Recent Government Enforcement and Compliance Guidance Affecting Healthcare

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The points of view expressed are those of the authors and do not reflect the official view of the Department of Justice

Agenda

➢ Civil and Criminal Enforcement Trends and Results
➢ Whistleblower Assessments and Parallel Proceedings
➢ Criminal and Civil Compliance Review Guidance
Civil Enforcement Remains Aggressive

- **2018**: healthcare recovery increased over FY 2017
- **First half of 2019**: approximately *three times* higher than same period 2018
Civil FCA Enforcement: Common Focus Areas

➢ Billing/up coding
➢ Waived co-pays
➢ Medical necessity
➢ Medicare Advantage / risk adjustment coding
➢ Healthcare fraud cases against individuals and doctors
➢ Joint ventures with physician practices
➢ AKS violations

Civil Enforcement: Electronic Health Records Vendors

Third-party EHR vendor(s) who caused others to submit false claims
Civil Enforcement: Telemedicine / Telehealth Services

Civil Enforcement Telemedicine: Where’s the Fraud?

Claims from non-rural or unauthorized originating sites

Claims for services provided by an unallowable means of communication

Claims for ineligible institutional providers
Civil Enforcement Telemedicine: Where’s the Fraud?

Kickbacks

Part D and DME Fraud Schemes premised on telemedicine visits

Call centers pay physicians to prescribe, by telemedicine, braces and pain creams that are not medically necessary. Prescriptions are sold to DME providers and pharmacies

“Telemedicine is a valuable service for our citizens, but it must not be abused.”

August 2019:
Telemarketer and Marketing Companies Pay $2.5 Million to Settle Allegations That They Operated Telemedicine Schemes Involving Illegal Kickbacks and Unnecessary Prescriptions
Civil Enforcement: Some Stark Law in 2019


➢ Various Settlements

Criminal Enforcement: Common Health Care Fraud Schemes

Common frauds include:
• Billing for services that were not provided
• Billing for unnecessary services
• Misidentifying services as covered when providing non-covered services
• Upcoding
• Misrepresenting providers of services
• Paying kickbacks for patient referrals
Criminal Enforcement: Results

➢ 2016 National Health Care Fraud Takedown
  • 301 defendants charged across 36 federal districts
  • 61 defendants were doctors, nurses, and other licensed medical professionals
  • Charges in connection with over $900 million in fraudulent billings

➢ 2017 National Health Care Fraud Takedown
  • 400 individuals charged across 41 federal districts
  • 115 defendants were doctors, nurses, and other licensed medical professionals
  • Charges against 120 defendants involved in the distribution of opioids
  • Charges in connection with $1.3 billion in fraudulent billing

➢ 2018 National Health Care Fraud Takedown
  • 601 defendants charged across 58 federal districts in connection with $2 billion in fraudulent billing
  • 165 doctors, nurses, and other licensed medical professionals were charged
  • 162 defendants charged in connection with the opioid epidemic; 132 defendants charged in cases involving pharmacy-related fraud

National Health Care Fraud and Opioid Takedown Trends

<table>
<thead>
<tr>
<th>Year</th>
<th>Defendants Charged</th>
<th>Loss Amount (M)</th>
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<tbody>
<tr>
<td>FY 2014</td>
<td>90</td>
<td>$260M</td>
</tr>
<tr>
<td>FY 2015</td>
<td>243</td>
<td>$712M</td>
</tr>
<tr>
<td>FY 2016</td>
<td>301</td>
<td>$900M</td>
</tr>
<tr>
<td>FY 2017</td>
<td>412</td>
<td>$1.3B</td>
</tr>
<tr>
<td>FY 2018</td>
<td>601</td>
<td>$2.0B</td>
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</tbody>
</table>

Federal Districts:
- May 2014: 10
- June 2015: 17
- June 2016: 36
- July 2017: 41
- June 2018: 58
Criminal Enforcement: Recent Examples

Telemedicine and Recruiting Frauds
- Operation Brace Yourself – 24 individuals charged in $2 billion Medicare fraud
- Genetic Testing – Recruiters, telemedicine, medically unnecessary tests, and kickbacks

Kickbacks
- Speaker programs, sham contracts, PODs

Criminal HIPPA Violations

Industries Susceptible to Fraud
- Home Health, Hospice
Sources for Civil Cases

What do we investigate:
- *Qui tams*
- Non *qui tams* (DOJ investigations)
- Voluntary disclosures
- Agency referrals
- Parallel cases

Civil Qui Tam Considerations

Realтор

Relator
DOJ Considerations of Relator’s Pre-Filing

- **Facts:** Knowledge of clear violation?
- **Evidence:** What are the documents, other proof of fraud, “who, what, when, where?”, specific examples of fraud?
- **Damages:** Sufficient damages to justify risk to Relator?
- **Initial assessment of Government’s interest in the area of law and type of fraud:** Is it material to the government?

