li> <li>✓ Others?</li> </ul>

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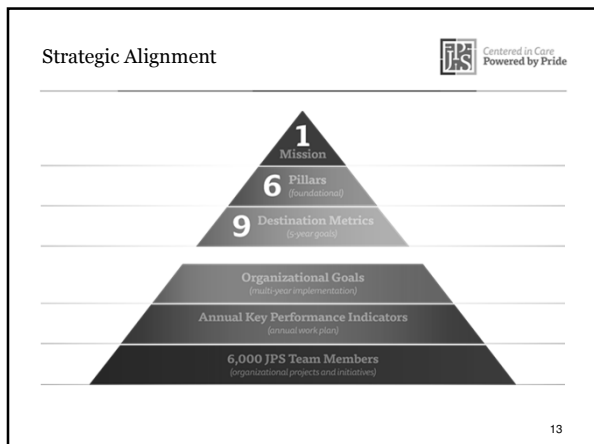
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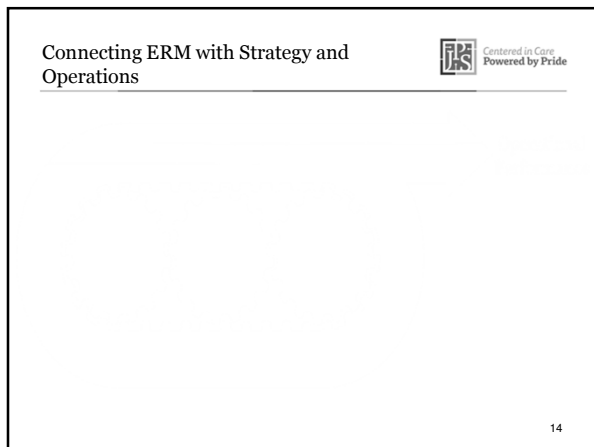
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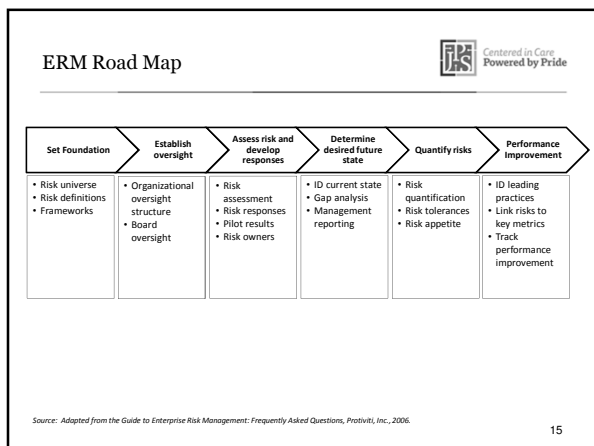
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**Risk Profile Elements**



1. ERM Risk Name / Executive Risk Owners
2. Risk Definition
3. Risk Category (JPS Pillar / Strategic / Regulatory)
4. Risk Drivers
  - External / Internal
5. Risk Events
  - (Rating: Impact / Significance / Velocity)
6. Risk Mitigation Strategies
  - (Effectiveness of Current & Proposed)
7. Risk Maturity Current and Desired
8. Risk Tolerance / Risk Appetite
9. Evaluative Metrics

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**Building Relationships and Support**



- Understand the business
  - Operational rounding
  - Off-site meetings and retreats
  - Goal setting and strategy meetings
  - Financial performance and incentives
- Understand the cultural and political environment
  - Backgrounds of board and senior leaders
  - Fast-paced or deliberative decision making process
  - Stated and hidden agendas
  - Key influencers
  - Historical organizational challenges

**The effectiveness of an ERM program depends on the relationship the risk leader has with the board and senior leadership.**

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**2017 ERM Goals**



- ❖ Develop risk profiles for the top 10 ERM risks
- ❖ Implement GRC Software
- ❖ Develop ERM reporting package for the Board, Executives, and broader management
- ❖ Collaborate to transition the management of the top ERM risks to the risk owners
- ❖ Align ERM with JPS goal setting and budget processes

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 Centered in Care  
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The JPS Quality and Patient Safety Program

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We are on our Journey to Excellence in our Quality and Patient Safety Program!

