Stark Self-Referral Disclosure Protocol

What It Says, What It Means, and What It Holds for the Future

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Overview

I. CMS's New Self Referral Disclosure Protocol
II. Case Study
III. Open Questions

I. CMS's New Self Referral Disclosure Protocol

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Overview of Protocol

- Review of Self-Referral Prohibition
- Basis for Protocol in PPACA
- To whom and when disclosure should be made
- What should be included in the disclosure
- What CMS does with the information included in a disclosure
- Basis for settlement discussions

Stark Self-Referral Prohibition, 42 U.S.C. § 1395nn

- A physician may not refer:
  - Medicare or Medicaid patients
  - For designated health services ("DHS")
  - To an entity with which the physician or an immediate family member has
  - A "financial relationship"
  - With exceptions that protect certain compensation arrangements and ownership interests

Patient Protection and Affordable Care Act ("PPACA") § 6409

- Required HHS, in cooperation with OIG, to develop a self-referral disclosure protocol no later than six months after enactment
- Authorizes reduction in amount providers would have to pay, in exchange for having self-disclosed
- Requires HHS to issue a report to Congress no later than 18 months after establishment of the protocol reporting on its implementation and the amounts collected

Until now…

- Historically, the OIG's self-disclosure protocol was available for disclosing a Stark violation
- In a March 24, 2009 Open Letter to Health Care Providers, OIG announced it would no longer accept Stark-related self-disclosure protocol submissions unless they also included Anti-Kickback Statute violations

Going forward…

- On September 23, 2010, CMS issued the Self-Referral Disclosure Protocol ("SRDP")
- CMS acknowledged that it has borrowed heavily from OIG Self Disclosure Protocol
- Providers and suppliers may self-disclose violations of the Stark self-referral prohibition and potentially benefit from reduced penalties
- An ongoing government inquiry (investigations, audits, routine oversight) does not automatically preclude disclosure via the SRDP, so long as the disclosure is made in good faith

To Whom Disclosure Should Be Made

- Providers and suppliers wishing to self-disclose should use CMS's SRDP for conduct that involves only Stark law violations.
- Violations that raise Stark law violations *and* violations of other federal criminal, civil, and administrative laws (e.g., the Anti-Kickback Statute) should be disclosed using the OIG's Self-Disclosure Protocol.

To Whom Disclosure Should Be Made (cont.)

- "CMS may conclude that the disclosed matter warrants a referral to law enforcement for consideration under its civil and/or criminal authorities…Accordingly, the disclosing party's initial decision of where to refer a matter…should be made carefully."

When a Disclosure Should Be Made

- An SRDP submission suspends that obligation until a settlement is entered (or the provider/supplier withdraws or is removed from the SRDP).
- Initial submission also tolls reopening rules (such that if provider is removed, greater look back period applies).
- "It is imperative for disclosing parties to disclose matters in a timely fashion once identified."

What Should Be in the Disclosure

- Detailed identifying information regarding the disclosing party and other entities implicated
- Description of the matter being disclosed
- Legal analysis of why a Stark violation may have occurred
- Circumstances of discovery and corrective measures taken

What Should Be in the Disclosure (cont.)

- Whether the party has knowledge that the matter is under investigation by a government agency or contractor
- A financial analysis of amount of "tainted" reimbursement received
- Certification

How a Disclosure Should Be Made

- Must be submitted electronically to 1877SRDP@cms.hhs.gov
- Also submit an original and copy by mail
- May not be faxed
- CMS will generate a response email immediately, acknowledging receipt of the submission

Then what?

- CMS reviews the disclosure and determines whether to accept or reject the disclosure
- CMS begins verification of disclosure information; may ask for additional documentation, financial statements
  - Matters outside the scope of the disclosure that CMS discovers may be treated as new matters for investigation
- CMS may refer the disclosure to other law enforcement authorities
- Settlement negotiations begin…

Settlement Payments

- Congress gave HHS the authority to reduce the amount due pursuant to an SRDP, and specified that it should consider:
  - Nature and extent of improper or illegal practice;
  - Timeliness of self-disclosure; and
  - Other factors.
- CMS determined that it also would consider:
  - Litigation Risk associated with the matter disclosed;
  - Cooperation in providing additional information related to the disclosure; and
    Financial position of the disclosing party.

Settlement Payments (cont.)

- CMS made clear that it may consider all of the factors, but it "has no obligation to reduce any amounts due and owing."
- Under the OIG Self-Disclosure Protocol, approach usually has been to settle for a multiplier of the financial benefit.
- Uncertainty about CMS's approach for some providers/suppliers may be a factor in determining whether or not to disclose through the SRDP.

