

PUBLICATION

CMS Finalizes New SRDP Disclosure Form and Process

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Parties disclosing actual or potential violations of the Stark law will use a new series of forms under CMS's Voluntary Self-Referral Disclosure Protocol (SRDP) process as of June 1, 2017. According to CMS, the new forms present a "streamlined and standardized format" for making SRDP submissions. While use of the new forms is not *required* until June 1, 2017, CMS encourages their use beforehand.

The new SRDP, announced March 28, 2017, was largely finalized as proposed. For a detailed discussion of the proposed provisions, see our *Health Law Alert* article, ["CMS Announces Plans to Streamline the Stark Self-Referral Disclosure Protocol."](#)

The new SRDP process represents a significant departure from the current SRDP. CMS has now provided SRDP participants with highly detailed and specific forms that require users not only to narrate the noncompliance at issue, but also to address the pervasiveness of the noncompliance, identify when an overpayment was first identified and submit an exhaustive "financial analysis worksheet." More specifically, the new SRDP is comprised of three main components, as outlined below.

SRDP Disclosure Form

The SRDP Disclosure Form requires disclosing parties to provide not only general identification information (e.g., business name, address, national provider identifier), but also to address the "pervasiveness" of the noncompliance at issue.

CMS defines the *pervasiveness of noncompliance* as "how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians." CMS's examples of how best to report pervasiveness of noncompliance include both percentages (e.g., the disclosed noncompliant compensation arrangements represent five percent of the disclosing entity's total financial relationships with physicians) and raw numbers (e.g., of a hospital's 25 physician owners, one was not authorized to perform services at the hospital as required by the Stark law).

Further, as with the current SRDP process, the SRDP Disclosure Form requires disclosing parties to indicate whether they are under current government inquiry, if they have a history of similar conduct and whether any specific steps have been taken to prevent future noncompliance.

Physician Information Form

Participants must also submit a "Physician Information Form" for each physician included in the disclosure. This form requires at the outset that the user provide the applicable physician's identifying information (e.g., name, NPI, physician organization if applicable, etc.).

In addition, disclosing parties must address, in narrative form, the nature of the financial arrangement at issue, the specific type of noncompliance, the method of cure or termination and the period of noncompliance. Of note, this narrative section also requires that participants state the "date of discovery" (i.e., when the provider determined that it received an overpayment). Such a requirement has significant implications as it relates to reporting and returning overpayments in compliance with the 60-day overpayment rule. Disclosing entities are now *required* to pinpoint for CMS the date on which the overpayment was "identified," which is the point at

which the clock will start ticking for disclosing entities to report and return amounts actually or potentially received pursuant to the Stark noncompliance.

The determination of the date of identification may, however, be subject to interpretation. CMS regulations define *identification* of an overpayment as the date when an entity or person has (a) determined, or *should have determined through exercise of reasonable diligence*, that an overpayment was received *and* (b) quantified the overpayment. See 42 C.F.R. § 401.305(a)(2).

For compensation arrangements, providers must also complete check boxes, identifying which requirements of the applicable Stark law exception were not appropriately adhered to.

Financial Analysis Worksheet

As with the current SRDP process, disclosing parties must provide a financial analysis of the potential overpayment. However, CMS is now modifying the format and details of how participants must capture such information.

Specifically, disclosing parties' financial analysis must list not only each physician included in the self-disclosure, but also the date that the overpayment associated with each physician was identified, and the overpayment arising from each physician's prohibited referrals, itemized by calendar year. In addition, the analysis must describe the methodology used to determine the overpayment, including whether estimates were used and, if so, how they were calculated.

The SRDP limits the financial analysis based on the six-year lookback period established under the CMS rules for reporting and returning overpayments, 42 C.F.R. § 401.305(f). Notably, the SRDP provides examples of the application of the lookback period, which is retrospectively measured from the date of *identification* of the overpayment. This is a departure from prior CMS guidance in Frequently Asked Questions (FAQs) specifying that the lookback period is measured retrospectively from the date of *submission* of the SRDP disclosure, rather than the date of identification. While the change provides some additional uniformity to the lookback period calculation, many within the provider community may be left to grapple with determining when the identification of the overpayment occurred.

Further streamlining the information requested, the SRDP states that unless specifically requested by CMS, disclosing parties do not need to provide CMS with data quantifying the remuneration received by the physician or physicians as a result of the actual or potential violation. Nevertheless, it is possible that a disclosing entity may still choose to do so by identifying the information in the narrative description of the noncompliance or in the optional cover letter (e.g., for purposes of illustrating a de minimis financial benefit to those physicians included in the self-disclosure).

All Financial Analysis Worksheets must be submitted in an Excel-compatible format.

Similar to the current SRDP, the disclosing party is instructed to submit all of the SRDP forms electronically to a CMS email address and to mail the agency a hard copy of a certification from an authorized individual (e.g., CEO, CFO). CMS leaves open the option for disclosing parties to submit a cover letter, though it is not required. A party may consider submitting a cover letter if there is information that was not captured in an SRDP form that the party believes may be relevant to CMS's review. Notably, the new SRDP highlights that parties have an obligation to update CMS within 30 days if the disclosing party files for bankruptcy, undergoes a change of ownership or changes the designated representative.

Comments

While lengthier in form, and representing a change for current users of the SRDP, the new SRDP may ultimately streamline the process for disclosing parties, while also potentially expediting CMS's internal review by standardizing the presentation of the information. Participants are provided detailed instruction, examples and increased insight into CMS's deliberative process.

That being said, self-disclosing parties are now faced with the often nuanced task of "identifying" an overpayment for purposes of establishing the 60-day clock for reporting and returning overpayments. Although health care providers have been subject to the 60-day overpayment rule for a number of years, this is the first time CMS has included a field for providers to proactively pinpoint the date of identification for purposes of the SRDP. In addition, participating providers are required to capture the pervasiveness of the noncompliance by comparing the conduct to similar financial relationships between the disclosing party and physicians.

If you have questions about the contents of this alert, please reach out to any member of the [Baker Ober Health Law Team](#)