Stark Law and Anti-Kickback Statute Hot Topics

Heart of America Chapter Healthcare Financial Management Association

Presented February 19, 2015
Agenda

- Overview of the Anti-Kickback Statute, Exceptions, Safe Harbors
- Overview of Stark Law, Exceptions
- Recent Enforcement Trends
- Hot Topics
For every dollar spent on health care-related fraud and abuse investigations from 2011-2013, the government recovered $8.10 (Health Care Fraud and Abuse Control Program report).

The government recovered a record-breaking $4.3 billion in taxpayer dollars in FY 2013.

$19.2 billion was recovered from 2009-2013, far greater than the $9.4 billion obtained over the prior 5-year period.

President Obama’s proposed 2016 budget seeks $706 million in Health Care Fraud and Abuse Control account funding.
Fraud and Abuse Laws

- Federal Anti-Kickback Statute
- Federal Stark Law
- Federal False Claims Act
- State Fraud and Abuse Laws
- State Criminal Law
Anti-Kickback Statute

- Prohibits knowingly and willfully soliciting or receiving any remuneration in return for:
  - Referring Patients; or
  - Purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, ordering, leasing of any good, facility, item or service paid for by a Federally funded health care program
AKS Key Elements

- “Remuneration” includes any kickback, bribe, or rebate
- Requires Intent (“Knowing and willful”)
- Penalties:
  - Civil and criminal, including $25,000 fine per offense, civil monetary penalties, imprisonment for up to 5 years, and exclusion from federal health care programs
New Anti-Kickback Statute Intent Standard

- PPACA Section 6402(f) states:
  - “With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” § 1128B(h)
Stark Law

42 U.S.C. 1395nn *et seq.*

- Prohibits physicians from:
  - Making a referral
  - To an entity
  - In which the physician or immediate family member has a financial relationship
  - For a designated health service (DHS)
  - For which payment may be made under Medicare or Medicaid
## Designated Health Services

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<th>Designated Health Services</th>
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<tr>
<td>Clinical laboratory services</td>
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<td>Durable medical equipment</td>
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<td>Physical therapy services</td>
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<td>Parenteral and enteral nutrients/supplies/equipment</td>
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<td>Occupational therapy services</td>
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<td>Prosthetics and orthotics</td>
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<td>Outpatient speech-language pathology services</td>
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<td>Home health services</td>
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<td>Radiology (X-ray, MRI, CT, ultrasound, nuclear medicine, PET)</td>
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<td>Outpatient prescription drugs</td>
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<td>Radiation therapy services</td>
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<td>Inpatient and outpatient hospital services</td>
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Stark Law Financial Interest

- Financial interest includes any direct or indirect:
  - Ownership or investment interest
  - Compensation arrangement
- The physician may not refer to the DHS entity and the DHS entity cannot bill Medicare for the referral
Stark Law Penalty

- Strict liability (intent not required)
- Civil penalties
- Exclusion
- May create False Claims Act liability
# Distinctions Between the Stark Law and Anti-Kickback Statute

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<thead>
<tr>
<th>Stark Law</th>
<th>Anti-Kickback Statute</th>
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<td><strong>Civil</strong></td>
<td><strong>Criminal</strong></td>
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<td>No proof of intent – conflict of interest presumed</td>
<td>Requires proof of unlawful intent – “knowing and willful” and intent to induce</td>
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<td>Applies only to arrangements with physicians: “REFERRAL” narrowly defined</td>
<td>Applies to any referral source: “REFERRAL” broadly defined</td>
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<td>Referral prohibited unless arrangement meets an exception</td>
<td>Safe harbor immunizes, but absence of safe harbor or exception does not = illegal (facts and circumstances analysis)</td>
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<td>Prohibits only Medicare referrals (but see Halifax)</td>
<td>Applies to referrals of federally funded state healthcare programs, in addition to Medicare and Medicaid</td>
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<td>Refund of improper billings; civil penalties</td>
<td>Incarceration; fines</td>
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60-Day Rule

- FCA: Any person who knowingly conceals an obligation to pay money to the Government or knowingly and improperly avoids an obligation to pay money to the Government can be held liable for a false claim.

- An overpayment must be reported and returned to CMS, a carrier, intermediary, or contractor as appropriate, with the reason for the overpayment, within 60 days of the date identified.

- Medicare or Medicaid payment to which not entitled after applicable reconciliation.

- “Overpayment” = “Obligation”
Trends: High Dollar Settlements

Tuomey Healthcare System (2013):
A federal judge imposed a $276.7 million judgment for violating the FCA by submitting Medicare claims in violation of the Stark Law.

