

# HEALTH REFORM IMPACT

## What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

### Risky Business? The Stark Voluntary Self-Referral Disclosure Protocol

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#### Introduction

As we discussed in an earlier issue of *Health Reform IMPACT*,<sup>1</sup> the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively "PPACA"), requires the establishment of a self-disclosure protocol<sup>2</sup> allowing healthcare providers and suppliers to self-disclose violations of the federal physician self-referral law known as the Stark Law.<sup>3</sup> This provision responds to concerns expressed by healthcare providers following the elimination last year by the Office of the Inspector General of the Department of Health and Human Services ("OIG") of the ability to self-disclose Stark-only violations to the OIG.

On September 23, 2010, the Centers for Medicare & Medicaid Services ("CMS") released its highly anticipated Self-Referral Disclosure Protocol ("SRDP").<sup>4</sup> The SRDP is a vehicle through which healthcare providers and suppliers may self-disclose actual or potential Stark Law violations. CMS will evaluate each disclosure on a case-by-case basis and has the power to proceed through a settlement process and potentially reduce the amount owed (however, CMS

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<sup>1</sup> Health Reform IMPACT, April 26, 2010, can be [found here](#).

<sup>2</sup> Pub. L. No. 111-148, Section 6409 of the Health Reform Legislation

<sup>3</sup> If a physician, or an immediate family member of a physician, has a financial relationship with an entity that furnishes designated health services ("DHS") payable by Medicare or Medicaid, the Stark Law prohibits the physician from referring patients to the entity, and the entity from submitting a claim for payment, for such DHS unless an exception applies. 42 U.S.C. § 1395nn(a)(1). Amounts received as a result of a prohibited referral must be refunded. Penalties for Stark Law violations may include denial of payment to the DHS entity, civil money penalties of up to \$15,000 per prohibited referral, up to \$100,000 for a circumvention scheme, exclusion from Medicare, recoupment of amounts paid pursuant to each prohibited referral, and potential federal and state False Claims Act liability.

<sup>4</sup> [https://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_SRDP\\_Protocol.pdf](https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf)

has no obligation to reduce any amount owed).<sup>5</sup> The five factors CMS may consider in reducing the amounts owed are: (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.

### **What Can A Party Accomplish with the SRDP?**

CMS is careful to emphasize that the SRDP is separate from the CMS Stark Law advisory opinion process and that a party cannot use the SRDP to obtain a CMS determination as to whether an actual or potential violation of the Stark Law has occurred. Rather, a disclosing party should make an SRDP submission only if it intends to resolve its overpayment liability exposure for the conduct it identifies. In other words, the purpose of the SRDP is to facilitate matters that “in the disclosing party’s reasonable assessment, are actual or potential violations [of the Stark Law].”

### **What is the Timeframe?**

Existing Stark regulations require an entity that collects payment for DHS performed pursuant to a prohibited referral to refund all collected amounts within 60 days of collecting the prohibited amounts. Further, Section 6402 of PPACA requires disclosure and repayment of overpayments within “60 days after the date on which the overpayment [is] identified.”<sup>6</sup> Although a disclosure under the SRDP will suspend the 60-day repayment period under PPACA, a party must nonetheless submit the required SRDP disclosure report within this 60-day period in order to toll the repayment clock.<sup>7</sup> Note that CMS does not clearly address suspension of the 60-day repayment period under the Stark regulations (which are technically stricter than the PPACA standard and require repayment within 60 days of “collecting” prohibited amounts as compared to PPACA’s standard of repayment within 60 days of “identifying” prohibited amounts). In any event, a party must expend significant time and effort within the first 60 days after identifying an overpayment.

### **Is the SRDP the Appropriate Self-Reporting Vehicle? What are the Risks?**

Once an overpayment is identified, a party must carefully consider whether the SRDP is the appropriate vehicle by which to address the overpayment.<sup>8</sup> The SRDP addresses only actual or potential Stark Law violations. If the disclosing party believes that its conduct raises potential liability under other federal laws in addition to potential liability under the Stark Law, the disclosing party should, if it opts to address the overpayment through a self-disclosure protocol instead of another method, self-disclose through the OIG’s Self-Disclosure Protocol (the OIG will accept disclosures that raise issues under both Stark and other federal statutes). CMS states

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<sup>5</sup> Prior to PPACA, CMS’ position was that it had no authority to negotiate settlement amounts and potentially reduce amounts owed. Now, however, PPACA has explicitly granted CMS that authority.

<sup>6</sup> Or the date any corresponding cost report is due, if applicable.

<sup>7</sup> In addition, despite the suspension of the repayment period, CMS has “encouraged” the disclosing party to place the funds in question in an interest-bearing escrow account until the SRDP is complete (despite the fact that CMS does not state how long the SRDP will take).

<sup>8</sup> Note that, with respect to parties who currently have corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with the OIG, CMS states that, effective September 23, 2010, “a reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in [the SRDP] with a copy to the disclosing party’s OIG monitor.”

explicitly that disclosing parties should not disclose the same conduct under the SRDP and under the OIG's Self-Disclosure Protocol.

