

**Health Care Compliance Association
Healthcare Enforcement Compliance Conference**

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INTERNAL AND EXTERNAL INVESTIGATIONS

1

1

Internal and External Investigations; Learning Objectives

- Response to initial government contacts; informal requests, subpoenas and search warrants
- Organizational governance and internal investigations; authority and practical considerations
- Methodology for internal investigations; establishment, 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
- Compliance professionals and best practices for internal investigations

2

2

Enforcement



- DOJ
- OIG-HHS
- Attorneys General (Medicaid Fraud Control Units)
- Other Federal and State Agencies
- Multi Agency Task Forces – HEAT Program

3

3

How Investigations are Initiated



- Competitor complaints
- Consumer complaints
- Current or former employee - "Whistleblower" complaints
- Insurance company complaints

4

4

Investigative Techniques



- Informal Interviews and requests for documents
- Insider Informants and Whistleblowers
- Search Warrants
- Subpoenas
- Electronic Surveillance

5

5

When The Government Knocks To Obtain Documents

- Subpoena or search warrant or request by government agent
- Employees notify executives immediately.
- Executives refer agent to company's counsel



6

6

Search Warrants

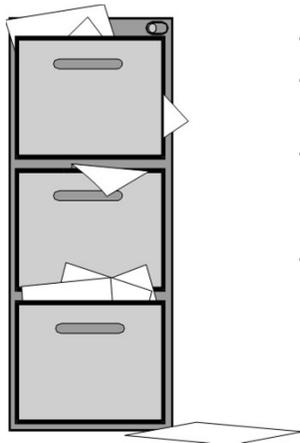


- Request copy of warrant and affidavit (may not be available)
- Accept warrant and immediately fax to counsel and/or organization contact (i.e. general counsel or compliance officer)
- If you are not there... have employee fax to you and your counsel
- Send all employees (except essential response team or coordinator) away from work location where search is taking place



7

Search Warrants



- Agents can seize original documents
- Corporations do not have 5th amendment privilege
- If agent demands copy of personal records – (5th Amendment) respectfully decline and refer to counsel
- Important to label documents

8

8

Search Warrants

- **DO NOT INTERFERE WITH AGENTS AND AVOID CONFRONTATION**
- **Review warrant carefully**
 - Technically, agents can only seize what is listed on warrant
 - Bring to agent's attention if search areas are not listed in warrant
- **List may include personal (5th Amendment) and corporate records and privileged documents**

9

9

Search Warrants

- **No requirement to speak to agents or respond to questions**
- **Respectfully decline & refer agent to counsel**
- **Search warrant is for documents and E data, not testimonial evidence**

10

10

Search Warrants

- Identify and determine agency of each investigator and the agent in charge and request contact information; government attorney assigned to case
- Agents will request signature on a vague inventory of items seized – avoid execution of document
- Keep your own inventory of areas searched, documents and items seized and questions asked by the agents

11

11

Post Search

- Counsel typically requests debriefing from investigators and/or government attorneys
- Consider public relations
- Debrief employees and response coordinator/team – prepare statement with counsel
- Attempt to obtain copies of documents seized through counsel
- Notice and instruction to employees
 - Notice of investigation
 - Litigation hold and suspension of document destruction
 - Instruction regarding interaction with government agents

12

12

Subpoena

- Served by Mail or Personally by Agent
- Does not Require Immediate Response
- Typically Has Future Return Date
- For Documents and/or Testimony
- Turn Over to Counsel for Appropriate Response

13

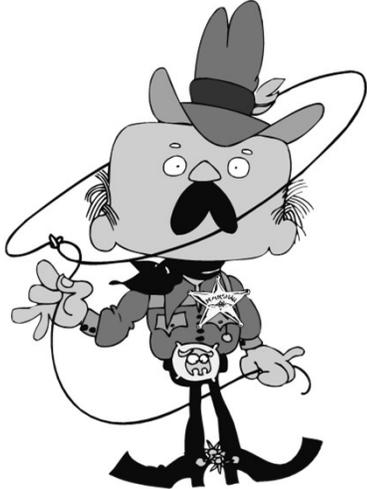
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Subpoena

