


Responding to a Compliance Investigation

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Introduction

Sean McKenna, Haynes and Boone, LLP

- Co-Chair of the firm's Healthcare Practice Group.
- 18 years of healthcare litigation and enforcement experience.
- Investigated and resolved hundreds of civil, criminal and administrative matters over nearly 16 years as a former Assistant U.S. Attorney and OIG and CMS attorney.
- Current practice focuses on defense of healthcare fraud and abuse and regulatory matters, conducting compliance reviews and internal investigations, and defending other white-collar investigations and cases.
- Frequent invited speaker with national organizations.


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Introduction (continued)

Bret S. Bissey, MBA, FACHE, CHC, CMPE
Senior Vice President, Compliance Services

- Eighteen years of healthcare compliance experience.
- Former SVP, chief of ethics and compliance officer at UMDNJ, where he is credited with re-engineering the compliance program of the nation's largest free-standing public health sciences university – one of the largest compliance programs in the country.
 - He successfully led the compliance program to be in adherence with a rigorous Corporate Integrity Agreement (CIA) with the Department of Health and Human Service (DHHS)/OIG that occurred following a Deferred Prosecution Agreement.
- Chief compliance and privacy officer at Deborah Heart and Lung Center.
 - Three-year CIA, first settlement of Voluntary Disclosure Protocol.
- Senior director, Medical and Scientific Affairs, Covance.
- Practice director of the Regulatory Compliance Practice at IMA Counseling.
- Lehigh Valley Hospital – eight years in management positions.
- Frequent national speaker and author on matters of healthcare compliance.
- Recognized compliance consultant.
- Author of Compliance Officer's Handbook.



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Session Objectives

- Enforcement landscape from federal, state, and commercial perspectives
- Developing coordinated and planned response to compliance-related investigations: points to consider
- Leading practices and suggestions for conducting investigations
- Addressing and mitigating allegations and misconduct to reduce organizational risk

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2015 DOJ Activity

DOJ recovered *more than \$3.5 billion* in FY 2015

- Down from last year's \$5.6 billion recovery
- But continues 4-year record of recoveries over \$3 billion

Of \$3.5 billion –

- \$1.9 billion from healthcare industry, including \$330 million from hospitals
- \$2.8 billion (more than half) from cases filed by whistleblowers

Number of *qui tam* suits exceeded 600

- Down from last year's 700
- But way up from 1987's 30
- Whistleblowers received record \$597 million

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Data Analytics – A Continuing Initiative

Investment into data analytics

- Prevent payment of fraudulent claims
- Identify trends and red flags
- Identify outliers

New Investigative and Enforcement Strategies

- The "Fraud Prevention System"
- Automated provider screening program
- Next Generation Desktop

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The Fraud Prevention System

"The Fraud Prevention System is the state-of-the-art predictive analytics technology required under the Small Business Jobs Act of 2010."

- Since June 30, 2011, it has run predictive algorithms and other sophisticated analytics nationwide against all Medicare fee-for-service claims prior to payment."

"For the first time in the history of the program, CMS is Systematically applying advanced analytics against Medicare FFS claims on a streaming, nationwide basis as part of its comprehensive program integrity strategy."

- Report to Congress: Fraud Prevention System, Second Implementation Year 2014

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Healthcare Fraud Prevention Partnership

Purpose is to improve the detection and prevention of healthcare fraud by:

- Exchanging data and information between the public and private sectors
- Leveraging various analytic tools against data sets provided by partners
- Providing a forum for public and private leaders and subject matter experts to share successful anti-fraud practices and effective methodologies for detecting and preventing healthcare fraud

See <https://hfpp.cms.gov/about/index.html>

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Enforcement Outlook

Government budget shortfalls

- Innovative methods to save healthcare dollars

Criminal and administrative activity increasing

Greater attention by DOJ and OIG-HHS on individuals and arrangements

Investigations becoming more complex

- Unprecedented focus on punishing medical decisions
 - e.g., implantable cardiac defibrillators
- Entire industry segments under scrutiny

Conduct of ancillary players affecting physicians and systems

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Enforcement Outlook (continued)

