



CMS Updates FAQs Regarding Self-Referral Disclosure Protocol

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The Centers for Medicare & Medicaid Services (“CMS”) recently released updated responses to frequently asked questions (“FAQs”) regarding its voluntary Self-Referral Disclosure Protocol (“SRDP”). A copy of updated responses to the FAQs can be found [here](#).¹

The SRDP, implemented on September 23, 2010, sets forth a process that enables providers and suppliers to self-disclose actual or potential violations of the federal Stark physician self-referral law (42 U.S.C. § 1395nn). The updated responses to the FAQs provide further clarification for providers and suppliers on certain issues, including the supporting documentation required under the SRDP, change of ownership issues, contemporaneous disclosure issues, and the scope of the release available to parties settling through the SRDP. The updated responses also give providers and suppliers some insight into issues that have arisen under the SRDP since it was enacted in 2010.

1. FAQs on General Disclosure Issues

FAQ #1(a) addresses the question of whether CMS prefers a certain format for a disclosing party’s initial submission to the SRDP. In its response, CMS clarifies that there is no preferred format for submissions to the SRDP; rather, CMS accepts submissions under the SRDP that contain the required information, regardless of format. Nonetheless, CMS encourages disclosing parties to ensure that any electronic submissions are in a readable format such as Microsoft Word, Microsoft Excel, or PDF. CMS further informs potential disclosers that it does not intend to provide any examples or redacted copies of submissions to the public.

In addition, FAQ #1(b) addresses the questions of how much information a disclosing party should include in its SRDP submission and whether CMS requires the submission of compliance program documents, valuation opinions, and other supporting documents. While copies of compliance programs and other supporting documentation are not required to be submitted, CMS states that a disclosing party may include as much information as it deems necessary to show the “severity and extent of the noncompliant conduct and how the noncompliant was cured” or otherwise brought into compliance. Such information may include information regarding its compliance program, institutional history and mission, and compensation determinations that it believes CMS should be aware of when reviewing the disclosure and determining the appropriate reduction of the total amount due and owing to Medicare, if any. CMS also encourages disclosing parties to provide any additional information that it believes CMS should be aware of for settlement purposes, including any pending sale, financial hardship, and rural provider status. With that said though, CMS stresses that disclosing parties should remain brief in their explanations and yet still include all relevant supporting documentation. But, to the extent that a disclosing party submits complex financial or other information, it should also include a “sufficient explanation” of the relevance of such information. Lastly, disclosing parties should always remember that CMS still reserves the right to request additional documentation if necessary to facilitate its review of a disclosure.

In FAQ #1(c), CMS answers the question of what type of narrative and/or documentation,

¹ <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQsPhySelfRef.pdf>

if any, should a disclosing party include with a submission under the SRDP to demonstrate that the arrangement at issue in the disclosure is currently in compliance with the federal Stark physician self-referral law. In response, CMS reminds disclosing parties to provide CMS with “information sufficient to demonstrate that the disclosed noncompliant arrangement was terminated or otherwise brought into compliance” with the federal Stark physician self-referral law, including copies of relevant written contracts or other formal documentation.

2. FAQ on Scope of Release Provided to Disclosing Parties

In FAQ #1(d), CMS emphasizes that any release it issues under the SRDP is limited strictly to administrative liabilities and claims under Section 1877(g)(1) of the Social Security Act, which specifically relates to the denial of payment for “designated health services” provided in violation of the federal Stark physician self-referral law. According to CMS, settlements under the SRDP do not include a release of liability under any other laws or regulations, including the federal Anti-Kickback Statute or False Claims Act. Moreover, CMS cannot and will not issue a release from potential civil monetary penalties or exclusion for the knowing submission of claims for which payment is not permitted under the federal Stark physician self-referral law. Enforcement of these authorities is instead left to Department of Health & Human Services Office of Inspector General (“OIG”). CMS encourages disclosing parties seeking a release of liability under these other authorities to contact the appropriate law enforcement agency.

3. FAQs on Change of Ownership Issues

Given the increasing number of merger/acquisition transactions in the health care industry, a common issue arising with respect to providers is whether the appropriate disclosing party would be the seller or the purchaser. In FAQ #3(a), CMS confirms that the liability for overpayment refunds lies with the entity that is currently the party to the relevant Medicare provider agreement, regardless of when the noncompliance occurred. Therefore, the current party to the provider agreement will be the only party to receive a release from liability under the federal Stark physician self-referral law.

In FAQ #3(b), CMS also addressed the question of whether a purchaser of a provider that previously disclosed an actual or potential violation of the federal Stark physician self-referral law under the SRDP must resolve the disclosure under the SRDP. As one would expect, CMS emphatically stated “No.” Adding to this answer, CMS stated that, to the extent the purchaser accepts assignment of the Medicare provider agreement, the purchaser is liable for the overpayments related to the noncompliance under the federal Stark physician self-referral law as of the effective date of the change of ownership, including any noncompliance that occurred prior to the change of ownership. CMS reminds potential disclosing parties, again, that a party’s participation in the SRDP is entirely voluntary. As a result, the purchaser effectively has three choices: (1) resolve the disclosure under the SRDP, or (2) withdraw the disclosure if it determines that a violation of the federal Stark physician self-referral law did not occur, or (3) withdraw the disclosure and repay the full amount of the overpayment to Medicare. If the purchaser elects to withdraw the disclosure, it must have made a determination that a violation of the federal Stark physician self-referral law did not occur, or, if a violation did occur, repay the full amount of the overpayment to Medicare.

4. FAQs Related to Law Enforcement Interactions

In FAQs #4(a) and (b), CMS responds to questions concerning whether a disclosing party should inform CMS of a contemporaneous disclosure to the OIG of arrangements related to, or involving the same parties as, the SRDP disclosure. The SRDP specifically requires disclosing parties to include a statement identifying whether the disclosing party has a history of similar conduct, or has any prior criminal, civil, or regulatory enforcement actions (including payment suspensions) against it. In its response to FAQ #4(a), CMS informs disclosing parties to also notify CMS of a contemporaneous disclosure under the OIG’s Provider Self-Disclosure Protocol that involves an arrangement related to, or involving the same parties as, the SRDP disclosure. CMS also reminds potential disclosing parties that parties should not use the SRDP to disclose conduct that potentially violates both the federal Stark physician self-referral law and the federal Anti-Kickback Statute, as such conduct should be disclosed only

under the OIG's Provider Self-Disclosure Protocol. Participation in the SRDP is strictly limited to actual or potential violations of the federal Stark physician self-referral law.

5. Take Away

Parties considering a disclosure under the SRDP should understand that there are many issues that must be addressed in determining whether the disclosure of an arrangement or violation through the SRDP is appropriate. The determination of whether to make a voluntary disclosure under the SRDP requires careful and deliberate analysis of the risks and benefits involved. These FAQs, along with previous FAQs and additional guidance provided by CMS, should be thoughtfully analyzed and considered as providers and suppliers determine how to resolve potential or actual violations of the federal Stark physician self-referral law.

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