Stark Self-Disclosure¹/

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A. Background

1. Stark Law

The Physician Self-Referral Statute (or the “Stark Law”) prohibits a physician from referring a Medicare patient for certain designated health services (DHS) to an entity with which the physician (or an immediate family member of the physician) has a financial relationship unless an exception applies.³/ The Stark Law also prohibits the DHS entity from submitting or causing claims to be submitted to Medicare, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral.⁴/ A financial relationship includes both ownership/investment interests and compensation arrangements.

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²/ The views expressed in these materials and in the seminar presentation are the personal views of the author and do not represent the formal position of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., any other individual attorneys at the firm, or any of its clients. The author expressly reserves the right to advocate freely other positions on behalf of clients.

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The statute and regulations provide a range of possible exceptions. Unlike the anti-kickback statute’s (“AKS”) safe harbors, because the Stark Law does not require proof of intent, compliance with the exceptions is mandatory.

The remedies for violations of the Stark Law are denial of payment for all DHS claims made pursuant to an illegal referral, refund of amounts collected for DHS claims, and civil money penalties (for knowing violations). The Stark Law does not provide CMS with discretion in administering the denial of payment sanction for claims that are submitted in violation of the referral prohibition. In addition, because the Stark Law remedies are directly tied to the claims-payment function, knowing violations of the law are actionable under the False Claims Act.

Considering that Stark Law liability attaches to the payment for services provided pursuant to an illegal referral, the measure of damages is not the amount paid to the physician by the DHS provider, but the Medicare reimbursement amounts. Thus, very large sums of money can be at stake as a result of noncompliance for seemingly technical violations (for example, a missing signature to a compensation arrangement).

Historically, the Federal Claims Collection Act prohibited the Centers for Medicare & Medicaid Services (“CMS”) from unilaterally compromising claims over $100,000. The compromise authority for debts over $100,000 resided with the Department of Justice.

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7/ 42 U.S.C. §§ 1395nn(g)(1)-(g)(4).
2. Stark Self-Disclosure Prior to OIG “Open Letter”

The Office of Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”) established a Self Disclosure Protocol (the “SDP”) on October 30, 1998. The OIG described its Self Disclosure Protocol as a "program for healthcare providers to voluntarily report fraudulent conduct affecting Medicare, Medicaid and other federal healthcare programs." Prior to March 2009, the OIG had accepted disclosures related to both the Federal Anti-Kickback Statute (the “AKS”) and the Stark Law, including matters in which there was liability only under the Stark Law.

3. March 24, 2009 OIG Open Letter

On March 24, 2009, the OIG announced that it would no longer accept disclosures for matters involving only liability under the Stark Law (the “March 2009 Open Letter”). Specifically, the OIG stated it would not:

“accept disclosure of a matter that involves only liability under the [Stark] law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the [Stark] law.”

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12/ Id.
Following the March 2009 Open Letter, providers with potential liabilities did not have an avenue within HHS to self-disclose Stark Law-only violations.

4. Health Care Reform

The Patient Protection and Affordable Care Act of 2010 (the “ACA”) contained four separate provisions of importance:

1. ACA provided an important stick to compel self-disclosures. Within 60 days after the date on which an overpayment has been “identified” (or the date of any corresponding cost report is due), ACA requires that providers must —

   ➢ “(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

   ➢ “(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.”

2. CMS must, in coordination with the OIG, develop a disclosure protocol – the Self-Referral Disclosure Protocol, or “SRDP” – for healthcare providers and suppliers to disclose an actual or potential violation of the Stark Law.


14/ ACA Section 6402, codified at SSA § 1128J(d).

15/ The ACA, § 6409(a)(1).
3. ACA gave providers a significant carrot to encourage self-disclosure under this new process by authorizing the Secretary of HHS to reduce the amounts due and owing for violations of the Stark Law.\textsuperscript{16} Although this provision is technically separate from the ACA requirement for the Secretary to develop the SRDP, in reality it is a cornerstone of this new process.

