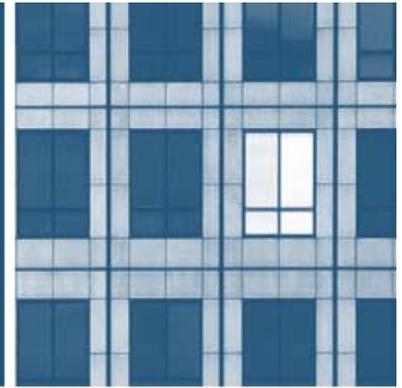


On the Subject



Health Industry Advisory

September 23, 2010

The U.S. Centers for Medicare & Medicaid Services posted its Medicare self-referral disclosure protocol describing how to disclose actual or potential violations of the Stark law and the associated Medicare overpayment.

CMS Posts Self-Referral Disclosure Protocol

As mandated by the Patient Protection and Affordable Care Act (ACA), on September 23, 2010, the U.S. Centers for Medicare & Medicaid Services (CMS) posted a Medicare self-referral disclosure protocol (SRDP) at https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf, which describes a process for providers and suppliers (Disclosing Parties) to disclose actual or potential violations of the physician self-referral or Stark law, and the associated actual or potential Medicare overpayment.

The SRDP does not include certain features the health care industry was hoping for. Notably, the protocol does not indicate circumstances in which CMS will accept less than the full amount of the Medicare overpayment and it does not distinguish between technical and substantive violations of the Stark law. In addition many providers may be surprised at the amount of financial and other information that CMS is requiring be disclosed. However, depending on how CMS exercises its discretion, the SRDP could still turn out to yield reasonable settlements of liability for “technical” Stark violations. Although it is expected CMS will wish to take an approach consistent with approaches that the Office of Inspector General (OIG) and the U.S. Department of Justice (DOJ) have taken in settling technical Stark violations, only time will tell whether the SRDP is the most sensible process for disclosing a technical Stark violation.

Summarized below are a few of the key provisions of the SRDP. Future McDermott newsletters will provide more detailed commentary regarding the SRDP.

No Guarantee the Medicare Overpayment Amount will be Reduced. CMS has the authority to reduce the amount due and owed as a result of a Stark violation, but is not obligated to resolve the actual or potential Stark violation in any particular manner. CMS will make an individual determination as to whether a reduction of the overpayment amount is appropriate based on the facts and circumstances of the disclosed violation.

Disclosure of Actual or Potential Medicare Overpayment Amount. The Disclosing Party is required to perform a financial analysis to determine the total amount, itemized by year, that is actually or potentially due and owing based upon the applicable “look-back” period.

Relevant Factors CMS May Consider in Reducing the Amount Owed. The factors that CMS may consider in reducing the amount otherwise owed include:

- The nature and extent of the improper or illegal conduct
- The timeliness of the self-disclosure
- Cooperation in providing additional information requested by CMS
- The litigation risk associated with the disclosed matter
- The financial position of the disclosing party

Overpayment Refund Obligation Suspended Pending Resolution. CMS emphasizes it is imperative that Disclosing Parties disclose Stark violations in a timely fashion once identified. Once a Disclosing Party receives confirmation from CMS that it has received the disclosure, the Disclosing Party’s obligation to refund Medicare overpayments (under Section 6402 of the ACA) within 60 days is suspended until a settlement is reached, the provider withdraws from the SRDP or CMS removes the provider from the SRDP.

Relationship to Other Federal Authorities. CMS will coordinate with the OIG and the DOJ, and may refer a disclosure to the OIG and DOJ for consideration under other federal authorities. CMS may also make a recommendation to the OIG and DOJ for resolution of False Claims Act, civil monetary penalty or other liability. It is not clear whether a settlement agreement with CMS of potential Medicare overpayment liability under the Stark law will release the Disclosing Party from potential liability under other federal authorities, in cases where the disclosure has not been referred to the OIG and DOJ.

SRDP Distinguishable from the Stark Advisory Opinion Process. The SRDP is not a vehicle for obtaining a determination by CMS that an actual or potential violation of the Stark law has occurred, and a Disclosing Party may not concurrently request a Stark advisory opinion regarding a financial arrangement that is the subject of a self-disclosure. CMS states that a Disclosing Party “should make a submission to the SRDP with the intention of resolving its overpayment liability exposure for the conduct it identified.” Accordingly, providers and suppliers may not wish to disclose *potential* Stark violations unless they are prepared either to make a full or reduced overpayment refund based on the violation, or to appeal a Medicare overpayment recoupment action by CMS based on the disclosure.

Submission Requirements. The disclosure must be submitted by email as well as by postal service and CMS will acknowledge receipt of the submission by email. CMS will notify the Disclosing Party or its designated representative by letter whether it has accepted or rejected the disclosure. The information that must be included in the disclosure includes:

- Identifying and contact information for the Disclosing Party and its designated representative
- A description of the nature of the matter being disclosed, including “the names of entities and individuals believed to be implicated and an explanation of their roles in the matter”

- A description of why the Disclosing Party believes a Stark violation may have occurred, including identification of the potentially applicable Stark exception(s), and identification of which elements of the exception(s) were met and which elements were not met
- A description of how the violation was discovered and the corrective action that was taken
- A description of the Disclosing Party’s pre-existing compliance program (its existence and adequacy), and efforts taken to prevent a reoccurrence of the violation

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