Update on Fraud & Abuse Issues Impacting Hospitals and Physicians

AHLA Institute on Medicare and Medicaid Payment Issues
March 21-23, 2007
Baltimore, Maryland

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I. Recent False Claims Act Developments

A. False Claims Act ("FCA") Remains Keystone of Fraud and Abuse Prosecutions

- 1987- 2005: $15 billion in FCA settlements & judgments
    - Health care: $5 billion (33%)
- 2006 alone: $3.17 billion in FCA settlements & judgments
    - Health care: in excess of $2.2 billion (over 70%)
- Median FCA recovery in health care fraud case recently exceeded $1 million
- Of the nearly 10,000 FCA cases filed, DHHS has been named as the defrauded agency 54% of the time
- Average recoveries and relators' shares are greater in health care fraud cases, as compared to other FCA cases, and continue to be greater when DOJ intervenes
    - Not surprisingly, DOJ intervenes more often in health care fraud FCA cases than any other type of case (nearly 33%)
    - DOJ increasingly reliant on relators as source of FCA cases. In 1995, relators were the source of 54% of all FCA cases; by 2005, that percentage had grown to 80%

B. Key 2006 Health Care-Related Developments

1. Increased Application of FCA to Kickback and Stark Violations

- Tenet Healthcare Corp. (San Diego)
    - Tenet allegedly paid "physician recruitment" packages to physicians "relocating" within San Diego area to Alvarado Hospital, in violation of the Anti-Kickback Statute

- FCA theory: false certification (i.e., violations of Anti-Kickback Statute made false the hospital's certifications that it had complied with the Anti-Kickback Statute, thus tainting all such certified claims)

- To resolve these allegations, Tenet paid $21 million to the government, and ultimately sold Hospital

- Hospital's physician recruitment director previously pled guilty to health care fraud

- Hospital's CEO faced two criminal trials; hung juries in both; government will not retry

- University Hospitals Health System (Cleveland, Ohio)

  - Former disgruntled co-chair of cardiothoracic surgery department blew whistle, alleged that hospital paid physicians to refer patients exclusively to other physicians within the UHHS system, in violation of Anti-Kickback Statute and despite repeated warnings over 12 years

  - FCA theory: false certification

  - To resolve allegations, UHHS paid $14 million to the government and entered into a corporate integrity agreement

- Northside Hospital (Atlanta)

  - Former CEO and billing manager blew whistle, alleged that hospital violated Stark Law by providing employees to physician practices free-of-charge, and by paying amounts in excess of fair market value for directorship services

  - FCA theory: false certification

  - To resolve allegations, hospital paid $5.72 million to government

- Marion County Medical Center (South Carolina)

    - Former hospital employee (physician) blew whistle, alleging that medical center paid two physicians for services at a rate "far in excess" of fair market value, in violation of Stark Law and anti-kickback statute

    - FCA theory: false certification

    Medical center paid U.S. government $3.75 million to resolve allegations

- Beebe Medical Center (Delaware)

    - Whistleblower alleged that Beebe Medical Center paid a fee to two gastroenterologists for patient referrals, and allowed the physicians to bill the government for performing the services

    - To resolve these allegations, Beebe Medical Center and the two physicians paid $1 million to the government

- Siouxland Surgical Center (South Dakota) and Center for Neurosciences, Orthopedics and Spine (CNOS)

    - CNOS physicians allegedly accepted payments from artificial joint manufacturer offered as an incentive to use certain orthopedic products, in violation of Ant-Kickback Statute

    - FCA theory: false certification

    - To resolve these allegations, the defendants paid $345,000 to the government

- U.S. ex rel. Roberts v. Aging Care Home Health, Inc., et al., (W.D. La., No. 02-2199, 2/16/2007)

    - Government intervenes in FCA false certification case, also claims payment by mistake and unjust enrichment. Underlying allegations: pre-2001 physician referrals

violated Stark II, as HHA's financial relationships with 5 physicians did not achieve statutory exception for "personal service arrangements"

- Court found that relationships did not achieve PSA exception: (1) written agreements failed to specify services actually performed; (2) services to be performed were unnecessary; (3) compensation exceeded fair market value; and (4) written agreements failed to include terms of at least one year