4. ACA requires the Secretary to submit a report to Congress on the implementation of the SRDP not later than March 23, 2012.\textsuperscript{17}

B. Self-Referral Disclosure Protocol

In accordance with this mandate, CMS published the SRDP on its website on September 23, 2010 (amended May 6, 2011).\textsuperscript{18} CMS’s establishment of the SRDP, which sets forth a process for self-disclosure of actual or potential violations of the Stark Law, is significant because CMS previously had no such protocol or process in place. Although CMS states it has “no obligation to reduce any amounts due and owing,” the SRDP offers factors it will use to determine whether, and the extent to which, it will reduce amounts owed:

- the nature and extent of the improper or illegal practice;
- the timeliness of the self-disclosure;
- the cooperation of the provider in the SRDP process;

\textsuperscript{16} Id. § 6409(b).
\textsuperscript{17} Id. § 6409(c).
• the litigation risk associated with the matter disclosed; and

• the financial position of the disclosing provider.19/

CMS indicates that it conducts a facts and circumstances analysis and “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.”20/

CMS reconciles the SRDP process with the ACA’s provision requiring providers and suppliers to report and repay Medicare and Medicaid overpayments within 60 days of the date the overpayments are first identified.21/ The SRDP states that “the obligation under Section 6402 of the ACA to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP.”22/ CMS encourages providers to place funds in an interest-bearing account pending resolution of the matter subject to disclosure. And CMS cautions that in the interim, “the disclosing party must refrain from making payment relating to the disclosed matter to the Federal health care programs or their contractors without CMS’s prior consent.”23/

19/ Id. at 6.
20/ Id. at 6-7.
21/ See the ACA, § 6402.
23/ Id.
C. Practical Considerations of Self-Disclosure Generally, and Under the SRDP

1. Where to Disclose?

The choice of where to disclose needs to be considered carefully because it may have a significant impact on the ultimate outcome of the matter.

a. Where to Disclose, Generally

Once the difficult decision has been made that monies need to be repaid Medicare or Medicaid funds or to otherwise make a disclosure, the decision of where to disclose must be made. There are few clearly right and wrong answers, and a number of factors to be considered. For example, matters that, upon investigation, appear to be merely negligent billing errors are more likely to be properly resolved through the claims processing system or discussions with the Medicare contractor.

In determining whether to disclose more than overpayments, providers should examine the following issues: Are there indicia of wrongdoing? For example, is the matter criminal or civil in nature, and what is the potential exposure for the provider? What is the risk that a third party to an enforcement agency will disclose the matter by a qui tam action, for example, or by the Medicare contractor? Do the facts and disclosure posture fit within the parameters of the self-disclosure provisions of the False Claims Act? There are credibility considerations in being the first to bring the problem to the government, and there are practical considerations of controlling the time, manner, and circumstance of the disclosure.
In sum, the disclosure may avoid or allow negotiation of subpoenas, both as to the content and timing of production; avoid or allow negotiation of the scope of the government's investigation and interviewing of employees; and allow a reasonable chance to mitigate fines and penalties.

b. When to Use CMS’s SRDP

CMS makes clear that participation in the SRDP is limited to actual or potential violations of only the Stark Law and that the OIG’s SDP “is available for disclosing conduct that raises potential liabilities under other federal criminal, civil, or administrative laws.”24/ In fact, the SRDP states explicitly that “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 AKS and should be disclosed through the OIG’s Self-Disclosure Protocol” and that providers and suppliers “should not disclose the same conduct under both the SRDP and OIG’s Self-Disclosure Protocol.”25/ Thus, the scope of the SRDP is limited.

Providers and suppliers considering a self-disclosure should understand that a submission under the SRDP does not necessarily mean that CMS will be the only agency reviewing disclosed conduct. The SRDP states:

Upon review of the disclosing party’s disclosure submission(s), CMS will coordinate with the OIG and DOJ. CMS may conclude that the disclosed matter warrants a referral to law enforcement for consideration under its

24/ Id. at 2.
25/ Id.
civil and/or criminal authorities. When appropriate, CMS may use a disclosing party’s submission(s) to prepare a recommendation to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability. Accordingly, the disclosing party’s initial decision of where to disclose a matter involving non-compliance with section 1877 of the Social Security Act should be made carefully.\(^\text{26/}\)

Further, CMS instructs that “a reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in this self-disclosure protocol \textit{with a copy to the disclosing party’s OIG monitor}.\(^\text{27/}\)

The SRDP offers the following limitations:

- The fact that a disclosing party is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude acceptance of 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 during the self-disclosure process will be removed from the SRDP.\(^\text{28/}\)

- The SRDP cannot be used to obtain a CMS determination as to whether an actual or potential violation of the Stark Law occurred. The SRDP is intended to

\(^\text{26/}\) Id. at 3.

\(^\text{27/}\) Id. at 3 (emphasis added).

\(^\text{28/}\) Id. at 2.
facilitate the resolution of only matters that, in the disclosing party’s reasonable assessment, are actual or potential violations of the Stark Law.\textsuperscript{29/}

If circumstances meet the requirements and limitations set forth above, the SRDP is a viable option to self-disclose actual or potential violations of the Stark Law.

