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CMS Opens its Doors by Creating the Stark Voluntary Self-Referral Disclosure Protocol—But Enter at Your Own Risk



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On Sept. 23, the Centers for Medicare & Medicaid Services issued the CMS Voluntary Self-Referral Disclosure Protocol (SRDP).¹ Creation of the SRDP was mandated by Section 6409 of the Patient

¹ See CMS Voluntary Self-Referral Disclosure Protocol available at http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

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Protection and Affordable Care Act along with the Health Care Education Affordability Reconciliation Act of 2010 (referred to collectively as the Affordable Care Act)² as the vehicle through which health care providers and suppliers can disclose actual or potential violations of the physician self-referral provisions of Section 1877 of the Social Security Act, commonly known as the Stark Law.³ The Affordable Care Act required CMS to create the SRDP within six months as a stand-alone protocol wholly separate from the CMS advisory opinion process under the Stark Law.

Although imperfect, the SRDP is a welcome and necessary vehicle for the health care industry. As a result of the “black and white” nature of Stark Law violations,

² Pub. L. No. 111-148, 124 Stat. 119 (2010) and Pub. L. No. 111-152, 123 Stat. 1029 (2010).

³ See 42 U.S.C. 1395nn.

the health care community has complained for years that relatively minor discrepancies in required paperwork can result in draconian penalties. This is particularly so where high referring specialty physicians are involved. Even the recent expansion in certain Stark Law exceptions for inadvertent violations did not fully alleviate this issue. Moreover, CMS had taken the position that it had no authority (prior to the Affordable Care Act) to compromise Stark overpayments in connection with settlement of Stark Law violations, even those that were self-reported.

Significantly, the Affordable Care Act mandated a self disclosure protocol and authorized the secretary of health and human services (secretary) to reduce amounts otherwise due for Stark Law violations where the violations are self-disclosed through the SRDP protocol, taking into account several factors, described below. Thus, the SRDP provides the formal mechanism for providers and suppliers to request a reduction in repayment arising from Stark Law violations where such a mechanism did not exist.

However, there are a number of significant issues in the current version of the SRDP. First, the SRDP requires the disclosing parties to act quickly but yet comprehensively (even more comprehensively than a disclosure under the OIG's Voluntary Self-Disclosure Protocol). Parties using the SRDP must submit a report concerning the Stark Law arrangements at issue, which is likely to require significant time and expense, within the 60 days after an overpayment is identified.

Second, the SRDP provides no guarantees as to the amount of payment reduction that will be awarded for the self-disclosure. Moreover, although CMS lists five factors that it will take into consideration as to whether to reduce the amounts owed (three of which were set forth in the statute), CMS does not provide any detail as to how these factors will be weighted nor does it fully define what these factors mean.

Third, the SRDP may not resolve potential follow-up inquiries by other government enforcement agencies such as the Department of Justice (DOJ) or the Office of Inspector General of the Department of Health and Human Services (OIG). In fact, the SRDP warns that decisions to enter the SRDP "should be made carefully," because CMS may make a recommendation to OIG or DOJ for resolution under other civil or criminal statutes. This may include the federal Anti-Kickback Statute (AKS), the federal Civil False Claims Act (FCA), the federal civil monetary penalties statute and others. Yet, the SRDP does not specifically provide for any government agency coordination in the event of disclosure of the same conduct under both the SRDP and the OIG's self-disclosure protocol, nor does it provide self-disclosure "credit" if CMS refers SRDP disclosures to other law enforcement agencies. Therefore, serious consideration must be given as to the venue of disclosure for actual or potential Stark issues to maximize protections and credit for disclosure.

Brief Summary of the Stark Law

By way of background, the Stark Law prohibits referrals from and payment of Medicare claims submitted by a physician (or on that physician's behalf) if (1) the physician has made a patient "referral," as defined by the Stark Law and CMS's regulations; (2) the patient referral was made to an entity for the purpose of furnishing a Designated Health Service as specifically defined; (3)

the physician or a member of the physician's immediate family has a direct or indirect financial relationship (through ownership/ investment or compensation) with the entity to which the patient has been referred; and (4) the financial relationship does not fall into one of the exceptions set out in the Stark Law or accompanying regulations.

Penalties under the Stark Law include the following: (1) the denial of payment and an obligation to refund all Medicare payments made for services as a result of referrals from the "tainted" arrangement; (2) civil monetary penalties of up to \$15,000 for each service that a person knows or should know violates the Stark Law; (3) civil monetary penalties of up to \$100,000 for schemes to circumvent the Stark Law; (4) possible exclusion from the Medicare and Medicaid programs; (5) the imposition of up to three times the amount for each item wrongfully claimed; and/or (6) potential liability under the Federal Civil False Claims Act.

