



Updated Procedures for Self-Reporting Stark Law Violations

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Updated Procedures for Self-Reporting Stark Law Violations

Written by Harold B. Hilborn - August 2, 2017

Beginning on June 1, 2017, providers must use specific forms published on the Centers for Medicare and Medicaid Services (CMS) website in order to utilize the Voluntary Self-Referral Disclosure Protocol (SRDP) to self-disclose actual or potential violations of the Physician Self-Referral Law (commonly referred to as the Stark Law). While voluntary disclosures do not eliminate the financial penalties that may result from an enforcement action, they do offer significant benefits that should be taken into consideration when deciding whether to self-report a violation of the Stark Law.

Stark Law Basics

The Stark Law prohibits physicians from ordering designated health services for Medicare and Medicaid patients from an entity with whom the physician, or an immediate family member of the physician, has a financial arrangement. When first enacted, the Stark Law applied only to relationships between physicians and clinical laboratories. Over the years, the list of designated health services expanded and now includes inpatient and outpatient hospital services; outpatient prescription drugs; home health services and supplies; prosthetics, orthotics, and prosthetic devices; parental and enteral nutrients, equipment, and supplies; durable medical equipment and supplies; radiation therapy services and supplies; radiology; occupational therapy services; and physical therapy services.

Under the Stark Law, a financial relationship includes compensation arrangements, investment interests, and ownership interests. Direct and indirect arrangements both implicate the Stark Law. As a result, when a physician has an ownership interest in a physician organization, financial relationships between providers of designated health services and the organization must be scrutinized.

The Stark Law is a strict liability statute. A violation is a violation, whether intentional, negligent, or inadvertent. While the Stark Law is not a criminal statute, providers who violate it face civil penalties of up to \$23,863 per violation and exclusion from participating in federal health care programs. A violation of the Stark Law can also trigger liability under the False Claims Act, which provides for substantial additional civil penalties and allows for private parties to file lawsuits in the name of the government. Each claim submitted by a provider constitutes a separate violation, so the civil penalties can very quickly become substantial.

The Voluntary Self-Referral Disclosure Protocol

The Affordable Care Act (ACA), enacted on March 23, 2010, provides for the establishment of a voluntary self-referral disclosure protocol, or SRDP, under which providers of services and suppliers may self-disclose actual or potential violations of the Stark Law. Specifically, section 6409(b) of the ACA grants the Secretary of the Department of Health and Human Services the authority to reduce the amount due and owing for all violations of the Stark Law.

The SRDP is separate from the advisory opinion process. A provider of services or supplier may not disclose an actual or potential violation

through the SRDP and request concurrently an advisory opinion for conduct underlying the same arrangement.

Voluntarily disclosing violations of the Stark Law can result in settlements that, while smaller than penalties in an enforcement action, may be still substantial. However, there are several significant benefits to using the SRDP:

First, voluntary disclosure typically indicates that the provider or supplier has a robust and effective compliance program. As a result, it may reduce the likelihood that the Office of Inspector General (OIG) will require a corporate integrity agreement in exchange for a release from exclusion from federal healthcare programs.

Second, self-disclosure extends the deadline established under section 6402 of the ACA for reporting and returning overpayments. Ordinarily, that deadline is 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. By submitting a disclosure under the SRDP, however, the obligation to return the disclosed overpayment is suspended until a settlement agreement is reached, the provider or supplier withdraws its disclosure under the SRDP, or CMS removes the provider or supplier from the SRDP.

Third, a voluntary disclosure can often bar private parties from bringing False Claims Act lawsuits. Although a party can submit a disclosure to CMS while it is already subject to a government inquiry or investigation, the disclosure must be made in good faith. If the disclosure is submitted in order to circumvent an ongoing inquiry, CMS will remove the disclosing party from the protocol. To help gauge a disclosing party's good faith, the SRDP requires that party to state

whether it has any knowledge that the matter is under current inquiry by a government agency or contractor and to specify the details of any such inquiry to the extent known.

The SRDP is intended to facilitate the resolution of matters that the disclosing party has, in its reasonable assessment, identified as actual or potential violations of the Stark Law. When reviewing a disclosure, CMS will not determine whether a violation actually occurred.

Consequently, a provider or supplier should not make a submission to the SRDP with the intention of obtaining a finding of no violation and paying nothing. In fact, a disclosure under the SRDP must include a statement that either (1) its financial relationship was noncompliant, or (2) because it cannot confirm whether its relationship complied with the Stark Law, it is certifying noncompliance.

