
The Role of Compliance in Government Enforcement

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Presented by:

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Shannon manages PYA's Compliance Advisory Services and serves as the Firm's Compliance Officer. A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due-diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

Agenda

- Government perspectives on corporate enforcement
- Overview of Deferred Prosecution Agreements (DPAs), Non-Prosecution Agreements (NPAs), and Corporate Integrity Agreements (CIAs)
- What can we learn from DPAs and CIAs regarding compliance programs?
- Wrap-up/key takeaways

Government Perspectives on Corporate Enforcement



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Recent Developments in Compliance

- The last two years have witnessed several notable developments in corporate enforcement
 - “Granston Memo”
 - Provides defense counsel and relators’ counsel guidance on which cases are candidates for a government motion to dismiss and a basis to argue that the government should (or should not) move to dismiss meritless claims over a relators’ objection
 - “Brand Memo”
 - Makes clear that guidance documents “lack the force of the law,” and emphasizes that DOJ lawyers should not treat them as though they are mandatory

Recent Developments in Compliance (cont.)

- Increased Coordination
 - May 2018 Memorandum discouraging “piling on”
 - So-called “piling on” occurs when one agency starts an investigation, and other agencies join in to seek punishment for the same alleged misconduct
 - July 2018 Establishment of the Working Group on Corporate Enforcement and Accountability
 - President Trump issued an Executive Order establishing a new Working Group on Corporate Enforcement and Accountability to promote consistency in white collar efforts

Moving Toward Greater Individual Accountability & Corporate Compliance

- The Justice Department’s interest in improving its “relationships with good corporate citizens” and incentivizing increased corporate compliance
 - Former DAG Rosenstein:
 - High corporate fines “do not necessarily directly deter individual wrongdoers,” because “at the level of each individual decision-maker, the deterrent effect of a potential corporate penalty is muted and diffused,” hence continued emphasis on enforcement against individual wrongdoers
 - “[M]any companies deserve great credit for taking the initiative to develop truly robust corporate compliance programs”
 - “Compliance programs promote” the Justice Department’s primary goal of deterring wrongdoing and encouraging prompt disclosure of violations to enforcement authorities.

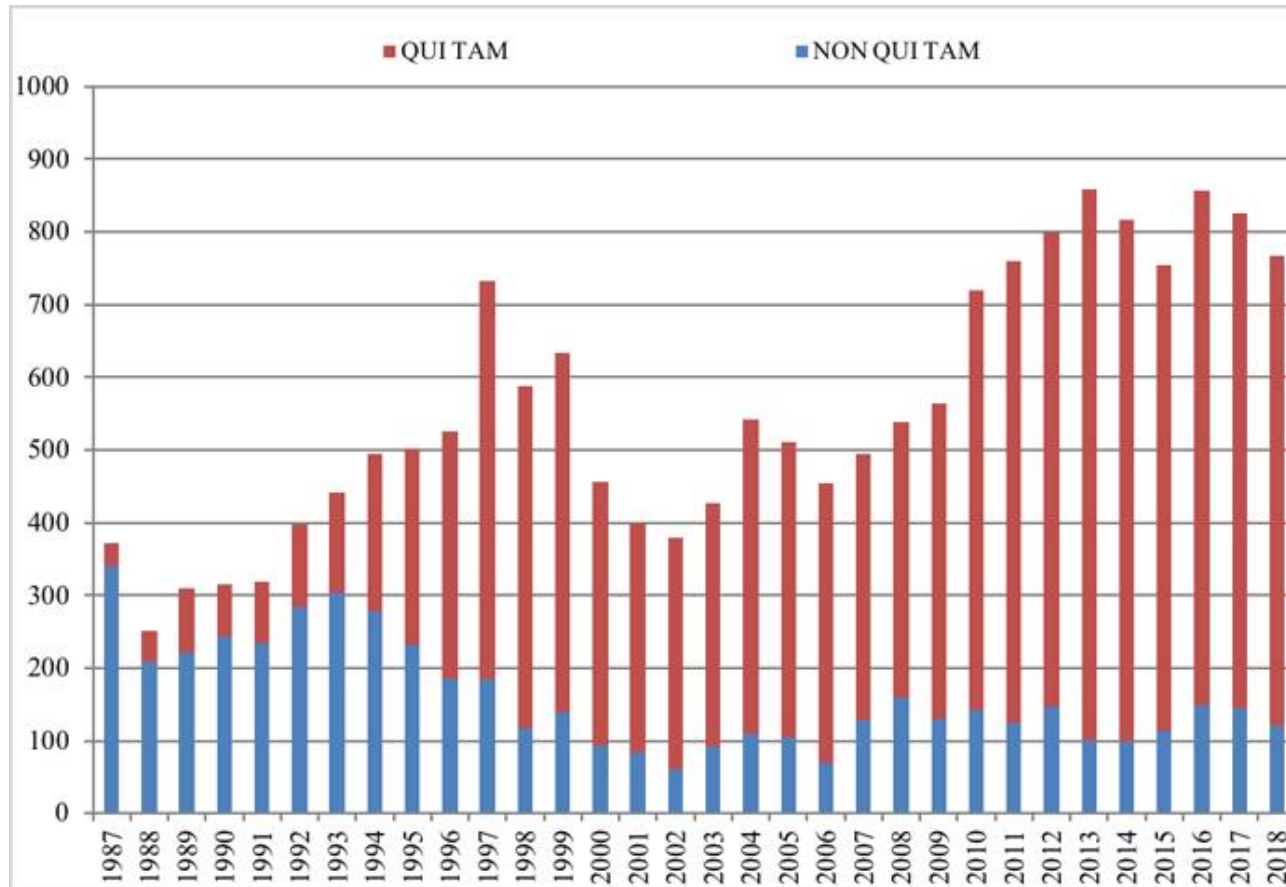
Moving Toward Greater Individual Accountability & Corporate Compliance (cont.)