CMS's Voluntary Self-Referral Disclosure Protocol

Traditionally, entities that discovered a Stark violation refunded monies to their Medicare contractor or, if more certainty was desired, they historically could self disclose to the OIG. However, in a March 24, 2009 Open Letter, the OIG closed that door by announcing that it would no longer accept Stark self disclosures that do not involve a violation of the Anti-Kickback Statute.⁴

Since the OIG's March 2009 Open Letter, entities that discovered potential Stark violations have not had a defined government avenue through which disclosure can be made. Moreover, more recent amendments to the False Claims Act by the Fraud Enforcement and Recovery Act (FERA) and the Affordable Care Act provisions regarding mandatory overpayment refunds have greatly increased the risk of not refunding claims affected by a Stark violation. The confluence of these factors has led to a great deal of angst and head scratching in the industry. Although imperfect, the SRDP should alleviate some of this uncertainty, since it establishes a clear pathway with possible incentives for participation.

Who is eligible for the SRDP?

Like the OIG's Provider Self-Disclosure Protocol, the SRDP is open to "all health care providers of services and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service." Unfortunately, CMS does not define the terms supplier or provider of services, nor does CMS use the defined Stark law term "entity." This raises the question as to whether an "entity" that merely performs, but does not bill, a service covered by the Stark Law (such as physician-owned entity acting "under arrangements") can use the SRDP as a vehicle to disclose a Stark Law violation.

When can a self-disclosure be made?

CMS states that the SRDP is intended to facilitate matters that "in the disclosing party's reasonable assessment, are actual or potential violations [of the Stark Law]." Accordingly, a party must have reasonable certainty that a violation has occurred. The SRDP cannot

⁴ See An Open Letter to Health Care Providers, March 24, 2009 available at <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

be used for purposes of seeking an advisory opinion from CMS on the legality of conduct under the Stark Law. In other words, parties seeking to enter into arrangements needing comfort that their arrangements do not violate Stark cannot use the SRDP, but instead would use the CMS advisory opinion process for this purpose.

Interestingly, the SRDP can be used even if the entity is being audited or investigated. However, CMS states that “the disclosure must be made in good faith . . . [a] disclosing party that attempts to circumvent an ongoing inquiry . . . will be removed from the SRDP.” Although unclear, presumably, this means that if the underlying investigation is not related to the particular Stark violation being self disclosed, the protocol can be used. But if it is related, the entity potentially could be rejected from the SRDP.

Another provision in the Affordable Care Act (Section 6402) sets forth that a person has engaged in a false claim under the Federal Civil False Claims Act if such person does not report and return overpayments on the later of either 60 days from discovery or the date on any corresponding cost report, if applicable. However, this timing requirement for returning overpayments is suspended upon entry into the SRDP to give the parties time to achieve resolution. As a practical matter, however, this means that in order to take advantage of the SRDP, an entity must submit the required comprehensive SRDP disclosure report before the 60 days from discovering a Stark Law violation or the date any corresponding cost report is due, whichever is later.

Is there any coordination among the various enforcement agencies?

As the SRDP is explicitly intended to be used for actual or potential Stark violations, CMS is the appropriate agency to address Stark self disclosures. However, violations that include potential liabilities under other federal statutes or laws are not appropriate for the SRDP. By way of example, CMS states “conduct that raises liability risks under the physician self-referral statute may also raise liability risks under the . . . anti-kickback statute and should be disclosed through the OIG’s Self-Disclosure Protocol.” Although CMS goes on to state that it will coordinate self disclosures with the OIG and DOJ, CMS also warns that “the disclosing party’s initial decision of where to refer a matter involving non-compliance . . . should be made carefully.”

What is the scope of the report required under the SRDP?

According to the SRDP, the submission to CMS should include the following:

