Emerging Trends in Healthcare Fraud Enforcement

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Government Fraud Enforcement Partners

- Department of Justice/USAOs
- HHS Office of Inspector General
- Federal Bureau of Investigations
- State Attorney General’s Office/Medicaid Fraud Control Units
- CMS and contractors (e.g., UPICs, MEDIC)
- State Boards of Medicine, Nursing etc.
Sources of Case Referrals

- *Qui tam* (whistleblower) complaints
- OIG Hotline- competitor/patient/family complaints
- Information developed during OIG audits, evaluations, and reviews
- Data mining
- Partner agency (e.g., UPICs, MEDIC) referrals
- Self-disclosures

Criminal, Civil & Administrative Proceedings

<table>
<thead>
<tr>
<th>Factor</th>
<th>Criminal</th>
<th>Civil</th>
<th>Administrative</th>
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</thead>
<tbody>
<tr>
<td>Standard of Proof</td>
<td>“Beyond a reasonable doubt”</td>
<td>“By a preponderance of the evidence”</td>
<td>“By a preponderance of the evidence”</td>
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<tr>
<td>Case Initiation</td>
<td>Indictment or Information</td>
<td>Complaint</td>
<td>Complaint or formal notice/demand letter</td>
</tr>
<tr>
<td>Prosecution Authority</td>
<td>Department of Justice</td>
<td>Department of Justice</td>
<td>Agency Head (HHS Secretary)</td>
</tr>
<tr>
<td>Purpose</td>
<td>To punish and deter</td>
<td>To remedy past and/or prevent future injuries</td>
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<tr>
<td>Remedies</td>
<td>Imprisonment, Supervision, Fines, Restitution, and Special Assessments</td>
<td>Civil Penalties, Damages, Injunctions, and Restraining Orders</td>
<td>Civil Penalties, Damages, Exclusions, Suspensions, Debarments, and other Adverse Actions</td>
</tr>
</tbody>
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Self-Disclosure Option

- HHS-OIG Self Disclosure Protocol
  - Good faith disclosure indicative of a robust and effective compliance program
  - Presumption against requiring an integrity agreement
  - Potential for a lower multiplier

- Disclosure Directly to the U.S. Attorney’s Office

DOJ Policy Changes

- Sept. 2015 - Memorandum Re: Individual Accountability for Corporate Wrongdoing (“Yates Memo”) is released
  - Announced formal policy of combating corporate crime by targeting and seeking accountability from the individuals involved in the wrongdoing
  - Required corporations to identify “all individuals involved in or responsible for the misconduct” in order to receive cooperation credit
  - Reiterated and formalized mandatory coordination among civil and criminal divisions in cases of corporate malfeasance
  - Applies to both Criminal and Civil investigations
  - Outlined 6 “key steps” for federal prosecutors to follow in order “to most effectively pursue the individuals responsible for corporate wrongs”
DOJ Policy Changes

- Nov. 2018 - Rod Rosenstein remarks on cooperation credit during International Conference on the FCPA announced a clarification of the Yates Memo’s requirements
  - Still a focus on pursuing individuals involved in corporate fraud
  - “Investigations should not be delayed merely to collect information about individuals whose involvement was not substantial, and who are not likely to be prosecuted”
  - To qualify for cooperation credit in criminal cases companies now need to identify individuals who were substantially involved in the wrongdoing

DOJ Policy Changes

- May 2019 – DOJ Civil Division issued guidance on False Claims Act Matters and updates to the Justice Manual

  - Cooperation credit in False Claims Act cases may be earned by:
    - Voluntarily disclosing misconduct unknown to the Government
    - Cooperating in an ongoing investigation
      - Sharing of information gleaned from an internal investigation
      - Identifying individuals involved in the misconduct or who have knowledge of the misconduct
      - Preserving/producing documents, information and metadata beyond what is legally required
      - Undertaking remedial measures in response to a FCA violation

  - The amount of credit that the DOJ will provide remains highly discretionary
False Claims Act Enforcement Activity

