Overview of Risk Assessments and Workplans

Andrea C. Merritt, Ed.D., CHC, CIA
Partner, Athena Compliance Partners

Andrei M. Costantino, MHA, CHC, CFE
Vice President of Integrity & Compliance

1

Regulatory Requirements

- The U.S. Sentencing Commission Guidelines Manual (USSG) states:
    - "In implementing [a compliance program], the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth…to reduce the risk of criminal conduct identified through this process."[1]
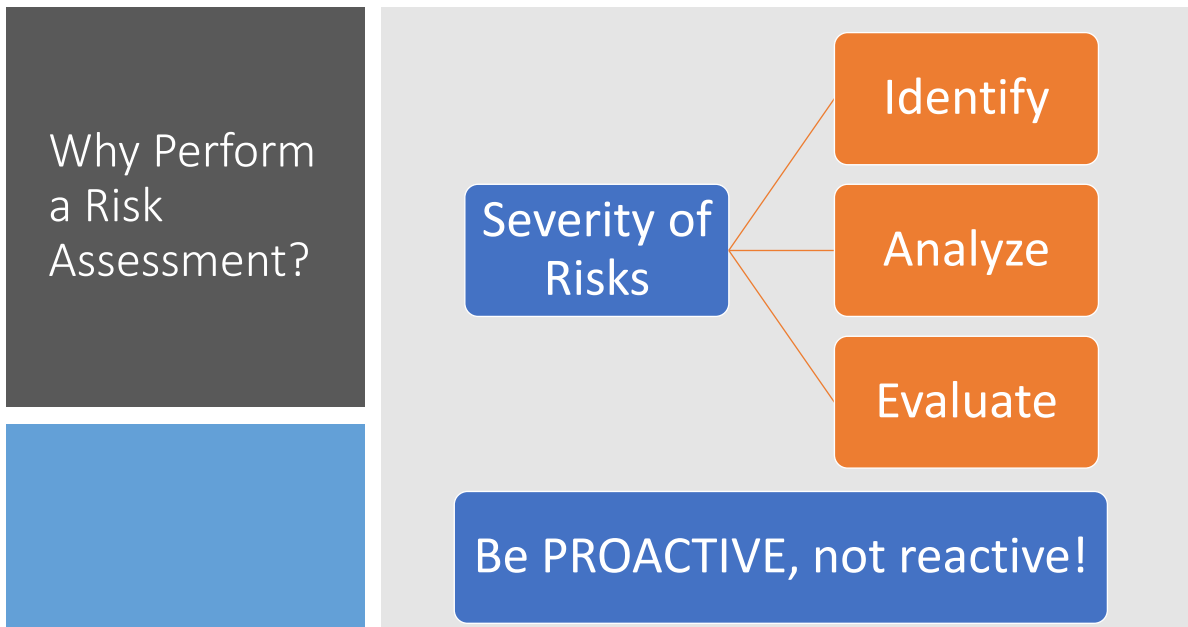- Requirement in Corporate Integrity Agreements

[1] U.S. Sentencing Guidelines Manual § 8B2.1(c)

2

Risk Assessment Process
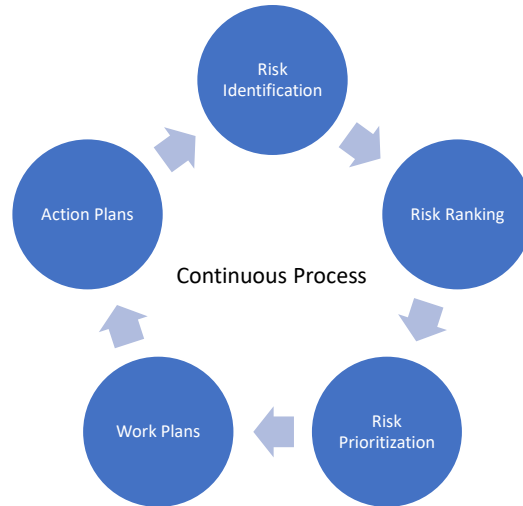
- Enterprise Risk Management or Compliance Risks?
  - Enterprise Risk Management
    - Addresses all forms of risk
      - Regulatory/Legal
      - Finance
      - Operational
      - Reputational
  - Compliance Risk
    - Limited to those areas under the umbrella of compliance (legal/regulatory)

3

Why Perform a Risk Assessment?