II. Case Studies

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SRDP – Case Studies

- Three Central Questions
  - Identifying A Stark Violation
    - Investigate facts, analyze potential Stark exceptions
  - When Is the Violation "Identified"
    - Deadline for reporting and returning overpayment is 60 days after date it is "identified" (PPACA 6402(d))
    - Time is of the essence
  - How to Disclose
    - If disclosure is necessary, to which agency?
      - MAC, CMS, OIG, DOJ?

Case Study 1

- Medical Office Lease
  - Facts:
    - Carefree Medical Group, a substantial admitter, leases space from Careless Hospital System
    - Signed written lease, ten year term, fair market value rent w/CPI escalator
    - After six months, Carefree begins to miss some rent payments
    - Careless asks about late payment, Carefree pays back-rent

Case Study 1 (cont.)

- Facts (cont.)
  - Pattern continues, Carefree falls further into arrears
  - By Year 2, Carefree is $100,000 in arrears (including penalties and interest)
  - Careless has requested payment in letters, emails, but takes no legal action
  - Over the 2 year period, "Stark-tainted" collections of Careless roughly $10,000,000

Case Study 1 – Stark Violation?

- Careless requests legal analysis
- Substantial nonpayment of rent renders arrangement non-fair market value
- However, actual lessor (and building owner) is a corporate affiliate of Careless System – not a Stark "entity"

Case Study 1 – Stark Violation? (cont.)

- Stark indirect compensation arrangement analysis:
  - Unbroken chain of financial relationships
  - Does the compensation vary with or take into account, the volume or value of referrals by Carefree to Careless? (see 42 CFR § 411.354(c)(2))
  - Rent amount does not (fixed, fair market value)
  - However, internal investigation concludes that although Careless initially was simply living up to name, it likely tolerated ongoing nonpayment of rent so as to not jeopardize Carefree's referrals

Case Study 1 – When Was Violation "Identified?"

- Extremely difficult question.
  - When did rent nonpayment actually even become a Stark violation?
  - Although Stark is not intent-based, question of when the compensation relationship began to reflect referrals is intent-based.
  - Commercial (non-healthcare related) landlord would not necessarily evict at outset.
  - Identification of Stark violation clearly requires significant factual investigation and legal analysis.
  - 60 days from what?

Case Study 1 – Agency for Disclosure?

- If situation resulted purely from carelessness, would be Stark violation alone.
- Disclosure to MAC means full repayment of all "Stark-tainted" revenue. Up to $10,000,000, depending on when violation is deemed to have begun.
- CMS – will it negotiate down from the $10,000,000 in tainted revenues, or base negotiations on multiple of $100,000 of remuneration? Difference is a factor of 100.

Case Study 1 – Agency for Disclosure? (cont.)

- Early indications are that CMS will look to the amount of tainted revenues.
- Hope that CMS will become more flexible as SRDP process evolves. Who wants to go first?
- CMS may also refer matter to OIG/DOJ for Anti-Kickback Statute, FCA investigation.
- If CMS refers, will it demand Stark damages in addition to bringing in other agencies?

Case Study 1 – Agency for Disclosure? (cont.)

- Colorable Anti-Kickback Statute Violation?
  - Arguably, almost by definition, if toleration of nonpayment reflected referrals.
  - If no reflection of referrals, then no Stark violation
  - Suggests disclosure to OIG (or, possibly, DOJ).
  - Per Open Letter, OIG will likely negotiate based on multiple of $100,000 in remuneration.

Case Study 1 – Agency for Disclosure? (cont.)

- Given uncertainty of how CMS will negotiate, facts suggest OIG a better venue.
- Forum Shopping?
- In close cases, do parties have an incentive to "manufacture" colorable intent?
- Will OIG release provide immunity from CMS seeking to impose Stark damages?
- Will OIG routinely share Stark disclosure with CMS?

Case Study 1 – Agency for Disclosure? (cont.)

- DOJ?
  - Parties have disclosed and settled with local U.S. Attorney's Office (USAO) in past.
  - Although DOJ has discretion in settling, not bound in any way by OIG's Open Letter.
  - DOJ may insist on bringing in OIG for approval.
  - Might DOJ insist on CMS's sign-off as well?
  - Therefore, results are unpredictable.

