

## The Role of Compliance in Government Enforcement

---

Presented by:

**Tamara Forys – Deputy Branch Chief, OIG/OCIG**

**David Ogden – Partner, Wilmer Cutler Pickering Hale and Dorr, LLP**

**Shannon Sumner, CPA, CHC – Principal, PYA, P.C.**

*Slides authored by:  
David Ogden and Shannon Sumner*



0

## Speaker Introduction

---



**Tamara T. Forys**

(202) 619-1306  
tamara.forys@oig.hhs.gov

HHS OIG  
330 Independence Ave SW  
Washington, DC 20201

Tamara serves as a Deputy Branch Chief in the Administrative and Civil Remedies Branch of the OIG's Office of Counsel. Tamara has been with OIG since 2009. At OIG, she has worked on a variety of health care fraud matters and has negotiated and monitored Corporate Integrity Agreements. Tamara earned her B.A. from the George Washington University and her J.D. from Loyola University Chicago School of Law with a certificate in health law.



1

## Speaker Introduction



**David W. Ogden**

(202) 663-6440  
David.Ogden@wilmerhale.com

WilmerHale  
1875 Pennsylvania Avenue, NW  
Washington, DC 20006

A nationally recognized litigator and counselor with more than thirty years' experience, David focuses his practice on complex disputes with serious financial implications.

David served as the Deputy Attorney General of the United States from 2009 to 2010 and as Assistant Attorney General for the Civil Division, United States Department of Justice, from 1999 to 2001. David is chair of the firm's Government and Regulatory Litigation Group. He currently serves as a DOJ-appointed co-monitor in a major health care monitorship.

David's clients have included leading companies in the health care services, pharmaceutical, petrochemical, oil and gas, technology, retail, insurance, defense, financial, manufacturing, transportation, media and entertainment industries, as well as major trade and professional associations, nonprofit foundations, and individuals.



2

## Speaker Introduction



**Shannon Sumner**

(800) 270-9629  
ssumner@pyapc.com

PYA, P.C.  
215 Centerview Drive  
Brentwood, TN 37027

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.



3

## 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, NPAs, and CIAs regarding compliance programs?
- ✓ Wrap-up and key takeaways



4

---

## Government Perspectives on Corporate Enforcement

---



5

## Recent Developments in Compliance

- Over the past few years, we saw multiple 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
    - In 2019, we were able to observe the early implications of this memo:
      - Since 2018, the DOJ has moved to dismiss 45-50 qui tam cases – up from one or two dismissal per year previously.
      - In moving to dismiss, the often government cited: the preservation of government resources; curbing meritless qui tam actions; and preventing interference with agency policies.
      - Circuit split has emerged: For example, in the Ninth Circuit: dismissals are warranted only if DOJ shows a valid government purpose, and a rational relationship between dismissal and that purpose. In the D.C. Circuit, DOJ has unfettered right to dismiss qui tam actions.



6

## Recent Developments in Compliance (cont.)



- **“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.
  - However, “[t]here are, of course, circumstances where it may be appropriate to cite agency guidance” including in FCA cases. (DAA Cox).
    - For example, guidance may be relevant to professional standards incorporated into statutes, such as requirements that procedures billed to Medicare be medically “reasonable and necessary.”



7

## Recent Developments in Compliance (cont.)

### ▪ FCA Guidance on Cooperation Credit – May 2019

- Cooperation credit can now be earned in FCA cases by voluntarily disclosing misconduct, cooperating in an investigation, or undertaking remedial measures. The credit usually will be in the form of a reduction in the damages multiplier and civil penalties.
- DOJ is willing to consider the “nature and effectiveness of a company’s compliance system in making the determination of whether [FCA] is the appropriate remedy.” This is because a robust compliance system can show lack of scienter. (DAAG Cox)

### ▪ DAAG Miner – September 2019

- Outlining the two primary goals of white collar enforcement as deterring and punishing “legally non-compliant behavior” and encouraging “greater compliant behavior” to create a “level playing field for those who play by the rules.”



8

## Recent Developments in Compliance (cont.)

### ▪ AAG Benczkowski Memo re: Inability to Pay – October 2019

- Provides guidance to prosecutors and defense counsel on specific factors contributing to a company’s inability to pay a criminal fine or monetary penalty; also provides a questionnaire to accurately assess the company’s financial picture.
- Emphasizes importance of transparency and prosecutorial uniformity.

