

CMS Publishes Stark Self-Disclosure Protocol

Healthcare Alert | 5 min read

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In compliance with the Patient Protection and Affordable Care Act (PPACA), the Centers for Medicare and Medicaid Services (CMS) on September 23, 2010, published its long-awaited “Self-Referral Disclosure Protocol” (SRDP) for providers of designated health services who wish to self-disclose actual or potential violations of the Physician Self-Referral Law (commonly known as the Stark Law). Section 6409 of PPACA required CMS to establish, within six months of the enactment of the Act, a self-disclosure protocol for health care providers to disclose actual or potential violations of the Stark Law. Exactly six months later, CMS published the protocol on its website and included direction to health care providers on how to self-disclose Stark Law violations.

Overview

The SRDP is open to all health care providers of services and supplies, and potentially enables health care providers to resolve liabilities for Stark Law violations through the Secretary of Health and Human Services’ authority to reduce the amount owed for such violations. While CMS indicated that it has no obligation to reduce any fees or penalties for Stark violations, it implied that it is open to resolve certain Stark violations for less than the maximum possible penalties for disclosures through the SRDP. Parties should note that the SRDP is completely separate from the CMS physician self-referral advisory opinion process and the Office of the Inspector General (OIG) Self-Disclosure Protocol. Submission to the SRDP is intended to facilitate the resolution of only actual or potential violations of the Stark Law.

CMS stated that upon its receipt of disclosures under the SRDP, it will review the circumstances and work closely with the disclosing party to reach “an effective and appropriate resolution.” One condition of the SRDP is that the disclosing party agrees that no appeal rights attach to any claims relating to the conduct disclosed, if such conduct is ultimately resolved through a settlement agreement with CMS. However, if a disclosing party withdraws or is removed from the SRDP by CMS, it would have the ability to appeal overpayment demand letters. CMS will work with other government agencies, including the OIG and U.S. Department of Justice (DOJ), if information relevant to those agencies arises in the course of the SRDP process. CMS retains the right to refer any disclosed information to appropriate law enforcement. Thus, CMS encourages disclosing parties to carefully consider their decision of where to refer a matter involving noncompliance with the Stark Law.

Disclosure Instructions

CMS set forth the instructions for the SRDP on its website. Any disclosing party is expected to submit information via e-mail and through hardcopy to the Division of Technical Payment Policy at CMS. The required information must include full identification of the disclosing party and its affiliations in any systems or networks, complete with descriptions and/or diagrams which explain the relationships with related entities and other departments involved in the actual or potential violation. A complete description of the nature of the disclosure must also be made, naming all parties involved, specific time periods within which the disclosing party might have been out of compliance with the Stark Law, and exactly what types of designated health services are at issue in the disclosure.

The disclosing party must identify specific elements and the applicable exceptions under the Stark regulations which were met by the disclosing party, as well as those elements that were not met. The disclosure must include a description of the potential causes for the violation, whether the disclosing party has a history of similar violations, and whether such previous acts have resulted in any criminal, civil or regulatory enforcement actions. Disclosing parties must describe the existence and adequacy of any pre-existing compliance programs and any efforts made to prevent a recurrence of the actual or potential Stark violation being disclosed. Parties must also certify that notices have been provided to other government agencies in connection with the disclosed matter and whether the disclosing party has knowledge that the matter is under inquiry by any other government agency or contractor. Finally, disclosing parties must conduct a complete financial analysis setting forth the total amount actually or potentially due based upon the applicable lookback period for the violation, describe the methodology used to compute this amount, and summarize the audit activities undertaken to complete such analysis.

CMS demands in the SRDP that all financial statements, disclosures and other supporting documentation requested must be provided without the assertion of privileges or limitations on the information produced and that additional information requested must be provided in a timely manner to facilitate cooperation with CMS.

The disclosing party's CEO, CFO or other authorized representative must certify to CMS that all disclosure information is true to the best of his or her knowledge and that the disclosure is made in good faith in order to bring the matter to CMS' attention for the purpose of resolving potential liabilities.

Review of Disclosure

After receiving a disclosing party's submission under the SRDP, CMS will begin a process to verify the information disclosed, during which time any matters uncovered will be considered outside the scope of the matters disclosed to CMS. Therefore, parties are encouraged to carefully self-analyze the organization's compliance with all applicable regulations, including those enforced by parties other than CMS to whom CMS may potentially refer non-Stark matters.

Upon completion of its review of any SRDP submission, CMS will formally notify the disclosing party and consider a reduced amount paid by the disclosing party to settle the matters disclosed. There is no commitment in the

SRDP for CMS to reduce any amount owed, and CMS instead defers such decision to a time after a complete analysis of facts and circumstances has taken place. Factors that CMS says it will consider include: the nature and extent of the improper illegal practice; the timeliness of the self-disclosure; the cooperation in providing additional information; the litigation of risk associated with the matter; and the disclosing party's financial position.

Parties considering disclosures under the SRDP are strongly encouraged to seek counsel familiar and experienced with the complicated maze of Stark law regulations and other government self-disclosure processes.

For more information, please contact your regular [Hinshaw attorney](#).

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