Anti-Kickback, Stark, And False Claims Act Liability

2012 HCCA Compliance Institute
April 29– May 2, 2012
Las Vegas, NV
Overview

- Anti-Kickback Law
- Stark Law
- False Claims Act
- What are hot issues in compliance?
- What are some trends in enforcement?

Internal Monitoring

- What are some methods or techniques for internal monitoring?
- How do you get leadership “buy-in” for compliance investigations?
- What is the value of internal monitoring and compliance investigations?
Overpayments

- What are some options for handling overpayment issues?
- When is an overpayment more than an overpayment and viewed as civil or criminal fraud?

Self-Disclosures

- When should you use the Disclosure Protocol?
- Can you just disclose to the payers?
- What about disclosures to the local Assistant U.S. Attorney?
Enforcement

- What are some recent cases?
- What are new tools / trends in health care fraud investigations?
- Is there coordination of States, DOJ, and other enforcement agencies?
- How does the government evaluate a case?
- How does defense counsel evaluate a case?

Individual Liability

- What are the trends for enforcement against individuals?
- Prosecution?
- Exclusion?
- What is the Responsible Corporate Officer doctrine?
Compliance Efforts

• How important are compliance efforts?
• How are compliance efforts viewed internally?
• How are compliance efforts viewed by enforcement agencies?

Stark Audit / Review
The DHS entity should first identify all financial arrangements that it has with referring physicians.

Sources for Identifying Physician Financial Arrangements

- Legal Department
- Accounting Department
- Compliance Department
- All Operational Departments
- Medical Staff Office
Stark Audit / Review

All documents regarding each financial arrangement need to be produced for review. A document production checklist is included as Exhibit A.
Stark Audit / Review

As part of Exhibit A, the financial arrangement needs to be defined by type of arrangement.

<table>
<thead>
<tr>
<th>Leases in MOB</th>
<th>Leases – other than MOB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment – Medical Administration</td>
<td>Employment – Clinical</td>
</tr>
<tr>
<td>Employment – Teaching</td>
<td>Independent Contractor – Medical Administration</td>
</tr>
<tr>
<td>Independent Contractor – Clinical</td>
<td>Independent Contractor – Teaching</td>
</tr>
<tr>
<td>Physician Recruitment</td>
<td>Hospital-Based Group</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

From Exhibit A, documentation regarding the financial arrangement should be produced.

- Executed copy of Contract and all Amendments
- Fair Market Value documentation supporting the financial arrangement in the Contract
- Minutes of meeting where Contract was discussed and approved
- List of all payments made to and from contract party related to the Contract
- Legal review of Contract (both internal and external)
- Timesheets submitted by contract party
- Productivity data if any portion of compensation is based upon productivity
Stark Audit / Review

After all documentation regarding each financial arrangement has been assembled, each financial arrangement must be analyzed for Stark Law compliance. The Stark Contract Review Form attached as Exhibit B can be used to evaluate each financial arrangement.

Exhibit B

<table>
<thead>
<tr>
<th>Issue</th>
<th>File Complete</th>
<th>Reviewer Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executed Copy and all Amendments</td>
<td>Agreement Name:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Term:</td>
<td></td>
</tr>
<tr>
<td>FMV Documentation Supporting Arrangement</td>
<td>Compensation:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FMV Justification:</td>
<td></td>
</tr>
<tr>
<td>Meeting Minutes with Discussion and Approval</td>
<td>Committee Minutes:</td>
<td></td>
</tr>
<tr>
<td>List of Payments To and From Party</td>
<td>Aggregate Amounts:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2007:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2008:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2009:</td>
<td></td>
</tr>
<tr>
<td>Legal Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timesheets Submitted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Productivity Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Comments:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Stark Audit / Review

After each financial arrangement is analyzed, the DHS entity will either need to determine if the financial arrangement conforms with all components of an applicable Stark exception, or corrective action needs to occur.

Stark Audit / Review

Type of Corrective Action

- Written agreement needs to be developed or modified.

- Financial terms need to be modified to be consistent with commercial reasonableness/fair market value.

- Items required to be paid need to be charged to physician (i.e., increases in operating expenses).

- The “period of disallowance” needs to be determined.