Severity of Risks

Identify

Analyze

Evaluate

Be PROACTIVE, not reactive!

4

Risk Assessment Process

5

Risk Identification

How	Who	When
Interviews Surveys Document review Audit results Industry concerns	Compliance Internal Audit Legal Risk Management Stakeholders	Annually, but a continuous process

6

Risk Rankings

Depends on:

- Likelihood of the risk occurring
- Severity of the impact to the organization
- Level of risk tolerance

Dealing with risk:

- Avoid
- Mitigate
- Transfer
- Assume

7

Risk Ranking

Severity

	Low	Medium	High
High	🟨	🟥	🟥
Medium	🟩	🟨	🟥
Low	🟩	🟩	🟨

Probability

🟩 Low risk 🟨 Medium risk 🟥 High risk

8

Workplans and Actions Plans

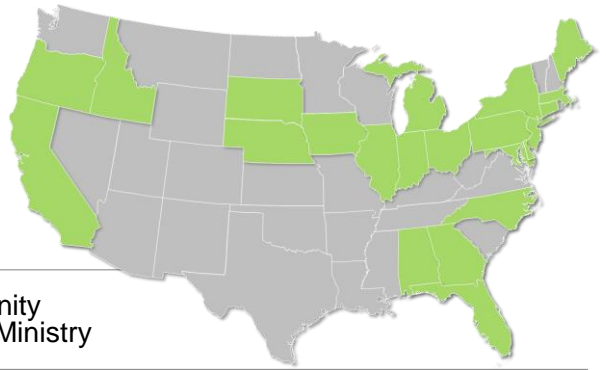| Workplans	• Reasonable • Responsible parties • Reportable
Action Plans	• Measurable • Planned follow-up • Future risk assessment

