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Responding to Investigations: How to Ensure Effective Compliance When Facing Scrutiny

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Overview

- Enforcement Agencies and Landscape
- Statutes
- Government Procedure
- Internal Investigations
- Responding to Government Action
- New Enforcement Agenda?
- Conclusion

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Enforcement Agencies

U.S. Department of Justice (DOJ)

> Commitment to prosecute healthcare fraud
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch
  - Healthcare fraud coordinators within 94 United States Attorneys' Offices
  - Federal Bureau of Investigation
  - Drug Enforcement Agency
  - Partnerships with private payors
> Distinct funding sources

Other Enforcement Players

> Local District Attorneys
> Offices of Inspector Generals
  - Federal and State
> Medicaid Fraud Control Units
> Centers for Medicare and Medicaid Services
> Medicaid State agencies
> Tricare Management Authority
> Federal/State contractors
> Commercial "Special investigative units"
> Licensing boards
> Whistleblowers

Enforcement Landscape

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Government Activity

- Big budget for enforcement
  - $672 million for Health Care Fraud and Abuse Program
  - ROI at least $5 to $1
- DOJ Recovery in 2016
  - Total $4.7 billion (up from $3.8 billion in 2015).
    - $2.5 billion paid from healthcare industry
    - $2.9 billion from whistleblower cases
      - Whistleblowers received a record $519 million.

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Notable 2016 Settlements

- Wyeth and Pfizer, Inc.: $784.6 million
  - Allegation that Wyeth underpaid drug rebates to Medicaid for drugs used to treat acid reflux
  - Largest health care settlement of 2016
- Olympus Corp. of the Americas: $646 million
  - Allegation that Olympus paid kickbacks to doctors and hospitals in exchange for the purchase of endoscopes and other medical and surgical devices

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Notable Settlements, continued

- Novartis Pharmaceuticals Corp.: $410 million
  - Allegation that Novartis paid kickbacks to specialty pharmacies to promote distribution of certain drugs
  - Novartis agreed to expand an existing CIA to include its specialty pharmacy relationships and extend agreement by five years
- Millennium Health: $260 million
  - Allegation that Millennium:
    - Billed Medicare, Medicaid, and other federal programs for excessive and unnecessary urine drug and genetic testing; and
    - Gave free items to physicians to obtain lab tests in violation of the Anti-Kickback Statute (AKS) and the Stark Law

OIG-HHS Activity

- Creation of Health Care Fraud Prevention and Enforcement Action Team
  - New laws and tools for government to combat fraud, waste, and, abuse
- In June 2015 announced formation of new affirmative litigation team to focus exclusively on pursuing civil monetary penalties and exclusions
  - Doubles number of litigators to bring cases
  - Team will review FCA cases as sources of potential enforcement actions

Measuring Compliance Program Effectiveness: A Resource Guide

- Known as the *Compliance Guide*
  Product of a January 2017 roundtable between OIG and HCCA professionals
- Provides health care organizations with an "idea bank" for measuring the elements of their compliance programs
- The Compliance Guide is *not* a checklist—organizations should select measures that are practical to their effectiveness reviews in any given year

The Compliance Guide: Seven Elements

- Standards, Policies, and Procedures
- Compliance Program Administration
- Screening and Evaluation of Employees
- Communication, Education, and Compliance Training
- Monitoring, Auditing, and Internal Reporting Systems
- Discipline for Noncompliance
- Investigations and Remedial Measures

DOJ's Yates Memorandum

- Yates Memo (9/9/2015): "*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"

A New Era?

Future Investigations Outlook

- State and federal enforcement actions rising
  - Increased *Qui tams* in 2016
- Medicare insolvent in 15 years
- State budget shortfalls
- Federal and commercial rules remain complex
- Demonstrating effective compliance is crucial
- Increasing attempts to ensure individuals accountable

ACA and Enforcement

- Patient Protection and Affordable Care Act
  - Enacted March 23, 2010
- Amendments to Anti-Kickback statute
  - Rejects stringent definition of knowledge
  - Violations result in falsity under the False Claims Act (FCA)
    - FCA violations can occur even if claim was submitted by an "innocent" third-party
- Clarification of sentencing guidelines
  - Presumption intended loss is value of claim, not actual payment

Changing Political Makeup and the Potential Effect on False Claims and Anti-Kickback

- A new administration could ease *Yates* policy and other agencies could follow lessening individual liability
- Change in Supreme Court
  - Could weaken interpretation of *Escobar* and what is "material" to a false claim
  - 100 vacancies for federal judges

Changing Political Makeup, continued

- Congress recently passed repeal and replace of ACA, but outcome on FCA remains uncertain
  - Public Disclosure Bar
    - Removed express reference to jurisdictional nature of public disclosure bar
    - Gave government the ability to object to dismissal due to the public disclosure bar
    - Narrowed categories of what constitutes as "public" disclosure
      - Repeal could expand the protections of this defense
    - Provided relator with a lower standard to qualify as an "original source"

