Investigation Overview

Who conducts investigations?

- Federal & State Governmental Investigations:
  - Criminal or civil
    - DOJ/USAO (incl. DEA, FBI)
    - OIG
    - FDA, Postal Inspectors, Labor, IRS, DOD, VA, OPM
    - MFCU/AG
  - Administrative
    - OIG (OI, OCIG)
    - MAC/ZPIC/UPIC/MEDIC
  - Insurer
    - SIUs
Investigation Overview

How do investigations originate?
- Qui tams/whistleblower complaints
- Complaints to Medicare/OIG hotline from beneficiaries, current/former employees, vendors/business associates, competitors, etc.
- Disclosures/information provided by related parties
- Proactive data mining and analysis
  i. HEAT Strike Force
  ii. OIG
  iii. CMS

Investigation Overview

How do you learn you’re being investigated?
- Voluntary/informal contact
  A. Request for information
  B. Call or knock on the door
  C. Letter, including target letter
  D. Heard it through the grapevine
    i. Former or current employee or beneficiary is contacted/interviewed
    ii. Someone you do business with is being investigated
Investigation Overview

How do you learn you’re being investigated?
- Site visit or request for records from CMS, State, or OIG
- Subpoena
  - A. Federal Grand Jury
  - B. HIPAA/AID subpoena
  - C. IG subpoena
  - D. Civil Investigative Demand (CID)
  - E. OIG administrative subpoena (42 USC 1320a-7a(j))
  - F. State AG/MFCU criminal or civil
- Search warrants

Basic Rules of Road

Basic rules to follow during investigations:
A. Understand the law;
B. Gather the facts:
   i. Documents, and
   ii. Witnesses;
C. Do not make assumptions;
D. Do not relay uncertain information to investigators; and
E. Request appropriate time, if required.
Preserve Relevant Materials

I. Visit IT Staff and have copy of hard drive made prior to *hold notice* being sent to individuals. Understand IT capabilities and deletion policies. Instruct IT on how to preserve.

II. Issue a Hold Notice to Relevant Employees and Individuals:
   A. Explain the subpoena/CID/request with enough specificity that it is easily understood;
   B. Instruct people on what is required;
   C. Invite questions;
   D. Attempt to allay fears and discourage rumor mill; and
   E. Set reasonable deadlines.

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Example of Hold Notice:

As you may know, the company has received a Civil Investigatory Demand (CID) from the U.S. Department of Justice (DOJ). We have retained the law firm of Smith & Doe to assist us, and we are fully cooperating with DOJ. While we address these issues, we want to make sure that any and all requested documents and/or other relevant materials are properly preserved. It is important that your files remain in their current order and location until our attorneys instruct us that the inquiries are complete. Please *do not destroy, change, or otherwise alter any document* that may be relevant to the inquiries, and we ask that you preserve all records and information related to this CID until further notice. For example, medical records, computer records -- including *work related* emails and text messages -- should not be deleted even if part of a regularly scheduled document retention process. The CID and its requests are described below. If you have any question or concern please call John Doe at ext. 867-5309.

Require individuals to acknowledge that they understand instructions.
Compliance or Legal -- Who is the Client?

• Depending on your circumstances, client can be: corporate entity; board committee; senior management team; an executive or employee; or independent monitor/review organization. Identify client and who is responsible for conducting internal review.

• Other than understanding the law, the first step is gathering the facts. **Q1: Who should gather the facts?**
  o Nature of allegations and legal issues involved;
  o Independence of people gathering facts (do in-house people have prior dealings with the issue, or could they be witnesses?);
  o Should client retain outside counsel?

• During an on-going governmental investigation, legal counsel should interact with investigators.

• Compliance professionals work for entity (work can be privileged only where reporting to and working as an agent of legal team).

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Why Conduct an Internal Investigation?

• Internal investigation conducted to understand the facts:
  o Goal is to get truthful and complete answers;
  o Do not use stress and uncertainty to pressure witnesses because they will provide unreliable answers;
  o Allow witnesses time to review key documents that refresh their recollections and recall events;
  o Address personal liability issues directly and honestly;
  o Clearly explain role of attorney (*UpJohn* Warnings);
Timely and Effective Corrective Action

• To earn credibility with government investigators, lawyers involved in an internal investigation must not only gain the information and cooperate with investigators, but must also timely act to prevent or detect and correct violations from occurring.

• Strategic considerations must inform the timing of adverse employment actions, etc.
  o Effect on pending M&A or tender offers
  o Risk of creating new whistleblowers
  o Risk of triggering “follow-on” litigation or additional investigations

Communicating with the Government

Strategic considerations
  o Responding to subpoenas and government inquiries
  o Negotiating resolutions of criminal or civil cases - DOJ
    – Settlement/plea
    – Global resolution
    – Sharing results of internal investigations
    – Individual liability
    – Cooperation
    – When and what to self-disclose
Communicating with the Government

**Strategic Considerations**

- Negotiating resolutions – OIG
  - OIG exclusion criteria and compliance considerations and obligations
    - Criteria for exclusion under 1128(b)(7) and 1128(b)(15) of the Social Security Act
  - CIAs and OIG fraud risk indicator
- Other administrative remedies and consequences
  - OIG: Exclusion, civil money penalties and assessments
  - CMS: Revocation, Preclusion, Suspension
  - States: Medicaid exclusion, suspension
- Reporting obligations (to OIG under CIA, to SEC, to insurers, etc.)

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Questions

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