- Prepare to assist counsel with response
- Different types of subpoenas (Civil Investigative Demand, HIPAA Subpoena, OIG Subpoena)
- Complete and timely response is important
- May negotiate scope and timing of response (i.e. Rolling production)
- Custodian of records for response to subpoena

14

14



What To do When The Government Knocks to interview You or Your Employees

15

15

Employee Rights

- May decline to speak with Agents
- May voluntarily speak to agents, but no obligation to do so
- 5th Amendment Right to Refuse
- May consult with counsel before speaking to agents
- Joint Defense Agreement – Share information between parties – still privileged
- Company can advance \$ for cost of separate employee counsel (if necessary)



16

16

Employee Rights (Cont'd.)

- Right to be represented by counsel at interview
- Organization's Counsel can assist, but typically does not directly represent Employees
- Organization's Counsel represents organization
- Employee can retain their own counsel
- Organization should not forbid Employee to speak to government agents
 - Obstruction of justice
 - Ask employees to advise if visited by government agents
 - Organization memorandum regarding investigation is advisable

17

17

Follow-up Response to Initial Government Contact Conducting an Internal Investigation

- Responding to reports of non-compliant activity and proliferation of Federal and State Government initiated investigations have led organizations to consider a response to and a strategy for such events and "internal investigations" are a central feature of an organization's ability to effectively deal with these situations.



18

18

Conducting an Internal Investigation (cont'd.)

- The initiation of an internal or parallel investigation is critical with reference to allegations raised against the organization or in connection with an internal compliance matter
- It is important for an organization's resolution of an external enforcement investigative matter
- It is also important for an organization's compliance strategy and compliance program and resolution of internal matters
- No substitute for the facts regarding a resolution of external and internal matters.

19

19

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.

20

20

Legal Standards in Investigations

- A reasonable, fair, thorough, and prompt investigation which reaches reasonable conclusions usually protects employers against claims
- The investigation process must be consistent throughout the organization
- An investigation can only be sustained if there is probable cause and/or reliable and credible evidence of non-compliant conduct
- An ultimate factual conclusion must be based on a preponderance of the evidence (i.e. more than 50% probability)
- Right of employee to generally know results of investigation and best practice, but no right to review privileged investigation report
- The attorney-client privilege does not necessarily apply to factual findings of internal investigation, but does apply to advise of lawyer based on the factual findings.

21

21

Legal Standards in Interviews

- Employees cannot refuse to cooperate and/or be interviewed by organization representatives without risking continued employment
- Do employees have Miranda rights?
- Employees have a basic right to fairness and this would be organization's "best practice"
- The employees right to be confronted with the proof and the opportunity to respond
- The prohibition against retaliation
- Confidentiality of the interview, subject to waiver of privilege
- The right to counsel
- Proper instructions protect the evidence.

22

22

Evidence Collection in Investigations

- You must prove each by a preponderance element of the allegation using appropriate evidence
- Proper evidence is relevant
- Proper evidence is material
- Proper evidence is competent
- Proper evidence is authentic/original
- Proper evidence can be direct or circumstantial
- You can use hearsay evidence-statements against interest and business records – statements by third parties – appropriate weight accorded to evidence.

