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Physician Self-Referral Disclosure After PPACA

Navigating New Stark Law Complexities Following Healthcare Reform

WEDNESDAY, OCTOBER 27, 2010

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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The Stark Self-Disclosure Protocol

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Background

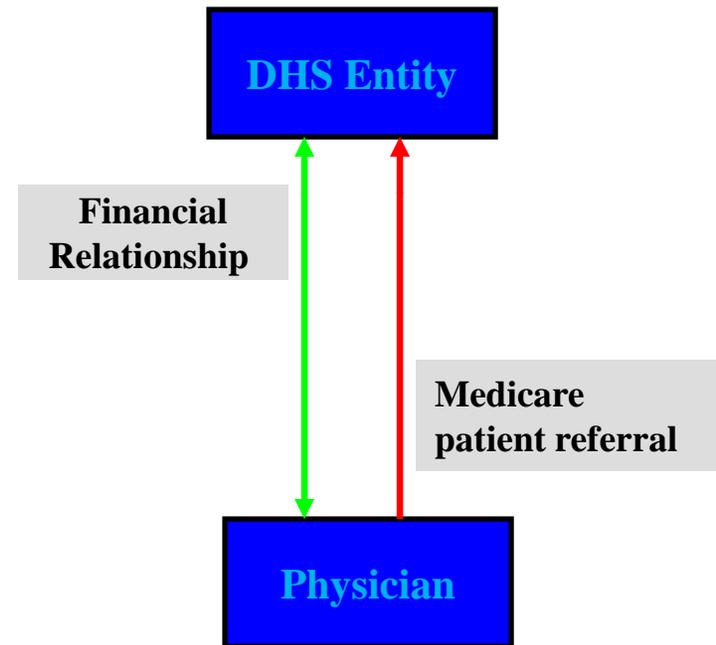
Introduction to Stark

- Physician Self-referral (Stark statute) – 42 U.S.C. 1395nn; regulations at 42 CFR, Part 411, §§ 411.350 et seq.
- Physician may not refer:
 - Medicare * patients
 - for certain specified “designated health services”
 - to an entity with which the “physician” *or*
 - an “immediate family member” has
 - a “financial relationship”
- *Unless* an “exception” applies

** Statute applies to Medicaid but not implemented thus far by CMS*

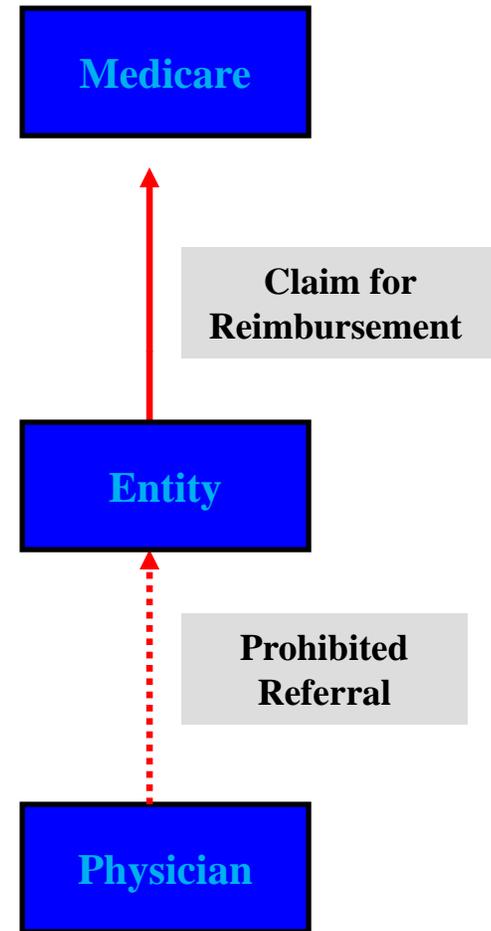
Introduction to Stark

- **Two Basic Prohibitions**
 - **First**, if a “physician” (or “immediate family member”) has a “financial relationship” with an “entity,” then the physician may not “refer” Medicare patients “to” the entity for the furnishing of “designated health services,” unless an exception applies



Introduction to Stark

- **Two Basic Prohibitions**
 - Second, an entity may not bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral



Stark Statute --DHS

- Designated Health Services (DHS) include
 - Clinical laboratory services
 - Physical therapy services
 - Occupational therapy services
 - Radiology services, including MRI, CT, and ultrasound services (also includes nuclear medicine services, effective 1/1/07)
 - Radiation therapy services and supplies
 - Durable medical equipment and supplies
 - Parenteral and enteral nutrients, equipment, and supplies
 - Prosthetics, orthotics, and prosthetic devices and supplies
 - Home health services
 - Outpatient prescription drugs
 - Inpatient and outpatient hospital services

Stark Statute -- Definitions

- “Entity” is person or entity that performs service billed as DHS or submits a claim for DHS
- “Physician” and “immediate family member” defined broadly (see 411.351)
- “Financial Relationship”
 - May be ownership/investment interest or compensation arrangement
 - May be direct or indirect*
 - May exist between physician and DHS entity *or* between physician’s immediate family and DHS entity

* Definition of indirect compensation arrangement is very technical

Stark Statute -- Penalties

- For knowing or unknowing violations:
 - Denial of payment
 - Refund of amounts collected from beneficiary as a result of improper billing
- For knowing violations, potentially:
 - Civil Money Penalties of \$15,000 per item or service plus 2X the amount claimed
 - Civil Money Penalties of \$100,000 for “Circumvention Schemes”
 - Exclusion
 - Enforced by OIG
- Through case law:
 - Potential False Claims Act Liability for knowing violation

Introduction to Stark

Exceptions

- Exceptions for both ownership/investment and/or compensation arrangements
 - Some exceptions apply just to ownership/investment arrangements (411.356), some apply just to compensation arrangements (411.357), and some apply to both types of arrangements (“service exceptions”) (411.355)
 - Many more exceptions for compensation arrangements than for ownership/investment arrangements
 - Some exceptions are specified by statute (and some of these give agency authority to engraft additional restrictions on use of exception)
 - Some created only by regulations pursuant to statutory authority. Agency can create these only when doing so would not pose a risk of program or patient abuse

SRDP Background

- CMS traditionally has had limited authority to compromise or waive Stark sanctions (or any other claims liability)
 - Under 42 CFR §405.376 claim can be compromised (incl. compromised to zero) only for certain reasons and §405.376 may be amended only with concurrence of DOJ and Treasury
- OIG has broad discretion to decide whether to impose CMP/assessment and the amount of CMP/assessment, and whether to impose exclusion and length of exclusion
 - See section 1128A(a) of the SS Act; 42 CFR Part 1003
- In March 2009 OIG announced it would no longer take Stark-only potential or actual violations into its self-disclosure protocol

PPACA Provision

- Section 6409 required Secretary to establish a self-referral disclosure protocol (“SRDP”) by September 23, 2010
- The SRDP must provide directions on—
 - (A) a specific person, official, or office to whom such disclosures shall be made; and
 - (B) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements
- CMS must publish on its web site instructions for how to access and use the SRDP
 - Informal self-disclosures are being made to CMS already (and have been prior to enactment)

PPACA Provision

- PPACA gave Secretary authority to reduce the amount due and owing for “all violations” under section 1877 of the SS Act
- In establishing such amount for a violation, the Secretary may consider the following factors:
 - (1) The nature and extent of the improper or illegal practice
 - (2) The timeliness of such self-disclosure
 - (3) The cooperation in providing additional information related to the disclosure
 - (4) Such other factors as the Secretary considers appropriate
- Will knowing violations be compromised?
 - Knowing violations are subject to CMPs/assessments and exclusion

PPACA Provision

- Report to Congress Not later than 18 months after the SRDP is established, the Secretary must report to Congress on:
 - (1) the number of providers and suppliers making disclosures pursuant to the SRDP
 - (2) the amounts collected pursuant to the SRDP
 - (3) the types of violations reported under the SRDP
 - (4) such other information as may be necessary to evaluate the impact of the SRDP

Stark Self-Disclosure Protocol

- On September 23, CMS Issued the SRDP
- The SRDP does *not* say whether knowing violations will be accepted into the SRDP
- Nor does it present a formula for how much claims liability will be compromised for any type of violation

Stark Self-Disclosure Protocol

- Instead the SRDP says:

The factors CMS may consider in reducing the amounts otherwise owed include:

- (1) the nature and extent of the improper or illegal practice;
- (2) the timeliness of the self-disclosure;
- (3) the cooperation in providing additional information related to the disclosure;
- (4) the litigation risk associated with the matter disclosed;
and
- (5) the financial position of the disclosing party.