- Past Deputy AG's have made similar observations:
 - Corporate enforcement should “incentivize corporations to establish effective compliance programs.”
 - Government should “make certain that responsible corporate citizenship is encouraged and rewarded.”

Aggressive Enforcement

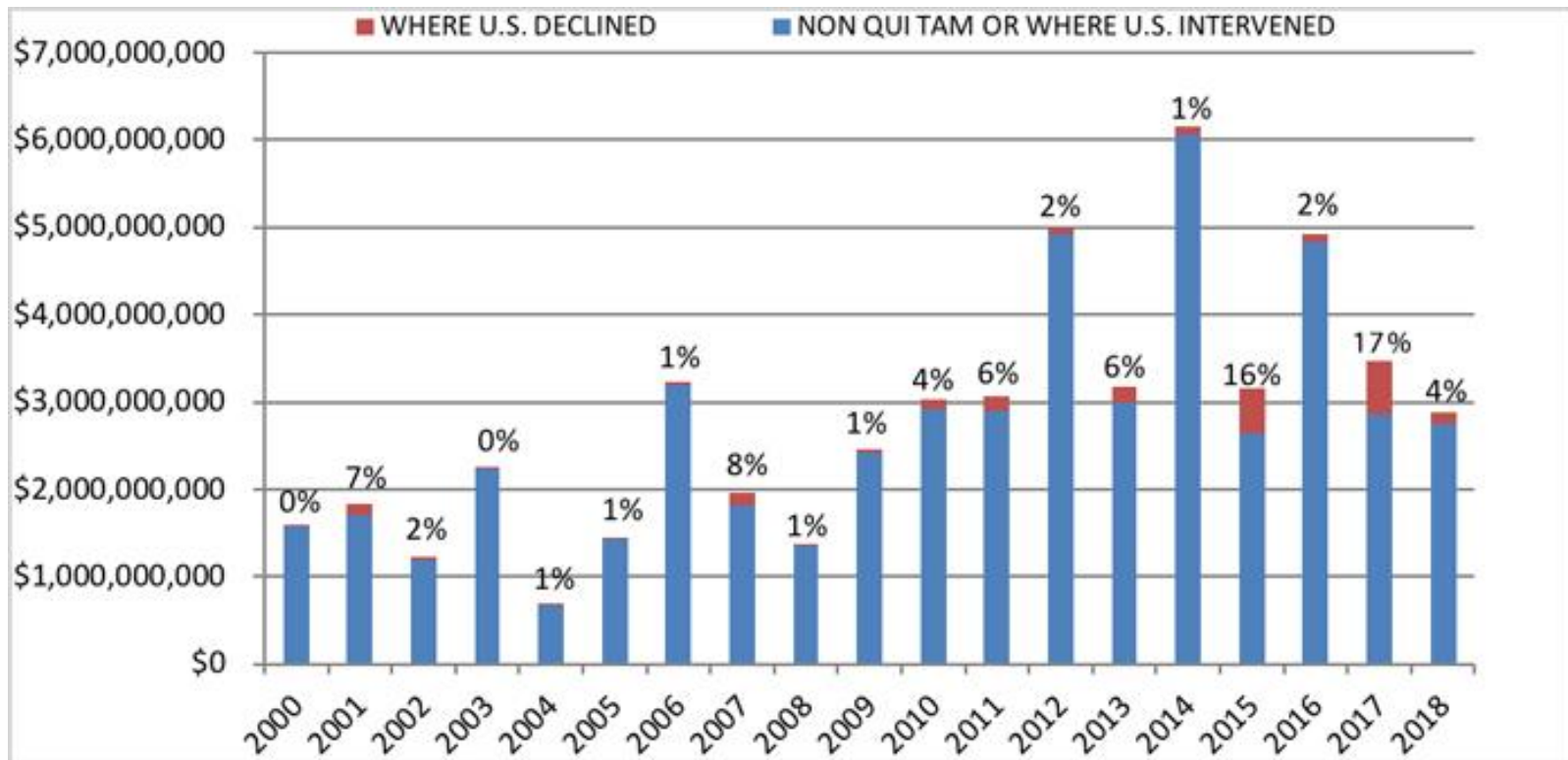
- **Increasing Focus on Enforcement Against Responsible Individual Wrongdoers**
 - In a single announcement in July 2017 the Justice Department announced charges against 412 individuals in 41 districts involving \$1.3 billion in alleged false billing. Charges included medically unnecessary treatments, treatments never provided, and kickbacks.
 - More recently, the Justice Department announced charges against 601 individuals in 58 districts involving over \$2 billion in alleged fraudulent billing schemes, kickbacks, and opioid distribution.