9

Trinity Health's Risk Assessment Methodology

10

Trinity Health's 22-state diversified system today

$19.3B In Revenue

1.5M Attributed Lives   **$1.1B** Community Benefit Ministry

125K Colleagues   **7.5K** Employed Physicians & Clinicians   **27.5K** Affiliated Physicians
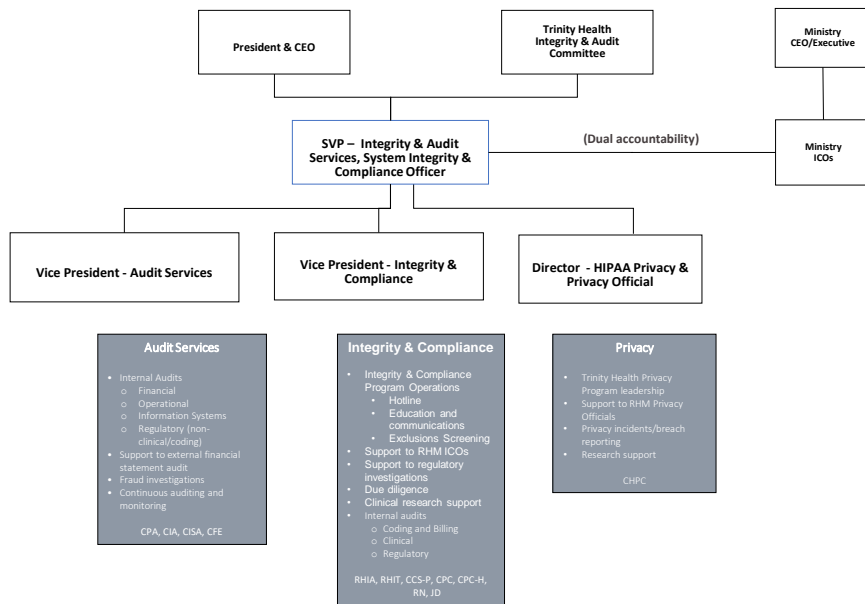
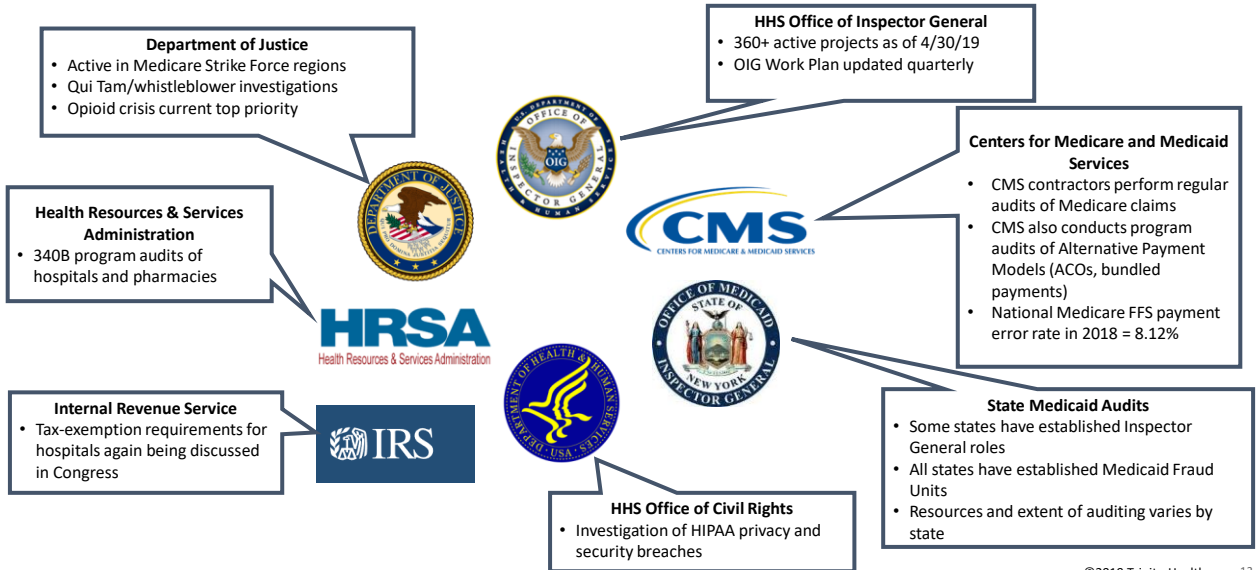**92** Hospitals* in 22 states   **18** Clinically Integrated Networks   **13** PACE Center Locations   **106** Continuing Care Locations

*Owned, managed or in JOAs or JVs.

©2019 Trinity Health   11

11

Integrity & Audit Services Leaders

| President & CEO | | Trinity Health Integrity & Audit Committee | | Ministry CEO/Executive |

SVP – Integrity & Audit Services, System Integrity & Compliance Officer

(Dual accountability)   Ministry ICOs

- Vice President - Audit Services
- Vice President - Integrity & Compliance
- Director - HIPAA Privacy & Privacy Official

Audit Services
- Internal Audits
  - Financial
  - Operational
  - Information Systems
  - Regulatory (non-clinical/coding)
- Support to external financial statement audit
- Fraud investigations
- Continuous auditing and monitoring

CPA, CIA, CISA, CFE

Integrity & Compliance
- Integrity & Compliance Program Operations
  - Hotline
  - Education and communications
  - Exclusions Screening
- Support to RHM ICOs
- Support to regulatory investigations
- Due diligence
- Clinical research support
- Internal audits
  - Coding and Billing
  - Clinical
  - Regulatory

RHIA, RHIT, CCS-P, CPC, CPC-H, RN, JD

Privacy
- Trinity Health Privacy Program leadership
- Support to RHM Privacy Officials
- Privacy incidents/breach reporting
- Research support

CHPC

12

12

Our risk assessment considers audit and enforcement priorities of health care industry regulators

Department of Justice
- Active in Medicare Strike Force regions
- Qui Tam/whistleblower investigations
- Opioid crisis current top priority

HHS Office of Inspector General
- 360+ active projects as of 4/30/19
- OIG Work Plan updated quarterly

Health Resources & Services Administration
- 340B program audits of hospitals and pharmacies