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Changing Political Makeup, continued

> Outcome on FCA remains uncertain
  - 60-Day Rule: A person who has received an overpayment must report and return such overpayment within 60 days after overpayment was identified
    - Repeal could cause confusion over timing and what qualifies as "overpayment"
  - Provided violation of Anti-Kickback constitutes a false claim
    - Repeal could weaken government's implied certification argument

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Overview of Healthcare Statutes

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Health Care Fraud Statute

> Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347
> Knowingly and willfully execute/attempt a scheme or artifice to:
  - Defraud health care benefit program; or
  - Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services
> 10-year imprisonment, restitution, and fine

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The Federal Anti-Kickback Statute

- Criminal statute, 42 U.S.C. § 1320a-7b(b)
  - Remuneration is anything of value
  - *One Purpose Test*
- Recommend or arrange for items/services under federal programs
  - Includes non-clinicians
  - State analogs may limit kickbacks in cash/private plans
- Greater compliance with safe harbor generally means less risk
  - Advisory Opinions address industry concerns
- Forms basis for civil liability
- Must be commercially reasonable

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FCA

- A false claim or statement for payment to the United States 31 U.S.C. § 3729(a)
  - Conspiracy
  - "Reverse" false claims is the knowing retention of a known overpayment
- Claim must be submitted "knowingly"
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
  - No specific intent to defraud required
- Other state/federal law violations may be bases for liability

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FCA, continued

- Six-year statute of limitations
  - Three years from date material facts are known or reasonably should be known by responsible official
    - DOJ is the official, not agent
  - Not more than 10 years after the violation
- Remedies
  - Damages not required
    - If found liable, mandatory ***treble*** damages and penalties
  - Attorneys' fees and costs
- Increased penalties for violations after Nov. 2, 2015
  - Minimum per claims penalties: $10,781 from $5,500
  - Maximum per claim penalties: $21,563 from $11,000

Statutory Considerations

- Civil (31 U.S.C. § 3729)
  - Either USAG or a relator (whistleblower) may bring FCA cases
  - *Qui tam* provisions filed under seal
    - DOJ has 60 days to intervene
    - Awards relator 15-30% recovery + attorneys fees
  - 6 year SOL and 3 year tolling provision
  - 29 states and D.C. have adopted a statute equivalent to FCA
  - Remedies: Mandatory treble damages and civil monetary penalties between $10,781 and $21, 563 per false claim
- Criminal

FCA *Qui tam* Provisions

- Relator files case on behalf of government
  - Under seal for at least 60 days as DOJ reviews and usually longer
  - May pursue without DOJ involvement
  - Protected from retaliation under section 3730(h)
- Plead with particularity under Rule 9(b)
- Relator entitled to share of proceeds
  - 15 – 25% if government joins
  - 25 – 30% if government declines
- Procedural defenses
  - Public disclosure bar
  - First-to-file rule

Dodd-Frank

- Dodd-Frank Wall Street Reform and Consumer Protection Act enacted on July 21, 2010
- Established "bounty" for reports by whistleblowers could receive 10-30% of the monetary sanctions over $1,000,000 collected
  - Has to be based on the original information provided by the whistleblower
  - *See* 15 U.S.C. § 78u-6(b)(1),
- A whistleblower is "any individual who provides, or 2 or more individuals acting jointly who provide, information relating to a violation of the securities laws to the Commission [SEC], in a manner established, by rule or regulation, by the Commission [SEC]"
  - *See* Section 15 U.S.C. § 78u-6(a)(6)

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Types of FCA Cases

- Fraudulent Billing
- Anti-Kickback Statute Violations & Stark schemes – physician salaries, discounted office space, etc.
- Pricing fraud - "Best Price" AWP fraud, best value, 340(b) diversion
- "Off-Label" marketing
- Switching schemes
- Hospice – ineligibility
- Nursing home worthless services
- Nursing home inflation of RUG scores/medically unnecessary
- Unnecessary lab testing – especially urine testing for opioids
- Manufacturing standards
- Other medical necessity claims
  - Ambulance
  - DME rentals
  - Home health

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Stark Law

> Prohibits self-referrals for federal business, 42 U.S.C. § 1395nn
  - Must involve physician referral
  - Designated health services
  - Medicare and Medicaid only
  - Ownership interest or compensation arrangement
  - Generally must be commercially reasonable and fair market value
  - State law may limit non-Medicare business agreements
> Strict liability
  - Must fully satisfy statutory or regulatory exception
> Remedy is payment disallowance
  - Exclusion and CMP liability
  - May be violation of FCA

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Civil Monetary Penalties Law

> HHS-OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)
  - Permissive exclusion and money damages for specific violations like payment or receipt of illegal kickbacks
> Mirrors FCA but not governed by civil rules of procedure or evidence
  - Limited discovery
  - Hearsay admissible
> OIG usually releases this authority in exchange for compliance obligations

