Compliance Program Development: What Are the Basics From Infrastructure to Risk Assessment?

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What is a Compliance Program and Why are they Important?

What is a Compliance Program?
- Utilizes tools to prevent and/or detect violations of law or policy
- Defines expectation for employees for ethical and proper behaviors
- Demonstrates the organization's commitment to "doing the right thing"
- Encourages problems to be reported
- Provides a mechanism for constant monitoring

Why are Compliance Programs important?
- Promotes a Culture of trust and credibility
- Promotes management accountability
- Increases awareness throughout the organization

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Five Practical Tips for Creating A Culture of Compliance*

- Make compliance plans a priority NOW.
- Know your fraud and abuse risk areas.
- Manage your financial relationships.
- Just because your competitor is doing something doesn't mean you can or should.
- When in doubt, ask for help.

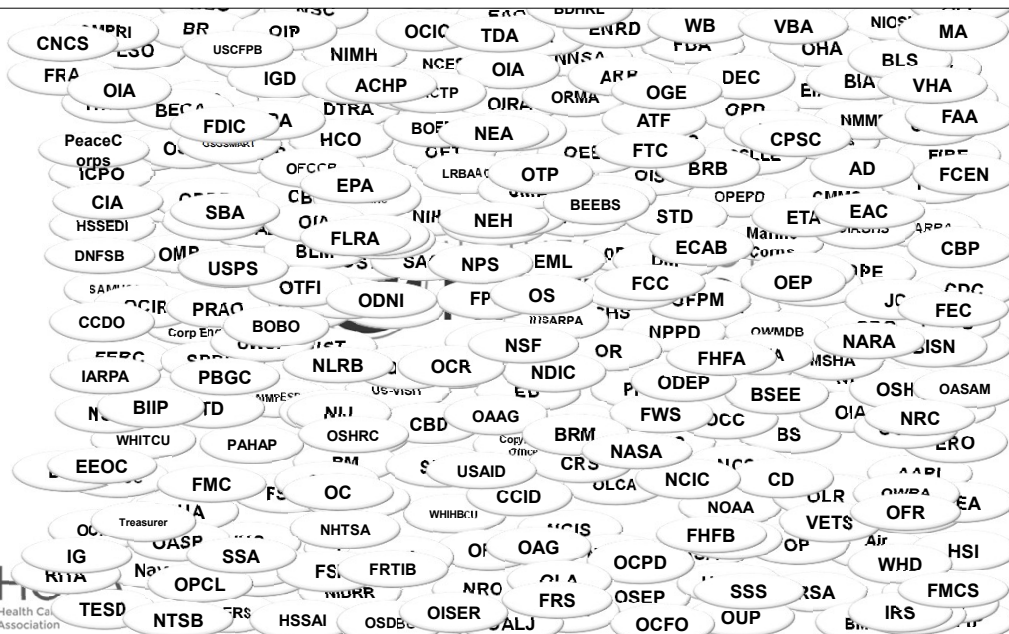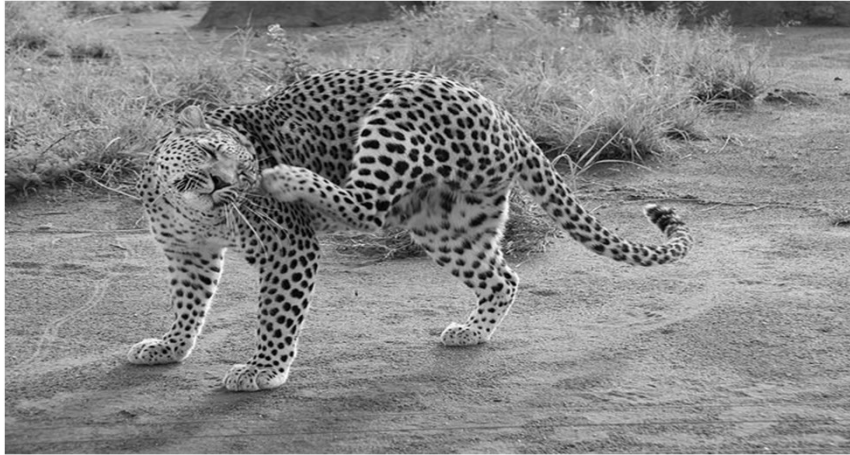*Health Care Fraud Prevention and Enforcement Action Team (HEAT) OIG

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Example of Relevant Regulatory Bodies for Compliance Matters- Comprehensive Program

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DON'T START FROM SCRATCH

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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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OIG – Practical Guidance for Health Care Governing Boards on Compliance Oversight - 2015

"A Critical element of a effective oversight is the process of asking the right questions…."

