STRESSFUL OR STREAMLINED? CMS'S NEW SRDP DISCLOSURE FORM PRESENTS NEW CHALLENGES FOR PROVIDERS

The Centers for Medicare & Medicaid Services ("CMS") recently updated its Voluntary Self-Referral Disclosure Protocol ("SRDP") when it posted a new form to be used as part of the SRDP process ("SRDP Form"). According to CMS, the SRDP Form is an attempt to "streamline and simplify" the SRDP process. CMS originally proposed the new SRDP Form on May 6, 2016, citing a need to "reduce the burden on disclosing parties by reducing the amount of information…required for submissions to the SRDP." Now finalized, the SRDP Form is mandatory (with limited exceptions) for all voluntary Stark Law self-disclosures **made on or after June 1, 2017**. While the SRDP Form streamlines some aspects of the SRDP process, certain questions on the SRDP Form may present challenges for health care entities when disclosing potential or actual violations of the physician self-referral statute found in Section 1877 of the Social Security Act, commonly known as the Stark Law. A copy of the new SRDP Form is available here.

BACKGROUND

The Affordable Care Act ("ACA") required the Secretary of the Department of Health and Human Services to establish a Medicare SRDP. The SRDP enables providers of services and suppliers to self-disclose actual or potential violations of the Stark Law. In accordance with the ACA, CMS initially established the SRDP on September 23, 2010, and information concerning how to disclose an actual or potential violation of the Stark Law was posted on the CMS website. The SRDP was subsequently updated on April 17, 2013 but has remained unchanged since that time.

CMS originally proposed the new SRDP Form via a Federal Register notice on May 6, 2016. CMS sought comments regarding the proposed SRDP Form but noted, pursuant to a supporting statement issued on September 9, 2016, that it did not receive any comments pertaining to the proposed SRDP Form. On March 28, 2017, CMS published the updated SRDP on its website and included a copy of the new SRDP Form. The new SRDP Form is mandatory to use for all disclosures submitted under the SRDP on or after June 1, 2017, with exceptions for disclosures related to physician-owned hospitals, which are required to self-disclose under separate special instructions that are available on CMS's website.

KEY CHANGES AND CHALLENGES RELATED TO THE NEW SRDP FORM

The updated SRDP process provides both CMS and health care providers with a standardized (and mandatory) means of disclosing potential or actual Stark Law violations. Under this updated process, the disclosing party must include in any disclosure: (i) a SRDP Disclosure Form; (ii) a Physician Information Form(s); (iii) a Financial Analysis Worksheet (with certain exceptions); and (iv) a certification as to the accuracy and truthfulness of the information submitted with the disclosure. A disclosing party may also submit an optional cover letter with additional information surrounding the self-disclosure.

While requiring the information in a different format, the new SRDP Form continues to request much of the same information under the current SRDP, which was last updated in 2013. There are, however, a number of key changes that may present challenges for health care entities in assembling the requisite information for a self-disclosure. A discussion of these key changes and the potential challenges the changes may present for providers follows.

- **Pervasiveness of Noncompliance.** Perhaps most notably, the SRDP Form now requires providers to identify the "pervasiveness of noncompliance" as part of any disclosure to CMS. For the purposes of the SRDP, "pervasiveness means how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians." Providers may report based on the type of noncompliance (e.g., lease arrangements) or in the aggregate, but they must explain how the calculations were determined. CMS also states that the pervasiveness question should be answered with a quantitative analysis and provides examples of such pervasiveness analyses in the SRDP Form. For example, an entity may disclose that 8 percent of the entity's medical director arrangements were potentially noncompliant and were therefore disclosed on the SRDP Form. Depending on the size of the organization, it can be a very cumbersome process to identify all financial arrangements in place during the applicable lookback period and may require a thorough review of historical documentation and records. Strategies for calculating the pervasiveness of

noncompliance might also vary based on the facts and circumstances. While CMS does not provide details on how it calculates proposed settlements under the SRDP, it is likely that CMS will consider the pervasiveness of noncompliance as a factor when calculating a proposed settlement amount and when considering whether it should seek imposition of a Corporate Integrity Agreement related to the disclosed inappropriate arrangements.

