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Handling a Healthcare Investigation and Internal Investigation

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“There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of matters addressed merely a passing phase.”

Chief Judge Ervin
United States Court of Appeals for the Fourth Circuit
in *Rehabilitation Association of Virginia v.
Kozlowski*, 42 F. 3d 1444, 1450 (4th Circuit 1994)

Why Are Internal Investigations Important?

- Enforcement remains aggressive
 - Federal Level
 - State Level
- Increasing promotion of self-identification and self-disclosure
- Government continues to view Fraud, Waste, and Abuse as a significant source of revenue

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Have You Seen the OIG's Website Lately?

OIG
★
**MOST WANTED
FUGITIVES**



REPORT FRAUD

HEAT Task Force
in Your Area



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Aggressive Enforcement



- From new joint DOJ/OIG website www.stopmedicarefraud.gov
 - "A joint effort by HHS and the Department of Justice recovered a record \$4 billion from fraudsters in FY2010."

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Fighting Fraud is Good Investment

- The return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFAC) program
 - Since 1997, \$4.9 returned for every \$1.0 expended.
 - 3-year average (2008-2010), \$6.8 returned for every \$1.0 expended

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Hypothetical

- As Compliance Officer, you are approached by an employee in the accounting department who has discovered that the hospital's highest admitting neurosurgeon ceased making space rental payments for space in the hospital's medical office building when his lease expired last year. She says she brought this to the attention of the CFO, but he told her the hospital's CEO had taken care of it and "not to worry." You call the CEO and he says he had no knowledge of this issue.
- What should you do?

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Investigate

How Investigations are Initiated

- “Whistleblower” complaints from current or former employees
- Competitor complaints
- Citizen/consumer complaints
- Insurance company complaints
- Government or regulatory action or investigation
- Internal/External Audito

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When Must You Investigate?

Any time there is:

- An allegation of a violation of law.
- A suggestion of improper conduct.
- A potential for an overpayment by the government.
- A potential for a significant overpayment by a commercial insurer or other third-party payer.
- A potential for whistleblower activity.

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How Much Must You Investigate?

- Depends on the facts.
- Initially, need to investigate enough to gauge the credibility of the allegation.
 - Believable on its face
 - Documentary evidence exists
- Dollar amount of potential exposure impacts practical decisions regarding scope, depth, and personnel involved in investigation.

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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 or outside).

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Who Should Investigate?

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 legal counsel.
 - Attorney-client privilege important – may want outside counsel involved to strengthen argument supporting attorney-client privilege.

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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)
- Prepare written investigation plan – the more serious the issue, the more detailed the plan

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Identify...

Issues

- What wrongdoing has already been identified? (e.g., non-payment on our doc's lease)
- What other wrongdoing might be uncovered by an investigation? (e.g., other expired leases, other unpaid bills, improper debt forgiveness, potential fraud by the CFO, CEO, or others)

Issues

What are the potential risks and benefits of an investigation?

- Risks include costs and disruptions
- Risk/Benefit of potentially uncovering unknown additional issues (*e.g.*, perhaps the CFO has been waiving lease payments for ALL of the high-referring physicians?)
- Benefits include potential advantages of early disclosure, cooperation with any government investigation, and potential for preferred treatment under sentencing guidelines and civil penalty provisions.

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Individuals

Who is likely to have relevant information about the case? In our example:

- Multiple members of hospital management
- Members of the hospital's accounting departments
- Hospital physicians who hold leases
- Staff of physicians with leases
- Hospital personnel responsible for drafting and following up on lease documents
- Others?

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Relevant Documents

- Obvious relevant documents – in our example, leases and payment records.
- Less obvious (but still relevant) documents
 - Communications (emails) regarding lease payments
 - Records of meetings (Did anyone meet with non-paying docs? When? About what?)
 - Records of referrals (How much is at stake?)
 - Recruitment records (Were the docs promised anything?)
 - Records of leases and payments made by other (perhaps less lucrative) physicians
 - Notes of meetings (Did the accounting personnel document their initial concerns/discoveries?)

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Preserve Relevant Documents

- Don't destroy documents
- Suspend routine document destruction.
 - Destroying relevant information could be viewed as criminal obstruction.
 - Destroying relevant information could ultimately lead to a negative inference by the judge and/or jury as to why documents were destroyed.
- Issue litigation hold memo
 - All persons likely to have potentially relevant documents
 - All potentially relevant documents (including home computers of employees)

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Investigative Personnel

- Investigations of serious issues (large amounts at stake, criminal issues) should be managed by counsel.
- Who should direct counsel?
 - Senior management
 - Board of Directors
 - Audit or other independent committee of the Board

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Counsel

In-house or Outside Counsel?

