DEALING WITH STARK AND ANTI-KICKBACK PROBLEMS IDENTIFIED IN REVIEWS OF HOSPITAL-PHYSICIAN FINANCIAL ARRANGMENTS

CORRECTIVE ACTION, PHYSICIAN NEGOTIATION, AND VOLUNTARY DISCLOSURE; CASE STUDIES

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RAISING THE STAKES IN HOSPITAL-PHYSICIAN FRAUD AND ABUSE ENFORCEMENT

- False Claims Act (FCA)
- FCA standard: false claims with knowledge, reckless disregard, or deliberate ignorance
- False Claims Act (FCA) Fraud Enforcement and Recovery Act of 2009 (FERA) broadens FCA liability:
  - new liability for the *retention* of overpayments, even if claim or receipt of overpayment was not knowingly false
  - false claim now includes claims to *agents* of the government
- Application of FERA to Stark violations
- CMS and governmental enforcement posture

Key Provider Fraud Enforcement Provisions of the PPACA

- Relaxes the intent requirements of the AKS—“repeals” the Hanlester case
  - Old test: Violation occurs if
    - “one purpose” of payment is to induce an illegal referral;
    - actual knowledge of the AKS’s prohibitions;
    - specific intent to violate the AKS
  - New test: Violation occurs if
    - “one purpose” of payment is to induce an illegal referral;

      no longer necessary to prove specific intent to violate the AKS

Key Provider Fraud Enforcement Provisions of the PPACA

- Requires DHHS to establish within 6 months a protocol for self-disclosure of Stark violations
- Sets time period to return overpayments — 60 days; retention of overpayments after 60 days is defined as an "obligation" and therefore can be an FCA violation
- Most providers and suppliers required to implement compliance programs as a condition to participation in Medicare or Medicaid

Key Provider Fraud Enforcement Provisions of the PPACA

- Knowing falsity is grounds for program exclusion
- Expands grounds for CMPs for: excluded providers and; falsities made in Medicare or Medicaid enrollment applications
- Suspension of program payments pending investigation of “credible allegations of fraud”

Key Provider Fraud Enforcement Provisions of the PPACA

- Increases funding — additional $350 million — to fight Medicare fraud and abuse
- Establishes a national health care fraud and abuse data collection program for reporting adverse actions against providers, information to the NPDB
- Establishes new grounds for terminating and excluding persons or entities from Medicaid who own or manage entities that fail to repay overpayments, that are excluded from Medicaid, or that are affiliated with excluded persons or entities

RECENT RECOVERIES AGAINST HEALTH CARE ORGANIZATIONS

- Dec., 2008: Condell Medical Center, Libertyville, Illinois - $36 million (self-disclosed Stark and Anti-kickback statute (AKS) violations discovered during due diligence for pending acquisition)
- Aug., 2009: Covenant Medical Center, Waterloo, Iowa - $4.5 million (to settle Stark and FCA claims that Medical Center compensated five doctors for referrals to hospital)
- Oct., 2009: Former Executive Director for Community Memorial Hospital of Ventura, California - $64,000 (to resolve allegations that Executive Director negotiated financial arrangements with physicians and directed improper payments to physicians that violated Stark)
- Oct., 2009: University of Medicine and Dentistry of New Jersey, Newark, New Jersey - $8.3 million (to settle allegations of Stark and AKS violations for entering into agreements with cardiologists to refer their cardiac procedures to the hospital)
- Oct., 2009: McAllen Hospitals, LP, d/b/a South Texas Health System, McAllen, Texas - $27.5 million (to settle Stark, AKS and FCA allegations that it paid physicians through sham contracts in order to induce them to refer patients to hospitals within the system)
- Dec., 2009: Boston Scientific Corp. - $22 million (to settle claims that it gave physicians kickbacks to use pacemakers and defibrillators)

RECENT RECOVERIES AGAINST HEALTH CARE ORGANIZATIONS

- Dec., 2009: St. John Health System, Tulsa, Oklahoma - $13.2 million (to settle self-disclosure of potential Stark and AKS violations stemming from payments made by the hospital to 23 physicians and physician groups in order to induce referrals)

- Feb., 2010: Mariner Health Care Inc., SavaSeniorCare Administrative Services LLC, and the companies' principals, Atlanta, Georgia - $14 million (to settle FCA allegations that the nursing home chains solicited kickbacks from Omnicare. Of the recovery, $6.16 million was allocated to certain state Medicaid programs and $7.84 million to the federal government)

- March 2010: Renal Care Group, Renal Care Group Supply, and Fresenius Medical Care Holdings, Inc., Nashville, Tennessee - $19.4 million plus interest (recovery awarded after U.S. District Court determined that the companies violated the FCA by establishing a sham billing company to submit home dialysis supply claims prohibited under the Medicare program)

- March 2010: Alpharma Inc. - $42.5 million (to settle allegations that the company violated the FCA by paying physicians to induce them into promoting and prescribing the drug Kadian. The federal government will receive $33.6 million from the settlement and the states will receive $8.9 million)