Civil Investigative Tools: Ways To Get Information
Civil Legal Framework

➢ False Claims Act (FCA)
➢ Anti-Kickback Statute (AKS)
➢ Stark Law
➢ Controlled Substances Act (CSA)

Civil FCA Update: Will This Qui Tam Ever End?
Sources for Criminal Investigations

➢ *Qui tams*
➢ Data-identified targets
➢ Voluntary disclosures
➢ Agency referrals (including those derived from hotline tips)
➢ Unified Program Integrity Contractors (UPIC) referrals
➢ Collaboration with state agencies

Criminal Investigative Tools

➢ Grand Juries
➢ HIPAA subpoenas
➢ Agency subpoenas
➢ Search Warrants
➢ Process under the Electronic Communications Privacy Act – 2703(d) orders
➢ Undercover Investigations
➢ Witness cooperation
Criminal Legal Framework

➢ Healthcare Fraud, 18 U.S.C. § 1347
➢ Mail and Wire Fraud, 18 U.S.C. §§ 1341, 1343
➢ Anti-Kickback Statute, 42 U.S.C. § 1320a-7b
➢ Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220
➢ False Claims, 18 U.S.C. §§ 286, 287
➢ Conspiracy statutes, 18 U.S.C. §§ 371, 1349
➢ Travel Act, 18 U.S.C. §1952
➢ Title 21: Controlled Substances Act

Criminal Sanctions for Healthcare Violations: How Bad is Bad?

Individuals: Sentences dependent on harm to the patients or public and amount of loss

➢ United States Sentencing Guidelines, Chapter 2, Section 2B1.1

<table>
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<tr>
<th>Loss (apply the greatest)</th>
<th>Increase in Level</th>
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<tbody>
<tr>
<td>(A) $5,000 or less</td>
<td>no increase</td>
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<tr>
<td>(B) More than $5,000</td>
<td>add 2</td>
</tr>
<tr>
<td>(C) More than $15,000</td>
<td>add 4</td>
</tr>
<tr>
<td>(D) More than $40,000</td>
<td>add 6</td>
</tr>
<tr>
<td>(E) More than $95,000</td>
<td>add 8</td>
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<tr>
<td>(F) More than $500,000</td>
<td>add 10</td>
</tr>
<tr>
<td>(G) More than $195,000</td>
<td>add 12</td>
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<tr>
<td>(H) More than $350,000</td>
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<tr>
<td>(I) More than $1,000,000</td>
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<tr>
<td>(J) More than $3,500,000</td>
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<tr>
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<tr>
<td>(O) More than $250,000,000</td>
<td>add 28</td>
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<tr>
<td>(P) More than $500,000,000</td>
<td>add 30</td>
</tr>
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</table>
Criminal Sanctions for Healthcare Violations: How Bad is Bad?

Organizations: United States Sentencing Guidelines: Chapter 8

➢ Part B: Remedying Harm from Criminal Conduct (restitution, remedial orders, community service, notice to victims)
  • Not part of punishment, but of making victims whole.
  • 8B1.1 provides requirements for an effective compliance and ethics program

➢ Part C: Fines: Based on seriousness of the offense and culpability of the organization.
  • If the organization operated primarily for a criminal purpose or primarily by criminal means, the fine shall be set at an amount (subject to statutory maximum) sufficient to divest the organization of all of its assets.
  • Otherwise, the base fine is the greatest of: (1) the amount from the table provided at right (based on Offense Level calculated from applicable Chapter 2 Guideline), (2) the pecuniary gain to the organization, or (3) the pecuniary loss from the offense caused by the organization, to the extent the loss was caused intentionally, knowingly, or recklessly. U.S.S.G. § 8C2.4(d).
  • Fine is increased or decreased from the “base” by culpability score that results in a multiplier.
  • Multiplier ranges from 0.05 for culpability score 0, to 4 for culpability score 10 or more. Fine is multiplier times fine amount in table associates with offense level. Anything below culpability score 5 yields a discount in the fine.

➢ Part D: Organizational Probation
  • Appropriate when needed to ensure another sanction will be fully implemented or that steps will be taken within the organization to reduce the likelihood of future criminal conduct (e.g., paying the fine or restitution, implementation of CIA)

Parallel Proceedings

JM 1-12.000 (January 2012): Criminal prosecutors and affirmative civil enforcement attorneys must consider parallel proceedings between criminal, civil, administrative, and regulatory investigations at every stage of the investigation and prosecution.

Justice Manual (4-3.100) (previously the Yates memo): focuses on individual accountability in corporate wrongdoing
Criminal and Civil DOJ Compliance Guidance

KEY DEVELOPMENTS

➢ Headline news
  ➢ Criminal Guidance on Corporate Compliance Programs
  ➢ Individual Accountability
  ➢ Civil FCA Guidance
Update #1: Criminal Division Guidance on Corporate Compliance

Background: Principles of Federal Prosecution of Business Organizations (USAM 9-28.000)

• Two Factors focus on corporate compliance: (1) existence and effectiveness of pre-existing compliance program; and (2) remedial actions, including efforts to implement an adequate and effective compliance program or to improve an existing one.

• Also emphasizes the focus on individual wrongdoers: “Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation. Because a corporation can act only through individuals, imposition of individual criminal liability may provide the strongest deterrent against future corporate wrongdoing.”