Stark Self-Disclosure Protocol

“While CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS has no obligation to reduce any amounts due and owing. CMS will make an individual determination as to whether a reduction is appropriate based on the facts and circumstances of each disclosed actual or potential violation. . . . CMS needs to evaluate each matter in order to determine the severity of the physician self-referral law violation and an appropriate resolution for the conduct.”

Stark Self-Disclosure Protocol

Disclose to OIG or CMS, but not both

- In cases where there is a potential or actual Anti-Kickback Statute violation, entity could choose OIG self-disclosure protocol *in lieu of* CMS SRDP
 - “conduct that raises liability risks under the physician self-referral statute may also raise liability risks under the OIG’s civil monetary penalty authorities regarding the federal anti-kickback statute and should be disclosed through the OIG’s Self-Disclosure Protocol. Disclosing parties should not disclose the same conduct under both the SRDP and OIG’s Self-Disclosure Protocol”
 - Difficult decision where Stark Law violation is accompanied by an uncertain AKS violation

Stark Self-Disclosure Protocol

- *Therefore ...*
- For now, Providers and Suppliers that self-disclose will be flying blind, with no guidance as to whether or by how much liability will be reduced

Stark Self-Disclosure Protocol

Who will use it ?

- Will entities facing potentially devastating FCA or CMP liability self-disclose in order to potentially mitigate the amount they owe?
- Will some or most entities take a calculated risk and avoid disclosing?
- Will some entities adopt a wait-and-see approach?
- Will entities that are subject to a CIA have nothing to lose by entering into the SRDP?
- “Effective September 23, 2010, a reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in this self-disclosure protocol with a copy to the disclosing party’s OIG monitor. ”

Stark Self-Disclosure Protocol

“The fact that a disclosing party is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude a disclosure. The disclosure, however, must be made in good faith. A disclosing party that attempts to circumvent an ongoing inquiry or fails to fully cooperate in the self-disclosure process will be removed from the SRDP.”

Stark Self-Disclosure Protocol

- The SRDP refers to PPACA's mandatory return of overpayments provision:
- “At the time the provider ... or supplier electronically submits a disclosure under the SRDP (and receives email confirmation from CMS that the disclosure has been received), the obligation under Section 6402 of [PPACA] to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider . . . or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP.”
- “As stated above, section 6402 of the PPACA establishes a deadline for reporting and returning overpayments by the later of: (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.”

Stark Self-Disclosure Protocol

What does this mean?

- Do providers and suppliers have the obligation to return self-discovered overpayments?
- Where is there an obligation to return a “potential “ overpayment?

Stark Self-Disclosure Protocol

Mechanics of making a self-disclosure

- Disclosure must be submitted electronically to 1877SRDP@cms.hhs.gov and by mail
- After reviewing the submission, CMS will send a letter to the disclosing party or its representative either accepting or rejecting the disclosure.
- The Disclosure must contain :
 - (1) Description of the conduct underlying the disclosure
 - (2) Financial Analysis
 - (3) Certification Statement

Requirements of a Self-Disclosure

1. Description of Actual or Potential Violation(s)
 - a. basic information on disclosing party and disclosing party's designated representative
 - b. nature of the matter, including type of financial relationship(s), parties involved, time period of noncompliance, DHS, type of transaction or other conduct giving rise to the matter
 - c. complete legal analysis of why disclosing party believes a Stark violation may have occurred, including an explanation of which element(s) of the applicable exception(s) were not met

Requirements of a Self-Disclosure

1. Description of Actual or Potential Violation(s)
 - d. the circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the issue and prevent future abuses
 - e. statement identifying whether the disclosing party has a history of similar conduct, or has any prior criminal, civil, and regulatory enforcement actions against it
 - f. description of any pre-existing compliance program that the disclosing party had, and efforts by the disclosing party to prevent a recurrence of the incident or practice
 - g. description of notices provided to other Government agencies

Requirements of a Self-Disclosure

1. Description of Actual or Potential Violation(s)

- h. An indication of whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor. If the disclosing party has knowledge of a pending inquiry, identify any such Government entity or individual representatives involved.
- The disclosing party must also disclose whether it is under investigation or other inquiry for any other matters relating to a Federal health care program, including any matters it has disclosed to other Government entities, and provide similar information relating to those other matters.

Requirements of a Self-Disclosure

2. Financial Analysis is “expected” and “should”
 - a. Set forth the total amount, itemized by year, that is actually or potentially due and owing based upon the time period during which the disclosing party may not have been in compliance with the Stark law
 - b. Describe the methodology used to calculate the amount that is actually or potentially due, and whether and how any estimates were used
 - c. Provide a summary of auditing activity undertaken and a summary of the documents relied upon.