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 Our Journey to Excellence

DESTINATION   
an important milestone along Our Journey to Excellence

  
"PERFECTION IS NOT ATTAINABLE, BUT IF WE CHASE PERFECTION WE CAN CATCH EXCELLENCE."  
VINCE LOMBARDI  
© Lifhack Quotes

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Excellence Begins with High Reliability

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THE POWER OF  
**ZERO:**  
STEPS TOWARD  
HIGH RELIABILITY  
HEALTHCARE

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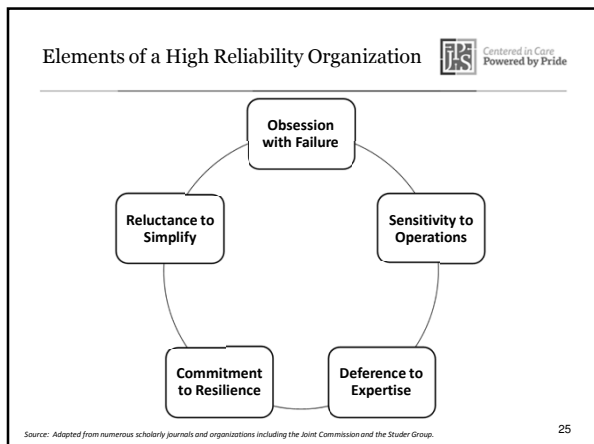
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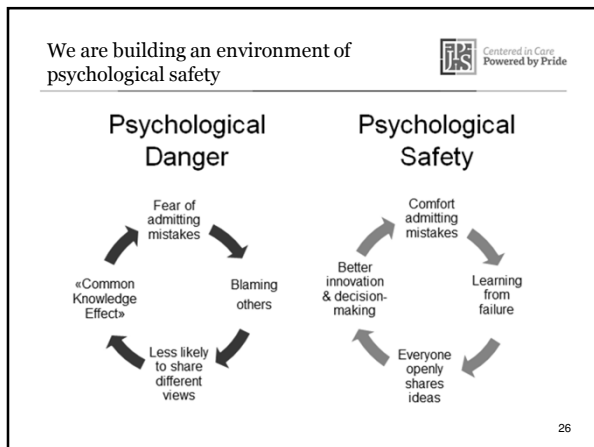
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- Psychological safety begins with the right leadership behaviors 
- Leadership Behaviors for Cultivating Psychological Safety
- Be accessible and approachable
  - Acknowledge the limits of your knowledge
  - Show you are capable of making mistakes; be fallible
  - Invite participation
  - Failures are learning opportunities
  - Be direct and clear. No uncertainty in communication.
  - Set boundaries for behavior
  - Accountability
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ERM and Quality Collaboration  
Success Stories

❖ Data Governance

❖ Physician Engagement

❖ Academics

Source: Images courtesy of US News and World Report, OLAP.com, and Odgers Low Group

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Centered in Care  
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Combining ERM, Quality, and Compliance

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Integration is about tearing down silos!

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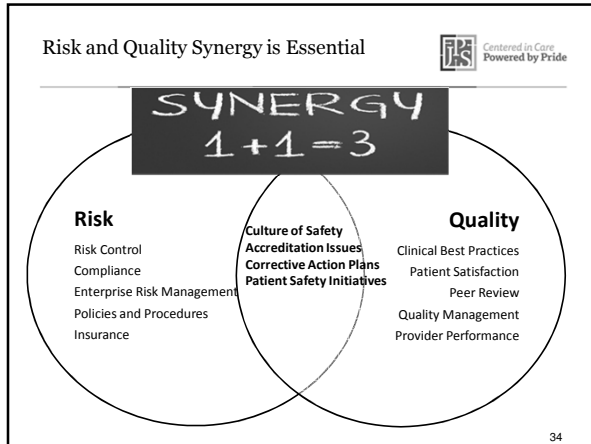
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**Clinical Quality ERM Risk Profile Summary**