- Possible repayment or self-disclosure will need to be made.
Self-Referral Disclosure Protocol

Overview of Protocol

- Introduction and Discussion of Protocol
- Cooperation with OIG and the Department of Justice
- Instructions regarding Submission
- Verification
- Payments
- Cooperation and Removal and timeliness of Disclosure
- Factors Considered in Reducing Amounts Owed
Self–Referral Disclosure Protocol

Cooperation with the OIG & DOJ

- Physician Self–Referral Law only violations or potential violations to CMS.
- Physician Self–Referral Law and additional violations or potential violations of other criminal, civil, and administrative laws to OIG.
- The same conduct should not be disclosed under both SRDP and OIG’s Self–Disclosure Protocol.
- Coordination with Law Enforcement.
- Corporate Integrity Agreements.

Self–Referral Disclosure Protocol

Introduction and Discussion of Protocol

- Purpose is to resolve actual or potential violations of the physician self–referral law
- Separate from the advisory opinion process
- Disclosure must be made in good faith
- Cannot appeal settlement
Self-Referral Disclosure Protocol

Instructions Regarding Submission

• Disclosure

• Required information related to the matter disclosed:
  ➢ Description of Actual or Potential Violation(s)
  ➢ Financial Analysis

Self-Referral Disclosure Protocol

Instructions Regarding Submission

• Description of Actual or Potential Violation(s)
  ➢ Identifying Information
  ➢ Description of the nature of the matter being disclosed
  ➢ Duration of violation
  ➢ Disclosing party’s legal analysis of how the matter is a violation
  ➢ Circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses
  ➢ Statement identifying a history of similar conduct or enforcement action
  ➢ Description of the pre-existing compliance program
  ➢ If applicable, a description of appropriate notices provided to other government agencies
  ➢ Whether the matter is under current inquiry by the government
Self-Referral Disclosure Protocol

Instructions Regarding Submission

• Financial Analysis
  - “Look Back” Period
  - Total amount actually or potentially due and owing
  - Description of the methodology used including estimates
  - Summary of auditing activity and documents used

Quantification of Potential Overpayment

Providers need to:

• Determine commencement and ending of period of time during which financial arrangement fell out of compliance

• Utilize the 6-month holdover period, where applicable (personal services arrangements and rental of space and equipment exceptions)

• If financial arrangement was with a group practice, identify each physician in the group practice
Quantification of Potential Overpayment

Providers need to (cont.):

- Determine when any applicable physician “referred” to the DHS entity during the period of disallowance
  - Referring physician
  - Admitting physician
  - Attending physician
  - Consulting physician

- Especially for the consulting category, determine if items or services ordered by “tainted” physician impacted the reimbursement received

Quantification of Potential Overpayment

- Due to the complexity of hospital’s financial data bases, especially if a recent conversion has occurred, providers may desire to hire external auditing firms to assist with the quantification process.

- Should the external auditors be hired in a manner to preserve the attorney/client privilege?
Quantification of Potential Overpayment

Assuming provider diligently quantifies the potential overpayment during the “lookback” period with due diligence, 60-day reporting period does not commence until the amount of the overpayment has been determined through a *Reasonable Inquiry*.

The Interplay of the SRDP and the Mandatory Reporting and Refunding of Overpayments

- Electronic submission of your disclosure stays the 60-day window for the refund of overpayments
  - Until a settlement agreement is entered, the disclosing party withdraws from the SRDP, or CMS removes the party from the SRDP
  - No (express) similar benefit under the OIG protocol
The Interplay of the SRDP and the Mandatory Reporting and Refunding of Overpayments

• CMS suggests placing the proffered overpayment in an interest-bearing escrow account
  
  ➢ CMS directs parties NOT to pay any money to CMS or its contractors
    • This is to keep a disclosing party from arguing that CMS accepted the overpayment and it has, therefore, satisfied its obligation with respect to the Stark violation
    
  ➢ No mention of which party is entitled to the interest

How to Participate in the SRDP

• Parties must submit electronically and send signed hard copies to CMS
  ➢ Acknowledgement of receipt of electronic submission will be sent by automatic email response
  ➢ Acceptance into the SRDP will be documented in a letter from CMS

• Numerous technical requirements regarding information that must be included in the disclosure
CMS Review Process

Collaborative review among multiple CMS components

- Center for Medicare
  - Intake of self-disclosures
  - Policy and legal analysis

- Center for Program Integrity
  - Coordination with law enforcement partners

- Office of Financial Management

Factors Considered, Reducing Amount Due and Owing

CMS may consider the following factors in reducing the amount due and owing:

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of the disclosing party
- Effectiveness of compliance program, especially if compliance program resulted in discovery of potential Stark infraction
Reducing Amount Due and Owing: Nature and Extent of Improper / Illegal Practice

Some of the sub-factors CMS will weigh include:

• Commercially reasonable? Fair market value?
• Takes into account volume or value of referrals?
• History of program abuse?
• Set in advance?
• Presence, strength of preexisting compliance program?
• Length, pervasiveness of noncompliance?
• Steps taken to correct noncompliance?