- Creation of Health Care Fraud Prevention and Enforcement Action Team
- New laws and new tools for the Government to fight fraud, waste, and abuse
- On June 30, 2015 HHS OIG announced formation of a new affirmative litigation team to focus exclusively on pursuing civil monetary penalties and exclusions
- Doubles the number of dedicated litigators to bring cases under the civil health care laws,
 - Team will be look at FCA cases as sources of potential enforcement actions

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Physician Compensation Concerns

- June 2015 – OIG Fraud Alert focuses on Physician Compensation Arrangements
- Targeted at physicians and directs all compensation arrangements need to be FMV and reflect payment for provided bona fide services
 - If any purpose of the arrangement is to compensate a physician for past or future referrals, the potential exists for violation of the Anti-Kickback Statute
 - Violations could result in criminal, civil or administrative sanctions, like exclusion and potential penalties under the False Claims Act
- Many new Clinical Integration Models which will need to be reviewed and monitored

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Why a Provider Should Be Compliant

- Quality reporting is the future
- Population-based medicine models of future care
- Reputational risk
- Both locally and regionally
- Never good to have bad data
- If this data (coding) is not accurate, what else is not properly being done?
- Where do auditors focus their energies - the good guys or the bad guys?
 - Learned whistleblowers
 - False Claims Act potential?
- Reduction in Medicare pay of 2-3 percent

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Yates Memorandum (Sept 2015)

Entitled "*Individual Accountability for Corporate Wrongdoing*"

Emphasizes DOJ's commitment to combat fraud "by individuals"

Recommends:

- Not to give cooperation credit unless company provides facts re: individuals
- To focus investigations on individuals "from the inception"
- Not to release "culpable individuals" from liability absent "extraordinary circumstances"
- Not to settle with company without "clear plan to resolve related individual cases"

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Sources of Compliance Investigations

- Enforcement agencies
- Data mining
- Competitor complaints
- Patient or family complaints
- Potential self-disclosures
- Employment or whistleblower litigation
- Social media
- Traditional media
- Hotline complaints

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Compliance Investigations 101

- Tracking all reports/assessments
- Documenting investigation plan
- Preservation of information
- Protections to ensure confidentiality
- Conducting investigation
- Determining scope of disclosure
- Reporting of conclusions/findings to appropriate parties
- Corrective actions for responsible persons/departments
- Discipline of bad actors
- Non-retaliation reinforcement
- Taking remedial measures (repayment or disclosure)

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Developing the Investigative Plan

Identify potential misconduct
Leverage internal & external resources

- Areas of Inquiry:
- Factual questions
 - Legal issues

- Locate responsible individuals:
- Initial targets
 - May change

- Steps to be taken:
- Document preservation and collection
 - Gather information
 - Review and research deadlines and projects

Assess position if know government timelines
Implementation and monitoring of corrective and remedial actions

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Establish the Appropriate Client Relationship

Determine the appropriate client (company, owner, employee or combination of the above)

Where the client is a company, clearly establish a point of contact (POC) in writing with authority to receive information and give direction

- Where possible POC should be neutral or uninvolved in the conduct at issue
- Discuss with client hierarchy and which department/person/entity has ultimate decision-making authority
- Investigations make employment inherently unstable
- Remember POC today can be unemployed or adverse tomorrow

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Preliminary Assessment

- Review potential issues with POC and other relevant individuals
- Goals are to get background intel and context of issue, identity of individuals with relevant information, and operational/business concerns of the client
- Recognize information received likely is incomplete and inaccurate
- Scope of investigation should be dynamic and consistently reassessed

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Additional Considerations

- Resistance from within organization
- Looking at a "heavy hitter"
- Complexity of matter vs. capability of internal staff
- Severity of misconduct
- Independence
- Maintaining privilege and protections

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Put a Hold Notice in Place

Necessary to protect yourself and your client

Substantial differences between companies on how a litigation hold will be received:

- Litigation holds are routine for some
- Such notices for others cause significant concern and can result in employee attrition

Nature of inquiry will determine scope and recipients of litigation hold

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Balancing Discretion and Transparency