Advantages to outside counsel:

- Preserves independence of investigation (and appearance of independence)
- Likely more familiar with process for conducting internal investigation
- Likely more familiar with government enforcement tactics and priorities.
- May have relationships with government enforcement officials
- May be more familiar with the applicable laws, regulations, and the potential penalties

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In-house or Outside Counsel?

• Advantages to in-house counsel:

- More familiar with internal politics of organization.
- May have more credibility within the organization (not always the case).
- May be more familiar with substantive laws and regulations
- Even if outside counsel is engaged, in-house counsel plays a key role.
 - Familiar with the organization -- invaluable in identifying appropriate document sources, interview candidates, and describing standard policies
 - Assist in gathering documents and other resources and keep costs down.

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Role of the Compliance Officer

- Knows the business and organizational culture
- Knows the people
- Less expensive
- Trend toward handling narrowly-focused investigations with internal resources, drawing upon external specialists as needed

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Independence of the Compliance Officer

- Dual Responsibility of compliance officers are suspect at large organizations
- Concern with sufficient commitment of resources
- Reporting to Board of Directors/Trustees
- Independent CCO

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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

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Consultants and 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

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Data

Electronic Data Collection and Analysis

- Data Preservation
- Data Capture
- Data Analysis
- Data Protection Concerns

90+% of business information is stored only electronically, but ...data retention policies and practices can impact what is available – requiring a thorough review of corporate data sources.

Investigations: Data Preservation

Goal: Identify and preserve all relevant data without interrupting normal business operations.

- Understand existing data retention policy v. practice
- Maintain repository of original data sources (including e-mail, accounting data, etc...)
- Consider suspension of manual and automated data destruction processes
- Pursue automated solutions where appropriate and practical – to limit additional IT costs
- Develop effective plan for communicating preservation requirements to all employees

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Investigations: Data Capture

- Work with IT to develop enterprise-wide “data inventory”
- Err on the side of acquiring too much vs. too little
- Identify which data sources are centralized
- Expect de-centralized data sources, retention policies, technology platforms to differ significantly
- Data sources may include e-mail, accounting data, hard-drives, file servers, and other devices
- Consider archives (backup tapes, etc.), encrypted or otherwise protected data

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Data Analysis

- Iterative process – requires close contact between analysts and investigators
- Accounting data – standard data anomaly reports to identify suspicious transactions/accounts for further review
- E-mail – keyword searching to identify relevant messages and attachments
- Language/character sets can increase complexity and costs

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Investigate

Prepare Written Investigation Plan

- In consultation with client, attorney should prepare written investigation plan and identify:
 - Potential issues
 - Individuals who may have relevant information
 - Potentially relevant documents
- Revise investigation plan as needed, add additional:
 - Issues
 - Individuals
 - Document sources/locations

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Investigative Work Streams

- Interviews of Employees (and third parties)
- Analysis of Financial Data
- Review of E-mails
- Reporting

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Conducting Investigation - Document Reviews

First step is to gather and review documents

- Authorized personnel should collect and deliver documents to counsel.
- 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

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Conducting Investigation – Interviews

- Interviews should be conducted in private.
 - To the extent practical, have witness (associate/paralegal) present during interview to take notes and corroborate your understanding of facts and impressions of witness
- Keep notes of interview
 - Do not record interviews
 - Do not transcribe interviews
 - Prepare written report describing facts of each interview
- Management should only be present when necessary
- Employees must be advised that legal counsel represents company, not employees individually, and what they say may not be kept private.
 - Depending on the severity of the allegations and potential culpability of the employee, you may choose to advise them of the potential need for counsel.
 - In some instances, company may pay for employee counsel.
- Employees must be encouraged to report if they have been threatened or asked to change their stories.

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Investigation Complete

- Counsel should prepare a written report for 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 be labeled attorney 'client-privileged'
- Report must remain confidential – limit circulation of report.

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Internal Investigation Report

Report "should" include a summary of the facts:

- Identify potential cause(s) of the incident
- Describe the incident in detail, including how it happened and/or continued
- Identify impact on health, safety, and quality of care
- Identify time period in question
- Identify individuals involved
- Identify individuals who should have detected non-compliance
- Include at least an estimate of the magnitude of issue

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Internal Investigation Report

Report should describe facts surrounding the discovery and investigation

- How incident was identified?
- Efforts to investigate the matter
- Chronology of investigatory steps
 - List of individuals interviewed along with their contact information
 - Description of files or materials reviewed
 - Summary of auditing activity and documents relied upon to form an estimation of losses.

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Major Cost Drivers of an Investigation

- Use of outside legal and forensic resources
- Use of specialists
- Scope of investigation
- Retrieval, storage and review of electronic data
- Production of documents
- Forensic analysis
- Counsel for employees, if necessary
- Company resources for liaison and assistance
- Type of report (oral or written)

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Now What?