Reducing Amount Due and Owing: Additional Factors

• Timeliness of self-disclosure
• Cooperation in providing additional information
• Litigation risk
• Financial position of disclosing party
What Type of Resolution Disclosing Parties Can Expect

- CMS has the authority to accept a reduced overpayment (i.e., less than 100%)

- CMS is clear to point out that it is under no obligation to accept the disclosing party’s calculation of its financial liability or to compromise the overpayment at all

- There are no limits on the reduction that CMS may make
  - Theoretically, CMS could reduce the overpayment to $0

Limitations of the SRDP

- Parties have no guarantee of acceptance into the SRDP

- CMS provided no guidance regarding how it views certain types of noncompliance
  - For example, is a missing signature on a written agreement as problematic as compensation that is not consistent with FMV?

- CMS will not waive the “refund to individuals” requirement in section 1877 of the Social Security Act which requires refund of any amounts collected that were billed in violation of the Stark law

- Does not prohibit intervention by law enforcement
Choice of Disclosure “Venue”

Disclose to OIG or CMS, but not both

- In cases where there is a potential or actual anti-kickback statute violation, entity could choose OIG self-disclosure protocol in lieu of the Stark SRDP
  - “[C]onduct that raises liability risks under the physician self-referral statute may also raise liability risks under the OIG’s civil monetary penalty authorities regarding the federal anti-kickback statute and should be disclosed through the OIG’s Self-Disclosure Protocol. Disclosing parties should not disclose the same conduct under both the SRDP and OIG’s Self-Disclosure Protocol.”
  - Difficult decision where Stark law violation is accompanied by an uncertain anti-kickback statute violation

Disclose to OIG or CMS, but not both (Cont.)

- Effect on overpayment obligation
  - OIG cannot release the 1877(g) liability, so party disclosing under the OIG protocol arguably still has CMS/Stark overpayment liability and failure to return the overpayment is a FCA violation
  - Will CMS sign off on mixed Stark/AKS settlements reached under the OIG protocol?
Words of Warning Regarding the SRDP

- CMS demands access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced
  
  This statement is unclear: does CMS suggest that parties cannot assert privilege or that it will demand access to all information that is not privileged (i.e., “without the assertion of privileges”)

- CMS is clear that referrals to law enforcement may be made based on information contained in the disclosure

- CMS may use the information contained in the disclosure to make a referral to OIG and DOJ for resolution of FCA liability, CMP liability, or other issues

Physician Fraud Investigations
Physician Fraud Investigations

This presentation provides general information and should not be construed as legal advice. Opinions expressed herein or otherwise are those of the speaker and do not necessarily reflect the views of the U.S. Attorney’s Office for the Northern District of Texas or the United States Department of Justice (DOJ).

Enforcement Agencies

- Offices of Inspector General (OIG)
  - HHS
  - OPM
  - DOD
- Medicaid Fraud Control Units
- State licensing boards
- Centers for Medicare and Medicaid Services
- Tricare Management Activity
- Federal/state contractors
2010 Health Care Fraud Benchmarks

- 1,116 new criminal matters
  - 726 criminal convictions

- 942 new civil cases

- $4 billion in health care fraud recoveries
  - $577 million in FY 2010 funding
  - $18 billion collected since 1997
    - Historical ROI $4.9 ($6.8 since 2008)

- HHS–OIG Semiannual Report
  - 3,340 exclusions
  - $25.9 billion in savings recommendations

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 law may address kickbacks in private plans
- Greater compliance with safe harbor generally means less risk
  - HHS–OIG Advisory Opinions
- Forms basis for civil liability

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 statute
  - Violations result in falsity under the FCA
    - Violations can occur even if claim was submitted by a third-party
- Clarification of sentencing guidelines
  - Presumption intended loss is value of claim, not actual payment
FCA

• 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
  ➢ Automatic treble damages
  ➢ Mandatory $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
    - Relators
  - 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 address private business agreements

