Health Care Fraud Enforcement – Intake to Prosecution

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Health Care Fraud and DOJ

• Commitment to prosecute health care fraud
  – Criminal/Civil/Antitrust Divisions
  – Consumer Protection Branch
  – Health care fraud coordinators within 94 United States Attorneys’ Offices
  – Federal Bureau of Investigation
  – Drug Enforcement Agency
• Distinct funding sources
FY 2012 Benchmarks

- $604 million in funding
  - 1,131 new criminal matters
  - 826 criminal convictions
  - 885 new civil matters
- $4.2 billion in recoveries
  - $24.8 billion collected since 1997
  - ROI of $7.90 since 2010
- HHS-OIG
  - 3,131 exclusions
  - $8.5 billion in savings recommendations

Parallel Proceedings

- Simultaneous civil/criminal/administrative investigation of same white collar defendants
  - Usually jointly handled
  - Can be federal and state/local or multi-district
- Examples
  - Procurement fraud
  - Healthcare fraud
  - Asset forfeiture actions
  - Drug diversion
  - SEC and antitrust investigations

Advantages of Parallel Proceedings

- Maximizes benefit to government/victim(s)
- Avoids duplication of investigation
- Leverages resources
- Provides greatest deterrent effect
- Investigation may survive fatal problems with parallel case
- Preserves assets for fines or restitution
Health Care Fraud Statute

- Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347
- Knowingly and willfully execute/attempt a scheme or artifice to:
  - Defraud health care benefit program; or
  - Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services
- 10-year imprisonment, restitution, and fine

The Anti-Kickback Statute

- Criminal statute, 42 U.S.C. § 1320a-7b(b)
  - Remuneration is anything of value
- Recommend or arrange for items/services under federal programs
  - Includes non-clinicians
  - State analogs may limit kickbacks in cash/private plans
- Greater compliance with safe harbor generally means less risk
  - HHS-OIG Advisory Opinions
- Forms basis for civil liability

False Claims Act

- Generally a false/fraudulent claim/statement made or caused to be made for payment to the United States, 31 U.S.C. § 3729(a)
  - Includes conspiracy and “reverse” false claims provisions
- Claim must be submitted “knowingly”
  - Actual knowledge
  - Deliberate ignorance
  - Reckless disregard
  - No specific intent to defraud required
FCA Cont.

- Six-year statute of limitations
  - Three years from date material facts are known or reasonably should be known by responsible official
  - Not more than 10 years after the violation
- Remedies
  - Treble damages
  - $5,500 - $11,000 penalty per false claim
  - Costs
  - Damages not required

Qui tam Provisions

- Relator files case on behalf of government
  - Under seal for at least 60 days
  - Pursue without DOJ involvement
  - Protection from retaliation under section 3730(h)
  - Recover fees and costs
- Jurisdictional issues
  - Public disclosure bar
  - “Original source” of allegations
  - Fraud with particularity under Fed. R. Civ. P. 9(b)

FERA Amendments Cont.

- Civil Investigative Demands – § 3733
  - Obtain testimony under oath and documents
  - May be delegated from Attorney General
  - Permits sharing of information
    - Relates
    - Materials only used for “official use”
      - Any use consistent with law or DOJ policy/regulations
  - Analogous State provisions
Stark Law
• Prohibits self-referrals for federal business, 42 U.S.C. § 1395nn
  – Must involve physician referral
  – Designated health services
  – Ownership interest or compensation arrangement
  – State law may limit non-Medicare business agreements
• Strict liability
  – Must fully satisfy statutory or regulatory exception
• Remedy is payment disallowance
  – Exclusion and CMP liability
  – May be violation of FCA

Additional Remedies
• Equitable
  – Payment by mistake/unjust enrichment
  – Disgorgement
  – Breach of contract
  – 6 year statute of limitations, 28 U.S.C. § 2415(a)
• Tort
  – 3 year statute of limitations, 28 U.S.C. § 2415(b)
• Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812
• Debarment or payment suspension

Civil Monetary Penalties Law
• HHS-OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)
  – Permissive exclusion and money damages for specific violations like payment or receipt of illegal kickbacks
• Mirrors FCA but not governed by civil rules
  – Limited discovery
  – Hearsay admissible
• OIG usually releases this authority in exchange for compliance obligations
Remember PPACA

