

**Virtual Healthcare Enforcement Compliance  
Conference  
November 16-18, 2020**



**Compliance, Internal Investigations and  
Self Disclosure:**

**Building the Team, Process and Resolution**

**Gabriel L. Imperato, Esq.**  
Managing Partner  
Nelson Mullins  
Fort Lauderdale, Florida

**Nancy Hayt, Esq.**  
Vice President  
Corporate Responsibility  
AdventHealth  
Orlando, Florida

1

1

**Learning Objectives**

- Identifying potential non-compliance through an effective compliance program
- Organizational governance and internal investigations; authority and practical considerations
- Methodology for internal investigations; establishment, personnel and resources, probable cause and preponderance of evidence, privilege and findings of fact
- Practical tips; investigation workplan, conducting interviews, collecting documents and e-data, establishing facts and final report
- Resolution; remedial action and self-disclosure and managing the risk
- Compliance professionals and best practices

2

2

## Building/Maintaining A Compliance Program

### Understand Your Organization:

- Culture
- Tone at the Top
- Significant Areas of Risk

### Building Your Team:

- Structure of the Department
- Different Skills and Knowledge within the Team
- Coordinate with Other Departments

### Ongoing Evaluation of the Program

3

## How to Identify Potential Issues

- Company-Wide and Targeted Education
- Team Members Reporting Directly
- Confidential Reporting Mechanisms
- Internal Auditing & Monitoring
- External Audits
- External Investigations

4

## Vetting Concerns

### Review Allegations

- Separate facts from opinions
- Identify compliance vs. HR, other issues
- Determine which parts of organization are impacted

### Is an Investigation Necessary?

- Not every allegation or concern warrants a “no-holds barred” investigation

5

## When Should You Investigate?

Any time there is:

- A report of improper conduct or non-compliant activity
- An allegation of a violation of law
- A potential for a government overpayment
- A potential for an overpayment by any other third-party payor
- A potential for whistleblower activity

6

6

## Doing Nothing is Risky

- Increased likelihood of diversion of attention from core business activities
- Greater potential for harm to reputation
- Greater potential for harm to individuals
- Potentially greater financial penalties and sanctions (i.e. suspension and/or exclusion) as issues walk out the door
- Lawsuits, including individual defendants
- Increased fees for counsel, consultants, experts
- Compliance with a government request for information (even if ill-founded) can be expensive and resource intensive under any circumstances
- Need to do the work and get a handle on situation before it becomes unwieldy and out of control and ends up in the hands of third parties, including enforcement and regulatory authorities

7

7

## Actual Failures Due to Lack of Investigation

- Compliance issues walk out the door-whistleblowers
- Demotions, counseling and bad evaluations after compliance issues reported
- Promotions of employees who caused non-compliance
- Complaints dismissed because employee was rude, incompetent, lazy, fill in the blank
- CFO knew of issue and commented, "if anyone finds out, we'll all go to jail"
- Multiple internal audit reports identified the issue and management ignored it
- Administrator looked the other way because the physician was a high admitter

8

8

## Risks and Benefits

What are the potential risks and benefits of an investigation?

- Risks include costs and disruptions to ordinary course of business – can be managed
- Risk/benefit of potentially uncovering unknown additional issues and/or misconduct
- Benefits include potential advantages of early disclosure, cooperation with any government investigation and potential for preferred treatment in charging decisions and under civil penalty provisions and sentencing guidelines
- No substitute for knowing the facts

9

9

## Key Purposes for Your Investigations

- You must determine the facts and the back story
- You must determine the root causes for any non-compliant activities for corrective action
- Your findings must establish accountability and those involved in the non-compliant activity-individuals
- Your findings must maximize the decision-making process for management
- Your findings must help the bigger needs of the business. This includes avoiding and mitigating damages
- The investigation must be done timely both for practical reasons as well as to prove there was no cover-up of improper conduct

10

10

## Investigation Roadmap

Investigations generally should follow the same basic roadmap:

- Identify potential issues – those already identified, others that should be investigated
- Identify individuals likely to have information, both inside and outside the company
- Identify potentially relevant documents and institute document “holds” to prevent destruction or disposal
- Identify individuals best suited to conduct investigation (in-house resources or outside counsel and/or consultants)
- Prepare investigation plan – the more serious the issue, the more detailed the plan

11

11

## How Much Must You Investigate?

- Depends on the facts
- Initially, need to investigate enough to gauge the credibility of the allegation
  - Reliable and credible evidence and preponderance of evidence
- Dollar amount of potential exposure impacts practical decisions regarding scope, depth, and personnel involved in investigation
- Tailored Investigation vs "Boiling the Ocean"

12

12

## Who Should Investigate?

Different categories of problems are best investigated by different personnel:

- Human resources issues (such as sexual harassment or discrimination) should generally be investigated by the HR Department and/or employment counsel
- Other general issues (non-criminal in nature, unlikely to result in substantial civil liability) can be initially investigated in-house
- Need to consider whether attorney-client privilege may be important – involve counsel (in-house and/or outside)

13

13

## Who Should Investigate?

(Cont'd.)