- **Physician Information Form.** The new SRDP Form includes as a component one Physician Information Form ("PIF"). Providers must submit a separate PIF for each physician involved in a noncompliant arrangement. While prior CMS self-disclosures may have only identified an inappropriate arrangement by the physician group involved, CMS notes now that for any "stand in the shoes" scenario, each physician must have a separate PIF. The PIF must include, among other details, a narrative explanation of the arrangement, information regarding the rate of compensation or the amount of remuneration provided under the problematic arrangement and the "date of discovery" of the potentially problematic arrangement. Health care entities often contract with physician groups but may not have specific information regarding the ownership structures or individual physician owners of the group. This information is also rarely available from public resources. This may present challenges in the self-disclosure process as providers work to identify all physicians that must be included in the PIFs and may require providers to have potentially sensitive discussions with the physician groups involved to obtain this information. Explicit identification of the date of discovery of a potentially problematic arrangement may also have implications for disclosing entities as such information may implicate the 60-day overpayment rule (more information on the 60-day overpayment rule is available here).

- **Financial Analysis Worksheet.** Any disclosing provider must also submit a financial analysis of the potential overpayment (based on a lookback period of up to six years) in Excel-compatible format. For each physician included in the disclosure, the worksheet must include: (i) the physician's name; (ii) NPI; (iii) the date that the overpayment associated with the physician was identified; and (iv) the overpayment arising from the physician's prohibited referrals, itemized by calendar year. The worksheet must also describe the methodology used to set forth the overpayment (in a text box) and specifically address whether estimates were used and, if so, how they were calculated. This new formatting requirement, which is more detailed than what CMS has previously requested, will make it easier for CMS to verify the data provided by the disclosing party and therefore make it all the more important for the disclosing party to provide thorough and accurate data. The Financial Analysis Worksheet may also provide an opportunity for CMS to more easily use data mining or perform their own financial calculations as part of their settlement analysis.

PRACTICAL TAKEAWAYS

The new SRDP Form, while providing some administrative clarity for both disclosing providers and CMS, raises a number of concerns regarding the proper documentation and tracking of physician arrangements. In many ways, the new SRDP Form actually requires more factual background about each arrangement and how each arrangement connects with the provider's other physician contracts than was previously necessary. Legal counsel can play a key role in assessing what information must be provided and offer skilled guidance on how to best present this information in a self-disclosure.

Particularly, health care entities entering into arrangements with physician organizations should be careful to request sufficient information regarding the physician owners so as to enable the entity to properly consider the potential scope of disclosure in the event of noncompliance. Asking for this information at the onset of a relationship with a physician entity may avoid potentially tense discussions with the physicians in the event a self-disclosure is required. Further, all health care providers will want to keep thorough and accurate records of all financial relationships with physicians.

While use of the new SRDP Form is technically only mandatory for disclosures made under the SRDP on or after June 1, 2017, CMS has already begun asking for information on the pervasiveness of noncompliance and financial analyses on an individual physician basis when responding to current pending self-disclosures. As such, health care providers preparing to make (or that have recently made) a self-disclosure to CMS should be fully prepared to provide the information requested on the new SRDP Form. Because the information is not yet required and may not be sought by CMS in all cases, providers currently contemplating the submission of a self-disclosure under the SRDP may, however, want to expedite their investigation and complete their disclosure before June 1, 2017 to potentially avoid some of the additional burdens imposed by the new process.

As the new SRDP Form presents new requirements for factual analysis surrounding potentially problematic arrangements, and may impact a provider's self-disclosure strategy, we continue to recommend that providers who are considering a self-disclosure seek appropriate legal counsel. Further, there is no indication at this point that the new SRDP Form will affect the current backlog of self-disclosures at CMS or the

multiple year wait to resolve these self-disclosures.

If you would like assistance navigating the SRDP process, or if you have any other questions related to health care compliance, please contact:

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