- "Technical violation": Court found that even if one financial relationship satisfied (1), (2) and (3) above, it still did not satisfy PSA exception because the written agreement failed to include a term of at least one year

- Government moved for summary judgment on theories of payment by mistake and unjust enrichment, sought return of $427,500 in payments made. Court: as HHA's cost report certifications were false and material to Medicare's decision to pay, payments were mistaken and HHA was unjustly enriched. Court orders return of $427,500

- Government also claimed that HHA owner who executed the physician agreements and certified the cost reports was unjustly enriched by salary of $150,000 and shareholder distributions of $850,000. Court, however, finds that unjust enrichment is limited to $427,500 that Medicare paid to HHA

2. Other Significant Health Care Settlements Based on FCA

- Tenet Healthcare Corp.
  - Relator alleged that Tenet manipulated the Medicare outlier system, upcoded diagnostics tests, and paid kickbacks to physicians for referring Medicare patients to Tenet-operated hospitals
  - To resolve these allegations – primarily the allegation related to manipulation of Medicare's outlier system – the company paid $725 million to the government and execute a rigorous corporate integrity agreement
- Saint Barnabas Corp. (New Jersey)
  - Relator (former employee) alleged that St. Barnabas improperly billed Medicare "outlier" payments based on inflated charges
  - To resolve these allegations, St. Barnabas paid $265 million to the government
- Jackson Memorial Health System (Miami)
  - To resolve allegations of Medicare cost reporting fraud, health system paid $14.3 million to government
  - Whistle blown by former employee of outside financial consulting firm retained by Jackson Memorial to reopen closed cost reports and seek further payment

C. Other Important False Claims Act Case Decisions

1. U.S. v. The Baylor University Medical Center (2nd Cir., 11/16/2006)

- Government intervened 8 years after relator filed complaint alleging that hospitals improperly billed

Medicare for inpatient hospital services using cardiac device granted "Investigational Device Exemption" status by FDA

- Court held that government's untimely intervention could not "relate back" to original claims, relying on FCA's 6-year statute of limitations

- Ruling is helpful from an FCA defendant's perspective, as it pressures the government to intervene earlier

2. Rockwell International Corp. v. U.S. ex rel. Stone (U.S. No. 05-1272)

- Supreme Court hears oral arguments on "original source" exception to public disclosure jurisdictional bar

- Court could decide, albeit unlikely, that if the relator is not an original source, then neither the relator *nor* the government would be entitled to recover funds

- Central issues to be decided: what knowledge must a relator have to qualify as an original source? When must she have that knowledge? What must the relator tell the government before filing suit?

- Will Court narrow the definition of "original source" by requiring a greater degree of knowledge of the fraud?

3. U.S. ex rel. Atkins v. McInteer (11th Cir., 12/1/2006)

- Psychiatrist-relator alleged that other psychiatrist submitted false Medicaid claims for, *inter alia*, services not rendered

- District court had previously determined that the defendants, by submitting claims for payment to a Medicaid agency, did not "present" claims to an "officer or employee of the U.S. government"

    - District court's reasoning demonstrated early application of *U.S. ex. rel. Totten v. Bombardier Corp.* to healthcare, and could have had

important ramifications for the applicability of the FCA to Medicaid claims

- However, the 11th Circuit rejected the lower court's analysis and determined that the relator had merely failed to plead with specificity how the defendants actually presented their claims to the government, and thus failed to satisfy Rule 9(b)

D. State-Based False Claims Activities

1. The Deficit Reduction Act of 2005

- States may retain higher share of funds ("incentive bonuses") recovered from actions brought under state false claims acts, but only if such acts are as stringent as the FCA

- However, of ten states' laws reviewed by OIG thus far, only three are sufficiently stringent to meet requirements necessary for "incentive bonus": http://oig.hhs.gov/fraud/falseclaimsact.html

- Ultimately, it is likely that many states will comply, thereby facilitating state-based FCA prosecutions and complicating FCA defenses

  - Multi-state health systems could face multiple suits in multiple jurisdictions based on the same allegations

  - Certain states may become "preferred" forums based on civil procedures, rules of discovery, etc.

  - Need for multi-state forum akin to centralized, multidistrict litigation forum for federal claims?