- March 2010: Robert Wood Johnson University Hospital Hamilton, New Jersey – $6.35 million (to settle allegations of FCA violations that the hospital fraudulently inflated charges in order to obtain supplemental outlier payments)

REFERRAL SOURCE ARRANGEMENTS REVIEW

- Review prompts
  - Increased regulatory activity
  - In house Legal Department work plan
  - Increased awareness and sensitivity among certain executives
  - Discovery of potential issues

REFERRAL SOURCE ARRANGEMENTS REVIEW

- Review challenges
  - Competing priorities and limited In house Legal Department resources
  - Compliance Department role clarification
  - Varied awareness and sensitivity among certain executives
  - Finances required to conduct the review

REFERRAL SOURCE ARRANGEMENTS REVIEW

- Review Process
  - Communication, communication, communication
  - Selection of Outside Counsel and Audit Firm
  - Document Request and Validation Request
  - Stop-gap, mid-stream and long-term enhancements and improvements
  - Sharing findings
  - Corrective Action

REFERRAL SOURCE ARRANGEMENTS REVIEW

- Use of Outside Counsel
  - Coordination with Compliance Department
  - Use of select Outside Counsel
  - Development of a work flow for both issue spotting and analysis

REFERRAL SOURCE ARRANGEMENTS REVIEW

- Enhancements
  - Executive attention to compliance
  - Policies and process flows
  - Review, approval and certification procedures
  - Arrangements database
  - Compliance Department Work Plan

TYPES OF PROBLEMS IDENTIFIED

Examples:

- No written agreement
- Unsigned agreement
- Expired agreement
- Payments do not match contract terms
- No FMV/changed FMV
- Changed or new services
- No physician time sheets
- Multiple agreements with same physician or group
- No community benefits assessment

GOT VIOLATION – WHAT NOW?!?

- No easy answers
- Verify legal finding of violation; tread carefully regarding admission of violation
- Capture attorney-client privilege – use of outside counsel
- Inform appropriate hospital stakeholders, e.g., compliance department, management, and/or board
- Limit participants to small, “need to know basis;” manage communications

GOT VIOLATION – WHAT NOW?!?

- Establish prospective compliance

  Examples:
  - execute written contract with physicians
  - sign unsigned agreements
  - obtain excess compensation from physicians
  - settle bona fide dispute with physicians
  - obtain fmv valuation
- Does establishing prospective compliance “fix” compliance for prior time periods?

DISCLOSE TO GOVERNMENT? FACTORS TO CONSIDER

- Follow compliance plan
- Strength/weakness of legal argument that no violation of Stark or AKS has occurred
- Amount of monetary repayment
- Likelihood government will discover violation
- Possible negative publicity. Is violation high profile?
- Sympathy/lack of sympathy anticipated from enforcement agency
- How will physicians react? Is disclosure consistent with agreement with physicians?

DISCLOSURE: PROS

- Cut off whistleblower
- Cut off FCA liability
- Limit/reduce fines and penalties (U.S. Sentencing Guideline, FCA, OIG)
- Avoid CIA or CCA
- Head off criminal indictment
- Allows hospital to negotiate subpoenas
- Allows hospital to “frame case” regarding law and publicity
- Avoid broader investigation

DISCLOSURE: CONS

- Government will discover violation
- Fine or penalty may be imposed – possibly worse than expected
- Further investigation – possibly into areas not the subject of disclosed violation
- Time and expense of cooperating with governmental investigation
- Negative publicity – possible “headline” damage
- May have to waive defenses/attorney-client privilege
- Will physicians react negatively or will contract with physicians be breached?

OPTIONS FOR GOVERNMENT DISCLOSURE: WHICH AGENCY?

- Disclosure to certain government agencies may resolve enforcement of some violations, but not others

DISCLOSURE: WHICH AGENCY?

FI

Routine billing errors but may not cut off whistleblower or FCA

CMS

Stark only; no criminal or FCA. CMS central may be best option. CMS has no real process in place to handle disclosures, therefore disclosure can be a bureaucratic mess. CMS says it cannot compromise Stark violations but, in fact, it does. CMS will refer matters greater than $100,000 to DOJ

DISCLOSURE: WHICH AGENCY?

OIG

Voluntary Disclosure Protocol (VDP) – AKS, or Stark violations with colorable anti-kickback violation; no FCA. Sometimes used for conduct involving low grade intent, or for rogue employee. May not absolve from all claims, e.g., FCA, but VDP could be a "cover" to head off enforcement by other agencies

DISCLOSURE: WHICH AGENCY?

DOJ

Can resolve all claims but potentially will be a higher profile disclosure. Can be somewhat of a "crapshoot" depending on which DOJ attorney is involved, so preferable to have someone you know within DOJ that can act as an advocate. Will cut off whistleblowers and FCA.

U.S. Attorney

Same as DOJ and hospital may be in a better position to identify local AUSA with prior relationship who will act as an advocate