- Criminal issues or issues likely to result in significant civil liability (whistleblower situations, high dollar overpayments, systemic problems) should typically be investigated with the assistance of competent and experienced legal counsel and investigative team
- Attorney-client privilege important – may want outside counsel involved to strengthen application of attorney-client privilege

14

14

## Stakeholders Removed From Process

- Independence
- Objectivity
- Candor
- Credibility
- Fairness
- Effective compliance program
- Anti-retaliation

15

15

## Getting Outside Counsel Involved

- Expertise in white collar and health care compliance
- Familiarity with government enforcement and regulatory personnel
- Conflicts of interest and objectivity and independence
- Government's perception and credibility of organization
- Familiarity with industry compliance matters
- Cost
- Disruption to ordinary business activities
- Availability

16

16

## Attorney-Client Privilege

- Attorney-client privilege protects communications between an attorney and client
  - Which were intended to be confidential
  - Which were made for the purpose of obtaining legal advice (not business advice)
  - As to which confidentiality has not been waived by disclosures to third parties or otherwise
- More difficult to demonstrate that communications to in-house counsel meet each prong of this test – Advantage of using outside counsel

17

17

## Attorney-Client Privilege/Consultants & Others

- Attorney-client privilege extends to agents retained by the attorney to assist in providing legal advice to the client
  - Applies to secretaries and clerks
  - Also applies to investigators, interviewers, technical experts, accountants, consultants, and other specialists
- Attorney-client privilege applies to communications with agents as if communications had been with attorney
  - Between client and agent
  - Between agent and attorney

18

18

## Considerations with Consultants

- Scope of engagement- Define and manage scope of investigation
- Qualifications for specific assignment
- Privilege and work product protection
- Flow of information and coordination with counsel and organization personnel

19

19

## Preparing a Work Plan

- Determine scope of the subject matter to be addressed.
- Clarify who will be directing the internal investigation and/or compliance investigative team and who will they be accountable to within the organization
- Notification of initial investigation and updates to management?
- Determine individuals to be interviewed, and documents and data to be gathered
  - Order of interviews can be important
  - Prepare standard/open ended questions
- Review and revise Work Plan as necessary

20

20

## The Duties and Rights of Employers and Employees Related to Internal Investigations

- The duty of an organization to investigate compliance matters
- The duty of loyalty and fair dealing for employees and the organization
- The duty of an employee to cooperate with an organization investigation
- The employee's rights to privacy and to work free from unreasonable interference and harassment
- The right to have your reputation protected.

21

21

## Evaluating the Evidence

- You owe it to the company, the investigation process, and the people involved to get done quickly
- Determine whether your gathered information matches your scope
- The burden of proof is the preponderance of the evidence
- Determine the credibility of the witnesses
- Don't be afraid to get a second opinion

22

22

## Investigation Complete

- Prepare a Report, including
  - Discovered facts
  - Remaining unknowns
  - All implicated or potentially implicated laws, and
  - Counsel's analysis of the facts (and unknowns) in light of those laws
- Report must remain confidential-limit circulation
- Oral or written

23

23

## Fix the Problem

- Using the report, identify corrective action needed to fix the problem and who is responsible
- Need to assess compliance process and policies to identify deficiencies in existing compliance programs and reporting mechanisms (i.e. "root cause analysis")
- Responsible employees should be disciplined, as appropriate
- Additional policies, procedures, or reporting layers should be added as necessary to promote future compliance

24

24

## Now What- - Voluntary Disclosure?

Need to discuss:

- Whether the past conduct involves liability to third parties, including the government and whether it needs to be resolved.
- Option of refund – to whom? MAC
- Options of self-disclosure – to whom? Department of Justice, Office of Inspector General of Health and Human Services, Center for Medicare and Medicaid Services, Attorney General?

25

25

## Self Disclosure Process

1. Investigation and Evaluation
2. Consider the Benefits and Risks
3. Consider Which Entity to Disclose to
4. Submit a Timely, Complete and Transparent Disclosure
5. Anticipate Government Validation
6. Resolution – Strategies and Options

26

26

## Is it “Voluntary?”

- Misprision of a Felony – 18 U.S.C. § 4 provides that “whosoever...having knowledge...of a felony...conceals and does not as soon as possible make known the same...shall be fined...imprisoned...or both
  - Requires active concealment
- Medicare Statute – 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or “fail to disclose” facts affecting right to receive payment