2. States Likely to Become More Aggressive in FCA Prosecution

Example:

- *Illinois ex. rel. Donaldson v. Midi LLC* (Ill. Cir. Ct., No. 06CH02513) (state intervenes 1/17/2007). Illinois

Attorney General intervenes in lawsuit against Chicago area radiology centers re: alleged payment of kickbacks to referring physicians (including allegations of "sham" lease arrangements and physicians purchasing MRI and CT scans for less than subsequently charged to commercial insurers)

II. Criminal Law Developments

A. The Anti-Kickback Statute

1. New Regulatory Safe Harbors Established For the Donation of E-Prescribing and Electronic Health Record Items and Services

- Health care organizations (health plans, hospitals, etc.) are permitted to donate (to certain providers , including physicians) EHR and e-prescribing technology items and services, as long as certain conditions are met, including (but not limited to):
  - Actual items and services must be donated, *not* cash earmarked for initiatives and purchases
  - Software/hardware must be certifiably interoperable with other e-health systems, and of limited use for personal and administrative chores
  - Physicians must front 15% of cost of donation of EHR technology items and services (42 C.F.R. § 1001.952(y)(11))
- Goal: remove large cost barriers that smaller groups of physicians cannot hurdle in order to implement EHR and e-prescribing capabilities
- Utility of safe harbors is debatable given restrictions to non-monetary donations and 15% cost-sharing required of physicians

2. OIG Guidance

a. Special OIG Guidance Regarding Physician Investment in Medical Device Industry (October, 2006):

http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20(2).pdf

- Reasoning of 1989 Special Fraud Alert on Joint Ventures is affirmed
- Highlights applicability of small entity investments regulatory safe harbor (42 U.S.C. §1001.952(a), i.e., no more than 40% of revenues may come from investors, including physician-investors)
- Reiteration that "participant-driven" referrals to joint ventures continue to be indicators of potential problems (see, e.g., 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005))

b. 2006 Advisory Opinions

Twenty-three Advisory Opinions were issued by the OIG in 2006. Of note:

- OIG Ad. Op. 06-01: For purposes of determining whether free items exceed "nominal value," calculate the value to the recipient, not the cost to the donor. Furthermore, by indicating that a recipient's "impression" of value is also important, the OIG may have unwittingly cast doubt on the reliability of typical valuation approaches, such as market rates and comparables
- OIG Ad. Op. 06-02: DME manufacturer and supplier proposed to allow physicians and groups to become DME suppliers for items and

services furnished to patients, allowing physicians to make a profit on items sold

- Affirmation that federal program carve-outs do not eradicate Anti-Kickback Statute scrutiny

- OIG stresses that it will scrutinize a contractual joint venture in its totality: "an attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services and then qualify each separate contract for protection under a safe harbor may be ineffectual and place parties at risk for prosecution"

- OIG Ad. Op. 06-17: organizer of dental preferred provider network permitted to pay marketing firm on percentage of compensation basis. OIG determined that only federal dollars at issue were small amount of FEHBP dollars, and that FEHBP is not a federal health care program for purposes of anti-kickback statute

3. Case Law and Decisions

- *U.S. v. Rogan*, N.D. Ill., No. 02C3310 (9/29/2006)

  - This case was originally brought as a criminal action based on anti-kickback allegations. Prosecutors also alleged $13.6 million of damages to Medicare and $4.5 million of damages to Medicaid under false claims theories

  - Three physicians and hospital administrator were sentenced to prison time

  - Peter Rogan, Owner and CEO, was then tried civilly under FCA false certification theory

- In a jury verdict, Rogan was found guilty of paying kickbacks to physicians for referral of Medicare and Medicaid patients for unnecessary care, thus violating both the Anti-Kickback Statute and the Stark Law

- Rogan ordered to pay $64.2 million of damages and penalties to U.S. government; calculation of damages being appealed

- *Florida v. Harden* (Fl. Sup. Ct., SC04-613, 5/18/2006).