Number of New FCA Actions



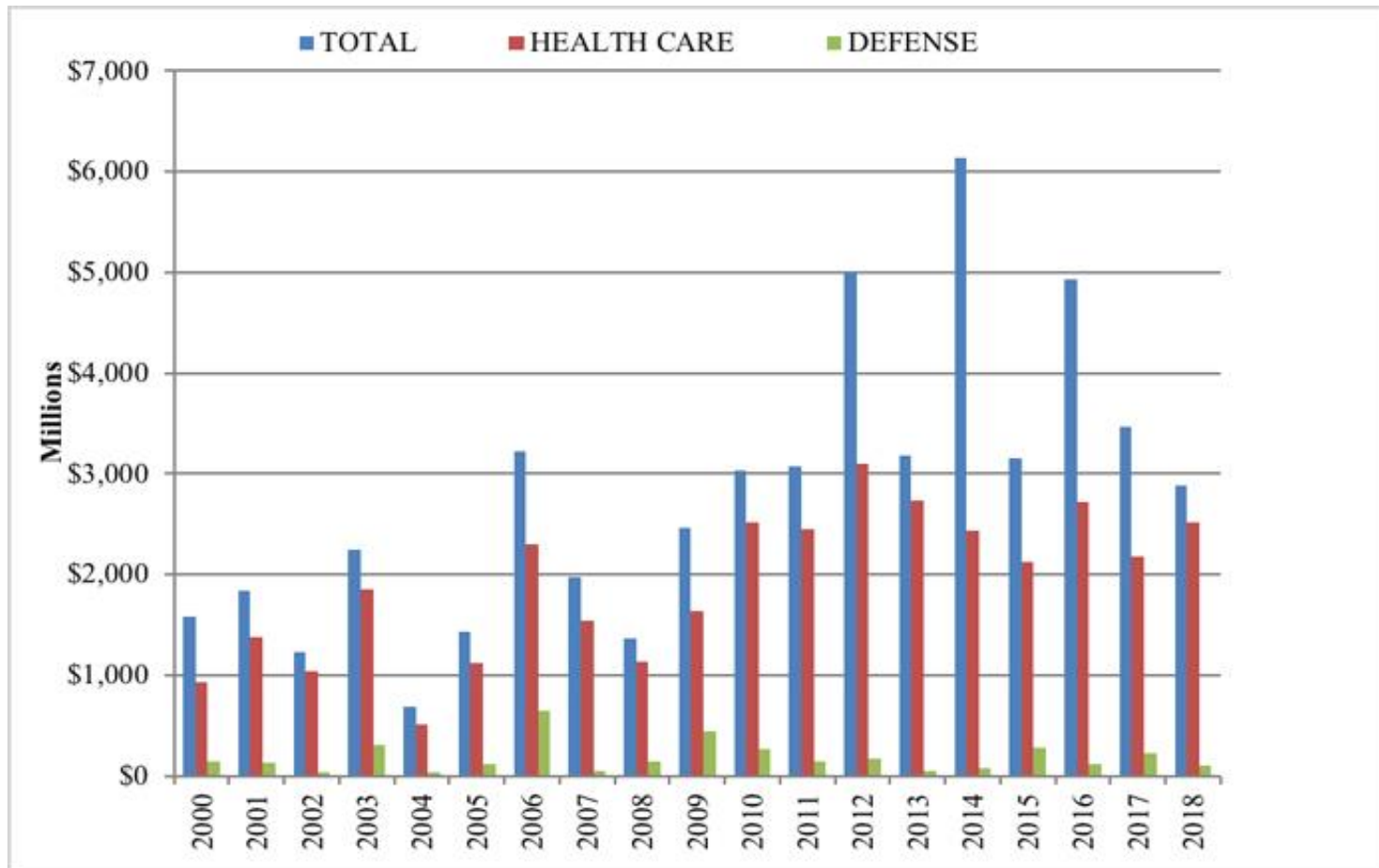
Source: DOJ "Fraud Statistics – Overview" (December 21, 2018)

- Settlement or Judgments where Government Declined Intervention as a Percentage of Total FCA Recoveries



Source: DOJ "Fraud Statistics – Overview" (December 21, 2018)

- Settlement or Judgment Recoveries by Industry



Source: DOJ "Fraud Statistics – Overview" (December 21, 2018)

Overview of DPAs, NPAs, and CIAs



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Definition of a Deferred Prosecution Agreement

- A DPA is a type of voluntary, pre-trial agreement used to resolve investigations into corporate misconduct without a guilty plea by the corporation.
- The agreement is between the company and the government, and it is designed to avoid the penalties of conviction.
- The government agrees to defer – and ultimately forego – prosecution of the matter pending the company’s complying with the requirements of the DPA during a specified term.
- A DPA is formally filed with a court along with charging documents.

Definition of a Non-Prosecution Agreement

- Like the DPA, an NPA is a voluntary pre-trial agreement used to resolve investigations into corporate misconduct.
- An NPA is not formally filed with a court.
- For this reason, NPAs are viewed as more favorable to the corporation than DPAs.



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Key Provisions of DPAs & NPAs

- Key provisions of DPAs & NPAs typically include:
 - Acceptance of responsibility
 - Statement of facts, which outlines the alleged misconduct
 - Prohibition against public statements contradicting the acceptance of responsibility
 - Requirement to cooperate in government investigations
 - Requirement to self-report evidence or allegations of certain misconduct
 - Appointment and terms for a corporate monitor

Factors Government Considers

- In deciding whether to impose a DPA or NPA, prosecutors consider several factors, including:
 - The underlying misconduct
 - The root cause of that misconduct
 - The company's prior history
 - Remediation efforts taken by the company
 - Cooperation with the investigation
 - The strength of the company's compliance program