• Strict liability
  ➢ Must fully satisfy statutory or regulatory exception

• Remedy is payment disallowance
  ➢ Exclusion and CMP liability
  ➢ May be violation of False Claims Act (FCA)

Additional Civil 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

Disclosure of Violations

- PPACA requires repayment within 60 days
- Self–reporting under FCA section 3729
  - Lower damages and no integrity obligations
  - April 15, 2008, and March 24, 2009, Open Letters
- CMS Voluntary Self–Referral Disclosure Protocol
  - Addresses potential/actual violations
    - Use OIG protocol if allegations implicate other laws
    - Do not disclose same conduct both to CMS and OIG
Sources of Compliance Information

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

Trends in Individual Liability
Trends in Individual Liability

• Historical case resolution model
  ➢ Corporate plea/FCA settlement
  ➢ CIA
    • Possible exclusion of irrelevant subsidiary
  ➢ No personal liability/exclusion

• Recent changes in the historical paradigm
  ➢ 10/2010 DOJ Civil Division announcement of intention to pursue individuals

• OIG/ Lewis Morris 2/2/11 Congressional testimony
  ➢ Notes large providers may consider settlement “cost of doing business”
  ➢ Wants to “alter the cost–benefit calculus” of corporate executives who run these companies
  ➢ Expresses intent to increase individual exclusions
Trends in Individual Liability

- DOJ criminal actions
  - Recent pharmaceutical manufacturer cases under the Park doctrine
    - Synthes/Norian
      - 10/10 corporate plea to felony off-label marketing/improper clinical trials.
        - $23.5 million settlement amount
        - Divestiture required
        - CIA
      - Four executives plead to Park misdemeanors
        - Jail sentences in each case

- Stryker Biotech, LLC. Settlement 1/30/12
  - Corporate misdemeanor plea with $15 million fine
  - Charges dropped against CEO and other individuals

- WellCare indictments
  - Indictment of five former executives of Medicaid HMO, including former CEO, CFO and GC
  - Awaiting trial

- Unsuccessful indictment and prosecution of GSK in-house counsel
United States v. Borrasi
2011 U.S. App LEXIS 9253 (11th Cir. May 4, 2011)

- Alleged conspiracy between physician and 2 executives of an inpatient psychiatric hospital to compensate Dr. Borrasi and his group in exchange for increased Medicare referrals.
  - Defense was that payments were for part-time employment relationships for administrative services.
  - Testimony at trial
    - “false titles,” “faux job descriptions,” “false time sheets.” Physicians did not perform any of the administrative duties.

- Criminal conviction of physician and CEO
  - 72 month sentence

OIG Exclusion Authorities

- Key authorities: 42 USC 1320a–7(a)
  - Mandatory exclusions
    - (a)(1) Conviction of program related offense
    - (a)(2) Conviction of patient abuse
    - (a)(3) Felony conviction of health care fraud
  - Permissive exclusions
    - (b)(7) Fraud or kickbacks
    - (b)(15)(i) Individuals with an ownership or control interest in a convicted or excluded entity
    - (b)(15)(ii) Officers or managing employees of a convicted or excluded entity
Recent Individual Exclusion Actions

• Purdue Executives
  - All had pled to *Park* misdemeanors
  - OIG excluded all under discretionary authority
  - Court upheld exclusions
    - Convictions met statutory test
    - Lack of intent irrelevant
  - Appeals pending

• KV Pharmaceuticals
  - CEO (Hermelin) excluded under (b)(15) after *Park* plea by company

Recent Individual Exclusion Actions

• Forest Laboratories
  - Criminal pleas and civil settlement relating to off-label marketing
  - No individual pleas
  - OIG letter re potential exclusion of CEO/Board Chairman Howard Solomon
  - OIG ultimately declined to exclude
OIG Guidance re Exclusions

- Will exclude
  - Owners if “knew or should have known” of conduct
  - Officer or managing employees ("operational or managerial control or directs day-to-day operations")
    - No statutory knowledge requirement
    - Will only go after those who “knew or should have known”
    - Rebuttable presumption that this standard is met

OIG Factors

- Circumstances of the misconduct and seriousness of the offense
  - Nature of sanction
  - Amount of harm
  - How pervasive
- Individual’s role
  - Position
- Individual’s actions
  - Compliance efforts
  - Cooperation/disclosure
- Size/record of entity