CMS Stark Voluntary Disclosure Protocol: Strategic Approaches and Practical Tips

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The federal Stark Law,[1] governing physician self-referral, has been the subject of debate since its inception. The Stark Law has a simple premise: to bar physicians from making referrals for certain health services to entities with which they, or their immediate family members, have a financial relationship. However, this simple premise has not been simple in application. The prohibition under the Stark Law against claims by providers and suppliers (including hospitals) submitted to anyone (including government programs such as Medicare) for services rendered as a result of improper referrals from physicians can result in severe consequences–including refunds of overpayments, fines, and the risk of exclusion from federal health programs.

Due to the complex nature of the Stark Law and its exceptions, even vigilant providers may find themselves having inadvertently sought and received reimbursement for services rendered in violation of the law. Historically, the government has provided channels for providers to self-report violations. The most recent example is the Affordable Care Act of 2010, which directed the Department of Health and Human Services (HHS) to develop a process for providers to self-report violations of the Stark Law in return for potentially reduced liability. Under this authority, the Centers for Medicare & Medicaid Services (CMS) issued its Voluntary Self-Referral Disclosure Protocol[2] (SRDP) in September 2010.

Since the SRDP program began, four settlements have been publicized. First, Saints Medical Center, in Lowell, MA, agreed to pay $579,000 to resolve its Stark Law liability, well below its estimated exposure of approximately $14 million.[3] CMS also settled several Stark Law violations with a critical access hospital in Mississippi for $130,000; the hospital's estimated exposure has not been publicized. Finally, CMS announced two new settlements in January 2012 that were, in each case, related to presumably limited violations of the Stark Law's non-monetary compensation exception: a California hospital settled its liability for $6,700, and a Georgia hospital resolved its liability for $4,500. According to the most recent reports, CMS had received 109 SRDP submissions as of September 2011. However, more current information should be available by no later than March 2012, which is the deadline for CMS to submit to Congress a detailed report on the SRDP program.

Under the SRDP, providers may report only actual and potential violations of the Stark Law and not violations of other federal fraud and abuse laws (such as the Anti-Kickback Statute or False Claims Act). However, if CMS determines that conduct disclosed under the SRDP also might violate other federal laws, the agency may refer the disclosing party's submission to the HHS Office of Inspector General (OIG) or the Department of Justice (DOJ) for further investigation. In deciding whether to use the SRDP, providers should therefore weigh the benefits of likely reducing their exposure under the Stark Law against the possibility of unanticipated consequences. The decision to make a SRDP submission should be made by a corporate fiduciary, such as a hospital's board of directors.

Here are six practical tips for hospitals and other healthcare providers to help them decide whether to use the SRDP, and if so, to then prepare a SRDP submission.

1. **Set Parameters for the Investigation:** Typically, a provider's path to entering the SRDP starts with the discovery of a single potentially non-compliant arrangement. Because the provider should ensure that it ultimately reports all existing issues, it will want to survey the level of its compliance. In some instances, a provider may be faced with a daunting task of conducting a Stark self-audit of various physician payment streams over many years. Prudent providers will set reasonable parameters for their self-audit. For example, a provider could consider starting with a review of all payment streams to or from physicians or physician practices during the past six years (typically considered the Stark Law statute of limitations period). Although it is possible that arrangements existing prior to such six-year cutoff also violate the Stark Law, the provider should circumscribe, with defensible boundaries, what might otherwise be an unlimited review.
2. **Establish a Plan for Allocating Responsibility:** Under the SRDP, disclosures and refunds of overpayments should be submitted within 60 days of (1) the date on which the overpayment was identified, or (2) the date a corresponding cost report is due. Conducting a self-audit and preparing a SRDP submission can be an extremely time-consuming process, and those 60 days are sure to pass quickly. So at the outset of a Stark self-audit, the provider should establish a timeline and clearly allocate responsibilities among its employees and between itself and its legal counsel.
3. **Carefully Prepare SRDP Submission:** A SRDP submission includes three components: (1) an extensive report describing, among other things, the actual or potential Stark violation, the circumstances under which the violation was discovered, whether the disclosing party has a history of similar conduct, and the nature and adequacy of the disclosing party's existing compliance program; (2)

a financial analysis of the amount due; and (3) a certification by a corporate fiduciary, such as a hospital CEO, that the contents of the submission were prepared in good faith and are accurate. The SRDP's good faith requirement makes careful preparation of the submission particularly important. To the extent that CMS sees errors or omissions as being uncooperative, as evidence of a continued lack of effort to comply with the Stark Law, or as an attempt to circumvent further investigation, it may demand a larger settlement. In the egregious case, the disclosing party risks being removed from the SRDP and having the submission referred to the OIG or the DOJ for further investigation. For these reasons, disclosing parties should have legal counsel involved in the preparation, compilation, and/or review of SRDP disclosures prior to submission to CMS.