27

27

## Is it “Voluntary?”

- False Claims Act – Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) – 31 U.S.C. § 3729(a)(1)(G)
  - Illegal to “knowingly conceal...or knowingly and improperly avoid...or decrease...an obligation to pay or transmit money or property to the Government...”
- Presentment of claim not essential for False Claims Act Liability under Affordable Care Act
- Affordable Care Act establishes “obligation” to report “identified” overpayment within sixty (60) days

28

28

## Disclosure Considerations

Decision to disclose should be made in conjunction with counsel, but is a business decision – weighing potential risks and benefits

- Where available, self disclosure may offer protections too significant to pass up and is it really voluntary
- Useful for substantial violations of law and whistleblower risk
- Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
- Continuing focus on compliance programs, good faith cooperation and prompt disclosure

29

29

## Weighing Pros and Cons

Potential advantages of self-disclosure:

- Goodwill with government
- Limiting possibility of external investigation
- Expediting process of resolution
- Reducing criminal and civil liability
- Neutralizing whistleblower threat and lawsuits
- Lessening overall damages and penalties

30

30

## Weighing Pros and Cons (cont'd.)

Potential disadvantages of self disclosure:

- Financial loss – government motivated by recovery whether discovered or disclosed
- Increased government scrutiny – validation process
- No immunity from liability or prior commitments
- Possible penalties for conduct that may have remained undiscovered.

31

31

## Choosing A Government Entity

Self-disclosure can be made to:

- Office of Inspector General of the Department of Health and Human Services (**OIG-HHS**) – Self Disclosure Protocol (SDP)
- Centers for Medicare and Medicaid Services (**CMS**) – Self Referral Disclosure Protocol (SRDP)
- Department of Justice, U.S. Attorney's Office (**DOJ**)
- State Attorney General's Office

32

32

## General Guidelines

- Disclose & payback billing errors and mistakes to entity processing claims and payment
- Disclose matters indicating civil liability under Civil False Claims Act to DOJ and/or OIG-HHS
- Disclose matters indicating criminal liability to DOJ and/or OIG-HHS
- Where, when and how to voluntarily disclose involves careful considerations

33

33

## OIG Self-Disclosure Protocol (SDP)

- Full cooperation and complete disclosure
- Submission violates laws, not a “mistake”
- Minimum settlement amount of \$50,000
- Submit within 60 days from discovery
  - False Claims Act - 30 days limits damages
- Ongoing fraud scheme = more immediacy
- Physician self-referral matter with colorable anti-kickback statute violation
- Follow Self-Disclosure Protocol, done in 3 months

34

34

## CMS' Stark Self-Referral Disclosure Protocol (SRDP)

- Report and return overpayment 60 days from identification or from when cost report due
- Follow CMS' Protocol - SRDP
- Open access to all financial records, including work product
- Intended to resolve physician self-referral matters ("Stark" law) without extraordinary financial liability
- When no anti-kickback matter exists, use CMS' Protocol
- When anti-kickback matter exists, must choose either CMS or OIG for disclosure, not both

35

35

## Settlement Factors

- CMS may consider the following:
  - (1) the nature and extent of the improper or illegal practice;
  - (2) the timeliness of the self-disclosure;
  - (3) the cooperation in providing additional information related to the disclosure;
  - (4) the litigation risk associated with the matter disclosed; and
  - (5) the financial position of the disclosing party

36

36

## Self-Disclosure to DOJ

- DOJ is a law enforcement agency
- Unlike OIG and CMS, No formal protocol
- Criminal jurisdiction and civil authority under the False Claims Act
- Ability to release organization from liability

37

37

## Agency Coordination

- OIG confers with DOJ before acceptance
- OIG confers with DOJ before resolution
- OIG resolution not binding on DOJ
- Disclosing party can request DOJ or OIG presence in settlement discussions to resolve parallel liability
- CMS or Fiscal Agents can refer matters to OIG and DOJ

38

38

## Many Possible Settlement Factors

- Effectiveness of pre-existing compliance program
- Nature of the conduct and financial impact
- Ability to repay
- First-time offender, isolated and distinct incident
- Low-level bad actors
- Efforts to correct problem
- Successor liability under former management
- Period of conduct
- How matter was discovered
- Level of cooperation, candor, flexibility
- Relationships
- Etc.

39

39

## Final Advice

- There is no “one size fits all” approach to voluntary self-disclosure
- These decisions should be made with the assistance of competent and experienced counsel

40

40

## Key Takeaways

- Establish Policy and Procedure for Organization Response to Reports or Discovery of Non-Compliant Activity
- Internal Investigation Capability is Important for Governance and Compliance Program Effectiveness
- Internal Investigations are Critical to the Organization Response and Resolution of Allegations of Non-Compliant Activity
- Establish Organizational Acceptance and Standards for Conducting Internal Investigation
- Remedial Action and/or Self-Disclosure is Important for Management of Risk
- Experience and Best Practices are Important for Effective Internal Investigations and Avoidance of Risk

41

41

**THE END**

**QUESTIONS?**

42

42