Strong Compliance Programs Are Essential

- Companies with strong compliance programs should be treated better than those with a weak compliance commitment.
- In evaluating the corporate compliance program, the government focuses on factors such as:
 - Compliance autonomy
 - Compliance resources
 - Oversight
 - The strength of compliance policies and procedures
 - Compliance controls
 - Training
 - Audits and risk assessments
 - Compliance incentives
 - Confidential reporting and investigations
 - Disciplinary measures
 - Compliance testing

Monitorships

- Monitorships are sometimes required as an aspect of an NPA, DPA or other consensual resolution.
- **Selection**
 - Monitors may be compliance experts, former prosecutors, or other individuals trusted by both sides to help the company avoid repeat violations.
 - Typically, the government and company will jointly select the monitor:
 - Company offers a slate of monitors
 - Government accepts one or asks for additional options before accepting a nominee

Monitorships (cont.)

■ Purpose

- Monitorships offer the opportunity to improve a company's compliance systems and ethical culture, reducing the risk of recidivism and improving relationships with regulators and law enforcement officials.



Image Source: Rawpixels for Pixabay: piixabay.com

Monitor Duties

- The monitor has several responsibilities, including overseeing, reviewing, and proposing modification of a company's compliance program.
 - In furtherance of those goals, monitors:
 - Review policies
 - Test system controls
 - Assess compliance risks
- **Periodic Reports**
 - The monitor provides periodic reports of its findings and recommendations to the government and the company, which make recommendations for improvements to corporate compliance.

Certification

- The monitor's investigations and assessments all lead to what could be the most important aspect of a monitorship: certification.
 - The terms of certification vary from case to case.
 - For example, some negotiated resolutions require the monitor to certify effectiveness of the compliance program related to the specific alleged misconduct that gave rise to the agreement, while others require the monitor to certify the effectiveness of the company's program to prevent and detect fraud broadly.
 - Example of certification language: “[T]he Monitor shall certify in a final report whether [the Company’s] compliance program, including its policies and procedures, is reasonably designed and implemented to prevent and detect violations of the [relevant statute].”
- Certification is a condition of non-prosecution.
 - If the monitor cannot complete the certification, the monitorship may be extended.

CIA's

- When are they used?
 - Civil Settlement Agreement
 - Not every settlement results in CIA
- How are they used?
 - Enforcement tool
 - Entity will not be excluded from participation in federal healthcare program
 - Typically five years

CIAs (cont.)

Core Elements (non-negotiable)

Board and Management accountability

Compliance Officer status

Board and Management Certifications

Ineligible persons

Policies and Procedures

Independent Review Organization (IRO) engagement

Reporting provisions

CIAs (cont.)

- Negotiable elements
 - Preamble (past compliance efforts)
 - Monitoring and auditing specific to key risk areas (e.g. one size no longer fits all entities)
 - Scope of IRO engagement

Key Takeaway

Evidence of Board and Management accountability is paramount and a core requirement under these recent CIAs

What Can We Learn From DPAs and CIAs Regarding Compliance Programs?

