Tools and Trends in Physician Health Care Fraud Investigations

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Health Care Fraud and DOJ

- Department of Justice is committed to combating health care fraud and economic crimes
- Criminal and Civil Divisions in Washington, DC
- Office of Consumer Litigation in Washington, DC
- Health care fraud coordinators within 94 United States Attorneys’ Offices
- Federal Bureau of Investigation
- Drug Enforcement Agency

Enforcement Agencies

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

• 1,104 new criminal matters
  – 583 criminal convictions

• 886 new civil cases

• $1.63 billion in health care fraud recoveries
  – $465 million in annual funding
  – $15.6 billion collected since 1997

• HHS-OIG Semiannual Report
  – 2,556 exclusions
  – $16.48 billion in savings recommendations

“Fraud, waste, and abuse in the Medicare and Medicaid programs cost taxpayers billions of dollars each year and put beneficiaries’ health and welfare at risk. The impact of these losses and risks is exacerbated by the growing number of people served by these programs and the increased strain on Federal and State budgets. Therefore, it remains critical that oversight of these essential health care programs be strengthened. To combat health care fraud, a comprehensive strategy of prevention, detection, and enforcement is required.”


Common Fraud Allegations

• False or 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
• Failure to disclose rebates/discounts
  – Hiding true costs

Health Care Fraud Investigations

• Freeze assets
• Seize/forfeit proceeds of fraud
• Suspend ongoing payments and participation
• Criminal charges against targets
• Civil recoveries from culpable parties
• Removal from government programs
• Ensure restitution is paid to victims
Tools & Trends #1 - Enrollment

- “Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment or reenrollment in the health care programs.”

- Initial enrollment requirements
  - Licensure reviews
  - Background checks
  - Apply existing standards
  - Inspections

Tools & Trends #2 - Payment

- “Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.”

- Review payment methodologies
  - Pay market rates
  - Reduce excessive profits
  - Avoid out-of-pocket expense for beneficiaries
  - Legislation to limit fee schedules
  - “Inherent reasonableness authority”
Tools & Trends #3 – Compliance

• “Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.”

• Promote compliance and education
  – Dishonesty is exception
  – Educate and assist legitimate providers
  – Provider Compliance Training Initiatives
  – Identify fraud risks
  – Share best practices

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 and criminal liability
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)

Physician Risk Areas

• Patient encounters
  – Visits and consultations
  – Medical necessity determinations
• Compensation arrangements
  – Medical directorships
  – Consulting and advisory boards
• Investment ventures
  • Physician-owned hospitals
• Off-label use and promotion
  – Defective products
  – Patient harm
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
    • Providers increasingly banning ALL gifts from vendors
    • Industry guidelines
      – PhRMA recommendation against giving branded items

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
  – Under *Principles* may be difference between repayment v.
    civil penalties v. criminal charges

Disclosure of Violations

• Self-reporting under FCA section 3729

• HHS-OIG Self-Disclosure Protocol
  – Lower damages and no integrity obligations
  – April 15, 2008, and March 24, 2009, Open Letters

• CMS Voluntary Self-Referral Disclosure Protocol
  – Addresses potential or actual Stark violations
    • Use OIG protocol if conduct implicates other laws
    • Do not disclose same conduct to both CMS and OIG
    – www.cms.gov/PhysicianSelfReferral/65_Self_Referral
      _Disclosure_Protocol.aspCompliance/ethics/intern
Sources of Compliance Information

- Advisory opinions
- Compliance program guidance
- Work plans and audits
- Published integrity agreements
- DOJ press releases
- GAO Reports
- Comments/preambles to proposed/final safe harbors/exceptions

Tools & Trends #4 – Oversight

- “Vigilantly monitor the programs for evidence of fraud, waste, and abuse.”
- Increase data mining and claims review
  - Implement innovative technology
  - Allow agents and AUSAs access to claims data
  - Identify schemes, trends, and “hot spots”
  - Coordination between law enforcement and private payors to detect, report, and prevent improper payments and fraud
Investigative Tools

- Surveillance
  - Consensual monitoring
  - Title III
- Interviews
- Search warrants
- Subpoenas
  - Grand jury
  - Inspector General
  - AID (HIPAA)
- Requests for information

Potential Referrals

- Referrals from law enforcement
- *Qui tams* under the FCA
- Data mining from contractors
- Initiatives, working groups, and task forces
- Complaints
- News media
- Self-disclosures
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

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)
Tools & Trends #5 – Response

- “Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.”