- Identifying information on the entity including: name, address, national provider identification numbers (NPIs), CMS Certification Number(s) (CCN), and tax identification number(s) and if appropriate a diagram of ownership and control relationships;
- a description of the matter being disclosed, including the type of financial relationship(s), the parties involved, the time periods of the noncompliance, the dates or a range of dates whereby the conduct was cured, the type of claims at issue and a description of why the conduct occurred and “the individuals believed to be implicated”;
- a “complete legal analysis” of why the entity believed it violated the physician self-referral law and any physician self-referral exception that applies to the conduct and/or that the disclosing party attempted to use. In addition, CMS states that “the submission should include a description of the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or Government regulations)”;
- a description of the circumstances under which the disclosed matter was discovered and the remedial measures taken since discovery;
- a statement regarding past similar conduct and other criminal, civil or regulatory actions;
- a description of the existence and adequacy of a pre-existing compliance program including remedial efforts to prevent a recurrence of the incident and efforts to restructure the noncompliant relationship;
- a description of appropriate notices, if applicable, provided to other government agencies, (e.g., Securities and Exchange Commission and Internal Revenue Service) in connection with the disclosed matter;
- disclosure of knowledge of other pending inquiries by government agencies or contractors;
- a financial analysis that demonstrates that a full examination of the disclosed conduct has occurred, which should (1) set forth the total amount, by year, that is actually or potentially owed; (2) describe the methodology used to set forth the amount that is actually or potentially owed; and (3) a summary of auditing activity undertaken and a summary of the documents relied upon; and
- a certification from the entity’s CEO, CFO, or authorized representative that the disclosure contains truthful information and is based on a good faith effort to bring the matter to CMS’s attention for the purpose of resolving any potential liabilities.

In summary, the SRDP requires a comprehensive disclosure, including a legal analysis and supporting materials that pertain to both the arrangement and the disclosing entity. Preparation of these materials, which CMS may share with other enforcement agencies, should be done carefully, honestly, and accurately. The concern is whether parties will be able to complete the steps required to assemble and authorize an appropriate disclosure within the expected timetables. Sixty days is a short time frame to conduct a thorough internal review of potential noncompliance, come to conclusions about whether a violation has occurred, assemble descriptions of the potential causes of the incident or practice at issue, draft descriptions of any similar conduct and of the compliance program, design remedial actions and describe them, conduct an accurate financial analysis of the potential repayment and present all of these materials to the compliance committee and/or governing body for review/approval for filing with CMS. The timetable for this process raises serious questions as to whether the SRDP process is a meaningful opportunity for providers to resolve significant or complex legal areas of potential noncompliance.

How does the SRDP compare to the OIG's Voluntary Self-Disclosure Protocol?

Although the filing required under the SRDP is similar, it is not identical to the requirements for filing under the OIG's Provider Self-Disclosure Protocol and, in fact, is arguably more complicated.

Specifically, under the OIG's Voluntary Self-Disclosure Protocol (the protocol), the OIG allows the disclosing party to conduct its internal review *after* the initial disclosure of the matter. The OIG promises to generally agree for a reasonable time period to forgo its investigation of the matter if the disclosing party agrees to conduct its internal review in accordance with the OIG's internal investigation guidelines and self-assessment guidelines (for estimated financial impact of the violation) that are included in the Provider Self-Disclosure Protocol. This allows entities to apply for entry into the protocol on a timely basis while permitting additional time for a comprehensive investigation and quantification to be performed and submitted to the OIG. As such, CMS should consider modifying the SRDP to adopt the OIG's approach to incremental submission of information in order to encourage providers to use the SRDP process and to provide enough time for the comprehensive review that CMS requires.

Unlike the OIG's self-disclosure process, the SRDP requires the disclosing party to conduct a "complete legal analysis." The legal analysis includes why the entity believed it violated the physician self-referral law and any physician self-referral exceptions that apply to the conduct and/or a description of the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or government regulations). In addition to raising issues of attorney-client privilege, this demand for a "legal analysis" appears to require those availing themselves of the SRDP to engage legal counsel to write a complete memorandum of law as a prerequisite to using the SRDP process, when many of the issues that parties will seek to disclose under the SRDP will involve merely technical noncompliance, such as inadvertent renewal or signature issues.

What are some of the reasons to consider a disclosure under the SRDP?

The incentives to enter into the SRDP are: (1) certainty and closure (at least with CMS); (2) potential overpayment reductions and; (3) although not specifically included in the protocol, potential avoidance of oversight and monitoring by government agencies.

Importantly, Congress provided CMS with the authority to reduce damages under the Stark Law for entities who participate in the SRDP. In the Affordable Care Act, Congress listed three criteria: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; and (3) the cooperation in providing additional information related to the disclosure. Congress also provided the secretary of HHS the ability to identify other factors. To date, the SRDP also includes, as potential factors that can reduce damages, the litigation risk associated with the matter disclosed and the financial position of the disclosing party. CMS notes however, that while it may consider these factors, it is under no obligation to reduce amounts owed and will evaluate each disclosure on a case-by-case basis. Unfortunately, CMS neither provided any further detail on how it would analyze these

factors nor described what these factors mean. For example, it is unclear what CMS means by "litigation risk" associated with a matter being disclosed under the SRDP or what factors will CMS take into consideration when analyzing the financial position of a disclosing party (i.e., what factors will go into an "ability to pay" analysis).