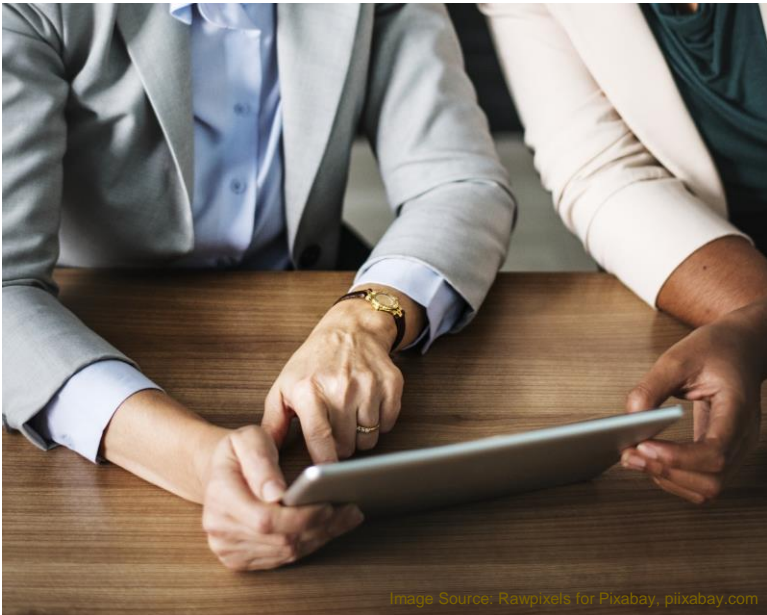


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Parties to CIAs Are Growing

- Hospitals and health systems
- Physician practices
- Long-term care facilities (e.g., SNFs)
- Pharmaceutical companies
- Medical device manufacturers
- DME suppliers
- Ambulance companies
- Laboratories
- Rehab and therapy providers

Key Takeaway

Entities should review recent CIAs applicable to their sector to be informed regarding the government's compliance program expectations. A compliance work plan should be designed to address these areas of exposure.

Definition of “Covered Persons” Expanding

- Employees
- Active medical staff
- Vendors/subcontractors
- “Arrangements” covered persons



Definition of “Covered Persons” Expanding (cont.)

- Essentially, the organization is responsible for actions for anyone “under their control”

Global operations	Subsidiaries or affiliates	Compliance corporate structures and joint ventures
Outsourced functions/departments	Complex supply chains	

Key Takeaway

Boards and management should assess the coverage of their compliance program to identify whether it is comprehensive enough to cover the span of control outlined in recent CIAs

Board Accountability and Mandatory Certifications

“The Board of Directors has made a reasonable inquiry into the operations of Signature’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, Signature has implemented and effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

Board Accountability/Mandatory Certifications (cont.)

- Annual reports to describe Board activity to demonstrate active oversight of compliance
 - Support for compliance officer reporting to Board (minutes, notes, dates)
 - Reports reviewed and actions taken
 - List of policies and procedures
 - Results of risk assessments performed
 - Work plans developed
 - Resources analyzed to address high risk areas
 - Audits performed
 - Corrective action taken
 - Continuous risk assessment process

Management Certifications and Expansion of “Certifying Employees”

“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 NBHD 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 NBHD is in compliance with all 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.”

Management Certifications and Expansion of “Certifying Employees” (cont.)

- Certifying Employees
 - Who and how many can vary depending upon the nature of the CIA
 - Ranges from C-Suite to Line Management and in between!
 - Controller
 - Human Resources
 - VP Philanthropy
 - Division Vice President
 - Chief Strategy Officer
 - Physician Recruiter
 - Education critical regarding roles and responsibilities for compliance

Key Takeaway

Assess the "certifying employees" in your organization to determine whether compliance education is specific enough to address individual accountability with case studies for maximum impact.

General Compliance 101 training is no longer sufficient.

Stature of Compliance Officer and Span of Control

Stature of Compliance Officer

Be independent and
protected from
executive level conflict
of interest



Have appropriate
reporting relationships
with the CEO and the
board



Be positioned as a
member of senior
management



CFO or General Counsel
as compliance officer
can result in conflicts of
interest and generally
frowned upon by the
OIG without appropriate
safeguards in place

Stature of Compliance Officer and Span of Control (cont.)

- Span of control to include additional high-risk areas
 - Information technology and cybersecurity
 - Physician contracting and recruiting
 - Real estate
 - Marketing
 - Procurement and supply chain
 - Quality
 - Joint ventures
 - Outsourced services

Key Takeaway

The compliance program stretches beyond billing and coding. The Compliance Officer should have authority to collaborate with other high-risk areas and departments and be endorsed by management and the Board.

Incentivizing Compliance Through Compensation

- Compliance “modifiers”
 - Adjustments to incentive compensation (up or down)
 - Individual, departmental and entity specific
- Performance appraisal systems
- Inclusion of compliance metrics in balanced scorecards
 - Culture surveys
 - Audit results (internal and external)
 - Specific compliance matters



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Incentivizing Compliance Through Compensation (cont.)

