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CMS Issues Revised Stark Self-Disclosure Form

On March 28, 2017, the Centers for Medicare and Medicaid Services (“CMS”) announced that effective June 1, 2017, all disclosures made pursuant to Self-Referral Disclosure Protocol (“SRDP”) must use new Form CMS-10328 available [here](#).

WHAT IS THE SRDP?

The SRDP was first established by CMS in 2010 in response to the Affordable Care Act’s provision requiring the establishment of a formal process for providers and suppliers to self-disclose actual or potential violations of the physician self-referral law, commonly called the Stark Law. The Affordable Care Act gave the Secretary of the U.S. Department of Health and Human

Services authority to reduce the amount “due and owing” for Stark Law violations that have been self-disclosed. Given the Stark Law’s dizzying complexity, strict liability standard, and severe penalties, the opportunity to disclose and resolve actual and potential violations has been welcomed by health care providers and suppliers.

From its inception in 2011 through 2016, there have been a total of 233 settlements pursuant to CMS’s SRDP, and settlements have been steadily increasing over time: (See figure 1 below).

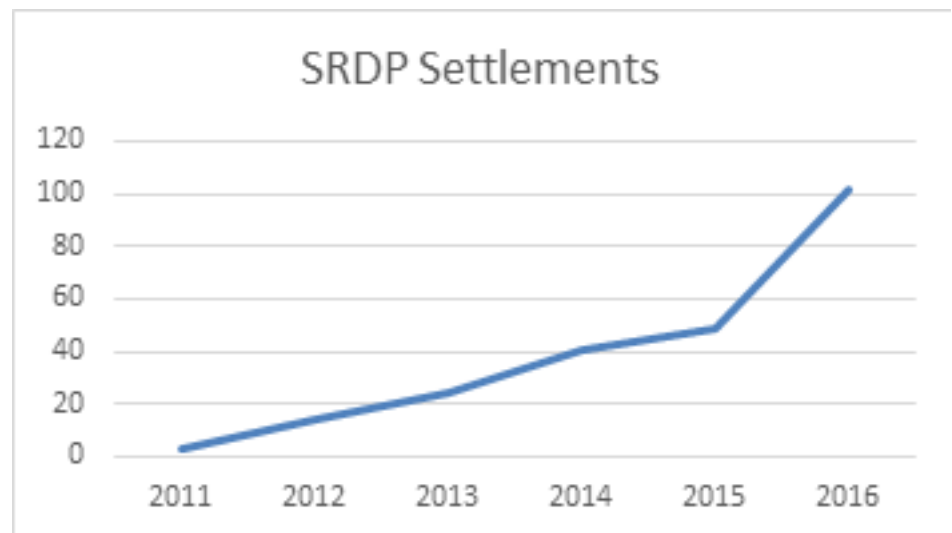


FIGURE 1

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html>

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In addition, as of March 1, 2017, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement, or settled by CMS's law enforcement partners. The dollar amounts of these settlements have varied widely, from as low as \$60.00 to as high as \$1,195,763. Because CMS neither publicizes the facts involved in each case nor explains how it determines the amount of each settlement, it is difficult to ascertain in advance how CMS might resolve a particular self-disclosure. However, the general consensus is that, when considered in proportion to the potential liabilities involved, CMS has been settling these cases favorably for disclosing providers and suppliers.

WHAT DOES THE NEW SRDP FORM REQUIRE?

In March 2017, CMS issued a required electronic form for SRDP submissions. CMS stated that the electronic form is intended to "reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information." Prior to the issuance of this new form, parties utilizing the SRDP drafted detailed narrative descriptions describing the violation and associated potential liabilities. Use of the new form will be mandatory starting on June 1, 2017. Until then, parties submitting self-disclosures pursuant to the SRDP are encouraged by CMS but not required to use the new SRDP form.

The new SRDP form has 4 parts:

1. SRDP Disclosure Form: On this form, the disclosing party provides information about itself; the pervasiveness of noncompliance; whether the disclosing party has knowledge that the disclosed conduct is under current inquiry by a government agency or contractor; whether the disclosing entity has a history of conduct similar to that being disclosed or any prior criminal, civil or regulatory enforcement action against it; and steps that the disclosing party has taken to prevent future noncompliance.
2. Physician Information Form(s): For each physician included in the disclosure, the disclosing party must submit a separate Physician Information Form providing details of the noncompliant financial relationship(s) between the physician and the disclosing party.
3. Financial Analysis Worksheet: The Financial Analysis Worksheet quantifies the overpayment for each physician who made referrals in violation of the Stark Law.

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4. **Certification:** The initial disclosure and any related supplemental submission must include a certification signed by the disclosing party or, in the case of an entity, its Chief Executive Officer, Chief Financial Officer, or other individual who is authorized by the disclosing party to disclose the matter to CMS and to certify the truthfulness of the information contained in the disclosure. The signed certification must state that, to the best of the individual's knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS's attention for the purpose of resolving the disclosed potential liabilities relating to the physician self-referral law. the disclosing party will be able to state that the noncompliant arrangement being disclosed represents a certain percentage of all of the disclosing party's similar arrangements. Disclosing the pervasiveness of compliance may be a complicated exercise for providers that have many different types of arrangements with physicians, especially since the analysis must incorporate the "stand in the shoes" analysis in order to determine how arrangements with physician organizations should be counted. For example, according to CMS, the disclosure of a noncompliant lease arrangement with a physician organization that consists of three owners and two non-owners might have to be counted as three separate agreements if the physician owners are deemed to be standing in the shoes of the physician organization.

WHAT CHANGED?

This new form standardizes the SRDP process and is meant to make the process simpler for both disclosing parties and CMS. However, the new form also requires the disclosing party to include certain information that was not previously required, such as a description of the "pervasiveness of noncompliance," which "means how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians." According to the instructions on the new form, the disclosing party must "report the pervasiveness of the noncompliance relative to the disclosing party's similar financial relationships or similar services furnished." The expectation is that

The new form also does not require a description of the disclosing party's compliance program or information regarding the specific financial benefit of the noncompliant relationship to the applicable physician – two elements that were previously required to be part of the disclosure.

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Perhaps most significantly, the revised SRDP explicitly requires the disclosing party to adopt a 6-year lookback period, meaning that the disclosing party must review the last six years of payment data in order to calculate the overpayment that resulted from the Stark Law violation. Previously, the SRDP required the disclosing party to look back only four years. This change was a result of CMS's final rule on the 60-day reporting and returning of overpayments obligation which established a 6-year lookback period for the reporting and returning of overpayments under 42 CFR 401.305(f). Although that 60-day rule became effective on March 14, 2016, CMS was prohibited from mandating that disclosing parties provide six years' worth of financial data in their SRDP disclosures before the formal OMB approval for and issuance of this new SRDP form.

If you have questions about this advisory or want to learn more about the Health Care Compliance, Fraud and Abuse Practice Group, contact Maureen Weaver at mweaver@wiggins.com or Jody Erdfarb at jerdfarb@wiggins.com.

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