

# APPROACHES FOR HOSPITALS CONFRONTING STARK AND ANTI-KICKBACK ISSUES

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
- 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

# 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)

# RECENT RECOVERIES AGAINST HEALTH CARE ORGANIZATIONS

- 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)

# 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

# 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
- obtain excess compensation from physicians
- settle bona fide dispute with physicians
- 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