  - Anti-Kickback Statute, regulations and sub-regulatory guidance preempts Florida Medicaid anti-kickback statute (analysis akin to conflict preemption)

B. HIPAA

- *U.S. v. Ferrer* (S.D. Fl., 06-60261)

  - Justice Department wins first HIPAA criminal prosecution to ever go to trial
  - Ferrer purchased individually identifiable health information from individual with access to computerized records, used information in connection with $2.8 million of false Medicare claims
  - Sentencing in April, Ferrer could face 10 years for wrongful disclosure of PHI

C. Health Care Fraud Statute

- Health care fraud statute (18 U.S.C. § 1347) expands opportunity to prosecute beyond federal health care programs

- *U.S. v. Jones*, (3rd Circ., No. 05-4898, 12/28/2006)

  - Clerk at self-pay only methadone clinic accused of siphoning $450,000 from clinic's daily cash receipts

over 3 year period; district court convicts her of violating of 18 U.S.C. §1347

- 3rd Circuit reverses, finds government failed to prove (1) misrepresentation "in connection with the delivery of, or payment for, health care benefits, items or services"; and (2) anything affected the delivery of, or payment for, health care benefits, items, or services

- 18 U.S.C. §1347 criminalizes health care *fraud*, and does not cover mere theft, which falls under the rubric of 18 U.S.C. §669 (simultaneously enacted per HIPAA)

- *U.S. v. Jones*, (5th Circ., Nos. 05-30942, 05-30998, Jan. 16, 2007)

  - Jones and Clark pled guilty to health care fraud for misrepresenting "related party" status of rehab hospital and management company. District court sentenced defendants, with sentencing guidelines enhancements, to 3 years, 3 months and 1 year, 1 day of prison time, respectively, and ordered restitution of over $1.2 million each

  - 5th Circuit vacated sentences, finding that government failed to prove that, despite concealed "related party" status, (1) government suffered loss; (2) compensation from hospital to management company was unreasonable; (3) services provided by management company were not worth amounts reimbursed

D. The UMDNJ Deferred Prosecution Agreement

- January, 2006, University of Medicine and Dentistry of New Jersey ("UMDNJ") entered into deferred prosecution agreement ("DPA") with U.S. Attorney for the District of New Jersey, who had discovered $4.9 million in Medicaid fraud

  - UMDNJ stipulated to facts alleged in complaint filed by U.S. Attorney, agreed to submit to federal monitor in return for U.S. Attorney's deferred (2 years) prosecution of various health care fraud claims

- DPA provided flexible, creative and dynamic oversight authority to government; UMDNJ's federal monitor has had and will continue to have extensive authority and access. Within first 12 months, UMDNJ's monitor had:
    - Obtained resignations of General Counsel and top compliance officers
    - Commenced 51 additional internal investigations that identified $400 million of additional fraud, waste and abuse
    - Issued Report describing potential Stark violations related to eighteen cardiologists
    - Invoiced UMDNJ for $5.8 million to cover monitoring services (just first six months)
- Use of DPAs may increase in future, based on effectiveness of monitor in this case

E. Change in DOJ Policy Regarding Attorney-Client Privilege

- December, 2006: "Thompson Memorandum" superseded by "McNulty Memorandum":
    - "Waiver of attorney-client and work product protections is not a prerequisite to a finding that a company has cooperated in the government's investigation"
    - Prosecutors may only request waiver when there is a legitimate need for the privileged information
- Lingering debate over whether and what the practical effects will be

III. Stark Law Developments

A. Specialty Hospital Moratorium Ends

- August 8, 2006: CMS releases final report to Congress on specialty hospitals; as of that date, moratorium not continued
    - As a result, physicians may once again avail themselves of Stark exception allowing referral of patients to specialty hospitals in which the physicians invest
- Congressional interest remains, however, due in part to repeated patient deaths at specialty hospitals
- Following 1/23/07 patient death, Grassley, Baucus and Stark ask CMS Acting Administrator Norwalk to account for any Medicare dollars that may have been paid to West Texas Hospital during Moratorium (2/8/07)