23

23

Legal Claims When Things Go Wrong

- Defamation of an employee
- Retaliation for cooperating with the investigation
- False imprisonment in interviews
- Intentional infliction of emotional distress
- Assault and battery
- Invasion of privacy
- Malicious prosecution

24

24

When Must 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

25

25

Validate and Investigation "Work Plan"

- Validation of the original compliance report is essential and is the reason for an internal investigation
- Avoid rush to judgment
 - Measured investigative response
 - Avoid siege mentality-define scope and develop "work plan"
 - Don't rely on unverified information
- You rarely end up where you thought you would upon initiation of an internal investigation
- Do not ignore privileges and protections
- Do the work and find out the facts

26

26

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

27

27

The Duty to Investigate

- The board of directors and corporate officers have a fiduciary duty to protect the company against unreasonable risks and to maintain compliance oversight
- *In re Caremark*: Part of a director's duty of care includes both monitoring and having current knowledge of risks
- *In re Caremark*: Directors should prescribe a compliance program that is "reasonably designed to provide senior management and the Board with timely, accurate information sufficient...to reach informed decisions concerning the corporation's compliance with law".
- Investigations are part of an "effective" compliance and ethics program. Detection and prevention of non-compliant activity is a compliance program goal.
- Employees have a duty to cooperate with the investigation

28

28

Key Purposes for Your Investigations

- You must determine the facts and the back story
- You must determine the root causes of the 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

29

29

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

30

30

Practical Initial Questions

- Differing agendas in integrated settings?
- Conflicts of interest?
- What is the time period at issue?
- What if there are collateral issues?
- Who are the people internally to report to?
- Who is and who is not on the investigative team?
- How to preserve privilege?
- Who are interview candidates? Who are custodians of relevant documents and data?
- How much to reserve or escrow?

31

31

Scope Of The Internal Investigation and “Work Plan”

- What is the scope of the subject matter to be addressed?
- Who will those directing the internal investigation and/or compliance investigative team be accountable to within the client organization
- The scope of the internal investigation and the proffer of fact and/or legal conclusions
- Notification of initial investigation to management
- Issues, individuals and documents and data
- Revise “Work Plan” when necessary

32

32

Stakeholders Removed From Process

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

33

33

Actual Stakeholder Quotes

- "I don't want to be squeaky clean. Just clean enough."
- "I don't want to be a poster child for compliance."
- "I can't believe he admitted doing that."
- "Oh, I thought you were against us. Now let me tell you the real story."
- "I can't imagine a situation in which I would admit we've done anything wrong."
- "Your job is to keep [Compliance Officer] out of our facility."

34

34

How Much Must You Investigate?

- Depends on the facts
- Initially, need to investigate enough to gauge the credibility of the allegation and to advise client as soon as possible
 - 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"

35

35

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)

36

36

Who Should Investigate? (Cont'd.)

- Different categories of problems are best investigated by different personnel:
 - Criminal issues or issues likely to result in significant civil liability (whistleblower situations, high dollar overpayments, systemic problems) should not be investigated without 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

37

37

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

38

38

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

39

39

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

40

40

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

41

41

Identify Investigative Personnel

- Investigations of serious issues (large amounts at stake, criminal issues) should be managed by counsel
- Who should direct counsel?
 - Senior management (CEO, COO, General Counsel?), but not “stakeholders”
 - Board of Directors
 - Audit or other independent committee of the Board of Organization

42

42

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

43

43

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

44

44

Conducting Investigation-Document Reviews

- First step is to gather and review documents
 - Authorized personnel should collect and deliver documents to counsel (i.e. custodian of records)
 - Track where documents came from
 - Keep confidential documents confidential
 - Identify “hot” documents
 - Documents that suggest wrongdoing
 - Documents that are exculpatory
 - Documents that raise questions and need further clarification

45

45

Getting the Proper Documents

- You don’t want or need every shred of paper to complete your inquiries. Don’t drown in paper
- Documents are needed only to help your specific investigation topic
- Each type of investigation presents a different paper trail
- E-mails generally tell useful snippets of the bigger story
- Personnel files of witnesses are helpful, but only to round out the picture, such as when there might be a pattern of conduct.
- There is no reasonable expectation of privacy in company systems, desks, or other company property

46

46

Conducting Investigation - Interviews

- Interviews should be conducted in private
 - To the extent practical, have witness (associate/paralegal, compliance professional) present during interview to take notes and corroborate your understanding of facts and impressions of witness
 - Sometimes need independent witness for potential impeachable testimony
- Keep notes of interview
 - Do not record interviews
 - Do not transcribe interviews
 - May prepare written report describing facts of each interview

47

47

Conducting Investigation – Interviews (Cont'd.)