RISK DEFINITION	RISK OWNERS	PILLAR	MATURITY	TREND
Clinical quality failures, reflected through patient outcomes and satisfaction, significantly affect the organization's reputation, efficiency, compliance and accreditation status, and reimbursement	Frank Rosinia, M.D. James Johnson, M.D.	Quality	Current: Initial Desired: Defined	Establishing Baseline

TOP RISKS	RISK MITIGATION STRATEGIES
1. Inadequate Clinical Documentation (High) 2. Inconsistent Care Coordination (High) 3. Medical Errors (High) 4. Resident Supervision (High) 5. Hospital-acquired infections (High) 6. Medical alarms are not responded to timely (Medium) 7. Hospital readmissions (Medium) 8. Clinical Staff Competencies (Low) 9. Patient falls/trauma (Low) 10. Mortality (Low)	1. Clinical Documentation Improvement initiatives 2. Improvements to inpatient access 3. Identify patient safety risks common to JPS patient population (falls/CAUTIs/CLABSI/SSI) 4. Strategic Recruitment 5. Infection Control 6. Continuing Education for all clinicians 7. New Leadership in Academic Affairs

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**ERM Internal Communication Plan**

The Quality ERM risk profile was presented to the following:

- CEO Senior Management Meeting
- Compliance Committee
- Patient Safety & Quality Committee
- Project Governance Committee
- Leadership Connection
- Medical Executive Committee
- Board Governance Committee

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Victory comes from strong leadership to foster an environment of change




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Questions




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 Email: [frosinia@jpshealth.org](mailto:frosinia@jpshealth.org)

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Do You Know What Your  
Business Associates'  
Subcontractors & Vendors Are  
Doing With Your PHI & ePHI?

Web Hull  
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HCCA 2017 Compliance Institute

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This presentation and discussion is for Educational  
Purposes only

Should you desire advice on your specific situation,  
please seek the counsel of an advisor of your own  
choosing

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The Challenge

- This is an evolving area
- There is no "Play Book" – only emerging, ad hoc approaches
- It takes time, resources, money, and management attention
- The numbers are daunting

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### Goal

- Begin to Develop a Subcontractor / 4<sup>th</sup> Party Program That Is
  - Effective
  - Implementable
  - Thoughtful, Respectful, & Sensitive
  - Appropriate to Your Size & Risk
  - Affordable
  - Doesn't "Boil the Ocean"

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### Key Tools for Meeting the Challenge

1. Your Contract with Your Business Associate
2. Your Business Associate / Third Party Risk Management Program

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### This Presentation

- Interactive
- Sharing Insights & Experiences
- Questions at Anytime
- A Few Exercises
- Discussion
- Some Handout Tools

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### Themes

- Having Something is Better Than Having Nothing
- Get Started Now
- Make Progress Everyday
- Document, Document, Document
- It's a Team Effort
  - BA / Third Party Risk Management
  - Security – Info, Physical
  - Privacy
  - Legal Contracts
  - ...

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### Definitions

- Business Associate
  - (A) "person (with respect to a covered entity) who: ... other than in the capacity of a member of the workforce of such covered entity ... **creates, receives, maintains, or transmits protected health information** ... "or ...
  - (p)rovides, other than in the capacity of a member of the workforce of (a) covered entity, **legal, actuarial, accounting, consulting, data aggregation ... management, administrative, accreditation, or financial services** to or for such covered entity, ... where the provision of the service involves the disclosure of protected health information"