CMS offers detailed instructions for how an actual or potential violation must be described in a self-disclosure submission. These requirements are similar to those set forth in the OIG’s SDP. The SRDP requires the disclosing party to conduct a financial analysis to “set forth the amount that is actually or potentially due and owing.”\textsuperscript{30/} The financial analysis may include estimates (so long as a description of how the estimates were calculated) and that the “total amount of remuneration a physician(s) received as a result of an actual or potential violation(s) based upon the applicable ‘look back’ period.”\textsuperscript{31/} “Look back period” is defined as “the time during which the disclosing party may not have been in compliance” of the Stark Law.\textsuperscript{32/}

Practitioners should note that applicable statutes of limitations may cut off liability to a period later than the start of the look back period. In other words, if a provider was out of compliance with Stark Law for a decade, liability under the reopening rules or without fault rules would cut off liability at a much later date. CMS has made clear that a provider will have complied with its reporting obligations under this part of the SRDP,
for example if it discloses the amount of remuneration when calculated in reference to the applicable reopening rules.  

Congress recently extended one statute of limitations period. The American Taxpayer Relief Act of 2012 (the ATRA) changed the without fault overpayment period from four years to six years when there is no finding of fault. This change to the overpayment collection period was made effective on the date of the ATRA’s enactment and not retroactive. Thus, this amendment should not be interpreted to revive claims for which the overpayment period has already expired as of the date of enactment of ATRA.

c. When to Use the OIG’s Self Disclosure Protocol

As stated above, the OIG SDP is an avenue to disclose various types of conduct beyond actual or potential violations only implicating the Stark Law. In general, the OIG SDP should be used once a provider conducts an initial assessment and determines there is conduct that potentially violates federal, criminal, civil, or administrative laws. Such violations could include Stark Law violations that also implicate the AKS. Although the OIG provides detailed guidance for the content of the self-disclosure submission, it acknowledges it “can offer only limited guidance” on the types of matters that should be disclosed under the OIG SDP. Notwithstanding these cautionary comments, the OIG states the SDP “gives providers the opportunity to avoid the costs and disruptions

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35/ ATRA, § 638(b).

associated with a Government-directed investigation and civil or administrative litigation.

CMS and the OIG have not well articulated their internal policies requiring disclosures both to CMS and the OIG when an organization finds some financial arrangements that only implicate the Stark Law and other arrangements that implicate both the Stark Law and AKS. This requirement for dual reporting under the two different protocols applies even when a provider identifies these arrangements in a single internal audit or investigation.

The OIG SDP indicates that it is not applicable to “an ongoing fraud scheme,” which, in the OIG's view, requires immediate notification. Even though the OIG does not automatically preclude a disclosure under the protocol regarding a matter that is subject to an ongoing Government investigation or audit, the practical benefits of such a disclosure may be limited, in part because investigators may object to such a parallel process.

The OIG has tried to make clear that providers should not use the SDP for resolving routine overpayments where there is no indicia of wrongdoing:

Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity (e.g., a contractor such as a carrier or an

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38/ Id. at 58,400.
39/ Id.
intermediary) that processes claims and issues payment on behalf of the government agency responsible for the particular Federal healthcare program (e.g., [CMS] for matters involving Medicare). The program contractors are responsible for processing the refund and will review the circumstances surrounding the initial payment. If the contractor concludes that the overpayment raises concerns about the integrity of the provider, the matter may be referred to the OIG. Accordingly, the provider's initial decision of where to refer matters involving non-compliance with program requirements should be made carefully.\textsuperscript{40/}

Beyond this guidance, the OIG leaves many unanswered questions as to when it should be used. It is often difficult to determine whether the government views matters as potentially violating federal, criminal, civil, or administrative laws.

\textbf{d. Other Self-Disclosure Options}

Matters that involve trivial Stark Law violations or routine billing errors may be disclosed to the Medicare contractor or state Medicaid agency, as appropriate.

When possible civil or criminal exposure has been identified, providers have a variety of options where to disclose a matter. They may contact the OIG, a local U.S. Attorney's office or the Department of Justice in Washington, D.C., and, for matters involving Medicaid or state funded programs, state Attorneys General, typically the state Medicaid Fraud Control Unit (MFCU). Generally, providers disclose perceived civil matters to the

\textsuperscript{40/} \textit{Id.} at 58,400-01.
OIG or a civil U.S. Attorney and potentially criminal matters to the criminal division of a
U.S. Attorney's office.

Consideration should also be given whether to self-disclose a matter to more than one
government agency for example a US Attorney’s office and the state MFCU in that
jurisdiction.

2. Practical Issues

The following is a list of the many practical issues providers need to
consider in filing a self-disclosure to CMS:

- Credibility is key above all else.

