How Compliance Efforts Can Help Avoid Enforcement Actions

Sean R. McKenna, Assistant U.S. Attorney
Northern District of Texas
214.659.8600 sean.mckenna@usdoj.gov

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DOJ’s efforts to investigate and prosecute those who commit health care fraud are “as strong as ever...”

May 28, 2008, DOJ Fact Sheet

The Department of Health and Human Services’ fiscal year 2008 budget request sought $1.3 billion in resources and legislation to strengthen oversight and reduce improper payments in the Medicare and Medicaid programs.

Secretary Mike O. Leavitt Before the Committee on the Budget, United States House of Representatives, July 17, 2007

Outline of Presentation

• Introduction
• Enforcement agencies and efforts
• Overview of fraud statutes
• Case study
• Practical tips for compliance
• Compliance considerations
• Questions
Health Care Fraud and DOJ

• DOJ’s strategic goal remains combating health care fraud in part through multidistrict investigations and multi-agency enforcement projects

• Criminal and Civil Divisions in Washington, DC

• Office of Consumer Litigation in Washington, DC

• 93 United States Attorneys’ Offices

• Federal Bureau of Investigation

Enforcement Agencies

• Office of Inspector General, Department of Health and Human Services (OIG)

• Defense Criminal Investigative Service

• Centers for Medicare and Medicaid Services

• Tricare Management Activity

• Medicaid Fraud Control Units

• Federal and State program contractors

• Local district attorneys
Health Care Fraud Statistics for 2007

- 878 new criminal health care fraud matters opened
  - 560 criminal convictions
- Opened 776 new civil health care fraud matters
- $1.8 billion in total health care fraud recoveries
  - Relators paid over $140 million
- OIG’s 2007 fiscal year Semiannual Report
  - 3,308 program exclusions
  - $43 billion in savings & expected recoveries

Sources of Health Care Fraud Cases

- Criminal referrals from federal and state agencies
- *Qui tams* under the civil False Claims Act (FCA)
- Data mining from CMS and Medicaid contractors
- Initiatives, working groups, and task forces
- Competitors
- Anonymous or hotline complaints
Health Care Fraud Enforcement

Federal/State/Local Enforcement Options

Criminal | Civil | Administrative

*Taken from Lafferty’s and McKenna’s The False Claims Act & Health Care Fraud, HCCA’s Annual Compliance Conference, April 23, 2007, Chicago, Illinois

Health Care Fraud Statute

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

- Criminal statute, 42 U.S.C. § 1320a-7b(b)
- Remuneration can be anything of value
- Persons who recommend or arrange for items or services payable under FEDERAL programs
  - Non-clinicians are subject to prosecution
  - May have State law that addresses kickbacks in private plans
- Greater compliance with safe harbor, generally means less risk
  - OIG Advisory Opinions
- Can form basis for civil FCA liability

FCA

- Generally a false or fraudulent claim or statement presented/made or caused to be presented/made for payment to the United States, 31 U.S.C. §§ 3729(a)(1) – (7)
  - Allison Engine Co., Inc. v. USA ex rel. Sanders, 128 S. Ct. 2123 (2008) discussing false records/statements and conspiracy
  - Proposed “corrective” legislation pending in Congress
- Must be “knowingly” submitted
  - 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 have been known by responsible official
  - Not more than 10 years after the violation

- Violators subject to treble damages, a $5,500 - $11,000 penalty per false claim, and costs
  - Damages usually not required

- Disclosure of potential FCA violations
  - Self-reporting under section 3729
  - Voluntary refunds to contractors
  - OIG Self-Disclosure Protocol
    - www.oig.hhs.gov/fraud/selfdisclosure.html

FCA Qui tam Issues

- *Qui tam* provisions permit whistleblowers to file cases
  - May pursue matter without DOJ involvement
  - Entitled to protection from retaliation under section 3730(h)
  - May be awarded employment damages, attorney’s fees and costs

- Jurisdictional questions
  - Public disclosure bar
  - “Original source” of allegations
  - Pleading fraud with particularity under Fed. R. Civ. P. 9(b)

- Evidentiary and due process concerns
Stark Law

- Civil statute prohibits self-referrals of federal business to entities in which the physician has prohibited financial relationship, 42 U.S.C. § 1395nn
  - Ownership interest
  - Compensation arrangement
  - May be State law that covers self-referrals of private business

- Usual remedy is payment disallowance - BUT

- Can form basis for FCA or administrative liability

- Applicable only if physician or family member is involved

- To avoid violation, must fully satisfy exception (strict liability)

Civil Monetary Penalties Law

- OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)

- Permissive exclusion and money damages for specific violations, including payment or receipt of illegal kickbacks

- Generally mirrors FCA provisions
  - Specific authority to address illegal kickbacks

- OIG usually releases this authority in exchange for integrity obligations
  - BUT see OIG’s April 15, 2008 Open Letter
Common Fraud Allegations

- Submission of false or fraudulent claims
  - Billing for items or services not rendered
    - Upcoding and product substitution
  - Seeking reimbursement for unallowable costs
  - Improper retention of known overpayments

- Improper financial relationships/remuneration
  - Is there compliance with safe harbor or exception

- Failure to disclose rebates or discounts for reimbursable items and services
  - Must include true cost to provider

Case Study

- Large health care company with fully integrated delivery system in competitive market
- Dozens of physician contracts and leases
- Corporate division handles contracting
- Multiple specialty physician groups with admitting privileges
- Vacant office space near hospital
- President of hospital wants all office space occupied
Case Study Cont.