Voluntary disclosures under the SRDP remain uncommon, though their use has increased each year. Between 2011 and 2016, CMS settled 233 disclosures, and an additional 92 disclosures were withdrawn, closed without settlement, or settled by CMS's law enforcement partners. The settlements during that period totaled \$23,209,222; individual settlements ranged from as low as \$60 to as much as \$1,195,763.

The 2017 Amendments

Effective June 1, 2017, a disclosing party must submit disclosures using standardized forms. Previously, CMS had only specified in narrative form the required content of disclosures, leaving it up to the disclosing party how best to format and package the disclosure.

Four forms are now required, each of which specifies in detail the information to be provided by the disclosing party and where on the form to provide it:

- *SRDP Disclosure Form*. The SRDP Disclosure Form provides information about the disclosing party, including information regarding the disclosing party's history of abuse, pervasiveness of noncompliance, and steps to prevent future noncompliance.
- *Physician Information Form*. For each physician included in the disclosure, the disclosing party must submit a separate Physician Information Form providing details of the noncompliant financial relationship between the physician and the disclosing party. While this may seem onerous, the form provides checkboxes that allow parties to more quickly identify which elements of exceptions may apply to a particular financial relationship.
- *Financial Analysis Worksheet*. The Financial Analysis Worksheet quantifies the overpayment for each physician included in the disclosure who made referrals in violation of the Stark Law.
- *Certification*. The disclosing party must sign a certification which states that, to the best of the individual signatory's knowledge, the information provided is truthful and is based on a good-faith effort to bring the matter to CMS' attention for the purposes of resolving the disclosed potential liabilities relating to the Stark Law. The disclosing party may, but is not required, to submit a cover letter that includes any additional information that the party believes may be relevant to CMS' evaluation of the disclosure.

The recent changes to the SRDP go beyond the form of disclosure. In substance, they add to a disclosing party's responsibilities by

specifying in the Disclosure Form that the disclosure must be updated within 30 days of a bankruptcy filing, change of ownership, or change of designated representative. In addition, under the Disclosure Form, the description of actual or potential Stark Law violations must include a report of the “pervasiveness of noncompliance.” Rather than simply providing a narrative description of what occurred and how that conduct may have violated the Stark Law, a disclosing party must now report on how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians. For example, a hospital might state that it has “numerous compensation arrangements with physicians” and that it “estimates that the noncompliant compensation arrangements disclosed herein represent less than three percent of all financial relationships with physicians.” The Disclosure Form, unlike the prior disclosure process, does not require a description of any pre-existing compliance program.

The Financial Analysis Worksheet replaces a more general requirement to provide a “financial analysis relating to the actual or potential violation(s) of the physician self-referral law.” Under the new procedure, a disclosing party must provide prepare an analysis worksheet in Excel-compatible format. For each physician included in the disclosure, the worksheet must include all of the following:

- Physician’s name and national provider identifier (NPI)
- Date that the overpayment associated with the physician was identified
- Overpayment arising from the physician’s prohibited referrals, itemized by calendar year, for the previous six years (this information must be placed in seven columns, one for each

calendar year covered by the disclosure, regardless of whether the disclosing party actually received an overpayment during a particular calendar year) The Financial Analysis Worksheet must include a text box describing the methodology used to set forth the overpayment. If estimates were used, the disclosing party must explain how they were calculated. Unlike the financial analysis that was required under the prior SRDP, the Financial Analysis Worksheet does not require the disclosing party to list the actual amount of remuneration between the parties unless otherwise requested by CMS.

The recent changes to the SRDP also suggest that CMS will consider fewer factors in reducing the amount owed by a disclosing party. Under the prior version of the SRDP, those factors included the following:

- The nature and extent of the improper or illegal practice
- The timeliness of the self-disclosure
- The cooperation in providing additional information related to the disclosure
- The litigation risk associated with the matter disclosed
- The financial position of the disclosing party
- The current SRDP, however, does not list litigation risk or the disclosing party's financial position as factors in calculating an appropriate settlement. Nonetheless, the current list of factors is non-exclusive, so it remains possible that CMS will evaluate a settlement under the SRDP the same way that any party to a dispute would and take into account the risks associated with litigation and ability to collect on a judgment.

Please contact your Much Shelist attorney for more information on the amended Voluntary Self-Referral Disclosure Protocol (SRDP) or any other health law issues.

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