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### Definitions

- Subcontractor
  - A person or entity that "**creates, receives, maintains, or transmits protected health information on behalf of (a) business associate.**"
  - A Subcontractor is also a Business Associate & subject to all the requirements of a Business Associate
- 3<sup>rd</sup> Party = Your Business Associate
- 4<sup>th</sup> Party = Your Business Associate's Subcontractor

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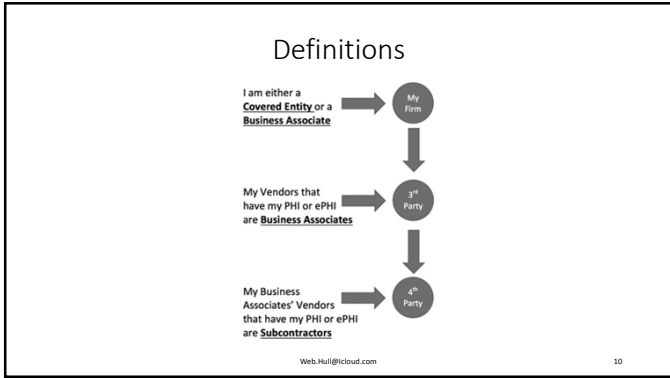
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### Subcontractor / 4<sup>th</sup> Party Data Breach

- Multiple Choice Question - If Your Subcontractor / 4<sup>th</sup> Party Breaches Your PHI or ePHI, Who's Got the Problem?
  - a) You
  - b) Your BA / 3<sup>rd</sup> party
  - c) Your Subcontractor / 4<sup>th</sup> party
  - d) All of the above
- Discussion Question - What's the Nature / Implication / Consequences of the Problem?

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### Why I Should Care What A 4<sup>th</sup> Party Does with My PHI & ePHI

- I Am Ultimately Responsible for My PHI & ePHI
- Breach Notification
- Confidentiality, Availability, & Integrity of Data
- My Reputation
- Costs to Me - \$, Time, Regulators, ...
- Others?

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### BA & Subcontractor Requirements

- Business Associates (“BAs”) and Subcontractors are required to comply with appropriate HIPAA / HITECH Rules
  - Security
  - Privacy
  - Breach
  - Have a Business Associate Agreement (“BAA”) – OCR Template - <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/batemplate/index.html>
  - Perform Risk Analysis
- Certain State Laws, Rules, & Regulations also apply

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### BA & Subcontractor Requirements

- Your requirements in regard to your BAs
  - Included in “Risk Analysis”?
  - Have a BAA
- Your Requirements in regard to your Subcontractors
  - Included in “Risk Analysis”?
- Your BA’s Subcontractor Requirements
  - Included in “Risk Analysis”?
  - Have a BAA between the BA and the Subcontractor
  - Flow your Business Associate Agreement requirements down to every Subcontractor

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### Step 1 – My Business Associates

- How Many Business Associates Do I have?
  - If I am a Covered Entity, I might already know this number because OCR asked for it in its Audit Request
  - The OCR also requested Contact Names & Addresses
  - If you don’t already have this inventory, now’s a good time to start it
- OCR Template Link
  - <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/batemplate/index.html>

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Tool #1 – Contract with Business Associate

- Consult / Coordinate with Legal Contracts
- If it is not in a contract, it is very difficult to have the other party do it

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Tool #1 – Contract with Business Associate

- Elements to consider
  - Business Associate Agreement
  - Other Agreements
    - Security
    - Data Protection
    - Privacy
    - Breach
  - Subcontractor Requirements
  - Flow Down Requirements

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Tool #2 – BA / 3<sup>rd</sup> Party Risk Assessment Program

- Key Elements of a BA / 3<sup>rd</sup> Party Risk Assessment & Management Program?
  - Executive Management Support & Reporting
  - Policies & Procedures
  - Adequate Resources – People, Budget, Tools, ...
  - Assessment / Reassessment – Questionnaire, Certifications (ISO 27001, AUP, SOC2, ... ), Evidence, Artifacts, Data Maps, Data Inventory, Subcontractors, ...
  - Auditing & Monitoring – On-site & Desk
  - Exceptions & Remediation
  - Others