- Management should only be present when necessary (i.e. rarely)
- Employees must be advised that legal counsel represents company, not employees individually and what they say may not be kept private (“UpJohn Warning” or “Corporate Miranda Warning”)
 - Depending on the severity of the allegations and potential culpability of the employee, you may choose to advise them of the potential need for their own counsel
 - In some instances, organization may pay for employee counsel
- Employees must be encouraged to report if they have been threatened or asked to change their stories

48

48

Interviewing the Reporter

- The reporter is your initial source of information. Take full advantage of the opportunity
- Make sure you understand the substance and source of their report
- Don't adopt the reporter's characterization of the facts
- Be alert to confidentiality and retaliation concerns
- Be sure to manage the reporter's expectations
- Start considering what the "back story" may be when the report is considered

49

49

The Interview Process

- Interview witnesses by starting with a "skeleton" and filling in the landscape
- Gather *intelligence* on your witnesses before you interview them
- Make a list of interview topics, not questions. A script will limit you unfairly
- The interviewer must control the interview
- Keep your opinions to yourself when conducting the interview
- Never ignore a witness's contradictions. And look for information to corroborate their statements too
- Always look for leads regarding other relevant areas of inquiry

50

50

The Interview Process

- Always maintain confidentiality during the interview
- Review your notes with the witness.
- Do not allow tape recording of interviews
- Phone interviews are a necessary fact of life, but they have limited value to the investigation
- Never allow joint interviews. They can be a recipe for disaster
- Interview questionnaires are good for discrete questions. Sometimes an in-person interview is not essential

51

51

Interviewing the Implicated Person

- There is a difference between an interview and an interrogation. The implicated person is not usually interviewed
- You are looking more for an admission from the implicated person rather than additional information
- The implicated person should be confronted with information, but there is a limit to the information to be shared
- The implicated person should respond and, if appropriate, offer mitigating circumstances to the allegation
- Be aware of the pitfalls of confronting the implicated person
- Prepare an interview memorandum after you are done.

52

52

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

53

53

Investigation Complete

- Counsel should report to client, 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 of report-oral report preferred

54

54

Internal Investigation Report

- Oral or Written?
 - Report is discoverable in litigation
 - The report should be distributed within organization on a limited basis.
- Report “should” include a summary of the facts
 - Describe allegation and how it was reported
 - Identify potential cause(s) of the incident
 - Describe the incident in detail, including how it happened and/or continued and procedure of investigation
 - Identify financial impact and any health and safety matters
 - Identify time period in question
 - Identify individuals interviewed and documents reviewed
 - Identify individuals who should have detected non-compliance
 - Include at least an estimate of the magnitude of issue and recommendations for corrective and other remedial action.

55

55

Fix the Problem

- Using the report, identify corrective action needed to fix the problem
- 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

56

56

Now What- - Voluntary Disclosure?

- Need to discuss with client:
 - Whether the past conduct involves liability to third parties, including the government and whether it needs to be resolved.
 - 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?

57

57

Key Takeaways

- Establish Policy and Procedure for Organization Response to Government Contacts
- Internal Investigation Capability is Important for Governance and Compliance Program Effectiveness
- Internal Investigations are Critical to the Organization Response and Resolution of Reports of Non-Compliant Activity
- Establish Organizational Acceptance and Standards for Conducting Internal Investigation
- Experience and Best Practices are Important for Effective Internal Investigations and Avoidance of Risk

58

58

THE END
QUESTIONS?

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59

59