Health Care Compliance Association
Handling a Health Care Fraud Investigation

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AGENDA

• HealthCare Fraud Investigation Contagion
  – Review of interested agencies, relevant statistics and conduct that attracts attention

• Symptoms of an Investigation: When and how a healthcare fraud government investigation can start

• Right Prescription: Best way to respond to/participate in healthcare fraud investigation

• Recovery: Aftermath of the healthcare fraud investigation
HealthCare Fraud Investigation Contagion
HealthCare Fraud: Government’s Current Gold Mine

- DOJ and HHS reported $4.2 billion dollar year for healthcare fraud and enforcement in 2012
  - Consumer Protection Branch and US Attorneys’ offices obtained nearly $1.5 billion in fines and forfeitures for FDA offenses
  - DOJ opened 1,131 new criminal health care fraud investigation and 885 new civil investigations
  - Hospitals, nursing homes, long-term care settings, residential treatment facilities, intermediate care facilities, institutes for mental disease, hospices, institutional healthcare providers, home health agencies (HHAs), hospitals, and nursing facilities government “targets”

- Department of Justice (DOJ) recovered nearly $5 billion in False Claim Act settlements and judgments in 2012
  - Pharmaceutical/healthcare industry made up $3 billion of that $5 billion
  - Healthcare industry remains the primary focus of enforcement, but other industries also being targeted
Hospitals, Providers, and Health Systems in the Cross-Hairs: Who’s Watching?

- DOJ/US Attorney Offices
- HHS-OIG
- State Attorney Generals/Medicaid Fraud Control Units (MFCU)
- FDA
- DOJ Consumer Protection Branch
- Medicare and Medicaid Contractors
  - ZPICs, MACs, RAs
- Whistleblowers
  - Federal, state and municipal False Claims Acts
- Competitors
- Congress/state legislatures
- Press
They’re ALL Watching You . . . .
• Types of allegations against providers:
  – Quality of care
  – Billing practices
  – Medically unnecessary level of service
  – National hospital initiatives and Stark Law
  – Arrangements and relationships for AKS compliance
  – Sales and marketing practices
  – Sunshine Law reporting?
Symptoms: Recognizing When and How the HealthCare Fraud Investigation Starts
How Can An Investigation Start

- Subpoena or CID from a government body
- Response to problems uncovered through compliance program audit or hotline call
- Response to allegations of wrongdoing reported through a whistleblower
- State licensing board surveys
- Non-compliance with federal regulations and statutes
- Compliance with consent decrees or statutes imposing investigative responsibility
- Actual or threatened civil litigation (class actions)
- Response to allegations raised by customers, vendors or competitors
Goals of An Investigation

• Quickly obtain accurate information, resulting in appropriate legal advice, compliance assessment and informed decision making

• Maintain the confidentiality of the investigation and protect the information acquired from an undesired or non-strategic disclosure

• Cooperate with the investigative body while protecting organization’s rights
Key Definitions: Subpoena

• What is a grand jury subpoena?
  – Order of the court for a witness to appear at a particular time and place to testify and/or produce documents in the control of the witness
  – Will require you to provide the requested materials and/or testimony
  – Deadline to respond varies

• Will you know it when you see it?
  – What does it look like?
Key Definitions: CIDs

- What is a CID?
  - Production of documents
  - Interrogatories
  - Sworn testimony
  - Usually 20 days to respond on face
  - Time frame negotiated in actuality
  - Becoming much more common /onerous

- What does it look like?
  - Will you know it when you see it?
Key Definitions: Attorney Client Privilege and Work Product Doctrine

• What is attorney client privilege?
  – Communications between an attorney and “client” made in confidence for the purpose of providing or obtaining legal advice
  – Usually attorneys interviewing/questioning, sometimes Compliance personnel
  – The “client” in most cases will be the Company, not You, but you must still maintain the communications as confidential as the privilege belongs to the client
    • Sometimes this will be explained to you orally or you will be required to sign consent form
  – Varies slightly by state