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### OCC Third Party Risk Bulletins

- Below are links to 2 OCC documents regarding 3<sup>rd</sup> and 4<sup>th</sup> Party Risk Management. The OCC is a major bank regulator & examiner
- These bulletins are relevant in that they address many issues that Healthcare professionals face in managing Business Associates & Subcontractors.
  - OCC Bulletin 2013-29 – “Third Party Relationships: Risk Management Guidance” - <https://www.occ.gov/news-issuances/bulletins/2013/bulletin-2013-29.html>
  - OCC Bulletin 2017-7 – “Third Party Relationships: Supplemental Examination Procedures” - <https://www.occ.gov/news-issuances/bulletins/2017/bulletin-2017-7.html>

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### Elements to Consider in Contracts, Amendments, & BA / 3<sup>rd</sup> Party Risk Management Program

• This list is suggestive, not exhaustive

➢ Staff	➢ Transition Plan	➢ Amendment
➢ Funding	➢ Changes	➢ Pricing
➢ Cloud	➢ Agent	➢ Resources
➢ Security Rule	➢ Shared Assessments	➢ Translations
➢ Privacy Rule	➢ Medicare Part D	➢ Who Pays
➢ Omnibus Rule	➢ Assessment	➢ Record Keeping
➢ Denied Persons	➢ Reassessment	➢ Insurance
➢ OCC BULLETIN 2017-7	➢ Crown Jewels	➢ Liability
➢ Termination	➢ Data Minimization	➢ Prior Approval
➢ Mission Creep	➢ Minimum Necessary	➢ Contract
➢ SLA	➢ Monitoring	➢ Return Of Data

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### Elements to Consider in Contracts, Amendments, & BA / 3<sup>rd</sup> Party Risk Management Program

• This list is suggestive, not exhaustive

➢ Data Ownership	➢ AUP	➢ Availability
➢ Permitted Uses	➢ ISO27001	➢ Integrity
➢ Disclosure	➢ SOC2	➢ Resilience
➢ Encryption	➢ HIPAA	➢ Data Map
➢ Background Checks	➢ OCC Bulletin 2013-29	➢ Data Inventory
➢ Risk Rating	➢ Log Monitoring	➢ Disaster Recovery
➢ InfoSec	➢ Asset Management	➢ Business Continuity
➢ Physical Sec	➢ Security Incidents	➢ Certify
➢ Detection	➢ Pen Test	➢ Attestation
➢ NIST	➢ Hotline	➢ Certifications
➢ PCI	➢ Confidentiality	➢ Artifacts

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### Elements to Consider in Contracts, Amendments, & BA / 3<sup>rd</sup> Party Risk Management Program

• This list is suggestive, not exhaustive

<ul style="list-style-type: none"> <li>➢ Evidence</li> <li>➢ Training</li> <li>➢ Laws</li> <li>➢ Regulations</li> <li>➢ Supplier Code</li> <li>➢ Fifth Parties</li> <li>➢ Flow Down</li> <li>➢ Policies</li> <li>➢ Vendor Program</li> <li>➢ Offshore</li> <li>➢ PHI</li> </ul>	<ul style="list-style-type: none"> <li>➢ PII</li> <li>➢ Trade Secrets</li> <li>➢ ITAR</li> <li>➢ M&amp;A</li> <li>➢ Access To</li> <li>➢ Access Controls</li> <li>➢ Records Retention</li> <li>➢ Backup</li> <li>➢ BAA</li> <li>➢ Security Addendum</li> <li>➢ Privacy Addendum</li> </ul>	<ul style="list-style-type: none"> <li>➢ Patching</li> <li>➢ Data Destruction</li> <li>➢ Procedures</li> <li>➢ Risk Ratings</li> <li>➢ Risk Management</li> <li>➢ Policies</li> <li>➢ Periodic Reviews</li> <li>➢ Software Escrow</li> <li>➢ Data Escrow</li> <li>➢ Audit Rights</li> <li>➢ Breach</li> </ul>
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### 4<sup>th</sup> Parties

- Do I already Assess & Audit My BA's
  - What is the Cost, Effort, & Success?
- Should I
  - Preapprove My Subcontractors?
  - Assess / Reassess My Subcontractors?
  - Audit My Subcontractors?

