Paul Hastings
StayCurrent
A Client Alert from Paul Hastings
October 2010

CMS' New Self-Referral Disclosure Protocol

BY PAUL A. GOMEZ

As required by Section 6409 of the Affordable Care Act of 2010 (the "ACA," also popularly known as healthcare reform legislation), CMS issued its new Self-Referral ("Stark Law") Disclosure Protocol (the "SRDP") on September 23, 2010. The new SRDP is viewed by many providers and suppliers in the healthcare sector as a welcome development, particularly in light of the pronouncement by the Department of Health and Human Services (the "Department") Office of Inspector General ("OIG") in its Open Letter to Health Care Providers date March 24, 2009, that the existing OIG Self-Disclosure Protocol ("SDP") would no longer accept disclosures pertaining solely to Stark Law violations (potential or actual). As a result of this, and many other reasons discussed below, additional guidance was needed from CMS to understand how healthcare providers and suppliers should proceed when faced with actual or potential Stark Law violations.

The SRDP

The SRDP is open to all healthcare providers and suppliers and is not limited to any particular healthcare industry, item or type of service. It is to be used only for matters that a disclosing party has reasonably determined is an actual or potential violation of the Stark Law. CMS makes plain that the SRDP cannot be used to obtain a determination from CMS as to whether an actual violation of the Stark Law has occurred.

CMS may consider the following factors in determining whether and by how much to reduce amounts otherwise owed:

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

In addition to the above, the disclosing party must agree that there will be no appeal rights with respect to any claims related to the conduct disclosed if resolved through the SRDP. However, if the disclosing party withdraws or is removed from the SRDP, that party may still appeal any overpayment demand letter it may receive per the usual appeal rules and regulations.

What Must Be Disclosed?

The SRDP is relatively specific in terms of where a disclosure must be made, how it must be made, and what the content of the disclosure must contain. For instance, the SRDP requires that disclosures be made electronically. CMS will subsequently issue a letter either accepting or rejecting the disclosure.

A detailed, careful review of the SRDP itself, which is beyond the scope of this Alert, is required in order to ensure compliance with all material requirements. Nevertheless, the disclosure requirements can be broken into two principal categories: 1) Description and analysis of the Stark Law violation; and 2) Financial analysis of the amount at issue.

For example, the description and analysis of the actual or potential violation of the Stark Law must include a description of the financial relationships and parties involved, the specific time periods in which the disclosing party was or may have been out of compliance and the types of designated health services at issue. Importantly, it must also contain a statement from the disclosing party about why it believes that a Stark Law violation occurred (or may have occurred), a complete legal analysis of the application of the Stark Law to the conduct being disclosed, and it must address measures taken to handle the disclosed issue. This last point, particularly with regard to the required legal analysis, must be handled with great care.

In addition to the above, the financial analysis must include an analysis of the total amount that is owed (or potentially owed) in connection with the disclosed conduct for the "look back" period during which the disclosing party was out of compliance. A description of the method used to calculate the amount due must also be included.

Disclosure Incentives

The following is a summary list of some of the principal incentives for healthcare providers and suppliers to consider whether to use the SRDP in appropriate circumstances:

- According to CMS, it will work closely with a disclosing party that structures its disclosure in accordance with the SRDP to reach an effective and appropriate resolution;
- Per Section 6409(b) of the ACA, the Department Secretary has been granted authority to reduce amounts owed for violations of the Stark Law (the Department has previously taken the position that it did not have such authority before), upon consideration of certain factors – this could be particularly useful in the context of so-called "technical violations" of the Stark Law;
- When a healthcare provider or supplier discloses under the SRDP and receives an electronic confirmation of receipt, CMS will suspend the obligation of the healthcare provider or supplier to return the potential overpayment due (Section 6402 of the ACA);
- The fact that a disclosing party is already subject to a government inquiry will not automatically preclude a disclosure pursuant to the SRDP, but particular care must be taken in deciding whether and how to make a disclosure in such instances;

- If a disclosing party withdraws or is removed by CMS from the SRDP process, the party will maintain its rights to appeal any overpayment demand letter; and

Although not expressly stated, presumably CMS, by issuing this SRDP, intends to make the process worthwhile (in appropriate circumstances) for the majority of healthcare providers or suppliers in order for the SRDP to truly serve as an incentive for parties to disclose pursuant to the SRDP.

Disclosure Concerns

An important distinction between the SRDP and the SDP is that the SRDP notably contains no general pledge of leniency, as the SDP did. However, as noted above, one would presume that CMS would work in good faith to resolve potential or actual Stark Law liabilities on the lesser side of the spectrum, where appropriate. Some additional causes for concern and caution in considering whether to use the SRDP follow below:

- CMS expressly states that it is not bound by any conclusions of the disclosing party and is not obligated to resolve any matter in any particular manner;

- Upon review of the disclosure, CMS will coordinate with the OIG and the U.S. Department of Justice ("DOJ") and may decide to refer a matter to law enforcement depending upon the nature of the disclosed conduct. As a result, the decision about which agency to initially disclose a given matter to remains one that must be subject to careful consideration;

- It is possible that, during CMS' verification of the disclosed conduct, new compliance matters may be uncovered (such matters will be treated as new matters, and not covered under the previous disclosure); and

- If CMS determines that a disclosing party is not working in good faith with CMS to resolve the disclosed matter, that factor will be considered when CMS determines an appropriate resolution of the matter.

Certain Open Questions Answered

The following previously open questions appear to have been answered, at least partly, by the SRDP:

- According to the SRDP, disclosure pursuant to same will suspend any potential repayment of an overpayment obligation under Section 6402 of the ACA;

- CMS instructs that matters that may involve both Stark Law violations and liability under the federal Civil Monetary Penalty Law and Anti-kickback Statute should be disclosed under the SDP and that the same conduct should not be disclosed under both the SRDP and the SDP.

- If a disclosing party has a Corporate Integrity Agreement or a Certificate of Compliance Agreement in effect, it should continue to comply with any disclosure or reportable event requirement pursuant to same. However, conduct related solely to a potential or actual Stark Law violation should be disclosed (if it is determined to disclose) according to the SRDP, with a copy sent to the disclosing party's OIG monitor.

Take Away

The new SRDP appears, on balance, to be a positive step and welcome development for healthcare providers and suppliers. It may be particularly useful to resolving so-called "technical violations" of the Stark Law in a more equitable and favorable manner to healthcare providers and suppliers than may have been the case previously. The factors described above that CMS may consider may also prove helpful to many healthcare providers and suppliers facing potential Stark Law liability. Moreover, suspending an otherwise applicable 60-day repayment requirement under Section 6402 of the ACA will also prove helpful while a disclosing party attempts to work out an equitable resolution of a potential or actual Stark law violation in good faith with CMS. Nevertheless, CMS makes clear that it is not bound to reach any particular resolution of the disclosed issues, it is not obligated to consider any of the factors described above and it is possible that a disclosure could result in CMS referring the matter over to the OIG and/or the DOJ for further action, as appropriate. As a result, healthcare providers and suppliers will still need to take great care in determining whether it makes sense to avail oneself of the new SRDP on a case-by-case basis.

✧ ✧ ✧

If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:

Paul A. Gomez
213-683-6132
paulgomez@paulhastings.com