Requirements of a Self-Disclosure

3. Certification Statement (to accompany all submissions)

- “The disclosing party, or in the case of an entity its CEO, CFO, or other authorized representative, must submit to CMS a signed certification stating that, to the best of the individual’s knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS’ attention for the purpose of resolving any potential liability under the Stark statute.”

CMS's Verification Process

- “The extent of CMS’ verification effort will depend, in large part, upon the quality and thoroughness of the submissions received.”
- Matters uncovered that are outside of the scope of the matter disclosed may be treated as new matters outside the SRDP
- CMS requires access to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced. In the normal course, CMS will not request production of written communications subject to the attorney-client privilege
- For work product that CMS believes is critical to resolving the disclosure, CMS will discuss with a disclosing party’s counsel ways to gain access to the underlying information without the need to waive the protections of privilege

Stark Self-Disclosure Protocol

Waiver of Reopening Period

- “[A]s a condition of entering the SRDP, providers . . . and suppliers agree that if they are denied acceptance into the SRDP, withdraw from the SRDP, or are removed from the SRDP by CMS, the reopening rules at 42 C.F.R. §§ 405.980 through 405.986 shall apply from the date of the initial disclosure to CMS.
 - Is the waiver of rights under the reopening rules effective without a change in the reopening rules? Will CMS amend the reopening rules?

The SRDP in Action

Hypothetical – Part 1

- Hospital identifies an expired equipment lease with a physician group Lessor
 - The lease agreement does not contain an automatic renewal provision, nor was it ever extended
 - The agreement expired over a year ago
- The parties have been performing under the expired lease agreement as if it were still in effect
 - Compensation is on a per-procedure basis

First Steps – Current Compliance

- Bring the arrangement into compliance as quickly as possible
 - continue to bill for referred DHS while arrangement is being brought into compliance??
- Terminate any arrangement that cannot be made compliant
- Consider an investigation to identify other instances of noncompliance
 - Attorney-client privilege issues
 - Design and scope of audit

First Steps – Core Analysis

- Is there remuneration?
- Is there a compensation arrangement?
 - Direct?
 - Indirect?
- Is there a referral for DHS?
- Is the organization furnishing the DHS an “entity” (as defined in the regulations)?
- Is Medicare the payor?
- Has the reopening period expired

First Steps – Core Analysis

- Apply rules that were in effect during the various periods of the arrangement
 - The Stark rules have changed a number of times and the analysis may be different during certain points in the arrangement
- Give proper, but not excessive, weight to preamble language
 - Statutory and regulation text govern

Special Stark Rules to Consider

- Stand in the Shoes
- Per-click compensation in lease arrangements
- Indirect compensation arrangements
 - does aggregate comp vary with V or V ?
 - knowledge element satisfied?
- Definition of “entity” as an organization that “performs” the DHS
- “Grace periods” for signature requirements
- Holdovers
- Temporary Non-Compliance

Period of Disallowance

- Determining the beginning and the end of the financial relationship
 - Impact of safe harbors
- Practical ability to continue the arrangement
 - Is it likely that the physician will make future referrals to the entity?
 - Is physician still in the geographic area?
- Nature of the previous relationship between the parties and the physician's past referrals

The SRDP in Action

Hypothetical – Part 2

- The investigation of the expired equipment lease arrangement led to the identification of three medical director agreements that have expired
 - The agreements do not have automatic renewal provisions, nor were they extended by the parties
- The contracting officer position was vacant for a period of five months, during which, all of the agreements at issue expired

Have you considered...

- Temporary Noncompliance (42 C.F.R. 411.353(f))
- Compensation Unrelated to DHS (42 C.F.R. 411.357(g))
- Payments by a Physician (42 C.F.R. 411.357(h))
- “Grace Periods” (42 C.F.R. 411.353(g))
- Isolated Transactions (42 C.F.R. 411.357(f))

Determining the “Overpayment”

- With respect to physician-hospital arrangements:
 - Consider all inpatient and outpatient hospital services
 - Is the referring physician the attending physician?
 - Did furnishing the improperly referred DHS affect the DRG payment?
 - Does this impact the amount of the overpayment?
 - Does this impact whether there is a Stark violation?
- With respect to physician organization-hospital arrangements:
 - Is the referring physician an owner of the physician organization?
- Consider the SRDP “look back” period (in contrast to the reopening period for cost reports or Part B claims)