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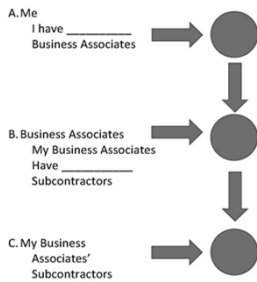
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### How Many 4th Parties Do I Have?



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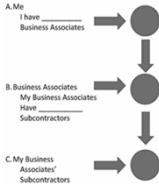
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### How Many 4th Parties Do I Have?

• Answer = A x B = Total Number of Subcontractors  
\_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

• If I have 10 Business Associates and each BA has 10 4th parties, I will have 100 4th parties - (10 x 10 = 100)

• If I have 100 Business Associates and each BA has 100 4th parties, I will have 10,000 4th parties - (100 x 100 = 10,000)




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### Subcontractor Challenges

- Preapprove / Reapprove Subcontractors
  - How Many Will You Have to Approve?
  - What About the Legacy Subcontractors?
  - What Criteria Will You Use to Approve / Disapprove?
  - What Will Your Turn Around Time Be?
  - What if you Approve a Subcontractor & Something Goes Wrong?
  - What if You Disapprove?
  - Others?

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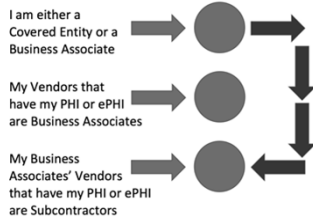
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### The 4th Party's Challenge

Some people recommend having the right to bypass the 3rd party and directly Assess and Audit the 4th party




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### The 4<sup>th</sup> Party's Challenge

- Often the 4<sup>th</sup> Party's Customer has many Customers of its own. For example:
  - The 4<sup>th</sup> Party's Customer is a Software As a Service (SAaS) Vendor
  - The SAaS provider has 4,000 customers.
- What If the 4<sup>th</sup> Party Has 100 Customers & Each Customer Has 100 Customers?
  - $100 \times 100 = 10,000$  Assessment & Audit Requests

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### Your 4<sup>th</sup> Party Challenge

- How reasonable is it for you to Directly Assess / Reassess & Audit your Subcontractors?
  - Large Number of Subcontractors
  - Large Effort & Cost
  - No Direct Relation with Subcontractor – Confidentiality, etc.
  - Subcontractor Push Back
- Your Key Building Blocks Are Already in Place
  - Contract with BA
  - BA / 3<sup>rd</sup> Party Risk Management Program

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

• 4<sup>th</sup> Party Worksheet

<u>Action</u>	<u>Effectiveness</u>	<u>Cost</u>	<u>Ease of Implementation</u>
	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

• 4<sup>th</sup> Party Worksheet

Action	Effectiveness	Cost	Ease of Implementation
	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

- Use it to define the building blocks that work for you
- In light of limited resources, the goal is to get all Greens
- Go for the "Low Hanging Fruit"
- Do a lot of "Actions" – and then pick the winners

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

• Example #1 - 4<sup>th</sup> Party Worksheet

Action	Effectiveness	Cost	Ease of Implementation
Assess Every 4th Party	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

• Example #2 - 4<sup>th</sup> Party Worksheet

Action	Effectiveness	Cost	Ease of Implementation
Encryption	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