- Most investigations are bad for morale
- Investigations by company can be worse
- Must be context specific: no one-size-fits-all solution
- Key is to make a conscious decision that realistically accounts for benefits and maintenance of discretion (including privilege)
- Consider size and culture of client, severity of alleged misconduct, publicity of initiating event, and amount and identity of employees to be interviewed
- Evaluate client's technical capabilities and ability to preserve evidence without inadvertent waiver or disclosure
- Often key tasks benefit heavily from discretion before disclosing or communicating with necessary parties

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Controlling Internal and External Communications

If client communicates investigation, you must message communications

- Company or employees must not undermine privilege
- No obstruction or interference with investigation
- No unauthorized disclosures

Draft talking points for unavoidable discussions with business partners

Organize and script informational meeting for employees

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Tools for Compliance Investigation

Data analytics

Interviews

Subpoenas – if in litigation

Social and traditional media

Requests for information

Active and passive surveillance

Consensual monitoring (recordings as permitted)

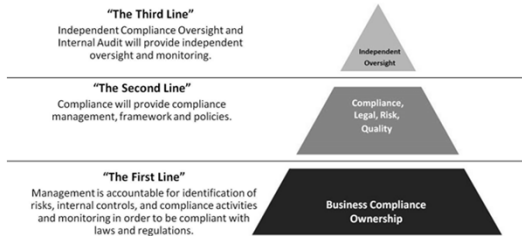
Monitoring electronic data (as permitted)

Reliance on client, legal or consultants

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Leveraging Compliance Resources



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Conducting the Compliance Investigation

- Obtain information
 - Claims/contracts/payments
 - E.g., interview
- Issue request
 - Internal/external correspondence/e-mails
 - Policies/practices/audits
 - Specific claims/patient files/contracts
- Review information gathered
 - What happened
 - Why
- Determine course of action to disclosure or repay
- Best course may not be legal requirement

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Document Collection and Review

Select custodians, time period, search terms

Client or vendor collection

Types of evidence:

- Emails, shared files, devices texts, instant messages, computer hard drive
- Expense reports, business notes, meeting minutes, phone records, etc.
- Government considers personal devices if used for business within scope of subpoenas or otherwise fair game

Cost sensitivity as document review often expensive

After initial review determine where else to look

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Explaining Employee Rights and Obligations

Sample reminders:

- Company is/intends to cooperate
- Government requests directed to the company must be forwarded to counsel
- Do not lie or mislead government or its agents
- Obey hold notices and preserve evidence
- You have right to counsel if the government wants to interview you
- *The company may provide such assistance at your request*
- Most interviews are voluntary – even during raids
- If compelled to testify, notify company and legal
- Understand implications of invoking 5th Amendment right

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Conducting Interviews

Before or after document review? Depends
 Employees (*Upjohn* warning) and third-parties
 Notification whether separate counsel may be prudent
 Sequencing is important

- Typically begin with those who will be most forthcoming/those with the least to lose

May need to get support from Top Levels of Organization for some interactions
 Some interviews may need to all be done on same day to minimize noise & cover-up potential
 Often lead to additional individuals needing to be interviewed. Make sure leadership understands this

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Corrective Actions

Critical step
 Disciplinary actions
 Training
 Policy revisions
 Corrective communications
 Culture adjustments
 Monitoring and implementation

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Repayment and Disclosure of Violations

FIRST fix any problems and stop the bleeding

Federal law requires repayment of known overpayments within 60 days

- CMS issued final rule at 77 Fed. Reg. 9179 (Feb. 16, 2016)

Disclosure to DOJ

- Possible non-prosecution of business entity
 - See USAM § 9-28.000, *et seq.*
- Limited civil FCA multiplier
 - See False Claims Act § 3729

HHS-OIG Self-Disclosure Protocol

- Lower damages/no integrity obligations

CMS Voluntary Self-Referral Disclosure Protocol

- Do not disclose both to CMS and OIG
- Use OIG protocol if implicates other laws

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Leading Compliance Practices

- Listen and investigate when an employee, contractor, agent, or anyone tells you that there is a "problem" at the company
- Identify potential sources of "obligations" to repay the government
 - Claims
 - Enrollment forms
 - Contracts
 - Certifications
- Keep up with evolving legal and clinical standards
- Receivables monitoring, auditing, and repayment demonstrate effectiveness

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Leading Compliance Practices (continued)

- Direct providers are not only targets
 - Billing companies, health insurers, third-party payers, and managed care plans face risk
- Evaluate and update current compliance policies and programs
 - New measures may be needed to address new risks
 - Train, train, and train again!