OIG – Measuring Compliance Program Effectiveness: A Resource Guide - 2017

Provides ideas on elements of effectiveness and how to measure

Other Resources

- Compliance 101
- The Health Care Compliance Professional's Manual with Quarterly Updates
- The HCCA HIPAA Training Handbook, third edition
- Health Care Auditing and Monitoring Tools
- Compliance and Ethics: An Introduction for Health Care Professionals
- 501 Ideas for Your Compliance and Ethics Program: Lessons from 30 years of practice
- Internet

Many others….

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Untied 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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2004 and 2010: FSG Amendments

- 2004- Corporate Responsibility and Transparency
- 2010- Gave insight into what an effective compliance program should look like

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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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Seven Elements of an Effective Compliance Program (paraphrased)

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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Code, 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, annual attestations
  - Post prominently – posters and/or intranet
  - Consider putting code in other languages
- Policies and Procedures (Compliance does not own all policies)
  - Assure that you are not writing policies that should be in the management arena
  - Follow institutional template, periodically review and revise
  - Responsible party is defined.
  - Education is provided to all affected staff

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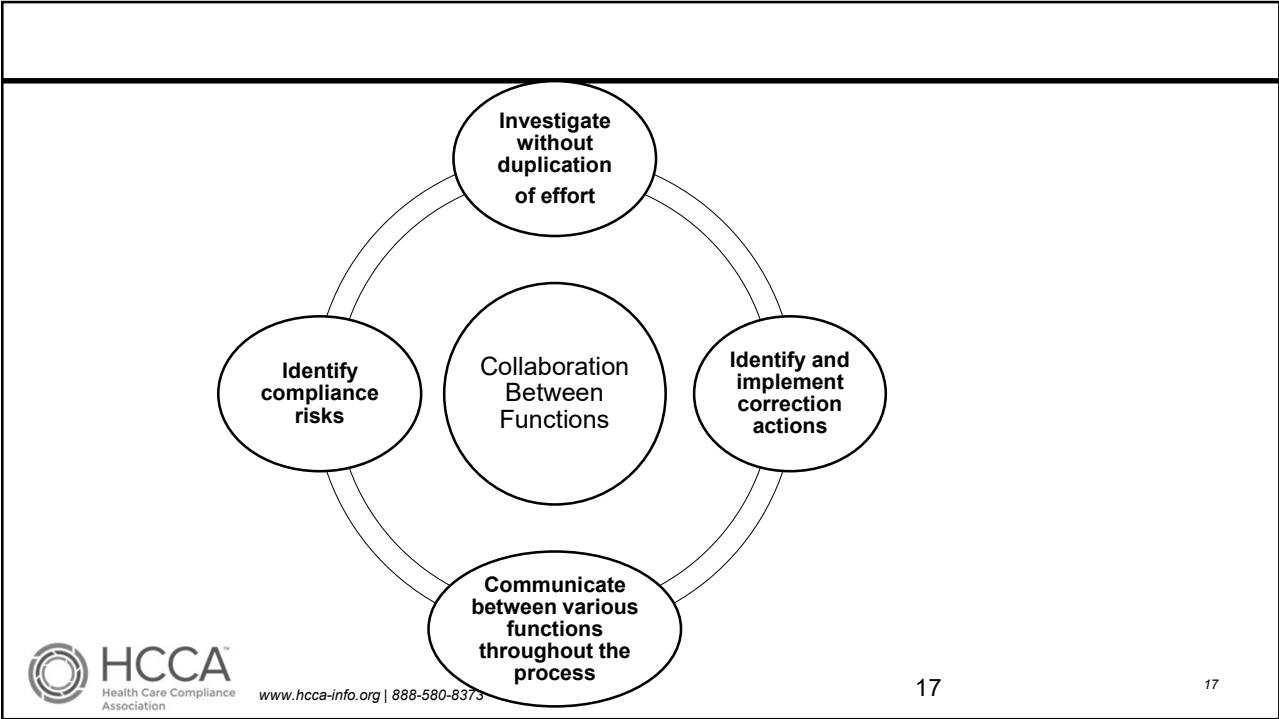## OIG: Practical Guidance for Health Care Governing Boards on Compliance