### ▪ DAAG Cox – January 2020

- “The False Claims Act is one of the most important tools we have to fight healthcare fraud, grant fraud, financial fraud, government-contracting fraud, and many other types of fraud on the taxpayer. Enforcing the False Claims Act is a top priority for the department.”
- “Since the 1986 amendments, which substantially strengthened the law, False Claims Act actions have returned over \$62 billion to the U.S. Treasury — over \$44 billion of which came through qui tam actions filed by whistleblowers.”



9

## 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.
    - DAAG Cox stated that piling on is “inconsistent with the concepts of fair play and the need for certainty and finality.”
  - **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.
  - **DAAG Cox – 2020 Remarks**
    - Further discourages “piling on”
    - The decision to dismiss a qui tam case is “for the department to make, but as the Granston Memo makes clear, it’s important to coordinate with and solicit the input from the relevant agencies in these decisions.”



10

## Moving Toward Greater Individual Accountability and 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.”
  - **DAAG Cox – January 2019**
    - “Strong compliance programs are good for business and fair competition.”
  - **DAAG McCusker – May 2019**
    - “American business is at its best when there is a level playing field, and a culture of compliance and fair dealing is a key component of that.”



11

## Aggressive Enforcement



### Increasing Focus on Enforcement Against Responsible Individual Wrongdoers

- In 2018, the Justice Department announced charges against 601 individuals in 58 districts involving over \$2 billion in alleged fraudulent billing schemes, kickbacks, and opioid distribution.
- In April 2019, the Justice Department announced charges against 24 individuals involving over \$1.2 billion in loss.
  - Charges included a scheme of illegal kickbacks and bribes made by medical equipment companies in exchange for medically unnecessary referrals by medical professionals.
  - The proceeds of this scheme were allegedly laundered through international shell corporations.



12

## Aggressive Enforcement (cont.)

- Overall, in fiscal year 2019, the Justice Department recovered \$3 billion from False Claims Act cases, including \$2.6 billion from the healthcare industry.
- In fiscal year 2018, the Justice Department recovered more than \$2.8 billion from False Claims Act cases, including \$2.5 billion from the healthcare industry.
- Whistleblowers filed 633 qui tam suits in fiscal year 2019, and this past year the department recovered over \$2.1 billion in these and earlier filed suits.
- Whistleblowers filed 645 qui tam suits in fiscal year 2018, and the Department recovered over \$2.1 billion in these and earlier filed suits in 2018.



13

## Aggressive Enforcement (cont.)

- From April 2019 to September 2019, Office for Inspector General for the U.S. Department of Health & Human Services (HHS OIG) reported expected investigative recoveries of \$5.04 billion, criminal actions against 809 individuals or entities, exclusion of 2,640 individuals and entities from participation in Federal healthcare programs, and civil actions against 695 individuals and entities.



---

## Overview of DPAs, NPAs, and CIAs

---





## 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.



## 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



18

## 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



19

## 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



20

## 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
- **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.



21

## 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.



22

## Certification

---

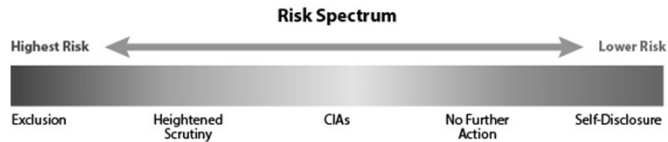
- The monitor's investigations and assessments all lead to what could be the most important aspect of a monitorship: *certification*.
  - The terms of certification vary from case to case.
    - For example, some negotiated resolutions require the monitor to certify effectiveness of the compliance program 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.



23

## Corporate Integrity Agreements

- When are CIAs used?
  - Civil or Administrative Settlement Agreement
  - Not every settlement results in CIA



- Background
  - Release of OIG's permissive exclusion authority
  - Five years
  - OIG's goals are **effective oversight** and **efficient resolution**



24

## 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



25

## CIAs (cont.)

---

- Tailorable elements
  - Preamble (past compliance efforts)
  - Claims Review Monitoring and auditing specific to key risk areas (e.g., one size no longer fits all entities)



### Key Takeaway

When negotiating a CIA, suggest claims reviews that the provider will find useful.