Upon review of the disclosing party's SRDP submission, CMS will coordinate with the OIG and the Department of Justice ("DOJ"). If CMS concludes that the disclosed matter warrants referral to law enforcement, CMS may use the submission to prepare a recommendation to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability. A party that has entered the SRDP process may find itself the subject of an unanticipated OIG or DOJ inquiry if CMS decides to pass the information along to other enforcement agencies. Therefore, prior to entering the SRDP process, a disclosing party should carefully analyze the matter submitted in order to determine if there is any basis on which a regulator could argue that the matter implicates federal statutes besides Stark. CMS warns that "the disclosing party's initial decision of where to refer a matter involving non-compliance . . . should be made carefully."

### **What Should be Included in the SRDP Submission?**

The scope, nature and types of materials required by CMS under the SRDP submission are quite expansive. According to CMS, the SRDP submission must include the following:

- (1) Identifying information including: name, address, national provider identification numbers (NPIs), CMS Certification Numbers(s) (CCN), and tax identification number. If appropriate, the disclosing party should include a diagram of ownership and control relationships;
- (2) A description of the nature of the matter being disclosed. This would include the type of financial relationship(s), parties involved, specific time periods of noncompliance, dates (or a range of dates) whereby the conduct was cured, type of designated health service claims at issue, description including the type of transaction or other conduct giving rise to the matter, and names of the entities and individuals believed to be implicated with an explanation of their roles in the matter;
- (3) A "complete legal analysis" regarding why the disclosing party believes a violation of the Stark Law may have occurred, along with a complete analysis of the applicability of any Stark Law exception. The analysis should identify and explain which elements of the applicable exceptions were or were not met;
- (4) A description of the circumstances under which the disclosed matter was identified, including any remedial measures;
- (5) A statement identifying any history of similar conduct or any prior criminal, civil and regulatory enforcement actions (including payment suspensions);
- (6) A description of the existence and adequacy of any pre-existing compliance program and any and all efforts to prevent any recurrence. The disclosing party should also describe any measures or actions to restructure the non-compliant relationship;
- (7) A description of appropriate notices, if applicable, to other government agencies in connection with the disclosed matter;

(8) Disclosure of knowledge of any other pending inquiries by any government agency or contractor (note that the fact that a disclosing party is already subject to government inquiry will not automatically preclude a disclosure under the SRDP made in good faith);

(9) A financial analysis: (a) setting forth the total amount, by year, that is actually or potentially due based on the time of potential or actual non-compliance; (b) the methodology and any estimates used to calculate the amount actually or potentially owed; and (c) a summary of auditing activity undertaken and a summary of documents relied upon; and

(10) A certification by the CEO, CFO or other authorized representative that, to the best of the individual's knowledge, the information submitted is truthful and is based on a good faith effort to bring the matter to CMS' attention for resolution of potential Stark Law violations.

Bear in mind that all of these elements must be compiled and submitted within 60 days of identifying an overpayment in order to suspend the PPACA 60-day repayment period. Additionally, CMS' verification process may uncover additional issues leading to further government investigation. CMS states: "Matters uncovered during the verification process, which are outside the scope of the matter disclosed to CMS, may be treated as new matters outside the SRDP."

### **What is the Post-Submission Process?**

After CMS receives the SRDP submission, it will review the surrounding circumstances to determine an appropriate resolution. CMS states that in some instances Medicare contractors may be responsible for processing any identified overpayments. Notably, one condition of disclosing a matter pursuant to the SRDP is that the party waives all appeal rights attached to claims relating to the conduct disclosed if resolved through a settlement agreement.

### **Conclusion**

In summary, although the SRDP represents a potentially useful tool for providers and suppliers grappling with how to address known Stark violations, careful consideration must be given to any decision to utilize this tool. There is no guarantee of a reduced settlement amount, and the disclosed information could be utilized in an unanticipated way by other law enforcement agencies. Parties should bear in mind, however, that an affirmative obligation to repay known overpayments remains regardless of which avenue they select to address Stark violations. Failure to repay amounts collected in violation of the Stark Law could result in significant penalties, including civil monetary penalties and False Claims Act (FCA) exposure (PPACA, for example, expressly ties failure to meet the 60-day repayment standard to FCA liability).

For this reason, providers should carefully analyze the facts surrounding an overpayment to determine the best course of action. Important to this process will be consulting with counsel to determine if there has, in fact, been a Stark violation and therefore a "known" overpayment. Stark is a highly complex statute, and a provider or supplier should not summarily conclude that there has been a violation without a careful assessment of the facts and circumstances surrounding the transaction at issue. In addition, any such assessment should include counsel's input on whether other federal statutes may be implicated.

If you have any questions regarding this issue of *Health Reform IMPACT*, please contact any of the attorneys in our Healthcare Practice Group listed below.

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