- GlaxoSmithKline (GSK) CIA – Executive Financial Recoupment Program
 - Potential for forfeiture and recoupment of an amount equivalent to up to three years of annual performance pay (annual bonus, plus long-term incentives) for any GSK executive who is discovered to have been involved in any significant misconduct.
 - Applies to all members of GSK’s corporate executive team and to any vice presidents and senior vice presidents who are based in the U.S. who are current GSK employees or former GSK employees at the time of a Recoupment Determination.

Key Takeaway

Assess how your employees are incentivized and whether these incentives align with the compliance culture of the organization.

Code of Conduct 2.0

Ethical
decision
making

Raising and
resolving
ethical issues

Third-party
contract
provisions

Ongoing
training and
case studies

Key Takeaway

Assess the last time your Code of Conduct was revised. Does it require commitment to a culture of compliance and does your training program provide real-life case studies of ethical decision making?

Evolution of Risk Assessments

- Completeness of risk universe
 - Joint ventures, outsourced services, third-party relationships
- Collaboration with “Internal Assurance Providers”
 - Compliance, legal, internal audit, finance, risk management, quality
- Collaboration with “External Assurance Providers”
 - External audit, outside counsel

Key Takeaway

A compliance risk assessment should include risks that result in audit coverage as well as those risks areas that cannot be covered due to resource constraints for the Board to either accept the risk or provide additional resources to address

Evolution of Risk Assessments (cont.)



New Positions, Functions, and Systems

- Arrangements officer
- Grants management system
- Focused arrangements system
 - Central tracking system
 - Written, signed, and approved agreements
 - Activities verified and supported
 - Appropriate remuneration
 - Fair Market Value
 - Commercial reasonableness
 - Conflicts of Interest

Key Takeaway

Assess whether the entity's current contract management system is capable of tracking arrangements as required by recent CIAs. Review expected criteria during vendor selection process if selecting a new contract management system.

Independent Experts



- Independent Review Organization
- Compliance “expert”
- Monitor
- Governance member with compliance expertise

Key Takeaway

Enlist the assistance of a compliance expert periodically to conduct an independent effectiveness assessment of your compliance program

Compliance Program Effectiveness

- Beyond the “7 Elements”
- Action plan follow-up is critical
- Independent assessment



Focused Education in High-Risk Areas by Experts

- Anti-Kickback, Stark, and FCA
- Employees and third parties
- Requirement in CIA regarding supervision of work
- Risk assessment should inform those to receive training

Providers (employed and medical staff)	Marketing
Case Managers	Physician Recruitment
Research	Medical Education Grants
Supply Chain/Procurement	Real Estate