• What is work product doctrine?
  – Materials created or collected by counsel in preparation for litigation
  – Materials containing an attorney’s thoughts, beliefs, and mental impressions
  – Varies slightly by state
Key Players: Counsel, Compliance, and Management

• Counsel
  – In-house counsel/legal department – lawyers employed by the Company to provide legal counsel to the Company, sometimes asked to conduct internal investigation by themselves
  – Outside/external counsel – specialized lawyers retained by the Company to provide neutral and objective perspective to assist in-house counsel advise Board/Management

• Compliance
  – Company’s department or officer – assessment of compliance even during investigation
  – Will work with both types of counsel during investigations

• Management/Board
  – Company’s decision makers and oversight body

• All are working for the Company’s best interest, but could disagree during the investigation as they have different focus
How to Respond to the Investigation

• Quickly determine the nature of the allegations
• Get the word out or keep to core group?
• Document preservation and retention
• Identify potential sources of documents and data
• Develop effective document collection, review, and production strategies
• Identify relevant employees/contractors “Custodians”
• Protect the attorney-client privilege and work product protected materials
• Conduct thorough and objective internal investigation
• Compliance enhancements
Determine the Allegations and Who Will Respond

• Scope and focus - prepare a work plan
  • Consider costs, needs of business to continue v. need to adequately conduct investigation

• Identify the right investigator
  • Outside counsel, in-house counsel, compliance department, or some combination of the above
  • In-house counsel would be more cost-efficient, but outside counsel provides independence, objectivity, and expertise in internal investigations and responding to government agencies and often heightened expertise in handling such matters

• A key question in deciding who conducts the investigation is whether you will be able to satisfactorily defend the company’s response to an allegation or problem if it came to the attention of criminal prosecutors, regulatory agencies, shareholders, or the public.
  • Your answer must be YES, so use the investigator that will help satisfactorily defend the Company
Responding to Subpoenas and CID

- The subpoena/CID makes its way to you . . .
  - What do you do?
    - Who is the subpoena/CID addressed to?
    - Hand it off to legal?
    - Compliance department?
    - If you know what it is about, do you try to talk to Legal about it immediately?
    - If you talk to Legal about it, what is Legal going to do with the information you give them?
Get the Word Out – Balanced Approach

• Determine who within the organization needs to know
  – Who can answer questions or issues relating to the allegations?
  – Who needs to know of financial and/or legal implications?
  – Who needs to assist Organization in responding to the allegations (e.g., collecting data)?

• Usual Suspects tend to be:
  – Executives
  – Board
  – Audit Committee/Compliance Department (if not already involved)
  – Investor Relations (for public company)
  – IT Department
  – Key Employees (all those with or likely to have knowledge)
  – Human Resources
Document Preservation and Retention

- **Preservation Notice/Document Hold Memorandum**
  - Notice/memo circulated to all employees to preserve relevant information upon learning of pending or threatened litigation or investigation, or receipt of a subpoena or CID
  - You may be asked to confirm receipt of this notice/memo
  - Retain all relevant documents – don’t delete or alter anything that would be considered responsive to the notice/memo
  - If you are responsible for identifying recipients, think of “record custodians” - employees who may be in the possession, custody or control of documents related to the investigation
  - A defensible preservation and collection methodology and protocol

- **Those who refuse to cooperate can be charged with obstruction of justice**
Identify Potential Sources of Documents and Data

- Cast a wide net - think of where ALL the relevant information could possibly be located
  - Employees’ hard drives
  - Employees’ personnel files, submissions to third parties,
  - Company’s databases
  - Company’s shared drives
  - Company’s archived files
  - Paper files forgotten in drawers, cabinets, etc.
  - At home?
  - Off-site locations (storage?)