Centers for Medicare and Medicaid Services
- CMS contractors perform regular audits of Medicare claims
- CMS also conducts program audits of Alternative Payment Models (ACOs, bundled payments)
- National Medicare FFS payment error rate in 2018 = 8.12%

Internal Revenue Service
- Tax-exemption requirements for hospitals again being discussed in Congress

State Medicaid Audits
- Some states have established Inspector General roles
- All states have established Medicaid Fraud Units
- Resources and extent of auditing varies by state

HHS Office of Civil Rights
- Investigation of HIPAA privacy and security breaches

©2019 Trinity Health   13

13

Trinity Health – planning and data gathering

- Initial Risk Assessment and Surveys process
  - Electronic Surveys
  - Compliance risk assessment tool
- Risk Assessment and Planning Meetings (Who, When, Where)
- Topics to discuss
  - Strategic initiatives
  - Significant System Implementations
  - Regulatory Compliance Matters
  - Market Pressures and Competition
  - Other Priorities

14

Top Survey Questions

* Please rank what you consider to be the top 3 risks, 1 being the highest risk, out of the risks listed below.
On the next page, you will be asked to provide comments explaining why you have chosen these risks.

	1	2	3
Cyber Security	◯	◯	◯
System Implementations	◯	◯	◯
IT Application Security	◯	◯	◯
Physician Financial Relationships	◯	◯	◯
Mergers and Acquisitions	◯	◯	◯
Physician Network Finances / Operations	◯	◯	◯
Significant Accounting Estimates	◯	◯	◯
Regulatory Compliance	◯	◯	◯
Pharmacy Controlled Substances	◯	◯	◯
Risk Contracting Models	◯	◯	◯
Health Plan Finances / Operations	◯	◯	◯
Clinical Informatics Quality Measures and Reporting	◯	◯	◯
Wage and Hour / Labor Relations	◯	◯	◯
Other (1)	◯	◯	◯
Other (2)	◯	◯	◯
Other (3)	◯	◯	◯

15

15

Top Survey Questions

Do you have any compliance risks with specific operating areas or process in your RHM?
◯ No
◯ Yes (please explain)

Over the past 12 months, have there been key management or significant staff turnover in key departments critical to compliance / operational / finance activities (e.g. PFS, HIM, Patient Access, Case Management, Clinical Documentation, Finance)?
◯ No
◯ Yes (please explain)

Are there significant new programs, service lines changes, or Ministry initiatives planned for the coming year?
◯ No
◯ Yes (please explain)

Are there any recent or anticipated changes in regulatory requirements at the local, state or national level that you expect will have a significant impact on your Ministry?
◯ No
◯ Yes (please explain)

16

16

Top Survey Questions

During the past 12 months, have any regulatory agencies such as CMS (e.g., MAC, RAC, ZPIC), DHHS-OIG, Medicaid, state attorneys general, IRS or HRSA conducted audits / investigations / reviews resulting in significant findings?

○ No

○ Yes (please explain)

With the increased focus on payment for quality and performance outcomes, are there specific compliance / operational / financial risks you think your Ministry / Trinity Health should focus on in the next 12 months?

○ No

○ Yes (please explain)

Are there specific areas or processes you would like Integrity & Audit Services to review in FY18?

○ No

○ Yes (please explain)

17

17

Top Survey Questions

* If applicable, please select the primary **clinical / operational** role that applies to you. Selecting one or more of these roles will direct you to detailed operational and compliance questions for the area.

○ Home Care / DME

○ Hospital (Operations / HIM / Billing / Revenue)

○ Inpatient Rehabilitation Facility

○ Physician Network

○ Skilled Nursing Facility

○ N/A

18

18

Risk Assessment Tool

Accountable Care Organizations (ACO)

Medicare Durable Medical Equipment and Supplies Risk Areas (DMEPOS)

Hospital Inpatient Services

Program for All-Inclusive Care for the Elderly (PACE)