SRDP entrants are left to apply complicated legal standards developed in other areas of government enforcement and compromise of claims. Parties submitting a disclosure under the SRDP should consider providing CMS with a written statement setting forth the analysis under each of these factors that supports a reduction in the amounts due, and including a proposal on the final amount of repayment based on these factors. The factor relating to "litigation risk" is especially important, because it gives the disclosing party the opportunity to express arguments in support of its arrangements, even though it nonetheless is making an "admission" that a potential violation has occurred in order to gain entrance into the SRDP.

What are some of the uncertainties in making a disclosure under the SRDP?

Overall, the incentives to entering into the SRDP are consistent with what we would expect from a voluntary disclosure protocol. However, there are a number of factors or risks that a provider/supplier must consider when entering into the SRDP.

First, any disclosures made to CMS may be viewed by the OIG and DOJ. Accordingly, materials submitted under the SRDP should be carefully considered to determine whether criminal conduct can be inferred from facts and circumstances. If so, entities will need to determine whether the DOJ or OIG should be the appropriate avenue for disclosure. When entering into the SRDP, entities also should consider the ramifications of volunteering evidence that can be used against them in future litigation. Understandably, the purpose of the SRDP is to avoid litigation; nonetheless, in the end, there may not be a resolution with CMS. Consequently, entities should carefully evaluate the evidence that they produce under the SRDP and make such submissions with an eye toward preserving their rights.

Second, once an entity enters into the SRDP, CMS "expects to receive documents and information . . . if a party fails to work in good faith with CMS to resolve the disclosed matter, that lack of cooperation will be considered when CMS assesses the appropriate resolution of the matter." CMS also states that it "must have access to all financial statement, notes, disclosures, and other supporting documents without the assertion of privileges or limitations." CMS clarifies that it will not specifically request attorney client privileged materials but it believes that materials covered by the work product doctrine may be necessary to resolving the disclosure. Although CMS states that it will work with disclosing entities to protect privileges, this is another example of critically important consideration that disclosing parties should weight carefully.

Third, any statements, documents, or assertions made through the SRDP are subject to criminal federal obstruction or false statements laws. In the SRDP, CMS specifically states that the submission of false or untruthful information, as well as intentional omissions of relevant information will be referred to DOJ or other federal agencies and could result in criminal liability,

civil sanctions and exclusion. Disclosing parties should carefully consider the adequacy of their internal processes used to assemble support for statements, documents, assertions and certifications made to CMS as part of the SRDP.

Fourth, the SRDP provides that Medicare contractors may be responsible for processing identified overpayments and, further, that a disclosing party under the SRDP has no appeal rights for claims resolved through settlement under the SRDP. This means that CMS potentially could conclude a disclosed matter by sending it to a Medicare contractor which then can make an overpayment demand without negotiation and also without appeal rights. As with other overpayment demands, amounts then can be recouped from other Medicare payments, and interest can be assessed for nonpayment after 30 days. Providers and suppliers availing themselves of the SRDP should be aware that the end result of self-disclosure through the SRDP may not necessarily be the cooperative negotiation of a meaningful and mutual resolution of the matter, but rather an overpayment demand. This is especially troublesome when CMS does not exercise its discretion to reduce the amount overpaid.

Fifth, unfortunately, both the Affordable Care Act and the SRDP are silent as to the effect, if any, that participating in the SRDP will have on influencing the OIG's decision to impose monitoring through corporate

integrity agreements (CIAs) in instances where CMS refers the disclosure to the OIG or DOJ. Presumably, the OIG would view disclosure in the SRDP as favorable, consistent with its treatment of similar voluntary disclosures. Nonetheless the OIG should consider issuing its own letter clarifying its position on crediting SRDP disclosures to ensure these incentives exist for the SRDP and to facilitate its use.

Conclusion

The SRDP creates an avenue through which the health care industry can resolve potential Stark violations. Nonetheless, the scope, nature and types of materials included in a SRDP submission require serious consideration. In addition, key potential benefits from self-disclosure—namely, avoidance of further liability and “credit” in the determination of financial payments—are not clear or certain. Nevertheless, Congress also included in the Affordable Care Act that 18 months after the SRDP is established the secretary must issue a report to Congress regarding the number of entities disclosing under the SRDP, the amounts collected, and the nature of the issues being disclosed under the SRDP. As such, some in the industry may choose to wait and see how CMS responds to the initial disclosures made through this process and the results as reported to Congress in March 2012 in order to evaluate its merits as a mechanism for resolution of Stark Law violations.