

Health Law Bulletin

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CMS ISSUES VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL FOR STARK VIOLATIONS

The federal health care reform legislation passed by Congress earlier this year included a provision requiring the Centers for Medicare and Medicaid Services (CMS) to issue a Voluntary Self-Referral Disclosure Protocol (SRDP) for the purpose of self-disclosure and resolution of potential or actual violations of the Physician Self-Referral Statute, better known as the Stark Law.

Previously, the Office of Inspector General would accept these disclosures of violations through its self-disclosure protocol; however, the OIG ceased accepting “Stark-only” disclosures last year.

A disclosure under the protocol must contain the following elements:

- Identification of the disclosing party.
- Description of the matter being disclosed.
- A statement why the disclosing party believes a violation may have occurred.
- The circumstances under which the disclosed matter was discovered and measures taken to address it.
- A statement identifying whether the disclosing party has a history of similar conduct.
- A description of the existence and adequacy of a pre-existing compliance program.
- A description of notices provided to other government agencies.
- An indication of whether the disclosing party has knowledge that the matter is under current inquiry by a government agency.
- The total amount actually or potentially owed.
- A description of the methodology used to calculate the amount owed.
- A summary of auditing activity undertaken.
- A certification by the disclosing party or an entity’s CEO or CFO that the information provided is truthful and based on a good faith effort to bring the matter to CMS’ attention for the purpose of resolving any potential liabilities.

Verification of the disclosure by CMS will depend on the thoroughness of the information submitted. CMS requires access to all financial statements and supporting documents. CMS even claims the ability in some cases to request written communication protected by the attorney-client privilege, subject to

discussion with the disclosing party's counsel, regarding ways to gain access to the information without waiving the protections of any privilege.

CMS expects cooperation from the disclosing party throughout the entire process. Failure to cooperate will be considered when CMS assesses the appropriate resolution of the matter.

CMS will consider several factors in reducing the amounts owed, including:

- The nature and extent of the illegal practice;
- The timeliness of the self-disclosure;
- The cooperation in providing information related to the disclosure;
- The litigation risk associated with the matter disclosed; and
- The financial position of the disclosing party.

The decision of whether to voluntarily disclose a potential or actual Stark violation involves many considerations. While the disclosure may relate only to Stark violations, CMS has said in the SDRP that, if warranted, they will also make a referral to the OIG or the U.S. Department of Justice. When the OIG gets involved, the possibility of greater penalties, exclusion from federal health care programs, and even imprisonment become possibilities. Because the decision to voluntarily disclose a Stark violation is one with such significant consequences, it should never be made without first consulting your attorney regarding the potential risks compared to the advantages of reduced financial risk from self-disclosure.