

# Centers for Medicare & Medicaid Services Voluntary Self-Referral Disclosure Protocol

## Frequently Asked Questions

The Centers for Medicare and Medicaid Services (CMS) Voluntary Self-Referral Disclosure Protocol (SRDP), implemented under the Affordable Care Act, is intended to facilitate the resolution of self-disclosed actual or potential violations of the physician self-referral law, section 1877 of the Social Security Act. The SRDP is available on CMS' Web Site.

The SRDP requires health care providers of services and suppliers to submit all information necessary for CMS to analyze the disclosed actual or potential violation of the physician self-referral law. To assist providers of services and suppliers to submit all information necessary and relevant to CMS' analysis, CMS published the following Frequently Asked Questions (FAQs) on the CMS.gov Frequently Asked Questions Web Site (<https://questions.cms.gov/>).

The FAQs are collected here for your convenience. Questions related to these FAQs or the SRDP, should be directed to the CMS Physician Self-Referral Call Center at (410) 786-4568.



### FAQ Topic Categories

- 1) **FAQs on General Disclosure Issues**
- 2) **FAQs related to the Required Financial Analysis**
- 3) **FAQs related to Change of Ownership Issues**
- 4) **FAQs related to Law Enforcement Interactions**



#### 1) **FAQs on General Disclosure Issues**

- a) **What is the preferred format for the initial submission to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP)? Are examples of acceptable submissions available to the public?**

There is no preferred format for submissions to the SRDP. CMS accepts submissions under the SRDP that contain the required information, regardless of the format. However, disclosing parties should ensure that electronic submissions are in a readable format, such as Microsoft Word, Microsoft Excel, or PDF.

At this time, CMS does not intend to provide examples or redacted copies of submissions to the public.

[Last Updated: September 30, 2013]

**b) When preparing a submission to CMS under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), how much information should a disclosing party include and does CMS require the submission of compliance program documents, valuation opinions, and other supporting documents?**

Section IV.B.1.a-h of the SRDP requests information related to the description of the actual or potential violation. 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 conduct was cured or the arrangement was otherwise brought into compliance with the law. The disclosing party may provide any additional information that it believes CMS should be aware of for settlement purposes, including pending sale, financial hardship, and rural provider status.

A disclosing party may include in its submission to the SRDP any 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. Disclosing parties are encouraged to be brief in their explanations and to include relevant supporting documents. However, a disclosing party's submission of complex financial or other information supporting its assertions or conclusions should include a sufficient explanation of relevance.

CMS does not require a disclosing party to submit copies of compliance programs, valuation opinions, or other supporting documents. However, CMS does request that disclosing parties submit copies of contracts used to bring a financial arrangement into compliance with the physician self-referral law, if applicable.

Disclosing parties should be aware that CMS may request additional documentation if necessary to facilitate CMS' review of a disclosure.

[Last Updated: September 30, 2013]

**c) What type of narrative and/or documentation, if any, should a disclosing party include with a submission under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) to demonstrate that the arrangement at issue in the disclosure is currently in compliance with the physician self-referral law?**

As indicated in section IV.B.1 of the SRDP, a disclosing party should provide to CMS information sufficient to demonstrate that the disclosed noncompliant arrangement was terminated or otherwise brought into compliance with the physician self-referral law. If formal documentation (such as a written contract) was necessary to bring a noncompliant arrangement into compliance with the physician self-referral law, then the disclosing party should submit that documentation.

Disclosing parties are reminded that CMS may require additional information or documentation to complete its review of disclosures under the SRDP.

[Last Updated: September 30, 2013]

**d) In a settlement under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), what is the scope of the release provide to disclosing parties?**

Under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), CMS may release the disclosing party from administrative liabilities and claims under section 1877(g)(1) of the Social Security Act (the Act). Settlements under the SRDP do not include releases for any other section of the Act, or other laws or regulations.

Sections 1877(g)(3) and (g)(4) of the Act are authorities of the Department of Health & Human Services Office of Inspector General (OIG). The OIG is not a signatory to settlement agreements entered into under the SRDP. Similarly, the Federal Anti-kickback Statute and the False Claims Act are authorities belonging to the OIG and the Department of Justice, respectively. Liability under those laws is not released under the SRDP. Disclosing parties seeking a release of liability under other authorities should contact the appropriate law enforcement agency.

[Last Updated: September 30, 2013]

**2) FAQs related to the Required Financial Analysis**

- a) On February 12, 2016, CMS published a final rule for the reporting and returning of overpayments (the “final overpayment rule”). See 81 FR 7653. The effective date for this rule was March 14, 2016. Among other things, the final overpayment rule established a 6-year lookback period for the reporting and returning of overpayments under regulations at 42 CFR 401.305(f). Before the final overpayment rule, CMS used the time frame established under the reopening regulations at 42 CFR 405.980(b) as a guide to determine the time frame of the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). As such, the time frame of the SRDP was limited to four years from the date that the disclosing party submitted the disclosure to the SRDP, unless reliable evidence of fraud or similar fault existed. How does the 6 year lookback period apply to disclosures submitted to the SRDP?**

Self-referral overpayments reported to CMS in accordance with the SRDP prior to March 14, 2016 are not governed by the 6-year lookback period specified in the final overpayment rule. This includes both overpayments reported and returned (via compromise and settlement) as well as those reported and still in the process of being reviewed through the SRDP. Providers and suppliers that reported self-referral overpayments to the SRDP prior to March 14, 2016 are not expected to return overpayments from the fifth and sixth years.