- Once sources are identified, work with counsel to determine best method of collection, review, and production
Develop Effective Document Collection, Review, and Production Strategy

• Effective Document Collection
  – When collecting all (especially electronic) documents, ensure all requested information is preserved (e.g., date, to, from, subject, author, source, custodian, etc.)
  – If collecting documents from foreign countries, be mindful of privacy laws (e.g., EU privacy laws)

• Effective Document Review
  – Review must be thorough – Cannot just be data dump
    • Usually outside counsel negotiates with the Government prior to review and production to determine what Government is seeking
  – Develop review protocol in which responsive/relevant and hot/key documents are described
  – Review to protect privileged documents

• Effective Production Strategy
  – Ensure docs are produced in appropriate/requested format preserving ESI
  – Keep record of what was produced and when (e.g., production letters and logs)
Identify Relevant Employees

• Cast a wide net - think of ALL employees that could possibly have relevant information
  – Who has the information?
    • Those in relevant dept?
    • Those working with relevant dept?
  – Who are they?
    • Current employees?
    • Former employees?
    • Executives?
  – Where are they?
    • Different office?
    • Different company?
    • Different country?
  – How can they be reached?
    • Strategic considerations in reaching out to certain employees (e.g., former employees)?
    • Specific procedures that must be followed prior to contacting them?
Protecting the Attorney Client Privilege

• Protect the attorney client privilege
  – Employee interviews
    • Consider employee indemnification
    • Must remain confidential
    • Pros and cons of memorializing employee interviews
    • Detailed versus high level summaries
    • No Legal Conclusions!

• Consider joint defense agreements
  – Might result if and when an employee requires his/her own counsel
Thorough and Objective Internal Investigation Is Necessary

• Conduct thorough and objective internal investigation
  – Helps to accurately assess potential liability
  – Helps to develop a strategy for dealing with the government
  – Demonstrates cooperation and that the company is taking the allegations seriously
  – Is critical to developing successful defenses
Key Considerations for Government Investigations

• Government investigation requires Company to respond to government agency’s inquiries
  – Would likely lead to Company conducting an internal investigation
• Obtain information from Government about focus of the investigation
• Discuss scope of subpoena and related issues with Government
• Set the proper tone
• Obtain control of the process
• Maintain open dialogue
## Internal Investigation v. Government Investigation

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| **Start**        | • Initiated by Company  
• Perceived discrepancy in routine monitoring  
• Receipt of internal/external complaint | • Initiated by Government Agency  
• Subpoena, CID, search warrant, whistleblower, etc. |
| **Goal/Strategy**| • Assess whether any wrongdoing has occurred, and determine appropriate action if any  
• Company must be convinced whether wrongdoing has/has not occurred  
• Playing offense and sometimes defense | • Identify basis and evidence behind government's allegations  
• Identify basis and evidence of any potential defenses (cooperation v. defense)  
• Playing defense |
| **Investigator** | • Compliance/audit department  
• Counsel (in-house and sometimes outside counsel) | • Government agency but with help from Company’s Counsel |
| **Investigation**| • Collect and review documents  
• Interview relevant employees  
• No production of documents | • Collect, review, and produce documents to Government  
• Interview relevant employees,  
• Outside Counsel (likely) will communicate with Government  
• Make presentations to Government |
| **Results/Consequences** | • Disclosure to Management,  
• Potential disclosure to Government,  
• Revised policies/compliance  
• Disciplinary actions | • Penalties (e.g., exclusion, CIA, etc.)  
• Disclosure in SEC filings  
• Revised policies/compliance,  
• Disciplinary actions |
Putting it Together: What an Investigation Usually Looks Like

• Preservation of relevant documents and electronic records
  – Receipt of a preservation notice/document hold memorandum asking you not to delete any relevant emails, electronic or hard copy documents, etc.