- But, consider avoiding legal admissions.

- Make clear the self-disclosure is part of settlement discussions

- What is a referral?
  - Definition includes the request by a physician “that includes the provision
    of any” DHS.\(^{41}\)
  - Consider implications when the DHS is paid under a DRG.

- Damages –

\(^{41}\) 42 C.F.R. § 411.351 (definition of referral).
In the above example, when the DRG payment is unaffected by the illegal “referral”, how do you measure damages?

In the above example, how do you go about quantifying damages when no hospital computer system identifies physicians who request items and services that are paid by an all-encompassing DRG payment?

The revised SRDP clarifies providers may submit information on the amount of the illegal remunerations based on the applicable look back period.

CMS claims it will not settle self-disclosure matters based on this information.

Reasonable estimates

Make advocacy arguments

- Period of Disallowance -- Look back rules

Does the self-disclosure extend beyond the period of permissible recovery?

Interplay with reopening rules

Interplay with various statutes of limitations

Address holdover periods when there is a failure of writings

Make advocacy arguments
• Assessment of commercial reasonableness even if no referrals are made

• Fair market value
  
  o When to get an independent appraisal

  o Is the measurement period at the time of the agreement or when a violation is found?

• Ability to pay issues

• Be prepared to pay something

6. Other Source Guidance


CMS has published a “Self-Referral Disclosure Protocol FAQ.”

D. Report to Congress on SRDP Implementation

HHS submitted its report on the implementation of the SRDP to Congress on March 23, 2012. From September 23, 2010 to March 20, 2012, a total of 151 disclosures were submitted under the SRDP. The vast majority of disclosures came from hospitals; disclosures were also made by community mental health centers, clinical laboratories,
DME suppliers, group practices, and ambulance companies. Disclosed violations included failure to comply with the personal service arrangement exception, the nonmonetary compensation exception, the rental of office space exception, and the physician recruitment arrangements exception.

E. Settlements under the SRDP

Considering that the SRDP is in its infancy, summaries of only sixteen cases have been published on CMS’s website. Selected settlement abstracts posted to the CMS Physician Self-Referral website appear below:45/

- On February 10, 2011, CMS settled several violations of the Stark Law disclosed by a general acute care hospital located in Massachusetts under the SRDP.
  - The Hospital disclosed under the SRDP that it violated the Stark Law by (1) failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital department chiefs and the medical staff for leadership services, and (2) failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain physician groups for on-site overnight coverage for patients at the Hospital.
  - All violations disclosed were settled for $579,000.00.

• On November 11, 2011, CMS settled several violations of the Stark Law disclosed by a critical access hospital located in Mississippi under the SRDP.
  
  o The Hospital disclosed under the SRDP that it violated the Stark Law by failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital and emergency room physicians.

  o All violations disclosed were settled for $130,000.00

• On January 5, 2012, CMS settled two violations of the Stark Law disclosed under the SRDP by a hospital located in California.

  o The Hospital disclosed under the SRDP that it violated the Stark Law by exceeding the calendar year non-monetary compensation limit for a physician.

  o All violations disclosed were settled for $6,700.

• On March 9, 2012, CMS settled violations of the Stark Law disclosed under the SRDP by a physician group practice in Iowa.

  o The Practice disclosed under the SRDP that it violated the Stark Law because the compensation methodology for certain employed physicians did not satisfy the requirements of the bone fide employment relationships exception.

  o All violations disclosed were settled for $74,000.
• On June 11, 2012, CMS settled a violation of the Stark Law disclosed under the SRDP by a hospital located in California.
  
  o The Hospital disclosed under the SRDP that it violated the Stark Law by not satisfying the requirements of the physician recruitment exception.
  
  o The violation was settled for $28,000.

• On October 25, 2012, CMS settled several violations of the Stark Law disclosed under the SRDP by a hospital and its hospice facility in North Carolina.
  
  o The Hospital disclosed under the SRDP that it may have violated the Stark Law by (1) failing to satisfy the requirements of the physician recruitment exception for an arrangement with one physician, (2) failing to satisfy the requirements of the fair market value exception for arrangements with two physicians to provide medical director services, (3) failing to satisfy the requirements of the fair market value exception for the provision of leadership stipends to thirteen physicians, and (4) failing to satisfy the requirements of the personal services arrangement exception for an arrangement with a group practice to provide ophthalmology services. The Hospital also disclosed on behalf of the Hospice that it may have violated the Stark Law by failing to comply with the fair market value exception for arrangements with two physicians to provide hospice services.
  
  o All violations were settled for $584,700.