Enforcement Trends – Compliance Investigations

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Today’s Agenda

• Enforcement update
• The investigative process as it related to compliance
• What to expect during and after settlement
• Using your compliance program to mitigate compliance risks
Enforcement Update
Enforcement Players

- Department of Justice
  - Fraud
  - Antitrust
  - Environmental
- SEC
- Administrative Agencies
- Federal/State Contractors
- Local District Attorneys

- States Attorneys General
- Offices of Inspector General - Federal and State
- Commercial Payor “Special Investigative Units”
- Licensing Boards
- Whistleblowers
- Private Litigants
Examples of DOJ Activity

- DOJ recovered more than $4.7 billion in FY 2017
  - Up from FY 2015’s $3.8 billion recovery
  - ROI for the Health Care Fraud and Abuse Control Program $6 returned for every $1 expended
- Of $4.7 billion –
  - $2.5 billion from healthcare industry, including $330 million from hospitals
  - $2.9 billion (more than half) from cases filed by whistleblowers under FCA
- SEC- filed 18 enforcement actions in 2018
- Antitrust- 35 case filings in 2018
- Number of *qui tam* suits exceeded 700
  - Up from FY 2015’s 600
  - Way up from FY 1987’s 30
  - Whistleblowers received $519 million
DOJ has stated it will continue the previous administration’s stance on Corporate Misconduct:

• The department will continue to investigate and prosecute individual wrongdoers for corporate misconduct
• The federal government will “not use criminal authority unfairly to extract civil payments”
• BUT new guidance recently issued could limit enforcement
  • See Granston and Brand memos
Yates Memorandum

• Issued September 9, 2015
• “Individual Accountability for Corporate Wrongdoing”
• Emphasizes DOJ’s commitment to combat fraud “by individuals”
• Purposes and Benefits:
  • Proper parties are held responsible for their actions
  • Results in a change of corporate behavior
  • Serves as a deterrent to future fraudulent behavior
  • Increases public confidence in the justice system
  • Increases consistency in handling outcomes of federal investigations
Granston Memo

• Leaked and dated January 10, 2018
• Michael D. Granston, Director DOJ Commercial Litigation Branch
• Addressed to all AUSAs handling False Claims Act cases
• Dismissal under FCA section 3730(c)(2)(A)
• Increase in *qui tams*, but not DOJ resources
• 7 “Granston Factors”
January 25, 2018

“... the Department may not use its enforcement authority to ... Convert agency guidance documents into binding rules.”

Example: Definition of “reasonable and necessary”

United States ex. Rel. Polukoff v. St. Mark’s Hospital

Uncertain future for HHS-OIG Advisory Opinions in FCA and criminal cases
Investigations
Sample Statutes

- False Claims Act
- Travel Act/Anti-Kickback Statute
- Criminal Fraud-related laws
- Licensure issues
- CMP laws
Government Investigations

• Surveillance
• Consensual monitoring
• *Qui tams*
• Data analytics
• Interviews
• Search warrants
• Civil Investigative Demands
• Subpoenas
  • Grand jury
  • Inspector General
  • AID/HIPAA
• Requests for information
Investigations, cont’d.

• 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
Internal 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)
Investigative Initiators

- 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
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 will be dynamic dependent upon findings, needs to be consistently reassessed
Investigative Plan

- Identify potential misconduct
  - Factual vs. legal
- Leverage internal/external resources
- Locate responsible individuals
  - Initial targets
  - May change
- Steps to be taken:
  - Document preservation and collection
  - Gather information
  - Review and research deadlines and projects
- Reassess if know government action or timelines
- Implementation and monitoring of corrective and remedial actions
Implementing Corrective Action

- Who best can communicate the plan
- Target high-risk areas
  - Monitoring vs. auditing
- Disciplinary actions
- Training
- Policy revisions
- Corrective communications
- Culture adjustments
- Monitoring and implementation
- Evidence of the Above?
Repayment and Disclosure

• FIRST fix any problems
• Federal law requires repayment of known Medicare/Medicaid overpayments within 60 days otherwise FCA violation
  • 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
Settlements
Settlements - Considerations

- Financial
- Regulatory
- Remedial
- Equitable
- Policy/Industry
Possible Outcomes

- Suspension of payments
- Civil recoveries from responsible parties
- Criminal convictions and restitution
- Exclusion/debarment/revocation/termination
- Licensing board action
- Compliance or integrity obligations
- Cost of responding
- Loss of business/goodwill/morale
Settlements

- Investigations’ Influence On Settlement
- Types Of Resolutions
  - Dismissal with No Action
  - Closed Fraud Matter, but Referral to Administrative Agency
  - Deferred Prosecution
  - Non-Prosecution Agreement
  - Negotiated (most common)
  - Self-Disclosures
Settlements

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

• Specific Issues
  • Covered conduct
  • Released parties and claims
  • Interplay between corporation and principals
  • Inability to pay
  • Administrative concerns
  • Collateral consequences
You’ve Settled – Now What?

- Corporate Dissolution
- Private Litigation
- Administrative Liability
- Individual Culpability
- Corporate Integrity/Integrity Agreement
  - What Is It?
  - Fines
  - Penalties
  - Disgorgement
  - Independent Review Organization
- Corporate Monitorship
Compliance Effectiveness: Leading Practices
Seven Elements of the OIG Model Compliance Program as an area to focus your evaluation

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Audit/Monitoring – Evaluation

- Looking for improvement
- Be careful – creative people can make audit results look better than they are
  - Must establish **consistent** measurements
- Consider using *Net Dollar Value Error Rate* on consistent universe annually as one review
  - 50 claim randomly selected probe sample – consistent with OIG requirements
  - Five percent or below is an acceptable error rate
  - Great way to have a consistent measurement year after year
- Complement with other planned and focused reviews and trend the results
- How many “for cause” reviews performed annually – comparison
Annual Audit Work Plan

• Based upon approved annual work plan
  • By Compliance/Audit Committee or Board
• How many projects were on original plan?
• How many projects were added during year?
• How many were completed? Not completed?
• Trend to answer resources and accurate planning
• If you are missing either bad budget or operational problem
Each circumstance is probably different

General thoughts:

- Consider an independent external review at some pre-determined interval of time (i.e. – every two or three years)
- Contract via the Board and include in budget
- Report to the Board
- Assure you have someone doing this who is experienced and bring value – interview them
- Utilize findings for improvement and then review again - good auditing approach, which can pay dividends in long run
- Develop scorecard of good statistics
Compliance Resources

• 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
Concluding Thoughts
In Sum

- Investigate Yourself - So The Government Won’t
- Carefully Consider Options
- Remediate – Begin Early
- Establish and Maintain An Effective Compliance Program
Benefits

If an organization is investigated for violations of state or federal laws, the government may offer a reduction in penalties if an effective, demonstrated compliance program exists.
Questions