B. Judicial Challenge to Use of Surveys In FMV Definition

- *Renal Physicians Assoc. v. DHHS, et al.*, (D.C. D.C., No. CIV. A. 05-0067 (RBW), 3/7/2006)
    - Association representing medical directors of outpatient dialysis facilities sought to enjoin CMS' implementation of portion of Stark Law exception offering fair market value "safe harbor" to physician personal service arrangements utilizing one of six national surveys to determine compensation rates
    - Association argued that "safe harbor" was issued "unexpectedly and without proper notice or a meaningful opportunity for public comment," that the surveys were outdated and arbitrary, and do not truly reflect fair market value of medical directors' services
    - District court found that association did not have standing
        - Injury not traceable to reliance on "safe harbor," as compliance with safe harbor is "voluntary"

and thus any adherence to it is the independent action of a third party, as CMS would determine higher rates of compensation to be "fair market value" if proven reasonable

- Injury not redressable, as invalidation of "safe harbor" would not require parties to existing contracts to revisit compensation rates and pay medical directors a higher rate

- District court also emphasized that CMS promulgated Stark II Phase II as an interim final rule with comment period, and that CMS will have opportunity to respond to comments on "safe harbor" within three years

C. New Regulatory Exceptions for the Donation of E-Prescribing and Electronic Health Record Items and Services

- Similar to the new regulatory safe harbors to the Anti-Kickback Statute, new Stark Law exceptions permit DHS entities to donate (to physicians) EHR and e-prescribing technology items and services, as long as conditions similar to the safe harbors are met

- Similar goal: remove large cost barriers that smaller groups of physicians cannot hurdle in order to implement EHR and e-prescribing capabilities

- Exceptions sunset December 31, 2013, consistent with President's goal of instituting health IT by 2014

D. Advisory Opinion on Physician Recruitment

- CMS Ad. Op. 06-01: Meaning of "relocation" at issue in joint recruitment arrangement between hospital, medical group and physician: http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-AO-2006-01.pdf

  - Permissible for hospital to be involved, even if arrangement provides that physician must dedicate

10-20% of practice outside of hospital's geographic service area

- Some leeway provided, but how much out-of-area practice is too much?

E. Whither "Stark III"?

- Section 902 of Medicare Modernization Act may require promulgation of final rule by March 26, 2007
- At a minimum, CMS must respond to comments made in response to March 26, 2004 "final rule with comment period"
- Issues that may be addressed in Stark III:
  - Stark Law's applicability to Medicaid
  - Physician recruitment exception may be expanded to accommodate practical requirements
  - In-Office ancillary services exception may be narrowed

IV. Recent Activities of the Office of Inspector General

A. OIG 2006 Workplan

1. Expected Health Care Fraud Investigations to Include:

- Medicare Part D
- Pharmaceutical fraud
- Quality-of-care for nursing home residents

2. New Hospital Audits for 2006

- Adjustments for Graduate Medical Education Payments
- Inpatient Hospital Payments for New Technologies
- Outpatient Department Payments (multiple procedures, repeat procedures, and global surgeries.)

- HIPAA Compliance

3. New Physician Audit for 2006

- Billing companies (structure of relationships with physicians; effect on physician billings)

B. Advisory Opinions and Other Guidance

- See II.A.2. and III.E., above

C. Increased Emphasis on Use of Exclusion and Other Administrative Penalties

- License revocation/suspension/surrender continues to be the most frequent basis for exclusion/penalty (nearly 50% of all exclusions/penalties)

- Program-related conviction continues to be the second-most frequent basis for exclusion/penalty (approximately 25% of all exclusions/penalties)

  - Some convictions require OIG exclusion; uneducated plea agreements continue to force the unwary into program exclusion

D. OIG April, 2006 "Open Letter to Health Care Providers"

1. Traditional OIG Provider Self-Disclosure Protocol ("SDP") Affords an Unappealing Process for Resolving Stark Violations

- Difficult for OIG to convince providers that use of SDP is worth it; calculus of whether to embark upon Stark Law disclosure strategy is often based upon likelihood of whistleblower action or government detection, OIG efforts to encourage disclosures has been frustrated

- Finalization of Phase II Stark II rules eliminated "technical violation" rationale for non-disclosure; providers were left with difficult dilemma when technical violations are detected

- Requires concession that "false claim" submission likely to have occurred

- Financial exposure is significant (CMP damages of 2x claims or greater), and imposition of CIA in many cases

2. OIG Open Letter Established New Enforcement Initiative to Encourage Stark Law Disclosures

- Initiative limited to matters involving a financial benefit "knowingly conferred by a hospital upon one or more physicians"