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Common Enforcement Causes

- Whistleblower/hotline calls
- Patient/family complaints
- Reports to management or compliance
- Vendor communications
- Departing employees
- Employment allegations
- Industry rumors
- Competitor complaints
- Social and traditional media
- Subpoenas or other government requests
- Government interviews of employees or related parties
- Other private litigation

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Investigations in Response to Enforcement Action

- Identify nature of investigation
 - Scope of representations
 - Preserve evidence
 - Initiate internal investigation
 - Containment vs. disclosure
 - Maintain applicable privileges/protections
- Type of request dictates posture
 - Criminal, civil or administrative
 - Multiple jurisdictions
- Assemble team
 - Client
 - Consultant(s)
 - Attorney(s)

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Enforcement Investigations (continued)

- Global settlements if requested by defendant
 - Criminal and civil each negotiate own agreements
 - DOJ cannot address administrative remedies
- Settlement parameters
 - Loss/issues determine level of DOJ involvement
 - Most terms are non-negotiable
 - No confidentiality clauses
 - Covered conduct and released parties are narrow
 - Reservation of claims against individuals
 - Gov't does not resolve relator's claims/fees
 - Relators/defendants directly discuss

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Enforcement Investigations (continued)

- Global settlements
 - Invoke only when appropriate
 - Early contact with administrative agencies
- Settlement Issues
 - Covered conduct
 - Released parties and claims
 - Interplay between corporation and principals
 - Inability to pay
 - Administrative concerns
 - Collateral consequences

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Goals of Enforcement Investigation

- Suspension of payments
- Termination from gov't programs
- Civil recoveries from responsible parties
- Criminal convictions and restitution
- Exclusion/debarment/revocation
- Licensing or board action
- Cost of responding
- Loss of business/goodwill/morale
- Mandated compliance

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Leading Practices for Enforcement Investigations

- Implement an effective compliance program
- Develop prior relationship with experienced counsel or consultant
- Assess status - target, witness, subject?
- Get ahead of government's investigation
- What is scope of representation
 - Does anyone need separate counsel (Yates)?
 - Has anyone talked to the Government?
 - Invoke insurance coverage
- Evaluate ALL liability - criminal, civil, admin, State, licensure, and private
- Strategy has implications for parallel case

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Leading Practices (continued)

- Preserve documents
 - Scope of hold notice
 - Beware of ramifications of company-wide notices
- Protect privileges/protections
 - Critical given current case law
- Compile right team
 - Consultants
 - Clinical and billing
 - Statisticians
- Client counseling
 - Early and often

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Leading Practices (continued)

- Meetings
 - Timing and purpose critical
- Do program rules differ?
 - Demonstrate confusion or lack intent
- Consider sampling of claims/record to show compliance
- Weigh disclosure options
- Fully advise on risks of knowing retention of overpayment

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Leading Practices (continued)

In some instances, it is beneficial to reach out early to the government

- To determine status and if company may benefit from cooperation
- If it is clear that the government is already aware and interested in the company or an individual (*see Yates*)
- If there is a likely raid that can be preempted by cooperation
- Notify stopped billing or harm
 - *Limit exposure and possibly make criminal or civil case less likely*
- To deter demand for employee interviews (in many instances this will not be successful)
- To obtain additional information

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Leading Practices (continued)

Document everything

- Each step of the investigation
- Validate process was fair and impartial
- Consider use of third-parties

Define initial scope

- Based on extent and severity of reported misconduct
- Scope should be dynamic dependent upon findings
 - *Needs to be constantly reassessed*

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Resources for Enforcement and Compliance Information

- Advisory opinion
- OIG Compliance program guidance publications
- State and federal work plans/audits/evaluations
- Settlement/integrity agreements
- Press releases
- GAO reports
- Comments/preambles to safe harbors/exceptions

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Compliance Must Be Effective

If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place

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Questions

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