Halifax Hospital Medical Center (2014):
Paid $85 million to settle allegations that it submitted claims to Medicare that violated the Stark Law.

DaVita HealthCare Partners (2015):
Has agreed to pay $389 million as part of a settlement regarding Anti-Kickback Statute allegations stemming from joint ventures with nephrologists involving 28 dialysis clinics.
Analyzing Risk

- **Deal Pressure**—We have to make this deal work, whatever it takes!
  - What is Fair Market Value?

- **Business Pressure**—How did we get here? We can’t afford to pay this much!
  - What is Commercially Reasonable?

- Identify the key compliance issues in each transaction—Every deal is different
The Three Hats of Transactional Awareness

- Planning, Drafting, Implementing
- Compliance Review and Correction
- Defending the Transaction

Tuomey found to have violated the False Claims Act by submitting billing Medicare for services referred by physicians whose contracts did not meet an exception: $237M judgment

While Stark Law jury trials were historically uncommon, Tuomey was decided by a 10-person jury

Case may serve as a precedent for encouraging the Justice Department to take nuanced Stark Law cases before a jury

May require hospitals to be more diligent about FMV and non-compete agreements with referring physicians perilous
“a productivity bonus based on services performed personally by the physician”
Government’s Expert Witness Report:

“I believe that the compensation terms of the employment agreements and [physician entity’s] business arrangements with the neurosurgeons were not commercially reasonable because absent the physicians’ referrals to [the hospital], there does not appear to be a legitimate business purpose for entering into or maintaining the described physician employment agreements.”

- For Most Years the Physicians’ Received 100% of their Collections Derived from their Professional Services
- [Physician entity] incurred Material Financial Losses related to the Neurosurgeons’ Practices
- The Neurosurgeons were Favorably Treated in Comparison to Other Employed Physicians
  - Only employed physicians paid above the 90th percentile
  - Additional subsidy not provided to other physicians:
    - 200% of the Medicare Fee Schedule for all trauma patients
    - Reimbursed for hospital employees workers comp claims
    - Collection expense is not deducted from collections
    - Bad debt expense is not deducted from collections
    - 80% of the Medicare fee schedule for district charity and self-pay patients like non-employed physicians.
- On call pay arrangement- not formalized in writing, paid for each day v. excessive call. Staff by-laws require physicians to take normal call.
- Continued compliance concerns not addressed by the hospital’s administration.
- Miscellaneous contract issues.
  - Technical violations (e.g. not signed or updated)
  - No payback provisions for moving and sign on bonuses
  - “Any other reasonable compensation as determined by Company from time to time.”
Beware of Commission-Based Agreements

- 2014 10th Circuit Case (Kansas, but not Missouri)

- A percentage-of-sales-based commission payment to an independent contractor for sales of items or services reimbursable under a Federal healthcare program violates AKS and the contract containing that payment is void and unenforceable.
  - Joint Technology, Inc. v. Weaver

- But, compare: Braun v. Promise Regional Medical Center
  - A contract that violates Stark may be unenforceable at law, but the party providing services to the “entity” may still recover for unjust enrichment.
U.S. ex rel. Kane v. Healthfirst, Inc. (pending)

- Allegations:
  - Claims submitted and paid with NY Medicaid incorrectly identified as secondary payor
  - NY identified a set of claims affected
  - Healthfirst performed an internal audit that identified additional claims potentially incorrectly billed
  - Healthfirst began making repayments, but not completed until 2 years later

- Issues:
  - When were overpayments “identified”
  - Did hospital act with “deliberate speed”
Attorney-Client Privileges for Providers Charged with FCA Violations

- **Barker v. Columbus Regional Healthcare (2014)**
  - Columbus employee claimed that company violated AKS and Stark Law by purchasing a cancer center for more than FMV to induce the cancer center to refer patients to Columbus
  - Barker also alleged that subsequent submission of reimbursement claims to Federal healthcare programs breached FCA
Barker v. Columbus Regional Healthcare (continued)

- FCA claim requires that Columbus knowingly submitted false claims with intent to violate the law
- In responsive pleadings, Columbus expressed intent to affirmatively assert at trial that its actions were made in a good faith effort to comply with the law
- Ruling: an affirmative defense waives the attorney-client privilege with respect to communications regarding the transactions at issue
Questions?
Thank You!
David Pursell
Partner
Kansas City, MO
816.983.8190
david.pursell@huschblackwell.com

David Solberg
Associate
Kansas City, MO
816.983.8393
david.solberg@huschblackwell.com