Compliance Program Risk Areas

Hospital Outpatient Services & Ambulatory Surgical Centers

Part C Medicare Advantage Plans

Research

Part D Prescription Drug Program

Skilled Nursing Facility Risk Areas

Other Hospital Compliance Risk Areas

Privacy and Security Risk Areas

Inpatient Rehabilitation Facility Risk Areas

Ambulance/Transportation Areas

Home Health / Community-Based Care Risk Areas

Physician and Other Professional Service Providers Risk Areas
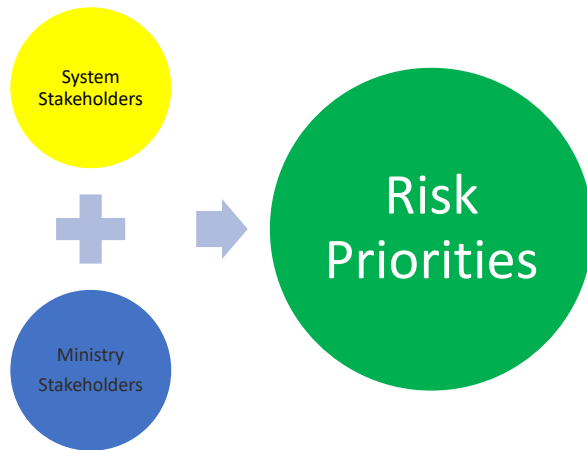
Hospice Risk Areas

Long-Term Care Hospitals (LTCH aka LTAC)

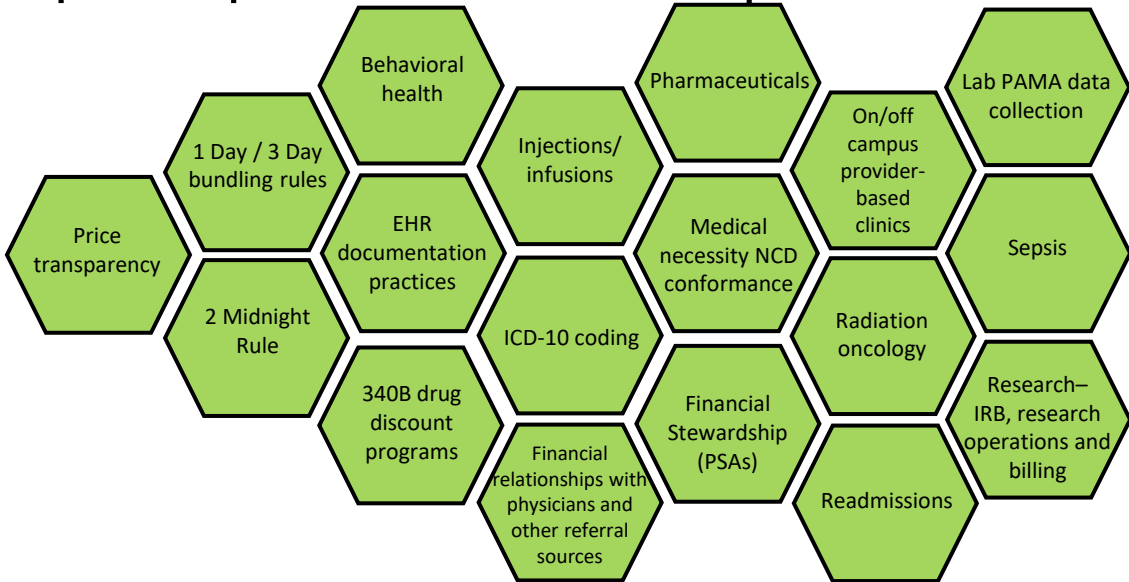| Risk Assessment = The probability (or the likelihood of an occurrence) and the impact (or the effect of an occurrence). Probability + Impact = Risk Assessment:		
High + High = High Risk	Moderate + High = High Risk	Low + High = Moderate Risk
High + Moderate = High Risk	Moderate + Moderate = Moderate Risk	Low + High = Moderate Risk
High + Low = Moderate Risk	Moderate + Low = Moderate Risk	Low + Low = Low Risk

19

19

Top Down Bottom Up Risk Assessment Process

- Finance
- Human Resources
- Legal
- Operations
- Physician Network Services
- Population Health
- Revenue Excellence
- Supply Chain Management
- Treasury
- Trinity Information Services
- Unified Clinical Organization
- External Auditors

- Integrity & Compliance Officers
- Ministry Compliance Committees
- Ministry Management and Leadership