- **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.
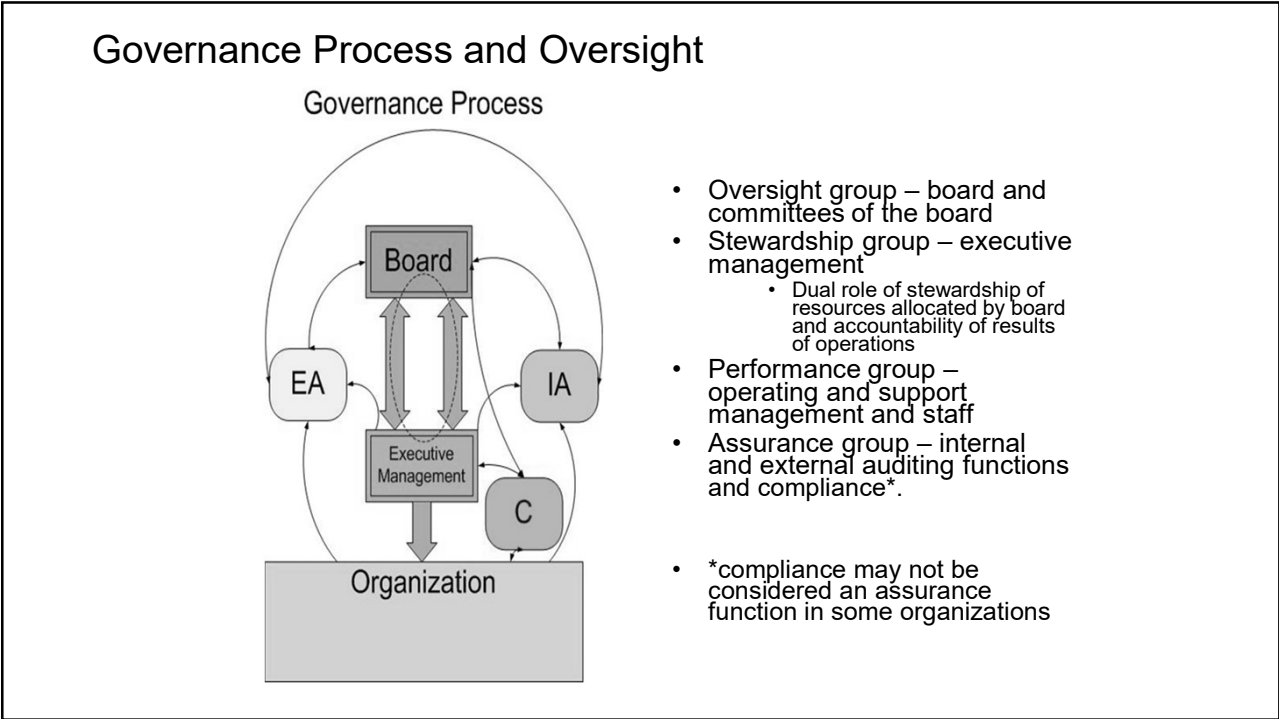
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Governance Process and Oversight

Governance Process

- Oversight group – board and committees of the board
- Stewardship group – executive management
  - Dual role of stewardship of resources allocated by board and accountability of results of operations
- Performance group – operating and support management and staff
- Assurance group – internal and external auditing functions and compliance*.

- *compliance may not be considered an assurance function in some organizations

Education and Training

- Role of Compliance Officer in developing
- 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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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
- Confidentiality and Anonymity
- Non-retaliation policy
- Caller knows how to receive updates and information related to their matter
- Tracking of investigations and results

- 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

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Reporting and Investigation (cont)

- Investigators should be trained in procedures related to interviews, objective methodologies and forensics, where applicable
- Investigations are confidential
- Reporting to leadership
- Use of performance reviews and exit interviews for identifying potential areas of concern

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Response and Prevention

- Root Cause Analysis
- MANAGEMENT CREATES Corrective Action Plans and COMPLIANCE audits and monitors to assure that the action plan mitigated the risk
- Prevention
  - Ongoing Monitoring
  - Training
  - Revision of controls to mitigate risk, ie: revise policies and procedures
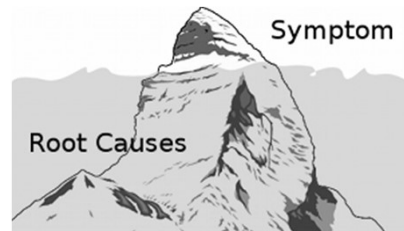
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Enforcement and Discipline

- 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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Once Infrastructure is in Place: 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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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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