Case Study 1 – Risks of Non-Disclosure

- Whistleblowers
  - Disgruntled employees of either hospital or physician, others in community who may be aware of situation
- Independent Enforcement Action by Governmental Agency
  - OIG/DOJ initiate its own investigation, possibly based on a complaint
  - Per SRDP, would not preclude self-disclosure to CMS at this point, but government may be less inclined to be lenient if parties wait
  - OIG or DOJ might inadvertently discover in course of other, unrelated investigation

Case Study 2 – No Formal Written Agreement

- Briefly:
  - Hospital - Medical Director arrangement, fair market value appraisal, draft agreement specifying services, term and termination, other material issues, but no signatures
  - Medical Director submits signed time sheets, specifying services and time performed, per draft agreement
  - Hospital signs checks with remittance advice, referencing services performed

Case Study 2 (cont.)

- Most Stark exceptions require a signed, written agreement
- Integration argument – reference to state law statute of frauds
- Combining separate writings to form a sufficient signed written agreement.
- Untested argument

Case Study 2 (cont.)

- Strength of argument is highly fact-specific. Facts here are very appealing
- No clear answer, but in light of apparent lack of flexibility in the SRDP, providers will want to explore all possible defenses before concluding disclosure is mandated

III. Open Questions

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Overview of Open Questions

- CMS Coordination with OIG and DOJ
- Intra-CMS Roles and Coordination
- Waiver of Attorney-Client Privilege
- Concerns Regarding Benefits Conferred by SRDP
- Publication of Information Regarding Settlements
- Effect on Stark Advisory Opinion Process

CMS Coordination with OIG and DOJ

- Review prior to acceptance. Similar to OIG's?
- In what situations will a provider be rejected? Who has ultimate decision?
- Referral for prosecution.
- CMS has stated that it will still presumably resolve matters independently under its own administrative authorities.
- Coordination on monetary resolution and obtaining releases.

Intra-CMS Roles and Coordination

- Sufficiency of resources
  - Both number and experience of personnel
- Center for Medicare Management
  - Intake and administrative review
  - Policy and legal analysis
- Center for Program Integrity
  - Coordination with law enforcement
  - Weigh in on administrative review
- Office of Financial Management
  - Will evaluate factors to determine whether compromise in monetary resolution is appropriate

Waiver of Attorney-Client Privilege

- Access to all supporting documents without assertion of privileges.
- In "normal course of verification," CMS will not require waiver of attorney-client privilege.
- CMS believes attorney work product may be "critical" to resolving disclosure.
- Open to discussions on how to avoid waiver.

Waiver of Attorney-Client Privilege (cont.)

- Waiver not absolute requirement.
- BUT may affect evaluation of extent of cooperation and by extension, evaluation of whether any reduction in overpayment is justified.

Concerns Regarding Benefits Conferred by SRDP

- Inconsistent messages regarding whether overpayments will be compromised.
- Lack of any comfort regarding potential range of compromise.
- Subject to much internal debate at CMS regarding potential ranges.
- Concern regarding delegation to OFM.

Concerns Regarding Benefits Conferred by SRDP (cont.)

- Who evaluates litigation risk factor and how will that factor be applied?
- Exclusion of consideration of benefit to physician as consideration.
- CMS direction to estimate if cannot analyze referral revenue.

Publication of Information Regarding Settlements

- Approximately 20 disclosures already in pipeline.
- CMS has made no commitment to disclose any information about settlements.
  - In contrast, OIG provides summaries on its website of each OIG Provider Self Disclosure Protocol settlement.
- Unclear how much detail CMS will include in its report to Congress, which is not due until mid-way through FY 2012.
- Lack of transparency on CMS's part could diminish interest in SRDP.

Coordination with Stark Advisory Opinion Process

- CMS has stated that providers cannot both disclose and seek an advisory opinion (statutory requirement).
- Creates another layer of decisionmaking for provider facing potential Stark Violation.
  - Will decision to seek advisory opinion be viewed as circumvention?
  - Will decision to seek advisory opinion be viewed unfavorably if CMS later determines violation and 60-day clock is not tolled?

Coordination with Stark Advisory Opinion Process (cont.)

- Relative paucity of Advisory Opinions highlights resource issue for CMS.
  - CMS has issued 7 between 1998 and present (with last more than 2 years ago).
  - OIG has issued 21 in this calendar year alone.

Questions and Answers

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Resources

- www.foley.com/STARK
- www.foley.com/FraudandAbuse
- www.cms.gov/PhysicianSelfReferral/
- CMS Physician Self Referral
  Call Center – 410-786-4568

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