PUBLICATION

CMS Announces Plans to Streamline the Stark Self-Referral Disclosure Protocol [Ober|Kaler]

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On May 6, 2016, CMS published a notice [PDF] (Notice), required under the Paperwork Reduction Act (PRA), seeking public comment on its plans to revise the information collected under the Medicare Self-referral Disclosure Protocol (SRDP).

CMS indicated that it plans to require the submission of data on overpayments for the entire 6-year lookback period required by CMS's recent, final 60-day overpayment rule. In addition, CMS announced an effort to streamline and simplify the SRDP through the required use of a **new series of forms [PDF]** for all SRDP submissions. Comments on these planned revisions are due **July 5, 2016**.

A summary of the planned revisions to the information collection process under the SRDP, along with key takeaways, is provided below.

Revised Lookback Period

Pursuant to CMS's final 60-day overpayment rule, providers and suppliers reporting and returning overpayments as of March 14, 2016, are subject to a 6-year lookback period. This change was applied to Stark violations reported through the SRDP.

Due to limitations imposed by the PRA, however, CMS is currently prohibited from requiring the submission of overpayment data for the entire 6-year lookback period and remains limited to a 4-year lookback period as provided in its previously approved information collection process. Despite this prohibition, CMS encourages providers and suppliers to voluntarily provide the full six years' worth of overpayment data, warning that disclosing parties could otherwise face two years of unresolved overpayment liability.

The May 6th Notice starts the formal approval process to allow CMS to require the submission of overpayment data for the entire 6-year lookback period. Under the PRA, CMS is required to publish notice of its intent to collect the additional information. The public is given 60 days to comment. The Office of Management and Budget must then issue final approval of the change. In the interim, providers and suppliers making disclosures through the SRDP as of March 14, 2016, are well advised to provide CMS with overpayment data for the entire 6-year lookback period.

New SRDP Form

CMS is also planning to require the use of a new series of forms for all SRDP submissions. The new forms are intended to streamline and simplify the SRDP submission process. In particular, CMS indicated in its Notice that this new process will "reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and provid[e] a streamlined and standardized format for the presentation of the required information."

As outlined below, the new process involves three forms:

- *SRDP Disclosure Form*: This form will address: (a) information about the disclosing party, e.g., legal business name, CMS Certification Number, NPI, etc.; (b) contact information for the designated representative; (c) the pervasiveness of the noncompliance, including a quantification of the frequency of the disclosed noncompliance as compared to similar financial relationships between the disclosing party and physician(s); and (d) whether the disclosing party knows if the disclosed conduct is under current inquiry by the government, if the disclosing party has a history of similar conduct, and if any corrective action has been taken by the disclosing party.
- Physician Information Form: A separate form will be required for each physician whose referrals are
 addressed in the self-disclosure. On the form, disclosing parties will provide identifying information
 (e.g., name, NPI, physician organization, if applicable, etc.). Disclosing parties will also be required to
 answer questions, in checkbox form, related to whether the noncompliant arrangement at issue arose
 due to a compensation and/or ownership interest with the applicable physician, and if a disclosed
 noncompliant arrangement was the result of a physician standing in the shoes of his or her physician
 organization. In addition, the disclosing parties must provide details on the noncompliant ownership
 or compensation arrangement, address why the financial relationship failed to comply with the Stark
 law, describe how the financial relationship was brought back into compliance or otherwise
 terminated, and identify the relevant period of noncompliance and date of discovery.
- *Financial Analysis Worksheet:* The financial analysis of the potential overpayment (based on the 6year lookback period) will be required to be submitted in Excel-compatible format. For each physician included in the disclosure, the worksheet must include the physician's name, NPI, the date that the overpayment associated with the physician was identified, and the overpayment arising from the physician's prohibited referrals, itemized by calendar year. The worksheet must also describe the methodology used to set forth the overpayment, and specifically address whether estimates were used. Unless otherwise requested by CMS, disclosing parties are not required to report the amount of remuneration between the parties.

To the extent a disclosing party believes additional information not captured in the required forms may be relevant to CMS's evaluation of the self-disclosure, a disclosing party may submit an optional cover letter.

Of note, the factors CMS may consider in reducing the amount otherwise owed by a disclosing party remain unchanged. Such factors continue to be limited to: (a) the nature and extent of the improper or illegal practice; (b) the timeliness of the self-disclosure; and (c) cooperation in providing additional information related to the self-disclosure.

Ober|Kaler's Comments

Providers and suppliers reporting overpayments to the SRDP on or after March 14, 2016, are already subject to the 6-year lookback period specified in the final 60-day overpayment rule. Therefore, providers and suppliers making disclosures through the SRDP on a going forward basis are well-advised to provide CMS with overpayment data for the entire 6-year lookback period. Failing to provide complete overpayment data could leave providers and suppliers at risk for the unreported overpayments in years 5 and 6.

The plan to require the use of a series of forms to gather the information needed under the SRDP reflects a desire by CMS to standardize and streamline the SRDP. Accordingly, this approach should not only reduce time and effort on the part of the disclosing party, but also should hopefully improve the efficiency of CMS's review process.

The new SRDP process seems to reflect a new emphasis on quantifying the pervasiveness of the noncompliance at issue and a de-emphasis on the role of physician remuneration data. That said, and while

CMS is no longer requesting physician remuneration data, disclosing parties still may want to include this information in trying to convey the nature and extent of the improper or illegal practice at issue in the disclosure.

Another important aspect of these changes to the SRDP is the requirement that the disclosing parties specifically identify when an overpayment was "identified." Presumably, one would rely on the final 60-day overpayment rule's definition of *identified*. The distinction between when an overpayment is identified compared to when it is disclosed can have important implications under the final 60-day overpayment rule.

Until finalized, providers and suppliers utilizing the SRDP will want to review the new process and forms as a means to inform the drafting of current CMS self-disclosures.