- My top "Building Blocks" – Yours might be different
  1. Have Flow Downs to every 4<sup>th</sup> Party in the 3<sup>rd</sup> Party Contract
    - Consider having a 4<sup>th</sup> and Downstream Parties section in the 3<sup>rd</sup> Party contract
    - This is a "One and Done" activity. Draft them once. Include them in each 3<sup>rd</sup> Party Contract
    - Make sure that you can have access to all the documents, evidence, artifacts, people, facilities, and the like that you will need to do a complete job
    - Remember – If it is not in the contract, you most likely will not be able to do it

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

#### Items to consider in the Flow Downs to every 4<sup>th</sup> Party

- BAA
- Data Protection Agreement
- Security & Breach Notification Requirements
- Right for you to Assess / Reassess & Audit 4<sup>th</sup> Party
- Process for Amendment
- Confidentiality, Availability, Integrity, & Return of Data
- Termination
- ...

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

- My top "Building Blocks" – Yours might be different
  2. Get evidence in your 3<sup>rd</sup> Party Risk Assessment that the 3<sup>rd</sup> Party has a mature & robust 3<sup>rd</sup> Party Risk Management Program that it uses on all of its 3<sup>rd</sup> parties (your 4<sup>th</sup> Parties)
    - This is a "One & Done" update to your assessment tool

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

Areas to consider in updating your 3<sup>rd</sup> Party Risk Assessment tool regarding your 3<sup>rd</sup> Party's Risk Management Program that it uses on its 3<sup>rd</sup> parties (your 4<sup>th</sup> Parties)

- Policies & Procedures
- Resources – Staff, Budget, ...
- Risk Assessments
- Supplier Code of Conduct

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

Areas to consider in updating your 3<sup>rd</sup> Party Risk Assessment tool regarding your 3<sup>rd</sup> Party's Risk Management Program that it uses on its 3<sup>rd</sup> parties (your 4<sup>th</sup> Parties)

- Control & Process Assessments and Reassessments – Questionnaires, Evidence, Artifacts, 3<sup>rd</sup> Party Assessments & Certifications, ...
- Monitoring
- Auditing
- Exceptions
- ...

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### Building / Designing a 4<sup>th</sup> Party Program That's Right for You

- My top "Building Blocks" – Yours might be different
  - 3. When Auditing the 3<sup>rd</sup> Party – either on site or a desk audit
    - Assess the 3<sup>rd</sup> Party's 3<sup>rd</sup> Party Risk Management Program
    - Review BA Inventory / List
    - Sample Contracts for Flow Downs
    - Sample Assessments / Reassessments
    - Review "Exceptions"
    - Sample Their Audits of Their 3<sup>rd</sup> Parties
    - Evaluate Staff
    - ...

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## Building / Designing a 4<sup>th</sup> Party Program That's Right for You

- My top "Building Blocks" – Yours might be different
- 4. Encryption!!!

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## Thank You!

### Questions & Discussion

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# 4<sup>th</sup> Party Subcontractor Word Search

There are 73 words in this puzzle that have a relation to 4<sup>th</sup> Party Subcontractors

Some of the words are two words without a space such as "SECURITYRULE". When you find a word, look on both sides of it to see if there is an additional word.

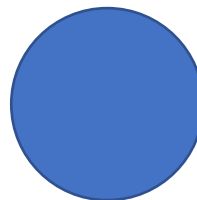
There are 3 words that refer to Outer Space. Be the first to find them and win a prize at the presentation