• Interviews of relevant people must be conducted
  – Request for an interview or meeting with you to understand the process and your role/action in the process in question
  – Remember your explanation will help the lawyers respond to the agency’s request and ultimately help the company and allow you to go back to your regular work duties
  – Interviews could be memorialized by interviewers

• Investigative steps should be documented in detail
Right Prescription: Responding to and Participating in the Investigation
Instructions/Information You Might Receive Prior to Responding/Participating

• General outline of the investigation/litigation (including details as to the divisions or products of the Company that are at issue)
• Requested to help lawyers conduct an investigation
• Treat all information as privileged and confidential
• Do not discuss investigative work or findings with others
• Do not make copies of their notes or reports and should deliver all originals and work papers to the lawyers
• Mark all investigative notes, reports or other documents or communications, including e-mail correspondence, “Privileged and Confidential”
Don’t Kill the Messenger: Be Helpful and Participate in the Investigation

• Calm influence to follow instructions given
  – Adhere to preservation notice/document hold memorandum
  – Honestly answer questions presented during all interviews
  – Respond to all follow up requests
  – Maintain all communications with attorneys confidential – do not share with anyone

• Failure to be truthful or destruction of documents is serious AND could result in prosecution for obstruction of justice
Scenario 1: Unjustified Procedures

- Hospital’s OR nurses have been speaking about the big spine surgeon on staff at the hospital who does a lot of procedures and they think they are not always medically justified.
- They meet with their supervisor who tells them to mind their own business – the neurosurgeon is highly productive and no major complaints from patients and only a few malpractice cases.
- One of the OR nurses decides to discuss a recent spine case with an orthopedic surgeon who works at another hospital, and who expresses concerns to her on clinical care. The OR nurse calls the Hospital’s Compliance Hotline.
Scenario 1: Unjustified Procedures

- What do you do?
  - Internal review/audits?
  - Involve the hospitals’ lawyers?
  - Peer review?
- When do you notify top management?
- When do you notify the Board?
Scenario Two: Subpoena Arrives

• In the midst of hospital’s compliance reviews above, hospital receives a government subpoena for records related to the spine surgeon’s procedures at hospital, financial arrangements, related compliance and audit reports, etc.

• NOW WHAT?
Scenario Three: Visit from the Feds

• FBI agents arrive at the Hospital requesting documents regarding the spine surgeon’s procedures at hospital, financial arrangements, related compliance and audit reports, etc.

• What should you do?
  – Should you speak with the government?
  – Should you reach out to in-house counsel? Outside counsel? Compliance?
  – What if you can’t reach any of them?
    • Who should you contact?
    • What should you do?
Scenario Four: FBI Visits Your Home as if You’re Tony Soprano

After you participate in the internal investigation regarding your knowledge of the spine surgeon’s procedures at hospital, financial arrangements, related compliance and audit reports, etc. FBI agents arrive at your home at 7 a.m. requesting to speak with you about the same issue. In-house counsel, outside counsel, and a compliance officer were all present at your interview during the internal investigation.

What should you do?
- Should you speak with the government?
- Should you reach out to in-house counsel? Outside counsel? Compliance?
- What if you can’t reach any of them?
  - Who should you contact?
  - Get your own lawyer?
So does all this want to make you want to scream, cringe or cry?
Recovery: Aftermath of the Investigation
Determining Investigation Results

• Potential criminal, regulatory or civil liability
• Reporting requirements to either the government, the board of directors or the company’s outside auditors
• Notification requirements to insurance carriers, state licensing boards?
• Need for employee disciplinary actions?
• Extent and content of any communication with employees or the public
Is It Over? Recognizing the End of the Investigation

• Internal/External Conclusion is communicated
  – In-house attorney/compliance person might communicate conclusion of investigation
  – Press Release might be issued as to fines, penalties resulting from investigation.

• Resulting policies (e.g., compliance programs) are introduced
  – Consistent and comprehensive training
  – Oversight, monitoring and reporting system (e.g., hotline)

• Improvements or modifications to existing compliance programs and practices
  – Ensure all practices adhere to applicable regulations
  – When in doubt, contact legal for their advice

• Disciplinary procedures to address violations
• Call to request or confirm results
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