Resolving Potential Violations of the Stark Law

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The dreaded call…

"I think we may have a Stark problem…"

Positive Spin

- Effective Compliance Programs are supposed to identify problems
- Based on the number of problems we've identified…

…we must have an extremely effective Compliance Program!

Step One – Perform a Stark Law Analysis

- **Analyze**, don't assume.
- There are a lot of misconceptions about the Stark Law (all of which are based in truth)
  - Requires a written agreement, signed by both parties
  - Must be for at least one year
  - Cannot be amended within the first year
  - Physician ownership prohibited
  - Compensation to the physician cannot be based on volume or value of referrals
- *Finally - don't forget the hold-over provisions and the rules on Temporary Non-Compliance*

Step Two– Consider Options

- Cure problems prospectively (*i.e.*, execute a new, Stark compliant agreement as quickly as possible)
- Attempt to cure retrospective problems – *but note CMS Preamble discussion in 2008*
- Determining whether other steps are necessary will require input of entire compliance/business/legal team
- Wide range of potential responses – vary depending on facts
  - Nothing
  - Internal corrective actions (training, employment action, restrictions, medical staff/professional board referral)
  - Submit a routine refund
  - Submit a self-disclosure

Risks & Benefits of Self-Disclosure

- Risks are fairly obvious
  - Government spotlight on your organization
  - Cannot predict amount of settlement or other potential consequences
  - Lengthy process
  - Cannot "un-ring the bell"
- Potential benefits
  - Cuts off potential *qui tam* actions & running of the "60 day clock" for FCA liability
  - Government policy is to take into consideration the fact that a provider self-disclosed
  - 2008 change in policy related to waiver of ACP
  - Allows you to control the narrative (or at least the first version of it)

Relationship Between FCA Revisions & Rise in Self Disclosures

- The utilization of various self-disclosure mechanisms has been increasing due, in part, to recent statutory changes to the False Claims Act
- Fraud Enforcement Act of 2009 (FERA)
  - Expanded FCA liability for retention of overpayments by a person who knowingly and improperly avoids or decreases an obligation to pay to the government
- Affordable Care Act (2010)
  - Providers must, within 60 days after the date on which an overpayment has been "identified" (or the date any corresponding cost report is due), report and return the overpayment and notify the recipient of the reason for the overpayment
- After the 60 day window closes ***the overpayment converts to a False Claim***

Where to Disclose

- DHHS OIG– disclosure must include AKS or FCA issue – no "pure" Stark violations
- CMS– Self Referral Disclosure Protocol (only potential or actual Stark violations)
- DOJ (Note recent Bristol Settlement related to Stark Law)
- Simple refund to MAC or other claims processor (generally limited to simple or negligent billing errors)
- If under a CIA – follow those reporting mechanisms
- If currently engaged with investigators – likely report to those investigators

The OIG Route

- OIG Self Disclosure Protocol has been around since 1998
- It is a known factor
- Many settlements have been reached through this process
- Can address AKS violations or CMP law (among other issues)
- In March 2009, OIG issued open letter stating they would no longer be accepting disclosures through the SDP that did not include "colorable" AKS violation. Leaving providers no where to go to address technical Stark law violations
- ACA also changed the law to state explicitly that claims submitted pursuant to kickbacks are, *per se*, false claims
- ACA required the Secretary of HHS to create a self-disclosure protocol for actual or potential violations of the Stark Law

CMS Self-Referral Disclosure Protocol

- Protocol is available on the CMS Website (first posted Sept. 23, 2010 and revised May 6, 2011)
  - http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html
- Limited to physician self-referral violations only
- Not for advisory opinions, but is for resolution of actual ***or*** potential violations
- Submission must contain detailed financial and legal analysis

