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CMS Publishes Voluntary Stark Law Disclosure Protocol

On September 23, 2010, the Centers for Medicare and Medicaid Services (CMS) published the Medicare Self-Referral Disclosure Protocol (Protocol), as required under the Patient Protection and Affordable Care Act (PPACA). The Protocol establishes a process for health care providers and suppliers to self-disclose actual or potential violations of the Stark Law.

Disclosure Under the Protocol

CMS confirms that the Protocol is limited to violations of the Stark Law only, and that the Office of Inspector General's (OIG) Self-Disclosure Protocol is available for disclosing conduct that violates other federal criminal, civil or administrative laws (e.g., the federal anti-kickback statute). Conduct that violates both the Stark Law and the federal anti-kickback statute should be disclosed through the OIG's Self-Disclosure Protocol and not through the Protocol. Furthermore, since CMS may use a disclosing party's submission to prepare a recommendation to the OIG or the Department of Justice for resolution of False Claims Act or other liability, health care providers and suppliers should make initial disclosure decisions carefully.

The Protocol includes detailed instructions and requires providers to submit extensive information. Unfortunately, although requested by the American Hospital Association and others in the industry, the Protocol does not provide for a bifurcated disclosure process—one that would treat complex disclosures differently than disclosures relating to more technical violations (e.g., a missing signature).

After reviewing an initial submission by a provider or supplier, CMS will inform the disclosing party whether CMS accepts or rejects the party's Protocol disclosure. Notably, while provisions of PPACA mandate a 60-day deadline for reporting and returning certain overpayments, such obligations will be suspended during the time period in which a party submits a disclosure under the Protocol. This suspension will continue until a settlement agreement is entered, the provider or supplier withdraws from the Protocol, or CMS removes the disclosing party from the Protocol.

CMS Verification of the Disclosure Information

CMS will verify the information submitted by providers under the Protocol. Providers should be aware that "matters uncovered during the verification process, which are outside the scope of the matter disclosed ... may be treated as new matters outside the [Protocol]."

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CMS also advises that to facilitate the verification process, it must have access “to all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations on the information produced.” In the normal course of verification, CMS will not request production of attorney-client communications. CMS advises, however, that documents that might be protected by a “work product” privilege may be critical to resolving the disclosure and thus may be requested.

Payments

CMS will not accept payments of presumed overpayments determined by the disclosing party prior to the completion of CMS’ evaluation of the submission. While CMS reviews the Protocol submission, the disclosing party may not make any payment relating to the disclosed matter to the Federal health care programs or their contractors without CMS’ prior consent. CMS cautions that if such consent is obtained, the disclosing party must acknowledge in writing that the acceptance of the payment does not constitute the Government’s agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not relieve the disclosing party of any criminal, civil, or civil monetary penalty liability, nor does it offer a defense to any further administrative, civil or criminal actions against the disclosing party. Under the Stark Law, a provider or supplier cannot bill an individual or entity for any designated health service performed pursuant to a prohibited referral. CMS also reminds providers and suppliers that the Stark Law provides that any amounts collected from individuals that were billed in violation of the Stark Law must be refunded to such individuals on a timely basis. It is not clear how CMS will treat refund obligations under the Protocol.

Reducing the Amounts Owed For Stark Law Violations

Under PPACA, the Secretary of Health and Human Services has authority to reduce the amount due and owing for Stark Law violations. CMS notes, however, that it has “no obligation” to reduce any amounts due. CMS will consider the facts and circumstances of each Protocol disclosure to determine the severity of the Stark Law violation and to reach the appropriate resolution. CMS may consider the following factors in reducing amounts otherwise owed: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party. It is unclear how CMS would apply these factors to any particular circumstance. One of the concerns of providers is the sense of disproportion between the nature of the violation and the potential damages that could result. Hopefully, this will be taken into account by CMS in applying the Protocol.

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Action Steps

Providers and suppliers considering a self-disclosure under the Protocol should PROCEED WITH CAUTION and take the following action steps:

1. Read the Protocol in its entirety. To view the Protocol, [click here](#) or visit http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf
2. Conduct a thorough self-investigation and analysis of the potential Stark Law violation
3. Analyze whether any other federal laws are implicated by the conduct in question and determine where the disclosure should be made
4. Carefully weigh the risks and benefits of participating in the Protocol

For more information regarding the Protocol, or for assistance with any of the action steps identified above or preparing a disclosure under the Protocol, please contact any member of the Honigman Health Care Department.

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