- Patient Protection and Affordable Care Act
  - Enacted March 23, 2010
- Amendments to Anti-Kickback statute
  - Rejects stringent definition of knowledge
    - No longer must prove intent to violate the “AKA”
  - Violations result in falsity under the False Claims Act
    - FCA violations can occur even if claim was submitted by an “innocent” third-party
- Clarification of sentencing guidelines
  - Presumption intended loss is value of claim, not actual payment

Common Risk Areas

- False/fraudulent claims
  - Billing for items or services not rendered
    - Upcoding and product substitution
  - Misrepresenting nature of items or services
    - Seeking reimbursement for unallowable costs
- Retention of overpayments
  - Refusal to return erroneous payments
- Improper financial relationships/referrals
  - Sham compliance with safe harbor or exception
  - Excessive payments
  - Insufficient documentation of work performed

Disclosure of Violations

- PPACA requires repayment within 60 days
- Disclosure to DOJ
  - Possible non-prosecution of business entity
    - See USAM § 9-28.000, et seq.
  - Limited civil FCA multiplier
    - See FCA § 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 implicate other laws
Hypothetical

- Provider had internal controls to prevent employees offering, promising or paying anything of value to referral sources
- Internal policies regularly updated and disseminated
- Specifically prohibited bribery and addressed risks of giving gifts, entertainment, travel, lodging, meals, and employment
- Repeatedly trained staff on regulatory restrictions
- Compliance monitored transactions, randomly audited employees, transactions, and business units
- Imposed stringent controls on all payments

Hypothetical cont.

- Employee schemed to offer/make unlawful payments to both existing and potential referral sources
- Falsified invoices/documents to avoid detection
- Disguised payments for entertainment, etc. under guise of legitimate marketing
- Prior discipline for failing to follow existing policies
- Provider fails to discover conduct
- Illegal payments of over $1 million

Initial Analysis

- Review complaint
  - Do allegations constitute fraud?
  - Harm to federal and/or private interests?
- Determine scope of investigation
  - Criminal, civil or administrative?
  - Multiple federal jurisdictions involved?
  - State and other federal programs?
- Assemble team
  - Agents
  - Auditors
  - Agency counsel
  - Program/contractor employees
Parallel Investigative Tools
- Surveillance
  - Consensual monitoring
- Interviews
- Search warrants
- CIDs
- Subpoenas
  - Grand jury
  - Inspector General
  - AID (HIPAA)
- Requests for information

Parallel Investigations
- 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

Defendant’s Response
- Identify nature of investigation
  - Scope of representations
  - Preserve evidence
  - Initiate internal investigation
  - Containment
  - Maintain applicable privileges/protectios
- Type of request dictates posture
  - Criminal, civil or administrative
  - Multiple jurisdictions
- Assemble team
  - Client
  - Consultants
Possible “Outcomes”
- Freeze/seize/forfeit fraud proceeds
- Suspension of payments
- Termination from programs
- Criminal charges against targets
- Civil recoveries from responsible parties
- Exclusion/debarment/revocation license
- Cost of responding
- Loss of business/goodwill/morale

Three Lines of Defense

“The First Line”
Management is accountable for identification of risks, internal controls, and compliance activities and monitoring in order to be compliant with laws and regulations.

“The Second Line”
Compliance will provide compliance management program, framework and policies

“The Third Line”
Independent Compliance Oversight and Internal Audit will provide independent oversight and monitoring

Sample Compliance Risk Assessment Interviewees
- Board Members
- Chief Executive Officer
- Chief Financial Officer
- General Counsel
- Chief Medical Officer
- Chief Nursing Officer
- Compliance Officer
- Quality
- Physician Contracting
- Case Management
- Pharmacy
- Chief Information Officer
- Information Security Officer
- Privacy Officer
- HIM
- Physician Relations
- Revenue Cycle
- Cost Reporting
- Chargemaster
- Risk
- Lab
### Sample Compliance Risks

<table>
<thead>
<tr>
<th>Identified Risks</th>
<th>Residual Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observational/Admit issues - Inappropriate admission status</td>
<td>H</td>
</tr>
<tr>
<td>HIPAA Security - Inappropriate access to electronic documentation systems</td>
<td>H</td>
</tr>
<tr>
<td>HIPAA Security - Lack of Role Based Definitions resulting in potential breaches</td>
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</tr>
<tr>
<td>RAC preparedness - Inability to respond to and track and defend RAC requests</td>
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<tr>
<td>Inappropriate Physician Relationships - Providing inappropriate incentives to physicians</td>
<td>H</td>
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<tr>
<td>Cost reporting - Inappropriate reporting of bad debt expense</td>
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<tr>
<td>Insufficient clinical documentation</td>
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</tbody>
</table>