T E N G S A N M D S E N R S S T O A G R C R Y D T Q T Q A S  
R L O N N S O A I E D O E E T N W U N I E I T T N A R P V E  
A U I I O S I R S S O I S R N E S D I S S S I R E L A Q A I  
D R T R I E T G C U C T I U E M L I R K L K U A M S N K I T  
E Y A O T S N O L D R P L D M S E T O R A R N P E M S K L R  
S C T T A S E R O E E Y I E S S W R T A C A I E G P L R A A  
E A S I L M T P S T I R E C S E E I I T I T T R A E A E B P  
C V E N U E E R U T L C N O E S J G N I S I N A N E T T I H  
R I T O G N R O R I P N C R S S N H O N Y N O C A R I U L T  
E R T M E T S D E M P E E P S A W T M G H G C I M C O R I F  
T P A G R P D N S R U D O S A E O S U S P S S D T N N N T I  
S B N O P C R E Y E S D L N D R R G E H T G S E E O S O Y F  
M F A L I I O V P P Z O D N E E C L I N N I E M S I N F I U  
H U A C I O C E I U R W A I R Z U P E I K S N Z S S Y D J A  
T H D V K T E F Z T K L J W A R A D D R A O I E A S D A J E  
A N A N Z G R Y N C P C O M H A I N X L D B S O O I V T F P  
R A E F E V R O J N V R A L S C U S T A F F U U U M A A W D  
B E L M A D C O O Z C J A B N F D E N I E D B S E G N A H C  
N G C N E S D I U S D V J I D A T A M I N I M I Z A T I O N  
Y O L O S G T A E N O J Y M I N I M U M N E C E S S A R Y A  
B Z I E R I A E Y R D T D I S A S T E R R E C O V E R Y A G  
Q R C T S D R N P T I C H U B B L E T E L E S C O P E Z U E  
S C U N A A K P A R I P H Y T I L A I T N E D I F N O C P N  
A U A N W N A E U M E R D E N O I T C U R T S E D A T A D T  
F R B T O R I C E R K U U L C S W E I V E R C I D O I R E P  
T G F I O M E M S P O S A C P K S N O I T A C I F I T R E C  
R O V I N S A O R L I W I H E V S D A T A O W N E R S H I P  
S A R S V M N R C E S N I R A S Y R O T N E V N I A T A D U  
L P T V I S O U S V T Y G S E C U R I T Y R U L E N I S T O  
C O S I M U D N E D D A Y C A V I R P N I T E L L U B C C O

# How Many 4<sup>th</sup> Party Subcontractors Have Access or Potential Access to My PHI & ePHI?

A. Me

I have \_\_\_\_\_  
Business Associates



B. Business Associates

My Business Associates  
Have \_\_\_\_\_  
Subcontractors



C. My Business Associates'  
Subcontractors



Answer = A X B = Total Number of Subcontractors

\_\_\_\_\_ X \_\_\_\_\_ = \_\_\_\_\_

## 4<sup>th</sup> Party Subcontractor Additional Resources

Below are links to two OCC documents that address 3<sup>rd</sup> and 4<sup>th</sup> Party Risk Management. The OCC is a major bank regulator and examiner.

Both documents are quite detailed and address multiple aspects of an effective program.

Although the documents are not directed to Healthcare, they are relevant in that they address many issues that Healthcare professionals face in managing Business Associates and Subcontractors.

OCC Bulletin 2013-29 – “Third Party Relationships: Risk Management Guidance” - <https://www.occ.gov/news-issuances/bulletins/2013/bulletin-2013-29.html>

OCC Bulletin 2017-7 – “Third Party Relationships: Supplemental Examination Procedures” - <https://www.occ.gov/news-issuances/bulletins/2017/bulletin-2017-7.html>

On January 25, 2013, Health and Human Services published on its website “SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS” - <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>. Every Subcontractor that has PHI or ePHI is also a Business Associate, and therefore must have a BAA.

OCR Business Associate Template - <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/batemplate/index.html>

## 4<sup>th</sup> Party Vendor Risk Management Worksheet

<u>Action</u>	<u>Effectiveness</u>	<u>Cost / Resources</u>	<u>Ease of Implementation</u>
	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

Notes

<u>Action</u>	<u>Effectiveness</u>	<u>Cost / Resources</u>	<u>Ease of Implementation</u>
	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

Notes

<u>Action</u>	<u>Effectiveness</u>	<u>Cost / Resources</u>	<u>Ease of Implementation</u>
	High	Low	Easy
	Medium	Medium	Difficult
	Low	High	Very Difficult

Notes