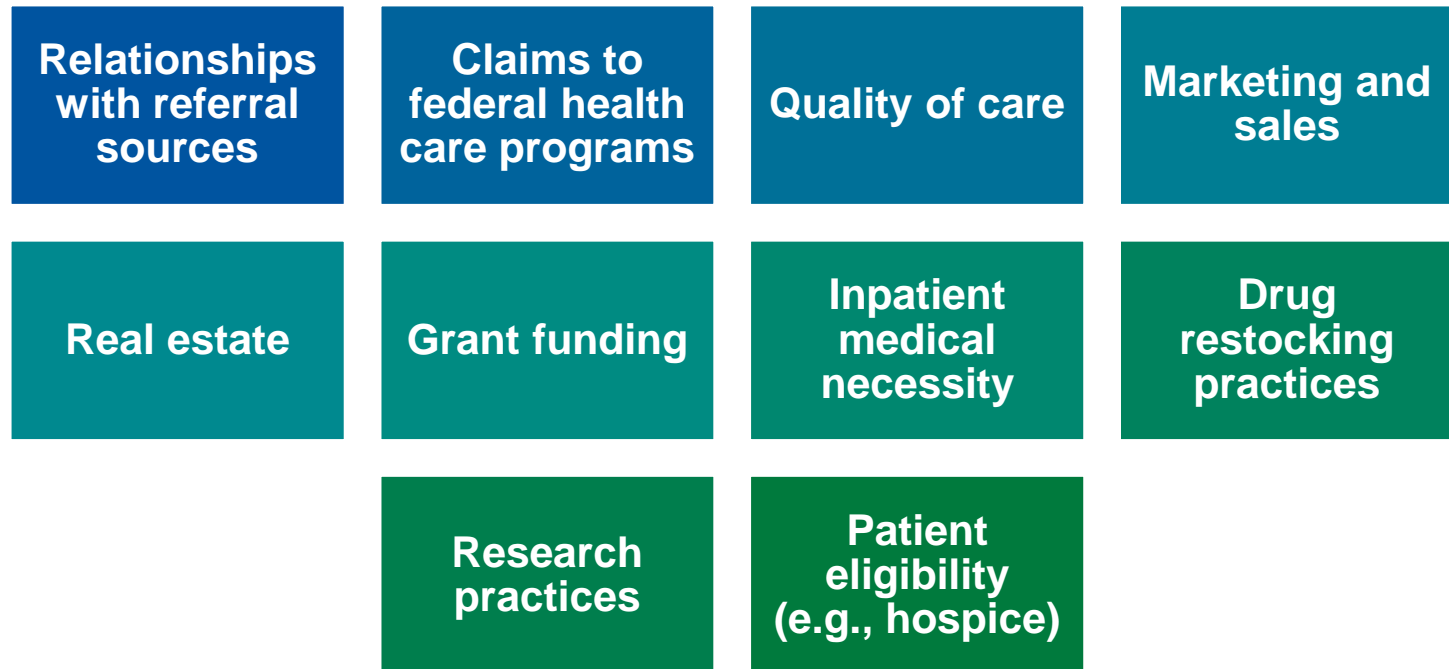
Measuring Behavioral Change

- Completeness of training no longer enough
- Did the education result in a behavioral change
- How do you measure?



Emphasis on Auditing and Monitoring of Control Environment in High Risk Areas

- Systems review, arrangements review, eligibility review, and claims review



Wrap Up

Key Takeaways

- | | |
|---------------------------------------|---|
| ➤ Board and Management Accountability | ➤ Assess Compliance Incentives |
| ➤ Review of Recent CIAs | ➤ Review Code of Conduct |
| ➤ Assess Compliance Program Coverage | ➤ Breadth of Compliance Risk Assessments |
| ➤ Assess Training Programs | ➤ Assess Current Contract Management System |
| ➤ Compliance Officer Span of Control | ➤ Compliance Program Independent Effectiveness Assessment |

Questions?



Thank You!

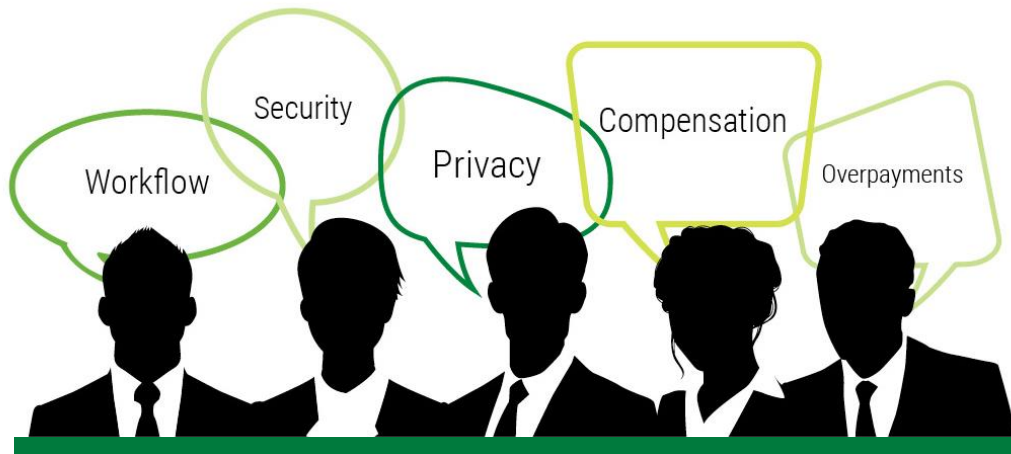


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Let's Talk Compliance



One-Day Compliance Master Class

Orlando, Florida

September 6, 2019

10:00 am – 3:00 pm

No charge to attend
Lunch provided
CPE, CLE, CHC credits

Watch your inbox for
registration info!

Co-presented by

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FOLEY & LARDNER LLP