### Sample Compliance Risks cont.

<table>
<thead>
<tr>
<th>Identified Risks</th>
<th>Residual Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician Contracting</td>
<td>M</td>
</tr>
<tr>
<td>HIPAA Security - Inability to accurately audit electronic documentation systems</td>
<td>M</td>
</tr>
<tr>
<td>HIPAA Privacy</td>
<td>M</td>
</tr>
<tr>
<td>HIPAA Security - Theft or loss of unencrypted hospital portable devices</td>
<td>M</td>
</tr>
<tr>
<td>Present on Admission - Inability to capture and document conditions present on admission</td>
<td>M</td>
</tr>
<tr>
<td>ICD-10 preparedness</td>
<td>L</td>
</tr>
<tr>
<td>EMTALA violations</td>
<td>L</td>
</tr>
<tr>
<td>Restraints - Inappropriate use of restraints</td>
<td>L</td>
</tr>
<tr>
<td>Serious Preventable Adverse Events - Inability to capture and document serious preventable adverse events</td>
<td>L</td>
</tr>
</tbody>
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### Compliance Strategies

- Review work plans
  - Assess high risk areas listed
  - Frequent monitoring
  - Are corrective action plans used
  - Is money being repaid

- Potential negatives of financial relationships
  - “If too good to be true...”
  - Beware of those bearing gifts
    - Standard of banning all vendors/gifts
    - Industry guidelines as baseline
      - March 31, 2013 reporting requirements
Compliance Self-Assessment

• Can personnel describe compliance program
  – How about key executives
• Are historical audits and assessments available for inspection or comparison
  – Are reviews done at regular intervals or only complaint-driven
• Do you trend high-risk areas and/or require corrective action
  – Or does corrective action = evidence of wrongdoing
• Is the hotline used for more than HR issues
  – Is there a log of all calls with documented responses

Self-Assessment Cont.

• Has the program evolved with the organization
  – Or is there dust on the compliance binder
• Is there a culture of responsibility and accountability
  – Or are “some more equal than others”
• Is the compliance team free to raise concerns
  – Or has the board asked who is the compliance officer
• Is there a commitment to compliance
  – Or is the budget less than optimal and the team housed in a offsite sub-basement
• Can you convince the government of any of the foregoing
  – Could be difference between repayment v. civil penalties v. criminal charges

Sources of Enforcement Information

• Advisory opinions
• Compliance program guidance
• Work plans/audits
• Settlement/integrity agreements
• Press releases
• GAO reports
• Comments/preambles to safe harbors/exceptions
Settlement

- Global settlements if requested by defendant
  - Criminal and civil each negotiate own agreements
  - DOJ cannot address administrative remedies
- Settlement parameters
  - Loss/issues determine level of DOJ involvement
  - Most terms are non-negotiable
    - No confidentiality clauses
  - Covered conduct and released parties are narrow
    - Reservation of claims against individuals
  - Gov’t. does not resolve relator’s claims/fees
    - Relators/defendants directly discuss

Representing Defendants in Settlements

- Global settlements
  - Invoke only when appropriate
  - Early contact with administrative agencies
- Settlement Issues
  - Covered conduct
  - Released parties and claims
  - Interplay between corporation and principals
  - Inability to pay
  - Administrative concerns
  - Collateral consequences

“Formal” Resolutions

- Indictment/information and conviction
  - Public allegations and trial
  - All questionable past statements/actions raised
  - Billed, not paid, amount drives loss
  - Special enhancements for fraud
  - “Relevant conduct” increases sentence/fine
  - Automatic exclusion/debarment
  - Collateral estoppel under FCA
  - State and private liability
“Formal” Resolutions – cont.

• Civil action and fraud judgment
  – Mandatory trebling/penalties
  – Most evidence admissible
  – To avoid self-incrimination = increase risk/liability
  – State and private liability
  – Agencies usually seek permissive exclusion/debarment

• Administrative proceedings and adverse finding
  – Multiple programs/agencies
  – Rules of evidence not applicable
  – Negative impact on civil/criminal case

Questions