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Government Procedure

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Risk Areas

- False/fraudulent claims
  - Billing for items or services not rendered
    - Upcoding and product substitution
  - Misrepresenting nature of items or services
    - Seeking reimbursement for unallowable costs
- Retention of overpayments
  - Refusal to return erroneous payments
- Improper financial relationships/referrals
  - Sham compliance with safe harbor or exception
  - Excessive payments
- Insufficient documentation of work performed

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Sources of Investigative Cases

- Partnering by enforcement agencies
- Data mining
- Initiatives, working groups, and task forces
- Competitor complaints
- Patient/family complaints
- Self-disclosures
- Whistleblowers
- Social media
- Traditional media

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Internal Investigation Triggers

- Hotline calls
- Reports to management or compliance
- Vendor communications
- Departing employees
- Industry rumors
- News articles
- Subpoenas or other government requests
- Government interviews of employees or related parties
- Private litigation

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Government Investigations

- Parallel proceedings are simultaneous civil/criminal /administrative investigation of same defendants
  - Usually jointly handled
  - Can be federal and state/local or multi-district
- Examples
  - Procurement fraud
  - Financial frauds
  - Healthcare fraud
  - Asset forfeiture actions
  - Drug diversion
  - SEC and antitrust investigation

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U.S. v. Jacques Roy: Dallas Doctor Guilty of Nation's Biggest Home Health Care Fraud Scheme

- Roy certified around 11,000 Medicare patients as part of a nearly $400 million home health care scam
  - Alleged "swapping" to certify so he could see homebound patients
  - Largest medical necessity case in Texas
- Roy recruited some patients – including some of Dallas' homeless to submit fraudulent health care claims
- In April 2016, Roy convicted of:
  - 8 counts health care fraud
  - 2 counts for making false statements to law enforcement
  - 1 count obstruction of justice
  - 1 count conspiracy to commit healthcare fraud

Investigations, continued

- Surveillance
- Consensual monitoring
- Qui tams
- Data analytics
- Interviews
- Search warrants
- CIDs
- Subpoenas
  - Grand jury
  - Inspector General
  - AID (HIPAA)
- Requests for information

Investigations, continued

- Obtain information
  - Claims/contracts/payments
  - Interview
- Issue warrant, subpoena, or request
  - Internal/external correspondence/e-mails
  - Policies/practices
  - Specific claims/patient files
- Review information gathered
  - What is knowledge/intent?
- Determine how to proceed
  - Civil/criminal/administrative or parallel

What to Do When facing an Investigation

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Preliminary Assessment

- Have an initial discussion of the issues with the point of contact and other relevant individuals
- Goals should be to get information on the background and context of the issue, the identity of individuals with relevant information, and the business concerns of the client
- Recognize that the information received likely is incomplete and inaccurate
- Scope should be dynamic dependent upon findings, needs to be consistently reassessed

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Corrective Action

>Critical step
>Disciplinary actions
>Training
>Policy revisions
>Corrective communications
>Culture adjustments
>Monitoring and implementation
>*Evidence of the Above?*

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Leading Practices 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)

Repayment and Disclosure

- FIRST fix any problems
- 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

Resources for Enforcement Information

- Advisory opinions
- Published cases
- 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

Outcomes and Remedies

Possible Outcomes of an Investigation

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

Criminal Resolution of Investigations

- Indictment/information and conviction:
  - Public allegations and trial
  - All questionable past statements/actions raised
  - Billed, not paid, amount drives loss
  - Special enhancements for fraud
  - "Relevant conduct" increases sentence/fine
  - Automatic exclusion/debarment
  - Collateral estoppel under FCA
  - State and private liability

Civil or Administrative Resolution

- Civil action and fraud judgment:
  - Mandatory trebling/penalties
  - Most evidence admissible
  - To avoid self-incrimination = increase risk/liability
  - State and private liability
  - Agencies usually seek permissive exclusion/debarment
- Administrative proceedings and adverse finding
  - Multiple programs/agencies
  - Rules of evidence not applicable
  - Negative impact on civil/criminal case

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Outcome - U.S. v. Jacques Roy

- Sentencing
  - Roy lost medical license and faces more than 80 years in prison
  - Each conspiracy and fraud count has statutory penalty of 10 years in federal prison and $250,000 fine
  - Obstruction of justice and each false statement have a maximum penalty of five years in federal prison and $250,000 fine
- Raising suspicion
  - OIG said Roy came to the agency's attention following a data analysis targeting suspicious billing.
  - Most physicians to refer fewer than 100 patients for home health services but Roy had "by far" submitted the most Medicare claims in the nation for home health services
  - This type of data analytics is routinely used to find outliers
  - Large majority of "innocent" home health agencies were suspended due to association with Roy.
    - Most out of business now

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Concluding Thoughts

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Takeaways

- Implement an effective compliance program
- Assess status - target, witness or subject
- Get ahead of government's investigation
- What is scope of representation
  - Does anyone need separate counsel (Yates Memo)
  - 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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Remember Compliance Matters

> 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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