System Stakeholders

Ministry Stakeholders

Risk Priorities

The risk assessment process is inherently subjective – not all stakeholders will necessarily agree on the identity and priority of risks
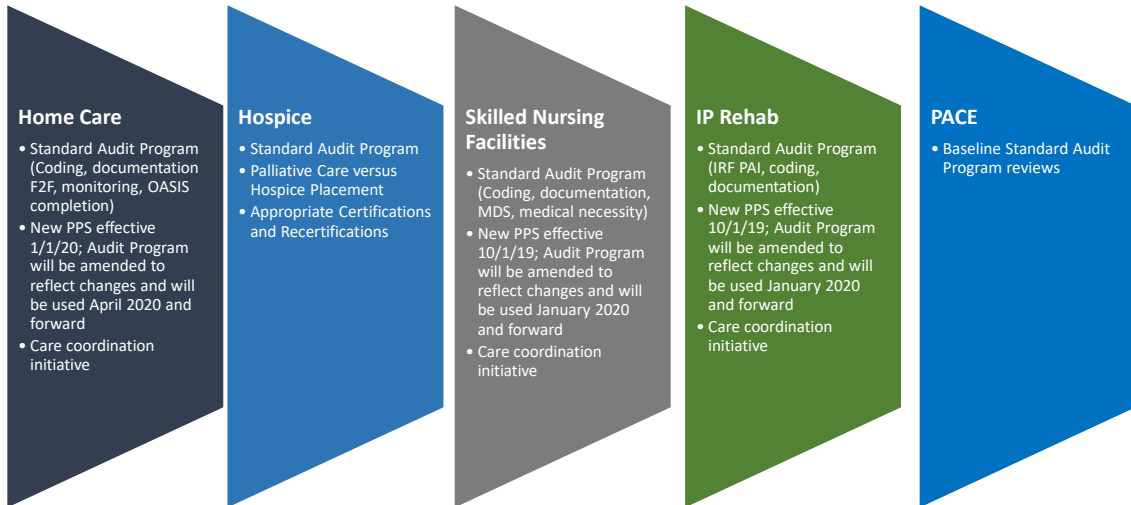
20

Top Compliance Risks – Hospitals

Behavioral health

1 Day / 3 Day bundling rules

Injections/ infusions

Pharmaceuticals

On/off campus provider-based clinics

Lab PAMA data collection

Price transparency

EHR documentation practices

Medical necessity NCD conformance

Sepsis

2 Midnight Rule

ICD-10 coding

Radiation oncology

340B drug discount programs

Financial relationships with physicians and other referral sources

Financial Stewardship (PSAs)

Research– IRB, research operations and billing

Readmissions

©2020 Trinity Health   21

21

Top Compliance Risks – Medical Groups and Provider Services

Diagnosis coding/ HCCs/ risk adjustment

Provider based "Creative Care" clinics

Highly productive providers

Advance Practice Providers

E/M services-documentation, coding

Prescribing practices for controlled substances

Telehealth/ Telemedicine

Transitional Care Management

EHR documentation practices

Annual Wellness Visits

Financial relationships with physicians and other referral sources

Chronic Care Management

©2020 Trinity Health   22

22

Top Compliance Risks – Continuing Care Services

Home Care
- Standard Audit Program (Coding, documentation F2F, monitoring, OASIS completion)
- New PPS effective 1/1/20; Audit Program will be amended to reflect changes and will be used April 2020 and forward
- Care coordination initiative

Hospice
- Standard Audit Program
- Palliative Care versus Hospice Placement
- Appropriate Certifications and Recertifications

Skilled Nursing Facilities
- Standard Audit Program (Coding, documentation, MDS, medical necessity)
- New PPS effective 10/1/19; Audit Program will be amended to reflect changes and will be used January 2020 and forward
- Care coordination initiative

IP Rehab
- Standard Audit Program (IRF PAI, coding, documentation)
- New PPS effective 10/1/19; Audit Program will be amended to reflect changes and will be used January 2020 and forward
- Care coordination initiative