• Orthopedic group wants office near hospital
• President negotiates lease with orthopedic group
• Parties “forget” to execute lease
• No payments made for space valued at $600 month
• Millions in referrals to hospital by orthopedic group
• Compliance officer discovers “free rent” arrangement
• FBI and OIG begin investigation after anonymous complaint

Goals of Typical Investigation

• Freeze assets belonging to defendants
• Seize/forfeit proceeds of health care fraud
• Suspend current provider payments
• File criminal charges against targets
• Obtain civil recoveries from culpable parties
• Exclusion of defendants from government programs
• Ensure restitution has been made to victims
Medicare Cost Reporting Fraud

• Certified by a representative with “knowledge”
  – Subjects provider to civil, criminal, and administrative penalties, including fines and imprisonment
  – Reserves or contingent liabilities do not absolve providers of fraud liability
  – If learn cost report is inaccurate must file amended report

• Despite payment limitations, still may include improper costs and charges
  – Services cannot be provided or procured through payment directly or indirectly of a kickback

Cost Reporting Fraud Cont.

• Billing for excluded providers

• Inaccurate organ acquisition costs

• Claiming unallowable procedures were outpatient services

• Improper costs or charges will inflate A/G or specific cost centers

• Related-party transactions

• Failure to disclose rebates or discounts for reimbursable items and services
Investigation

- Surveillance
- Interviews
- Requests for information
- Search warrant
  - Judicial finding of probable cause
- Subpoenas
  - Grand jury v. Inspector General v. AID (HIPAA)
  - Privacy considerations
- Statistically valid random samples
- Consultants and experts

Investigation Cont.

- Review complaint
  - Do allegations constitute fraud
  - Harm to federal and/or private health care programs
  - Is DOJ involvement appropriate

- Scope of investigation
  - Criminal, civil or administrative
  - Multiple federal jurisdictions
  - State and federal programs

- Investigative team
  - Agents and Auditors
  - Agency counsel
  - Expert/litigation consultant
Investigation Cont.

• Request claims history, sample or medical review

• Interviews
  – Informants
  – Former employees
  – Current employees

• Issue subpoena or request for information
  – Internal/external correspondence and e-mails
  – Focusing on specific policies, practices or contracts
  – Internal investigation and reports

• Review and analyze relevant documents
  – Looking for knowledge or intent
  – Theories of recovery

Investigation Cont.

• Develop overpayment or damages
  – Calculate for each payor
    • Medicare and Medicaid UB04’s and filed cost reports
  – Claims profile shows categories of items and services
    • Amount and number of referrals by physician during relevant time period

• Determine which issues should be pursued
  – Tainted claims under FCA
  – Criminal kickbacks for Medicare/Medicaid referrals
  – Stark violations arising from lease arrangement

• Approach defendant to discuss plea or settlement
  – Establish dialogue before initiating action(s)


Resolution of Investigation

• Stark law violations due to free rent to physician group
  – Hospital paid millions from improper referrals
  – Additional questionable physician agreements discovered

• Criminal case declined
  – President of hospital fired
  – Physicians’ admitting privileges suspended/revoked
  – Past rent collected from physicians

• Civil FCA settlement
  – Rejected defense that violations were FMV and/or “technical”
  – Company paid $1.94 million (plus own costs and attorney fees)
  – Entered into 3-year Certification of Compliance Agreement
  – Publication of settlement


Benefits of Compliance

• Helps ensure providers are properly paid

• Avenue for employee grievances and complaints

• Shown to prevent and deter fraud and abuse

• Elimination or reduction of potential liability to DOJ or a whistleblower under the FCA

• Avoid justifying to the OIG why integrity obligations are unnecessary
Why Bother With Compliance

• Disclosure of overpayments and other errors
  – OIG Integrity agreements already require disclosure
  – April 15, 2008, Open Letter
    • Self-disclosure protocol can limit imposition of integrity obligations
    • Damages may be benefit conferred instead of harm to program
• DRA mandates employee education as Medicaid condition of participation
  – $5 million in Medicaid payments threshold
  – Must discuss the FCA and whistleblower protections
• Recovery Audit Contractors
  – Detect and correct Medicare improper payments
  – Mandated for all states by 2010
    • 3-year look back period
    • No review of claims paid before October 1, 2007

Simple Steps to Reduce Fraud

• Review OIG work plans for areas of regulatory or enforcement interest
  – Assess any high risk areas identified
    • When is the last time your grant program was audited
  – Frequent monitoring
  – Are corrective action plans used
  – Is money being repaid

• Analyze potential negatives of financial relationships
  – If it is too good to be true, it is
  – Beware of those bearing gifts
    • July 2008 PhRMA Code of Conduct
    • Providers increasingly barring ALL gifts from vendors
Simple Steps Cont.

• Receiving money for continuing medical education
  – *Pfizer Ends Support for Commercial doctor Courses*, Peter Loftus, CNN, July 2, 2008

• Medical device and pharmaceutical adverse reporting
  – Do you have physicians who consulted on recalled products
    • *A Call for a Warning System on Artificial Joints*, Barry Meier, NY Times, July 29, 2008
  – What has been done to notify patients or trial participations
  – Risk of not only FDA scrutiny, but private lawsuits

• Settlements and criminal prosecutions are barometers of unacceptable conduct
  – Are you acting or failing to act under similar facts
  – *Providence Health and Services* HIPAA Resolution Agreement
    • Paid $100,000 and Corrective Action Plan for failing to secure PHI of 386,000 patients

Sources of Compliance Information

• OIG advisory opinions
• OIG compliance program guidance
• OIG work plans and audits
• Published OIG integrity agreements
• DOJ press releases
• GAO Reports
• Comments/preambles to proposed/final Anti-Kickback safe harbors
Questions to Ponder

• 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

Questions 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
  – It could be the difference between simple repayment v. civil penalties v. criminal charges
Questions