Government Enforcement

Health Care Compliance Association
24th Annual Compliance Institute
(On-Line, Webinar)
March 26, 2020

A M A N D A  P . M .  S T R A C H A N
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M O D E R A T O R

Agenda

• COVID-19 Fraud Scheme Enforcement
• Impact of COVID-19 on On-Going Matters
• Impact of COVID-19 on enforcement trends – 2020 and beyond
• The Government’s Investigative Tools
• Best Practices for Handling a Government Investigation
COVID-19: Current Impact

- COVID-19 shelter in place orders across country
- Closed courts and businesses
- Focus of providers on combating disease
- Grand Jury operations and delays
- Statutes of Limitations
- Speedy Trial waivers

COVID-19: DOJ Response

- COVID-19 presents an opportunity for criminals to take advantage of beneficiaries, providers, and governmental assistance programs
- US DOJ has experience with opportunistic fraud (e.g., TARP, Katrina)
- Price Gouging Task Force
- Types of Schemes
Frequently Investigated Conduct

- Fraud/False Claims
- Kickbacks/Financial Relationships with Health Care Providers
- Insurance Reimbursement
- HIPAA/Patient Privacy Violations
- Opioid Distribution/Diversion
- Misbranding/Off-label Promotion
- Conspiracy/Racketeering Conspiracy
- False Statements
- Obstruction of Criminal Health Care Investigation
- Witness Tampering

Health Care Fraud: One of DOJ’s Favorite Targets

- DOJ Health Care Fraud Unit
  - Charged 344 individuals in 2019 (alleged $401B in fraud losses)
  - More than 75 prosecutors
  - Strike force model (includes FBI, HHS-OIG, CMS CPI, DEA, IRS, DCIS, USAO, and state/local law enforcement)
  - Major actions in 2019:
    - “Operation Brace Yourself” - $1.2B nationwide health care fraud scheme involving telemedicine and DME
    - Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedowns – 60 defendants charged
    - Coordinated takedown of nationwide $2.1B fraudulent genetic testing scheme
Health Care Fraud: One of DOJ’s Favorite Targets

- FY 2019 FCA
  - $3B in total recoveries
    - $2.6B from healthcare sector
    - 10th straight year of recoveries exceeding $2B

FCA Trends: Total Recoveries Deconstructed

<table>
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<th>Year</th>
<th>Government Intervention</th>
<th>Government Declined to Intervene</th>
<th>Original Government Actions</th>
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Note: Specific data values are not provided in the text.
Common Origins of Healthcare Fraud Investigations

- Qui Tam Complaints
- Agency Investigations
  - HHS-OIG
  - FBI, FDA, VA, IRS, etc.
  - Consumer/Public Complaints
- Data Analytics
- Public Events
  - e.g., COVID-19 Outbreak, Opioid Epidemic
- Actions against industry competitors
- News/Press

Investigative Tools

- Criminal Tools
  - Search warrants
  - Electronic surveillance
  - Subpoenas (grand jury/HIPAA)
  - Cooperating witnesses (i.e., relators)
- Civil Tools
  - Civil Investigative Demands
  - Administrative Subpoenas
  - Informal requests
- Covert vs. Overt Investigations:
  - Investigators seek to learn as much as possible before issuing a subpoena and making investigation overt
  - Recipient is often playing catch up to the investigating agency
You’re Under Investigation: Now What?

- **Who to tell?**
  - General counsel/other in-house lawyers
  - Corporate officers/managers
  - Depending on circumstances, outside lawyers

- **What to do?**
  - Have counsel issue litigation hold/document preservation notice
  - Identify persons likely to have relevant documents and knowledge
  - Collect relevant documents and data sources (e.g., emails, laptops, cell phones)

- **Communicate with investigators**
  - Identify subject matter of investigation
  - Narrow scope of document requests

- **Initiate parallel internal investigation**
  - Learn the facts to respond to government inquiries & demonstrate cooperation and commitment to compliance

Benefits of Conducting Parallel Internal Investigation

- **Gain understanding of relevant facts**

- **Assess potential exposure/liability**
  - Company versus individual exposure/liability
  - Ascertain whether certain employees/individuals need independent counsel

- **Take any appropriate remedial action**
  - Update corporate policies
  - Enhance compliance program and training

- **Engage the government early on substance**
  - Opportunity to address potential areas of concern & establish relationship and open dialogue

- **Analyze potential defenses**
Factors Likely To Impact Criminal Enforcement Decisions

- Nature and Circumstances of Conduct
  - Rogue or systemic within company?
  - Does target have history of similar conduct?
  - One-off event or scheme to defraud?
  - Government focus is on actual fraud, kickbacks
- Patient Harm
- Economic Harm
- Whether Defendant Occupies Position of Trust
  - e.g., Health Care Provider, etc.
- Timing/Resources
  - Government has limited resources and wants to make an impact

Strategic Considerations: Cooperation/Self-Disclosure

- Cooperation/Self-Disclosure:
  - Credit is available for companies that cooperate and disclose
  - Government cannot condition cooperation credit on waiver of privilege...
  - BUT, will want to know:
    - What the company knew about alleged misconduct
    - Who the bad actors were (especially senior managers/executives)
    - The results of the company's investigation
  - Facts/evidence not privileged
Conclusion

Questions?

Thank you and stay safe!

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