PACE
- Baseline Standard Audit Program reviews

©2020 Trinity Health   23

23

Flexibility in Risk Assessment Process

24

Flexibility in Risk Assessment and Work Plan

- Trinity Health fiscal year is from July 1 – June 30, risk planning starts in January prior to fiscal year (6 months before new fiscal year)
- Work plan is developed for the whole year
- Work plan audits and activities are evaluated on a continuous basis
  - Ask the question, does this project still makes sense today
  - Make adjustments based on new information
- OIG updates work plan on a monthly basis to capture emerging risks
- Targeted Probe & Education (TPE)
- OIG/MAC/State audits   **Develop tracking tool**
- Monthly Integrity & Compliance officers meeting
- Current auditing results

25

25

Trinity Health's work plan development process – ongoing auditing and monitoring based off of Risk Assessment

26

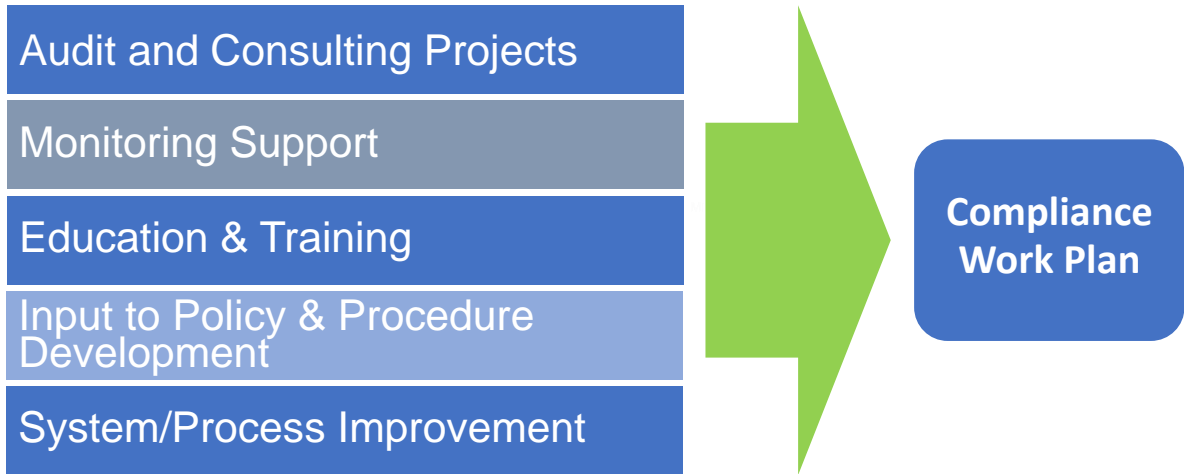# Trinity Health – Auditing and Monitoring
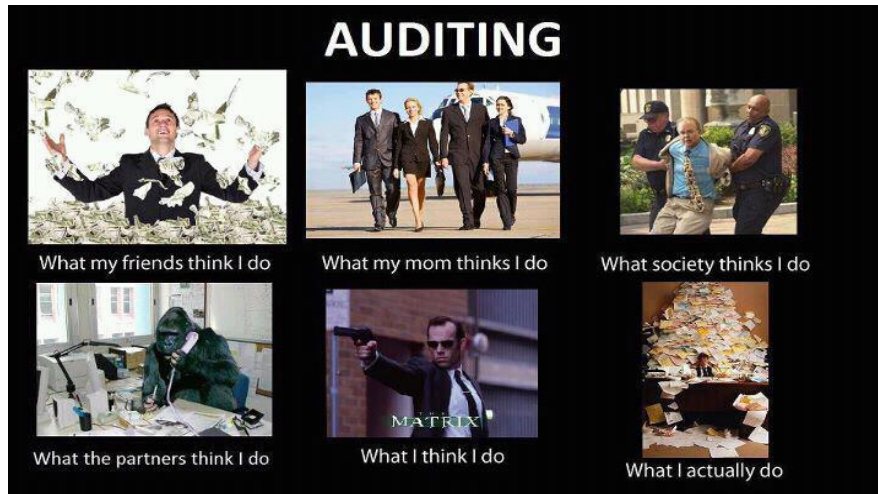
27