- New and improved authorities and resources
  - Legislation and rulemaking
  - Health Care Fraud Prevention and Enforcement Team
  - Criminal and civil prosecutions
  - Suspensions, terminations, recoupment, and offsets
  - Exclusion
  - Derivative sanctions

Amendments to the FCA

  - Decision (among others) impetus for new legislation

- Fraud Enforcement Recovery Act of 2009 (FERA)
  - Numerous anti-fraud measures
  - Clarifies and expands FCA provisions
  - Overrules and limits several federal court decisions
  - Effective dates of amendments vary
FERA - Liability

• False claim - 3729(a)(1)(A)
  – Removes presentment of claim to United States
  – Now whether claim submitted to obtain federal funds or if government will reimburse recipient

• False record in support - 3729(a)(1)(B)
  – Eliminates *Allison Engine* intent requirement
  – False record or statement material to false/fraudulent claim for federal funds
  – Material defined as natural tendency to influence or capable of influencing payment

FERA - Liability Cont.

• Conspiracy - 3729(a)(1)(C)
  – Expanded to all substantive provisions
  – Overrules *Allison Engine* restrictions

• Reverse false claim - 3729(a)(1)(G)
  – False record/statement material to “obligation”
    • Obligation is established duty or retention of any overpayment
    • Includes duty to pay that is not “fixed”
  – Conceals or improperly avoids or decreases obligation to pay or transmit money/property
    • Improperly means contrary to law
Noteworthy FERA Amendments

• Definition of claim – 3729(b)(1)(A)
  – Includes claims made to grantee/contractor if United States provides the funds
  – Applies whether or not the government has title
    • Addresses seized monies from foreign sovereigns

• Relation back – 3731(c)
  – Government’s claims relate back to relator’s original complaint
    • Must arise out of same conduct alleged by relator
  – Applies to common law claims

FERA Amendments Cont.

• Retaliatory action – 3730(h)
  – Covers employees, contractors, and agents
  – Protects lawful acts in furtherance of efforts to stop FCA violations
  – All relief to make person whole
    • Compensation for “special damages”

• Service on States or local government – 3732(c)
  – Any entity named as plaintiff
  – Eliminates court approval to share pleadings
  – Extends seal to named parties
FERA Amendments Cont.

• Civil Investigative Demands – 3733
  – Obtain testimony under oath and documents
  – Delegated from Attorney General
  – Permits sharing of information
    • Relators
    • Congress and federal agencies
  – Materials only used for “official use”
    • Any use consistent with law or DOJ policy/regulations

• Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code. §§ 36.053 and .054
  – Similar means to obtain testimony and records

FERA Effective Dates

• Retroactive amendments
  – False record in support - 3729(a)(1)(B)
    • Claims pending on/after June 7, 2008
  – Relation back – 3731(c)
    • Cases pending on May 20, 2009
  – Civil Investigative Demands – 3733
    • Cases pending on May 20, 2009
  – Service on States or local government – 3732(c)
    • Cases pending on May 20, 2009

• All other changes apply to conduct occurring post-enactment
PPACA

• Patient Protection and Affordable Care Act
  – Enacted on March 23, 2010
• Substantive changes to FCA *qui tam* provisions
  – Narrowed public disclosure bar
    • DOJ has say whether case is barred
    • Addresses only federal not state or administrative disclosed conduct
  – Expands original source exception
    • Eliminates “direct knowledge” requirement
    • Now knowledge independent of and materially adds to publicly disclosed allegations

PPACA Cont.

• Amendments to criminal provisions
  – Rejects more stringent definition of knowledge under the anti-kickback statute
    • No longer must prove intent to violate the Anti-Kickback Statute
  – Intended loss is the value of the claim, not the payment in criminal sentencings
  – Violations result in falsity under the FCA
    • Kickback violations may occur even if the claim is submitted by a third-party
• Mandates return of overpayments within 60-days
Questions