B. Effective Strategies for Dealing with Physician-Related Fraud and Abuse Enforcement Trends

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The contents of this presentation do not reflect the views of the U.S. Department of Justice

Relevant Fraud and Abuse Laws

- Physician Self-Referral Statute/Stark
- Anti-Kickback Statute
- False Claims Act
- Federal Criminal Statutes
- Administrative Penalties & Sanctions
**Stark Law**

- Prohibits physicians and immediate family members with a direct or indirect financial interest in an entity from referring Medicare patients to that entity for “designated health services”
- Strict liability statute
- Numerous exceptions may apply
  - Space leases
  - Medical directorships
  - EHR donations
- Violations may result in civil monetary penalties and possible exclusion
- May form basis of False Claims Act violation

**Anti-Kickback Statute**

- Prohibits asking for or receiving anything of value in exchange for referrals of federal healthcare program business
- OIG has issued safe harbors
  - Space and equipment leases
  - Personal services and management contracts
- Criminal statute; violation punishable by **$25,000 per violation** and/or **up to five years in prison**
- Conviction implicates OIG mandatory exclusion from federal healthcare programs
- May form basis of False Claims Act violation
**False Claims Act**

- Prohibits knowingly making or causing the submission of false claims for payment to the federal government
- Prohibits knowingly retaining money owed to the government
- Provides for treble (3x) damages and per claim penalty of between $5,500 and $11,000
- Allows for private parties (qui tam relators) to bring suit on behalf of the government and participate in % of any recovery

**Relevant Criminal Statutes**

- Offenses Involving False Claims and False Statements
  - 18 U.S.C. §§ 287 (circuit split regarding materiality), 1001 (false statements), 1035 (false statements relating to healthcare matters)
- Fraud Scheme Statutes
  - 18 U.S.C. §§ 1341 (mail), 1343 (wire), 1347 (healthcare fraud – covers all “healthcare benefit programs” not merely federal programs)
- Aggravated Identity Theft
  - 18 U.S.C. § 1028A – covers transfer, possession or use of identification without lawful authority; mandatory 2 year minimum sentence
- Obstruction of Audits and Investigations
- Medicare/Medicaid Fraud Statutes
**Administrative Enforcement**

- Mandatory and permissive exclusion governed by 42 U.S.C. §§ 1320a-7(a), (b)(1)-(16)
  - Resulting from convictions for certain types of criminal offenses or other specified conduct
- Civil Monetary Penalties of $10,000 to $50,000 authorized by 42 U.S.C. § 1320a-7a; 42 C.F.R. § 1003.102
  - Resulting from violations of Anti-kickback Statute, certain Medicare provisions or submission of false or fraudulent claims

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**Enforcement Results**

**Civil Fraud Recoveries**
FY 2009 - 2013 ($ Billions)

<table>
<thead>
<tr>
<th>Year</th>
<th>Recovery Amount</th>
</tr>
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<tbody>
<tr>
<td>2009</td>
<td>$2.5</td>
</tr>
<tr>
<td>2010</td>
<td>$3.1</td>
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<tr>
<td>2011</td>
<td>$3.1</td>
</tr>
<tr>
<td>2012</td>
<td>$4.9</td>
</tr>
<tr>
<td>2013</td>
<td>$3.8(*)</td>
</tr>
</tbody>
</table>

(*) nearly 70% of recoveries in FY 2013 involved HHS as victim agency

*Source: Fraud Statistics – Overview, Civil Division, U.S. DOJ (Dec. 23, 2013)*
New Qui Tam Lawsuits

Number of New Qui Tam Lawsuits Filed by Year (FY 2009 - 2013)

Source: Fraud Statistics – Overview, Civil Division, U.S. DOJ (Dec. 23, 2013)

Enforcement Priorities: Physician Billing

- OIG Work Plan explains focus on billing for E/M services and “incident to” services
- Recent FCA results suggest focus on billing issues:
  - U.S. ex rel. Craig v. Sound Inpatient Physicians, No. 09-cv-5301 (W.D. Wash.) - $14.5 million FCA settlement
  - U.S. ex rel. Freedman v. Suarez Hoyos, No. 04-cv-0933 (M.D. Fla.) - $26.1 million FCA settlement with Florida-based dermatologist
  - U.S. v. Malik, No. 1:12-cv-01234 (D.D.C.) - $17.1 million FCA judgment against nuclear cardiologist related to unbundling
  - U.S. ex rel. Oughatigan v. IPC The Hospitalist Co., No. 09-cv-5418 (N.D. Ill.) – United States announced intervention is FCA action based on physician billing issues
  - U.S. v. Hamilton, No. 2:13-cr-00231 (M.D. Tenn.) – misdemeanor plea of guilty by pediatrician related to infant hearing tests and urinalysis testing with microscope where practice did not have requisite equipment to perform such tests
Enforcement Priorities:
Physician Compensation

- Increased scrutiny related to reemergence of employed physician model and acquisition of physician practices
- Results in recent FCA cases suggest focus on valuation issues regarding physician compensation:
  - *Intermountain Health Care Inc.* - $25.5 million to settle FCA allegations that hospital paid incentive compensation to physicians in violation of Stark
  - *U.S. ex rel. Luque v. Adventist Health*, No. 2:08-cv-1271 (E.D. Cal.) - $14.1 million to resolve FCA allegations that hospital paid physicians above fair market value compensation

Enforcement Priorities:
Unapproved Drugs and Devices

- FDCA prohibits use of unapproved drugs and medical devices, 18 U.S.C. § 331
- Provides for misdemeanor or felony liability; no intent required for misdemeanor conviction
- FDCA conviction implicates OIG exclusion
- Recent matters:
  - *U.S. v. Shrum*, 4:09-cr-00295 (D. Ark.), gynecologist convicted of misdemeanor violation of FDCA for using non-FDA approved IUDs; forfeited proceeds of fraud and excluded
  - *McLoud Cancer and Blood Center, Knoxville, TN*: Physician pleaded guilty to felony FDCA violation related to non-FDA approved cancer drugs and sentenced to 24 months; physicians in practice paid $4.25 million to settle civil FCA allegations
Navigating Compliance and Enforcement Matters

Hypothetical Facts
Qui tam action filed asserting FCA allegations and alleging that Cardiologist and Cardiology Group performed medically unnecessary cardiac stenting at Hospital’s Cath Lab

In addition to inserting cardiac stents in the Hospital’s Cath Lab, Cardiology Group also leases space from Hospital’s Medical Office Building and Cardiologist serves as the Medical Director of the Hospital’s Cath Lab

Navigating Compliance and Enforcement Matters

Hypothetical Facts
Cardiology Group receives Authorized Investigative Demand (AID) requesting documents regarding financial relationships with Hospital

Hospital receives Civil Investigative Demand (CID) for medical records and for testimony regarding Hospital’s financial relationships with Cardiology Group
Navigating Compliance and Enforcement Matters

**Hypothetical Facts**
DOJ considers intervention in *qui tam* action and considers criminal charges concerning Cardiologist

Cardiology Group evaluates how to accomplish resolution of civil, criminal, and administrative issues