

HEALTH REFORM IMPACT

What you need to know NOW

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Self-Disclosure Revival

April 26, 2010

The newly enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "Health Reform Legislation"), requires the establishment of a statutory self-disclosure protocol¹ ("Stark Self-Disclosure Protocol") allowing healthcare providers and suppliers to self-disclose violations of the federal physician self-referral law known as the Stark Law.² This provision responds to concerns expressed by healthcare providers following the elimination last year by the Office of Inspector General of the Department of Health and Human Services ("OIG") of the ability to self-disclose Stark-only violations to the OIG.

Before this action by the OIG, which was published in an Open Letter to Health Care Providers dated March 24, 2009 (the "2009 Open Letter"), healthcare providers could voluntarily disclose evidence of potential fraud and abuse, including both Stark and federal anti-kickback violations, to the OIG. However, in the 2009 Open Letter, the OIG said it would no longer accept self-disclosure of matters involving liability under the Stark Law unless the improper arrangement also included evidence of a "colorable" violation of the federal anti-kickback statute. The OIG noted that the decision to narrow the scope of the Self-Disclosure Protocol was being made for "resource purposes" so as to reduce the overall number of disclosures submitted to the agency, and to allow the agency to prioritize and allocate work in a more efficient manner.

The 2009 Open Letter left providers with few options for self-reporting Stark violations. Under the Health Reform Legislation, providers now will have the ability to self-disclose actual or potential Stark-only violations. The Stark Self-Disclosure Protocol must be established within the next six months by the Secretary of Health and Human Services ("HHS") in cooperation with the OIG. The protocol will include the designation of a person, official or office to whom the disclosures shall be made, as well as instructions on the implications of the protocol on corporate integrity agreements and corporate compliance agreements.

¹ Pub. L. No. 111-148, Section 6409 of the Health Reform Legislation.

² If a physician, or an immediate family member of a physician, has a financial relationship with an entity that furnishes designated health services ("DHS") payable by Medicare or Medicaid, the Stark Law prohibits the physician from referring patients to the entity, and the entity from submitting a claim for payment, for such DHS unless an exception applies. 42 U.S.C. § 1395nn(a)(1). Penalties for Stark Law violations may include denial of payment to the DHS entity, civil money penalties of up to \$15,000 per prohibited referral, up to \$100,000 for a circumvention scheme, exclusion from Medicare, recoupment of amounts paid pursuant to each prohibited referral, and potential federal and state False Claims Act liability.

Significantly, the Health Reform Legislation also provides HHS with the authority to resolve Stark violations and to reduce the amount owed for a violation. In determining the appropriate penalty for a violation, the Secretary of HHS may consider the nature and extent of the violation, the timeliness of the disclosure, the amount of cooperation in providing additional information, and such other factors as the Secretary considers appropriate. This provision of the Health Reform Legislation potentially opens the door to settlements based on the amount of improper remuneration paid to a physician and not on the amount of the “tainted” claims submitted by the DHS entity as a result of referrals to that physician.

The Secretary of HHS will post information on the Centers for Medicare & Medicaid Services’ Website to inform stakeholders how to disclose actual or potential violations pursuant to the self-disclosure protocol. Although self-reporting will not likely absolve a reporting provider from all penalties, the OIG previously has indicated that voluntary disclosures under a self-disclosure protocol may mitigate the severity of penalties and avoid the costs and disruptions of a full-scale audit and investigation by the federal government.

Accordingly, healthcare providers should carefully consider their options in deciding whether and how to use the Stark Self-Disclosure Protocol to self-disclose violations. If you have any questions about the self-disclosure protocol or other matters discussed in this issue of *Health Reform IMPACT*, please do not hesitate to contact any of the attorneys in our Healthcare Practice Group listed below.

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