• Directs prosecutors to review Chapter 8 of the U.S.S.G., which identifies features of an effective compliance program.

Criminal Division Guidance on Corporate Compliance

March 2018 – FCPA Corporate Enforcement Policy as “nonbinding guidance”

• When there is (1) voluntary self-disclosure, (2) full cooperation, and (3) timely and appropriate remediation, in accordance with the policy, there presumption that the company will receive a declination absent aggravating circumstances

• If a criminal resolution is warranted, the government:
  • Will recommend 50% reduction off low end of the U.S.S.G. fine range, except for a criminal recidivist; and
  • Will not require a monitor if the company has, at the time of resolution, implemented an effective compliance program.
  • To qualify, the company must pay all disgorgement, forfeiture, and restitution.

• If no initial self-disclosure but later cooperation, 25% recommended reduction off low end U.S.S.G.

• Compliance program is evaluated in context of determining whether there was timely and appropriate remediation.
Criminal Division Guidance on Corporate Compliance

October 2018: Benczkowski Memorandum

In general, the Criminal Division should favor the imposition of a monitor only where there is a demonstrated need for, and clear benefit to be derived from, a monitorship relative to the projected costs and burdens. Where a corporation’s compliance program and controls are demonstrated to be effective and appropriately resourced at the time of resolution, a monitor will likely not be necessary.

Factors:
(a) whether the underlying misconduct involved the manipulation of corporate books and records or the exploitation of an inadequate compliance program or internal control systems; (b) whether the misconduct at issue was pervasive across the business organization or approved or facilitated by senior management; (c) whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal control systems; and (d) whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future.

Criminal Division Guidance on Corporate Compliance

May 2019: Evaluation of Corporate Compliance Programs

Purpose of the Guidance: Assist prosecutors in determining whether a compliance program was and is effective, for purposes of determining appropriate (1) form of any resolution or prosecution, (2) monetary penalty, if any, and (3) compliance obligations in any criminal resolution.

2019 Guidance focuses on 3 questions:
1. **Design**: Is the corporation’s compliance program well designed?
2. **Implementation** - Is the program being applied earnestly and in good faith? That is, is the program implemented effectively?
3. **Results** - Does the corporation’s compliance program work in practice?
Criminal Division Guidance on Corporate Compliance

Design
Assess whether the program is designed for maximum effectiveness to prevent and detect wrongdoing, and whether corporate management is enforcing the program or tacitly encouraging or pressuring employees to engage in misconduct

Design Factors:
➢ Internal Corporate Risk Assessment: tailored to detect misconduct likely to occur in business and regulatory environment, periodically updated, and should include revisions based on lessons learned.
➢ Policies and Procedures: Give effect to ethical norms and reduce identified risk
   • Code of Conduct setting forth commitment to full compliance that is accessible to all employees
   • Incorporate culture of compliance into day-to-day operations
➢ Training and Communication: appropriately tailored and integrated into the organization; implemented to be “truly effective”
➢ Confidential Reporting Structure and Investigation Process: anonymous or confidential process
➢ Third Party Management: risk-based due diligence of third party relationships
➢ Mergers and Acquisitions (M&A): comprehensive due diligence of acquisition targets

Effective Implementation
➢ Commitment by Senior and Middle Management – create and foster a culture of ethics and compliance
➢ Autonomy and Resources – sufficient personnel and resources with autonomy from management, such as direct access to board or board’s audit committee
➢ Incentives and Disciplinary Measures – clear procedures, consistently enforced, discipline commensurate with violation
Criminal Division Guidance on Corporate Compliance

Does the program work in practice?

➢ Continuous Improvement, Periodic Testing, and Review – evolve to adjust to changes in company, environment, and law
➢ Investigation of Misconduct – timely, well-funded, and thorough
➢ Analysis and Remediation – root cause analysis of misconduct

A Culture of Compliance?
Update #2: Pursuing Claims Against Individuals (JM 4-3.100)

➢ September 2015: Yates Memo
➢ November 2018: Justice Manual
➢ DOJ will hold individuals accountable for corporate wrongdoing.

1. Focus on individuals from the inception of the investigation
2. Communicate during parallel investigations
3. Corporations must provide “meaningful assistance” to be eligible for “cooperation credit”
4. Don’t release individuals from liability when resolving with a company, unless further action isn’t necessary or in public interest
5. Have a plan for individuals and memorialize any declinations
Update #3: Civil FCA Disclosure, Cooperation and Remediation Guidance (JM 4-4.112)

What not to do…

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Update #3 Civil FCA Disclosure, Cooperation and Remediation Guidance: How?

1. Voluntary Self-Disclosure

2. Cooperate in Ongoing Government Investigation: 9 examples

3. Undertake Remedial Measures in Response to Violation: 4 examples

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Update #3 Civil FCA Disclosure, Cooperation and Remediation Guidance: Potential Upsides?

1. Reduction in penalties
2. Administrative agencies notified of cooperation
3. Public acknowledgement of cooperation
4. Assistance with *qui tam* resolution