Trinity Health - developing the compliance work plan

- Now what?????
  - What do you do with all of this data and information
  - Need to balance resources and experience compared with the different risks identified
  - No right or wrong way (high level analysis, heat maps, matrixes, etc.)
- Trinity Health System office compliance work plan
  - Projects performed using System level resources to support local compliance program
- Hospital Compliance Officer internal work plan
  - Use of local resources to support the local compliance program

28

Trinity Health – identified risks addressed on the work plan

| Audit and Consulting Projects |
| Monitoring Support |
| Education & Training |
| Input to Policy & Procedure Development |
| System/Process Improvement |

Compliance Work Plan

29

Developing the compliance work plan – the basics

- Purpose of the work plan is to address key risks identified in compliance risk assessment process through risk mitigation activities
- Consider available resources and risk appetite of organization
- Typical activities – audits, monitoring, education and training, policies and procedures, technology implementation, etc.
- Typical format
  - Description of risk
  - Controls present
  - Accountable stakeholder
  - Description of risk mitigation activity
  - Timeline for completion
  - Categorized by business unit and line
- Work plan should be reviewed and approved by board and senior management
- Work plan should be communicated to key stakeholders

what's the plan?

30

Trinity Health - **examples** of work plan projects

Project Description	Objective/Scope
Home Care Services	Evaluate compliance with Medicare home health regulations, focusing on recent changes to OASIS assessments, physician face-to-face visit requirements, and the Medicare prospective payment system (PPS) for home care.
Hospital Services: Inpatient and Outpatient Review	Assess documentation quality, ICD-10-CM and ICD-10-PCS coding accuracy, query composition and overall compliance with Medicare/Medicaid and other third-party payer requirements for a sampling of inpatient and outpatient hospital claims.
Hospital Services: Proper Patient Placement (Two Midnight Rule)	Data analytics will be used to assess compliance with CMS Two Midnight Rule requirements and Company standards for the proper placement of patients in inpatient or outpatient level of care.
Inpatient Rehabilitation Services	Assess documentation, coding and billing for compliance with Medicare Conditions of Participation and payment requirements for inpatient rehabilitation facilities (IRF), with particular focus on recent changes in IRF assessments and reporting.
Professional Services: Compliance Benchmarking and Monitoring	Benchmarking employed providers claims data in comparison to CMS and industry data with focus on areas of compliance risk identified by CMS audit contractors and DHHS-OIG. Results of analyses are used to support continuous compliance monitoring by provider networks.
Professional Services: Physician Practice Review	Assess the adequacy, completeness and timeliness of medical records documentation, usage of provider documentation templates, coding systems, internal controls, charges, and coding in accordance with Medicare and Medicaid requirements for Trinity Health provider networks. Additionally, ICD-10 coding will be evaluated to identify appropriateness of assignment which is aligned with costs and risks associated with Hierarchical Condition Categories (HCC).
Professional Services: Education and Support	Education and training support provided to management and staff working in employed provider networks and clinics, including monthly and annual education programs.

31

Other considerations and tips

- Don't reinvent the wheel - leverage existing materials when possible
- Communication is key – difference between compliance risk assessment and other similar processes, importance, timing, etc.
- Consider developing a work group to lead efforts
- Define scope, e.g. all business lines?
- Risk universe – don't need to identify every conceivable risk out there
  - May be a point of diminishing returns
  - Focus on high risks and material risks
- Use of data

32

Other considerations and tips (continued)

- Risk assessment should be dynamic and tailored to your organization
  - Think of it as a living document
- Consider efficiency – the mitigation activities that will provide the most benefit
- Important to document your efforts and processes
- Multi-state health systems need to consider state law
  - Local and regional compliance personnel are essential in this process
- Know when to engage external experts
- Leverage data when possible to identify risks

33

Other considerations and tips (continued)

- Track changes to risk ratings over time – can provide useful insights
- Consider implementing new technologies – reputation monitoring tools, social media data, surveys, risk mapping tools, etc.
- Don't let the process become just a routine exercise – a good process can add tremendous value to the compliance program and the organization

HELPFUL TIPS

34

✉ Questions

Andrea Merritt
amerritt@athenacompliance.org

Andrei Costantino
costanta@trinity-health.org

35