---

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

---



## Parties to CIAs

- 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
- Electronic Health Record vendors



### 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"

Employees

Vendors and  
Subcontractors

Active Medical Staff

"Arrangements"  
Covered Persons



## Definition of “Covered Persons”

- 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.



30

## 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.”



31



## 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



32

## Management Certifications and “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.”



33

## Management Certifications and “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
  - Division Vice President
  - Human Resources
  - Chief Strategy Officer
  - VP Philanthropy
  - 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.

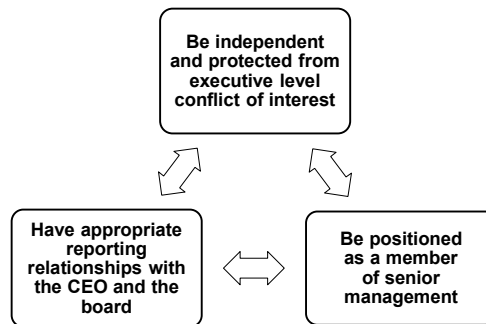
***General Compliance 101 training is no longer sufficient.***



34

## Stature of Compliance Officer and Span of Control

### Stature of the Compliance Officer



#### Red Flag:

CIA's: "The Compliance Officer shall report directly to the CEO and Board and shall not be subordinate to the General Counsel or the CFO...or have any legal counsel responsibilities."



35

## 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.



36

## 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



37

## Incentivizing Compliance Through Compensation

- 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.



WILMERHALE

40

## Evolution of Risk Assessments



WILMERHALE

41

## 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



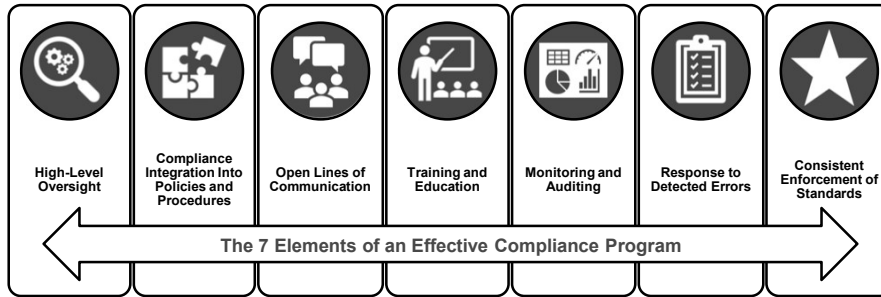
### Key Takeaway

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



44

## Focused Education in High-Risk Areas by Experts

- Anti-Kickback, Stark, and FCA
- Employees and third parties
- Includes supervision and oversight of key risk areas
- Risk assessment should inform those to receive training

Providers (Employed and Medical Staff)	Supply Chain/ Procurement
Case Managers	Physician Recruitment
Research	Medical Education Grants
Marketing	Real Estate

45

## Measuring Behavioral Change

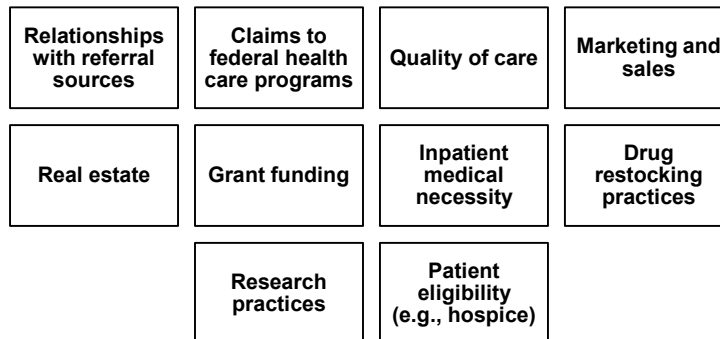
- Completeness of training no longer enough
- Did the education result in a behavioral change?
- How do you measure?



46

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

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



47



## 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



48

## Questions?



49

## Thank You!

---



**Tamara T. Forsys**  
HHS OIG  
tamara.forsys@oig.hhs.gov



**David W. Ogden**  
WilmerHale  
David.Ogden@wilmerhale.com



**Shannon Sumner**  
PYA, P.C.  
ssumner@pyapc.com