4. **Add Up the Exposure:** Even though the whole point of the SRDP–at least from the provider's perspective–is to settle potential Stark liabilities for less than its full exposure, CMS nonetheless requires that the provider's submission include a full financial analysis of the "total, itemized by year, that is actually or potentially due and owing" under the Stark Law, factoring in the period of noncompliance. The SRDP requires financial analysis of any potentially non-compliant arrangement over the entire "look back" period–the period during which the disclosing party was potentially not in compliance with the Stark Law. Thus, in some cases, the "look back" period for calculation purposes will exceed even the Stark statute of limitations period. The provider's exposure under the Stark Law is therefore the sum of all Medicare reimbursements received from any and all referrals of "designated health services" (including all hospital services) made by any physician(s) with which the provider had a direct or indirect financial relationship that did not meet a Stark exception. Moreover, according to CMS, the provider's SRDP submission should list the total amount of remuneration paid by the provider to the physician(s) as a result of the reported Stark Law violations during the applicable "look back." The provider's financial analyses should be based on a clearly defined methodology and should rely on the most accurate data available. It is imperative that CMS have confidence in the disclosure and its underlying methodology to both minimize any follow-up inquiries from CMS and set a good tone for discussions with CMS on the nature and amount of any penalties.
5. **Identify Factors that May Support a Payment Reduction:** While the SRDP statute does not require CMS to reduce any amounts owing or potential fines as a result of a provider's submission under the SRDP, the agency has authority to do so. CMS will consider a number of factors in determining whether to reduce an amount owing, including (1) the nature and extent of the illegal conduct; (2) the timeliness of the disclosure; (3) the level of cooperation of the disclosing party; and (4) the disclosing party's financial position. To the extent possible, submissions should highlight any factors that support a liability reduction. For example, a rural hospital will want to emphasize that it serves a disproportionate number of underserved patients. To the extent applicable, the lack of ability to pay should be at the forefront of the argument.
6. **Prepare for Your Response to CMS Inquiries:** The SRDP process does not end with the initial SRDP submission. Following the initial submission, CMS will conduct its own verification of the submission and may request additional information and documents from the disclosing party. The disclosing party should establish a mechanism for rapidly and accurately responding to CMS' information requests. A disclosing party's level of cooperation may factor into CMS' ultimate decision on the outcome (penalty) in each case. Moreover, the disclosing party should take time to think proactively about its responses to questions that CMS may ask in its follow-up. A financially distressed hospital, for example, should have explored what documentation it will provide when CMS asks for backup as to its lack of financial wherewithal to pay a large penalty.

The strategic approaches and practical tips outlined above have been gleaned from our work with providers using the SRDP in its first year of existence. Although only four settlements under the SRDP program have been publicized so far, it is clear that participating in the SRDP is a lengthy and protracted process that requires careful legal and financial analyses of a provider's business relationships over many years. Providers should seek immediate counsel by a qualified attorney if they suspect that they have violated the Stark Law.

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John B. Garver III (jgarver@rbh.com) has a practice that includes work in joint ventures, healthcare and insurance law. In the healthcare law area, he regularly advises clients on compliance and regulatory issues, including the federal Anti-Kickback and Stark laws. He has a broad transactional healthcare practice, including assisting hospitals, physicians and providers, in acquisitions, affiliations, joint ventures, and ownership transfers.

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Endnotes

1 42 U.S.C. § 1395nn.
2 Office of Management and Budget Control No. 0938-1106, *available at* www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.
3 *See* Saints Medical Center, Press Release (dated Feb. 10, 2011), *available at* www.saintsmedicalcenter.com/news/CMS/.