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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Understanding CMS Self-Referral Disclosure Protocol

Law360, New York (October 15, 2010) -- On Sept. 23, 2010, the Centers for Medicare and Medicaid Services (CMS) issued its Voluntary Self-Referral Disclosure Protocol (SRDP), under which health care providers may report actual or potential violations of the federal Stark law (42 U.S.C. § 1395nn).

The CMS's actions came in response to Section 6409 of the Patient Protection and Affordable Care Act of 2010 (PPACA), which required it to issue a disclosure protocol by that date. However, while the CMS has met the congressional mandate, it has offered no assurances to health care providers that it will be flexible in its approach to settling matters contained in such disclosures.

The Stark penalties that the CMS may impose under its jurisdiction include an obligation upon the provider to refund, on a timely basis, all payments received for designated health services that were performed pursuant to a prohibited referral. See 42 U.S.C. § 1395nn(g)(2); 42 CFR § 411.353(d).

CMS has defined "timely basis" as meaning within 60 days from the date such payments were collected. See 42 CFR § 1003.101. (This 60-day deadline has been reinforced under Section 6402 of PPACA, which established a deadline for reporting and returning overpayments of any nature by 60 days after the date the overpayment was "identified" (or, if later, the date any corresponding cost report is due).)

As such, Stark penalties even for minor Stark violations can be very substantial. For example, where a referring physician admits numerous inpatients to a hospital during the time period that is "tainted" by the Stark violation, the payments the hospital receives for its services, and hence the applicable Stark damages, can total in the tens of millions of dollars.

In many instances, these penalties may dwarf the amount of the improper benefit conferred upon the referring physician (i.e., the benefit that formed the basis for the Stark violation).

Furthermore, many Stark violations arise out of situations where no benefit whatsoever is conferred upon the physician, such as in the case of personal service or lease arrangements that the parties have failed to reduce to a signed written agreement, but which otherwise are consistent with fair market value and comply with all other legal requirements.

Unfortunately, although Congress expressly authorized CMS to reduce the amount of the Stark penalty, CMS states in the SRDP "that it has no obligation to reduce any amounts due and owing." PPACA lists three specific factors that CMS may consider in reducing the amounts otherwise owed: 1) the nature and extent of the improper or illegal practice; 2) the timeliness of the self-disclosure; and 3) the cooperation in providing additional information related to the disclosure.

In its protocol, CMS lists two additional factors that it will consider: 1) the "litigation risk associated with the matter disclosed" (presumably, this means the risk that the government would not prevail in an actual Stark action brought against the provider), and 2) the disclosing party's financial position.

Rather than providing any guidance as to the dollar amount of settlements it may seek in particular types of Stark violations, CMS merely indicated that it will "make an individual determination as to whether a reduction is appropriate based on the facts and circumstances of each disclosed actual or potential violation."

CMS explained that, given the variability of the nature and circumstances of different violations, it will need to evaluate each matter to determine an appropriate resolution.

CMS's position is in striking contrast to the self-disclosure protocol (SDP) that the Office of the Inspector General (OIG) has had in place for Stark and federal Anti-Kickback Statute violations since 1998. In its "Open Letter" dated April 24, 2006, which focused particularly on self-disclosures by hospitals, the OIG announced that, "subject to the facts and circumstances of the case, OIG will generally settle SDP matters for ... a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s)."

In its subsequent open letter dated April 15, 2008, OIG stated that it "committed to settling liability ... generally for a multiplier of the value of the financial benefit conferred." (The OIG more recently imposed a $50,000 minimum settlement amount, in its March 24, 2009 open letter.)

As noted above, the amount of the improper benefit conferred upon the referring physician will, in many cases, be considerably less than the Stark penalties (i.e., refund of all "tainted" payments). Furthermore, the improper benefit amount appears to be a far more equitable basis upon which to base a settlement, as it tends to reflect the gravity of the underlying violation.

The amount of the tainted payments, on the other hand, will often bear no relation whatsoever to the seriousness of the violation itself. Nonetheless, not only has CMS declined to adopt the OIG's approach, its protocol fails even to mention it as a possibility.

It is also notable that CMS has declined to address any separate standards that it might apply to purely "technical" Stark violations, such as failure to reduce an otherwise fully compliant arrangement to a signed, written agreement.

CMS's silence regarding technical violations comes in spite of recommendations from the provider community that such violations be treated in a lenient manner. For instance, the American Hospital Association, in its July 16, 2010 letter to HHS Secretary Kathleen Sebelius, had advocated that CMS implement an expedited review process and a stipulated, modest penalty amount for technical violations.

CMS's protocol, however, makes no distinction at all between technical violations and more serious violations, such as those involving arrangements where physicians may be unjustly enriched, and where their medical judgment may potentially be influenced by improper considerations.

Types of Disclosures CMS Will Accept

Although it is unclear how CMS will go about determining penalty amounts for Stark violations brought to it under the SRDP, it is clear that CMS will accept only those disclosures that are limited to Stark issues. CMS's protocol states that issues that may raise liability risks under the Anti-Kickback Statute in addition to Stark should be disclosed through the OIG's SDP, and that parties should not disclose the same conduct to both CMS and OIG.

Therefore, a provider will need to assess whether the conduct in question could be viewed as an Anti-Kickback Statute violation, in which event it will need to disclose to OIG rather than CMS.

Given the OIG's clear guidance and relatively reasonable approach as to penalty determination, many providers may find that, given a choice, they would rather deal with OIG than CMS on self-disclosures. However, this may not always be possible, depending on the particular facts of the arrangement in question.

In all cases, providers would do well to heed the statement in CMS's protocol that "the disclosing party's initial decision of where to refer a [Stark] matter should be made carefully."

--By Lawrence C. Conn, Foley & Lardner LLP

Larry Conn (lconn@foley.com) is special counsel at Foley & Lardner LLP and a member of the firm's health care industry team.

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