- More than $3 billion in FCA recoveries in Fiscal Year 2019
- Approximately $2.6 billion relates to matters that involved the health care industry
- Insys Therapeutics: $195 million to settle civil allegations that company paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys – sham speaker events, lavish meals and entertainment, etc.
- Reckitt Benckiser: $1.4 billion to resolve criminal and civil liability related to the marketing of opioid addiction treatment drug Suboxone
- Avanir Pharmaceuticals: $95 million to resolve kickback allegations and false and misleading marketing to induce providers to improperly prescribe Neudexta

United States v. AseraCare

- FCA case where *qui tam* relator alleges that AseraCare knowingly and falsely certified that certain Medicare recipients were terminally ill in order to receive Medicare reimbursements.
  - Bifurcated trial between falsity and other FCA elements.
- After a partial verdict in favor of the government on falsity, the district court judge reversed, noting:
  - Falsity requires proof of an objective falsehood, difference of opinion between physicians is not enough.

*176 F. Supp. 3d 1282 (N.D. Ala. 2016)
*938 F. 3d 1278 (2019)*
Application of AseraCare

  - “The conflicting hospice care eligibility expert testimony involves a subjective difference of medical opinion.”
  - “However, the Complaint here alleges objective falsity—for example, that Dr. Pandya falsely diagnosed cataracts and then performed unnecessary cataract surgeries on those patients.”

Exclusion Risk Spectrum

- OIG assessment of future risk posed by persons who have allegedly engaged in civil health care fraud
  - Makes **public** all health care providers that refuse to agree to enter into a CIA in connection with an FCA settlement

https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp
FCA Settlements on the OIG Risk Spectrum
FY 2019 Q1-Q4

Enforcement Focus: Opioids

- High government spending on opioids
  - Medicare prescription drug program spent more than $4 billion on opioids in 2016
- Mechanisms for DOJ enforcement?
  - Anti-Kickback Statute;
  - False Claims Act;
  - Controlled Substances Act-
    - Distribution and ordering,
    - Prescribing,
    - Corresponding responsibility,
    - Theft and loss reporting
- OIG Work Plan: Steady addition of opioid-related items

https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp
Enforcement Focus: Opioids

- In 2018, DOJ announced its vigorous attack on the opioid crisis
- Opioid focus in largest-ever enforcement action (June 2018)
  - Of 601 defendants, 162 (76 physicians) charged related to opioids and other narcotics
  - Of 2,700 individuals excluded from federal health care programs from July 2017 through June 2018, 587 providers were excluded related to opioid diversion and abuse
- Strike Forces
  - April 2019 – Appalachian Regional Prescription Opioid Strike Force charged 60 individuals, including 53 medical professionals, across 11 federal districts, for their alleged participation in illegally prescribing and distributing opioids in a health care fraud scheme.
  - DEA/DOJ: New Opioid Fraud and Abuse Detection Unit, $20M plus 12 DOJ attorneys to focus only on opioid-related fraud; focus districts.
  - FBI/DOJ: Joint Criminal Opioid Darknet Enforcement (J-CODE) team.
Enforcement Focus: Genetic Testing Fraud

- CGx (cancer DNA test) – collected by buccal swab, this test determines an individual’s predisposition to developing certain types of cancers based on an analysis of genetic markers

- PGx (pharmacogenomic DNA test) – collected by buccal swab, this genetic test can predict an individual’s likelihood to experience an adverse event or not respond to a given drug based on how he or she metabolizes and responds to medications

- CGx and PGx billing can be in excess of $13k per beneficiary

- CGx and PGx reimbursement is approximately $6k to $9k per beneficiary

Enforcement Focus: Genetic Testing Fraud

- Genetic testing fraud focus in nationwide takedown (September 2019)

- Charged 35 individual for their participation in genetic testing schemes that caused $2.1 billion in losses

- Includes 9 charged physicians
Enforcement Focus: Telemedicine

- April 2019 Telehealth Takedown - 24 telemedicine and durable medical equipment (“DME”) company executives and physicians charged for their alleged participation in a $1.2 billion healthcare fraud scheme.

- General Telehealth Fraud Allegations
  - Physicians never talked to or treated patients
  - Patients did not need or even want prescriptions, DME, genetic testing, etc.
  - Prescriptions, DME, genetic testing was routed directly to specific pharmacies, DME distributors, or laboratories
  - Kickbacks/fee-splitting between pharmacies, DME companies, or laboratories and telemedicine companies

Predictions for 2020?