Fix The Problem

- Using the report, corrective action needed to fix the problem
- Need to assess compliance process and policies to identify shortfalls in existing compliance programs and reporting mechanisms
- Responsible employees should be disciplined, as appropriate
- Additional policies, procedures, or reporting layers should be added as necessary to prevent reoccurrence.

Next Steps

Need to discuss with client:

- Whether the past conduct needs to be reported
- To whom past conduct should be reported

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Next Steps

- In the case of our example, let's assume outside counsel was hired, and a lengthy investigation was undertaken with the Hospital as the Client, and with you, as the Chief Compliance Officer, directing the outside counsel.
- Lets also assume the written report has uncovered that there has been a long unspoken policy at the hospital where physicians who refer "enough" patients don't get pursued for overdue lease payments.

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Voluntary Disclosure

Voluntary Disclosures

Potential Benefits:

- Avoid criminal liability
- Minimize civil exposure.
- Avoid Corporate Integrity Agreements.
- Neutralize *qui tam* suits

Voluntary Disclosures

Potential Harms:

- Invites detailed scrutiny
- May encourage government to require additional investigation
- May result in penalties for conduct that would have remained undiscovered

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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.

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Is It “Voluntary?”

- False Claims Act – Changes to the FCA language 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...”
 - Failure to return overpayments can subject a provider to penalties under the FCA.
- False Claims Act – Penalty Reduction to double damages where information is provided within 30 days and full cooperation is provided prior to government investigation. 31 U.S.C. §3729(a)(7).

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Is It “Voluntary?”

60-Day Overpayment Reporting – PPACA requires reporting and repayment of overpayments within 60 days of identification (or due date of next cost report, if applicable)

- What’s “Identification”?
- Violations actionable under FCA

False Claims Act

- Potential FCA liability remains enormous in healthcare context
- Liability
 - 3X Damages
 - \$5,500 to \$11,000 per claim

Sample Penalty Calculation

- Defense Contractor
- \$100,000 damages X 3 = \$300,000
 - 12 (# of claims) X \$11,000 = \$132,000
 - Total liability = \$432,000

Sample Penalty Calculation

Healthcare Provider

- \$100,000 Damages X 3 = \$300,000
- 2,000 (# of claims) X \$11,000 = \$22,000,000
- Total Liability = \$22,300,000

What Gets Disclosed?

- To the OIG – only “potential fraud against the Federal health care programs, rather than merely an overpayment.”
 - “Potential fraud” does not include Stark violations only – there must be at least a “colorable” violation of the anti-kickback statute.
- To CMS – Stark only violation
- To Contractor – “merely an overpayment”
- To U.S. Attorney’s Officer – depends
- To State – depends on state laws
 - NY OIG has been aggressive in seeking disclosures

Stark As Special Case

- Bury your head in the sand and hope no one will find out?
 - Too many *qui tam* relators
- Disclose under to OIG?
 - "Open Letter" requires anti-kickback violation.
- Disclose to CMS?
 - CMS has established self-disclosure protocol
 - Lack of experience on how CMS will compromise claims given potential for huge over-payments.
- Disclose to Medicare contractor?
 - Liability under Stark requires return of all amounts from Medicare based on inappropriate referral.
 - No clear authority to compromise claims.
- Disclose to the local AUSA?
 - Uncertainty?

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What is Involved in Disclosure?

OIG has specific protocols – written submissions to begin the process, followed by internal investigations, and provider self assessments.

- Self-disclosure protocol (63 Fed Reg. 58,399 (October 30, 1998))
- Open letters in 2006, 2008, and 2009.
- Likely involves the creation of separate, additional investigative and corrective action reports.
 - Original reports may be requested by OIG

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What is Involved in Disclosure?

CMS has self-referral disclosure protocols

- Disclosure submitted by email and hard copy
- Return e-mail tolls 60-day repayment obligation
- Requires description of actual or potential violations
- Requires financial analysis

What is Involved in Disclosure?

Each government contractor has its own specific protocols

- Information usually provided in online provider materials
- Disclosure to contractor appropriate where no fraud – Contractors required to refer to OIG if fraud suspected

Disclosure Calculus

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

- Where available, disclosure offers protections too significant to pass up
- Useful for substantial violations of law
- 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

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Operating Under a CIA

Completely alters disclosure calculus

- Corporate Integrity Agreements require disclosure of “reportable events”
 - “substantial overpayment”
 - Matter that a reasonable person would consider a probable violation of criminal, civil or administrative laws applicable to federal health care programs
- Failure to report can carry substantial sanctions, including exclusion from federal health care programs

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Back to Our Hypothetical

Do we disclose? If so, to whom? Do we need to investigate further?

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Questions?

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