Providers and suppliers reporting overpayments to the SRDP on or after March 14, 2016 are subject to the 6-year lookback period specified in the final overpayment

rule. However, at this time, CMS is only authorized under the Paperwork Reduction Act to collect financial analysis of overpayments that occurred during a 4-year time frame. In connection with the final overpayment rule, we are seeking authorization from the Office of Management and Budget (OMB) to collect financial information regarding overpayments using the 6-year lookback period. Until the revised collection is approved by OMB, providers and suppliers reporting overpayments to CMS in accordance with the SRDP have no duty to provide financial information from the fifth and sixth years, that is, the 2 years outside of the currently authorized 4-year time frame. Accordingly, until notification of changes to the SRDP, providers and suppliers submitting to the SRDP may voluntarily provide financial information from the fifth and sixth years or report and return overpayments from the fifth and sixth years through other means.

[Last updated: March 16, 2016]

### 3) FAQs related to Change of Ownership Issues

**a) If a provider goes through a change of ownership, should the seller or the purchaser submit a disclosure under the CMS Voluntary Self-Referral Disclosure Protocol?**

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 correct party to disclose noncompliance with the physician self-referral law under the SRDP depends on whether the purchaser accepted assignment of the seller's Medicare provider agreement.

If the purchaser accepted assignment of the seller's Medicare provider agreement, the purchaser is liable for a Medicare overpayment (regardless of any contractual obligations of the seller and purchaser to the contrary) and is the correct party to submit a disclosure under the SRDP.

If the purchaser did not accept assignment of the seller's Medicare provider agreement, the seller is the correct party to submit a disclosure under the SRDP.

However, if the purchaser did not accept assignment of the seller's Medicare provider agreement, but the noncompliance continued after the change of ownership and the purchaser billed Medicare for designated health services provided under its Medicare provider number, the purchaser may also be in violation of the physician self-referral law and should consider whether a disclosure under the SRDP is appropriate.

[Last Updated: September 30, 2013]

**b) If a purchaser takes assignment of a Medicare provider agreement from a seller who disclosed actual or potential noncompliance with the physician self-referral law under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) before the change of ownership, must the purchaser resolve the disclosure under the**

## **SRDP?**

No. Beginning on the effective date of the change of ownership, the purchaser is liable for overpayments related to noncompliance with the physician self-referral law that occurred prior to the change in ownership because the purchaser took assignment of the Medicare provider agreement. However, a party's participation in the CMS Voluntary Self-Referral Disclosure Protocol is voluntary. The purchaser may decide whether to (1) resolve the disclosure under the SRDP, (2) withdraw the disclosure if it determines that a violation of the physician self-referral did not occur, or (3) withdraw the disclosure and repay the full amount of the overpayment to Medicare.

If the purchaser elects to resolve the disclosed conduct under the SRDP, the purchaser must certify to CMS that to the best of the purchaser's (or an authorized representative of the purchaser) knowledge, the information disclosed under SRDP is truthful, and is based on a good faith effort to bring the matter(s) disclosed to the attention of CMS for the purpose of resolving any potential liability under the physician self-referral law for the matters disclosed. The purchaser must also acknowledge that it took assignment of the relevant Medicare provider agreement from the seller and agree to substitute itself as the disclosing party under the SRDP in a good faith effort to resolve any potential liability under the physician self-referral law.

[Last Updated: September 30, 2013]

- c) Which party receives a release from section 1877(g)(1) of the Social Security Act if a purchaser takes assignment of a Medicare provider agreement from a seller that disclosed a violation of the physician self-referral law under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) before the change of ownership?**

Liability for an overpayment arising from noncompliance with the physician self-referral law lies with the entity that is the current party to the relevant Medicare provider agreement, regardless of when the noncompliance occurred. Therefore, only the entity that is a party to the relevant Medicare provider agreement at the time of settlement under the SRDP will receive a release of section 1877(g)(1) of the Social Security Act.

[Last Updated: September 30, 2013]

## **4) FAQs related to Law Enforcement Interactions**

- a) Under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), should a disclosing party inform CMS of a contemporaneous disclosure to the Department of Health & Human Services Office of Inspector General (OIG) of arrangements related to, or involving the same parties as, the SRDP disclosure?**

Yes. Under Section IV.B.1.e of the SRDP, disclosing parties should 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. Under this section of the disclosure, disclosing parties should inform CMS of a contemporaneous disclosure under the OIG's Provider Self-Disclosure Protocol (SDP) that involves arrangements related to, or involving the same parties as, the SRDP disclosure.

Disclosing parties are reminded to consult Section III (Cooperation with OIG and the Department of Justice (DOJ)) of the SRDP. In cases where the conduct implicates and potentially violates both the physician self-referral law and the Federal Anti-kickback Statute, the matter should be disclosed only to the OIG's SDP. The disclosing parties should not disclose the same conduct under both CMS' SRDP and the OIG's SDP.

For those parties that currently have corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with OIG, the parties should comply with any disclosure or reportable event requirements under such agreements and should disclose this information in their submission to CMS as instructed in Section IV.B.1.e of the SRDP.

[Last Updated: September 30, 2013]

- b) What procedures are in place to ensure that the government does not recover duplicate overpayments where a party discloses conduct under both the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) and the Department of Health & Human Services Office of Inspector General (OIG) Provider Self-Disclosure Protocol (SDP), and the violations involve the same parties but different arrangements covering the same time period?**

Disclosing parties should notify CMS of a disclosure under the OIG's SDP of related conduct to that disclosed under the SRDP. CMS will coordinate with OIG to appropriately resolve the disclosed conduct.

[Last Updated: September 30, 2013]