- Under new initiative, Stark and Anti-Kickback based disclosures to OIG will first be screened by DOJ; proposed OIG resolution will also be reviewed by DOJ; satisfaction of OIG will not be binding on DOJ

- Damages continuum upon which such cases can be settled runs from:

  - Stark-based CMP damage calculations based on the number and dollar value of improper claims

  - Anti-Kickback-based CMP damage calculation based on the number and dollar value of improper payments or remuneration to the physician

- Subject to the facts and circumstances of each case, the OIG will "generally settle SDP matters" for an amount "near" the lower end of the continuum: "a multiplier of the value of the financial benefit confirmed by the hospital upon the physician(s)"

- CCA, or CIA, or no additional compliance measures may also be imposed

- Participation in initiative contingent upon full cooperation and complete disclosure

- http://www.oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf

3. Remaining Issues/Concerns Under Protocol

- Protocol is available only for "knowing" violations; "innocent" Stark violations may still be in limbo
- What does "financial benefit knowingly conferred" really mean? How close is this to an admission of an Anti-Kickback violation? Fifth Amendment issues? What will DOJ's reaction be to such a concession?
- Repayment of claims paid would also need to be made in addition to SDP settlement
- Unclear whether "financial benefit" is total compensation paid or only the difference between actual compensation and FMV
- No clear cut guarantees re: a) level of damages multiple; b) how broad any further review of client's physician relationships would need to be, c) when involvement of DOJ would arise

V. Future Risk Areas for Hospitals and Physicians

A. Implications of Deficit Reduction Act of 2005

- Promulgation of new and/or stricter state false claims acts
- Medicaid Integrity Program ("MIP"): joint federal-state effort to "identify, recover and prevent inappropriate Medicaid payments"
- Medicaid contractors' employee and agent education requirements (re: False Claims Act)
  - Recent CMS guidance, while confusing, appears to lessen requirements (dissemination of manuals and policies, rather than active training seminars)

B. Continued OIG and DOJ Scrutiny of Creative Business Relationships

1. IDTF Leases

- July 2006: OIG audit determines that Medicare may have overpaid California and Florida IDTFs by as much as $71.5 million in 2001, for services not reasonable, necessary, ordered by a physician, or sufficiently documented

- January 26, 2007 CMS Transmittal indicated, among other things, that:

  - IDTFs may not share space and equipment with other IDTFs and suppliers. Implicated current lease arrangements designed to satisfy safe harbors and exceptions

  - IDTF technologists must be full-time employees. Could have disrupted current employment arrangements, management agreements, and staffing arrangements designed to satisfy safe harbors and exceptions

- February 16, 2007: CMS rescinds January 26, 2007 guidance

- It is possible that CMS will attempt to implement the January guidance via more formal rulemaking processes

2. "Under-Arrangements" Relationships

- Recent revival in this form of wall-to-wall management relationship between hospitals and physicians, spurred by consultants

- If physician-managers are also referrers, variable compensation arrangements will need to be clearly related to proper incentives other than volume or volume-related variables

- If physician-managers are referrers, more recent case law suggests that physicians could be at greater risk for FCA-based prosecution under theory that their improper relationship "caused" false claims

C. Other Areas of Continued Concern

1. Physicians' Relationships With Medical Device Companies

- If penalties imposed on device companies have not stymied improper relationships, must penalties be imposed on physicians?

2. Broadened Application of False Claims Act to Quality of Care Cases

- U.S. Attorneys indicate that sources of data that will be considered in initiating or pursuing an investigation will include information from the "reporting hospital quality data for annual payment update" (RHQDAPU), JCAHO, state reporting, mandated reporting of errors and near misses, apologies mandated by state laws, QIOs and pay-for-performance private sector contracts

- Quality of care theories heretofore constrained to nursing homes likely to expand to other providers

3. Commercial Insurers' Increased "Prosecution" of Health Care Fraud

- August, 2006: Blue Cross and Blue Shield plans announce FY 2005 recoveries of more than $144 million in fraudulent insurance payments, and another $106 million in prevented payouts. Increase of 20% from FY 2004

- Private cases traditionally brought on theory of breach of contract shifting to "fraud" allegations