

PUBLICATION

CMS Requests Comments on Proposed Changes to Stark Law Self-Referral Disclosure Protocol Forms

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On June 9, 2022, the Centers for Medicare and Medicaid Services (CMS) solicited comments to proposed changes to the Self-Referral Disclosure Protocol (SRDP) for physician practices disclosing group practice noncompliance. While the proposed changes would constitute a welcome streamlining of the SRDP process in a very limited context, there may well be opportunities to further enhance the efficiency of the SRDP process that warrant submitting comments to CMS.

The SRDP is a voluntary process by which providers may self-disclose actual or potential violations of the physician self-referral law (commonly referenced as the "Stark Law") resulting in prohibited referrals of designated health services (DHS) by physicians whose arrangements are non-compliant ("tainted referrals"). Medicare payments received by a provider for services provided pursuant to tainted referrals constitute an overpayment.

Upon identification of tainted referrals, providers may (1) refund the full amount of the Medicare overpayment to the applicable Medicare contractor; or (2) self-report to CMS under the SRDP and request that CMS compromise the amount of the Medicare overpayment. Failure to do either of the preceding within 60 days of the identification of the Medicare overpayment may lead to exposure under the False Claims Act and the imposition of substantial monetary penalties in excess of the Medicare overpayment. Over the years, the SRDP has been appropriately beneficial to providers in reducing any required repayments.

Current SRDP Process

The current SRDP process has been in place since 2017 and replaced what had typically become quite voluminous letters prepared by counsel with tighter, standardized forms.

Currently, the SRDP process requires submission of the following:

1. The SRDP disclosure form;
2. Physician information form(s) for each physician included in the disclosure;
3. A financial analysis worksheet; and
4. A certification signed by the disclosing party.

For non-compliant financial relationships involving *just one* physician, the current process is in many ways more user-friendly than the prior lengthy disclosure submissions under the predecessor SRDP. However, due to the application of "stand in the shoes" standard, any non-compliant financial relationship with a physician group with multiple owners has been viewed as a financial relationship with multiple physicians, requiring a separate physician information form for each owner.

The process of completing a form for each physician is duplicative and time-consuming in a practice where the non-compliance is groupwide, without material, if any, deviation at the individual-physician level. In instances where there are differentiating factors between physicians, the one-form-per-physician submission does not visually highlight such differences for CMS in larger groups with dozens or even hundreds of physician owners.

Moreover, the one-form-per-physician requirement can complicate the drafting, editing, and submission process.

The Benefits and Scope of the CMS Proposal

CMS has proposed that physician practices disclosing "group practice noncompliance" be permitted to submit a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice in lieu of submitting physician information forms for each such physician.

While this seems to be a helpful step in the right direction that would streamline the process for disclosing physician practices, a number of questions arise. First, CMS does not fully define "group practice noncompliance." Presumably, this would include any failed element of the [in-office ancillary services exception](#), rather than merely the related [definition of group practice](#), although confirmation from CMS would be useful. More importantly, even assuming a broad application of "group practice noncompliance," the proposal does not provide any relief for any other types of providers submitting self-disclosures (such as a relationship between a hospital and a multi-owner physician group). Rather, those disclosures would still be required to follow the cumbersome one-form-per-physician approach.

In addition to promoting accuracy and encouraging a smooth disclosure process for all providers, the decrease in paperwork should help expedite agency review and potentially help resolve the significant backlog of SRDP filings.

Takeaway

In an ideal world, providers would never have to concern themselves with the SRDP process, but to be in the best position possible should the need arise, providers should consider taking this opportunity to provide valuable insight and opinion on how to simplify this process for all involved parties through the comments process. Comments must be received by August 8, 2022, and may be submitted electronically at <http://www.regulations.gov> or by regular mail to CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: 0938-1106, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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