CMS Report to Congress on the Self-Referral Disclosure Protocol

- PPACA Required CMS to submit a Report to Congress on the progress of the SRDP
- As of March 9, 2012, 150 total disclosures submitted (with 6 settled)
  - 125 hospitals
  - 2 community mental health centers
  - 11 clinical labs
  - 2 DME
  - 1 Ambulance
  - 8 Group Practices
  - 1 other

CMS Report at AHLA Last Month (as of 09/10/12)

- Total of 176 submitted
- 13 Settled
- 55 Awaiting Requested Information
- 78 Under CMS Review
- 18 Administrative hold
- 3 Referred to law enforcement
- 9 Withdrawn by disclosing entity

- Settlements have ranged from $60.00 to $579,000

13 SRDP Settlements To Date

- $60
- $4,500
- $6,700
- $6,800
- $22,000
- $22,000
- $42,000
- $59,000
- $74,000
- $125,000
- $130,000
- $208,000
- $579,000

Reported Self Disclosure Settlement

- CMS only publishes the final settlement amount – not the potential liability.
- This makes it impossible to determine the extent to which they're using their authority to reduce Stark liability
- Saints Medical Center Case – the first disclosure settled under the SRDP
  - Potential liability = $14,000,000
  - Settlement amount = $579,000
  - Amount paid as a percentage of potential = 4%
- But it's only one data point!

Recent Proposed Rule Related to Retention of Overpayments

- Applicable look back period
  - 4 years – current re-opening period for CMS
  - 6 years – statue of limitations for false claims
  - 10 years – recently PROPOSED re-opening period by CMS
- But see – FAQ released by CMS in the last few months
  - "A disclosing party will satisfy [the requirements of the SRDP] by submitting a financial analysis setting forth the total amount actually or potentially due and owing for claims improperly submitted and paid within the time frame established for reopening determinations…"

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Recent Proposed Rule Related to Retention of Overpayments

- Definition of "Identified"
  - First moment it is alleged (even if not confirmed)?
  - When the fact is confirmed, but amount unknown?
  - When the amount has been determined?
  - Proposed Rule: When "the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment"
    - Cannot take a "head in the sand" approach and stop doing self-audits or compliance checks
  - If facts warrant it, the Preamble allows time for a "reasonable inquiry" made with "all deliberate speed" before the 60 day clock starts

Trends in Self-Disclosures

- Potential buyer diligence – Pre-closing Activity
- New owner diligence – Post-closing Activity
- Clear violation comes to light
- Pure Stark law issues identified through routine compliance efforts
  - Much trickier than they used to be
  - Note – often an argument exists that arrangement appearing to be a Stark violation is actually in compliance. Requires careful review of facts and analysis of Stark guidance

Hypotheticals

- Accidental payments
  - Contract is signed
  - A/P department begins making payments
  - But there's a delay in services starting

Hypotheticals

- Payments based on mistaken square footage
  - Contract says leased space = X square feet
  - Update the lease on renewal and learn the earlier amount was incorrect

Hypotheticals

- Recruitment agreement signed – pay relocation expenses – begin one year income guarantee
  - 6 months later discover the recruited physician was granted active medical staff privileges before the agreement was executed

Hypotheticals

- Waiver of a late fee
  - Lease imposes a $500 fee if any payment is made more than 15 days after the due date
  - Hospital has been routinely waiving these penalties for physicians leasing space in Hospital MOB

Hypotheticals

- The case of the missing agreement
  - Hospital acquisition involves 15 – 20 physician service agreements
  - 2 years after the acquisition, Hospital discovers there was never a written agreement for one of the arrangements

Proposed Technical Deficiency Exception

- Would explicitly allow for after-the-fact "curing" of inadvertent, technical Stark violations
- Would provide mechanism for repayment and reconciliation of over/underpayments
- Would require transparency for regulators and auditors through an agreement that states the parties are relying on the exception
- Could not be used in cases involving the Antikickback Statute
- Avoids the expense (in time and resources) of a self-disclosure
- Encourages and rewards compliance programs that discover problems on their own

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