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Practical considerations: A guide to voluntary self-disclosure

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Enforcement by federal agencies is on the rise, and chief among the new enforcement mechanisms is the amendment to the False Claims Act by the Affordable Care Act (ACA). The ACA requires, among other things, that all providers and suppliers of services, Medicaid managed care organizations, Medicare Advantage organizations, and prescription drug plans to report and return overpayments to the appropriate state or federal agency or government contractor. Specifically, an organization must report and return the overpayment by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due.

This amendment imposes an affirmative obligation on organizations to first, track and identify any overpayments, and then report and return the funds to the appropriate party. To address this requirement, organizations are conducting more audits across all business lines, and Compliance departments are investigating related issues with more regularity. As a result, organizations are finding that their compliance programs are more effective at not only identifying overpayments, but also at identifying the source of such overpayments, which in some cases may be an actual or potential violation of the physician self-referral law (the Stark Law) or the Anti-kickback Statute (AKS).

In cases where a compliance investigation has uncovered an actual or potential violation of the law, the organization must decide the best course of action for reporting and returning the overpayment and disclosing the actual or potential violation of law. There are a number of disclosure mechanisms that an organization may consider. Included among them is a disclosure to the Department of Justice or repaying the alleged overpayment to the Medicare or Medicaid Administrative Contractor. In addition, an organization may decide to make a voluntary self-disclosure to either the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) or to the Centers for Medicare and Medicaid Services (CMS). Depending on the circumstances, a voluntary self-disclosure may give the provider an opportunity to mitigate the potential costs associated with a government investigation. Moreover, voluntary self-disclosures allow providers to preemptively disclose an issue, negotiate a settlement, and possibly avoid exclusion from the federal health care programs or the execution of a Corporate Integrity Agreement with the OIG.

This article will address the OIG's and CMS's voluntary self-disclosure protocols (SDPs) for providers to disclose actual or potential violations of law. We will discuss the history of both the OIG and CMS SDPs, what to expect once an organization commits to submitting a self-disclosure to OIG and CMS, and considerations that every organization's Compliance department should reflect on when contemplating self-disclosure.

History of SDPs

The OIG's Provider Self-Disclosure Protocol (OIG SDP) was established in 1998 as a result of the Operational Restore Trust initiative pilot program and informal work with providers and suppliers.

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Historically, the OIG SDP was intended for matters that actually or potentially violated a federal criminal, civil, or administrative law. In 2006, through an Open Letter to Health Care Providers, OIG encouraged the use of the OIG SDP to resolve civil monetary penalty liability under the Stark Law or AKS. Since 2006, OIG has issued two additional Open Letters regarding the OIG SDP. In 2008, in addition to setting forth items that must be included in the initial submission, OIG reemphasized that the OIG SDP requires that only those matters that implicate potential fraud against federal health care programs be disclosed, as opposed to mere overpayments.

Finally, in 2009, OIG announced that it was narrowing the OIG SDP to no longer accept disclosures that were solely related to liability under the Stark Law. OIG emphasized that it would continue to accept disclosures that involved a colorable violation of the AKS, whether or not it included violations of the Stark Law. In addition, in the 2009 Open Letter, OIG set forth a minimum settlement amount requirement of $50,000 to resolve anti-kickback liability, although at the same time, OIG reemphasized its commitment to resolving matters toward the lower end of the damages continuum.

Although OIG announced in 2009 that it would no longer accept disclosures related solely to potential Stark Law violations, it was not until the enactment of the ACA that HHS was required to establish a self-referral disclosure protocol (CMS SRDP). This mandate came on the heels of a combined effort by government agencies and the health care community to lobby Congress to take action in requiring CMS to develop a Stark Law self-disclosure protocol. In response to the ACA mandate, the CMS SRDP was posted on September 23, 2010.

Basic steps of the SDPs

Once an organization has committed to submitting a good faith voluntary self-disclosure pursuant to either the OIG or CMS SDPs, the submission and subsequent interactions with the government must contemplate the various components of the specific SDP. Organizations should be cognizant of the fact that both OIG and CMS have discretion whether or not to accept a provider into the SDP. It is critical to reflect on the elements of the SDP and strategically craft a submission that addresses each component of the SDP in order to maximize the chance of admission into the protocol and success thereafter. However, it is also important to strategically convey information and advocate a position vis-à-vis the facts underlying the disclosed matter. Based on the content of the written submission, OIG or CMS will decide whether the matter is ripe for resolution through the SDP. A disclosing party may not make simultaneous disclosures to CMS and OIG regarding the same conduct.

Each SDP sets forth the specific information to be included in the disclosure that is submitted but, overall, both SDPs require similar information. However, there are a few significant differences in the requirement elements between the OIG SDP and the CMS SRDP (see table 1 on page 31).

OIG SDP

Once a provider has decided to make a disclosure to OIG, they must begin the preparation of the written submission. In addition to including basic information on the provider (e.g., National Provider Identifier, Tax Identification Number) and any other relevant parties, the submission should address the background on how the organization became aware of the matter and what, if any, internal investigation the organization has undertaken. The internal investigation and self-assessment may occur after the initial disclosure of the matter; however, in order to resolve a disclosed matter with the OIG, a comprehensive self-assessment must be completed and reported pursuant to the guidelines outlined in the SDP. OIG will generally agree to allow the organization to conduct the internal investigation

independently, without OIG involvement or oversight.

The complexity of the issues involved in the disclosure will dictate whether an organization should complete the internal investigation and self-assessment prior to submitting the self-disclosure. Regardless, prior to making the initial submission, it is prudent for an organization to begin (if not complete) a formal investigation, conducted by the organization at the direction of counsel, in order to understand the scope of the issues involved in the matter and to help frame the arguments and facts.

The internal investigation should aim to address the circumstances surrounding the incident or practice at issue and the scope of the disclosed conduct. The report to OIG should detail, among other things, the incident or practice that is the subject of the disclosure, identify the potential causes of the incident or practice, and identify the corporate officials or employees who knew or should have known about the conduct. The report should also thoroughly describe the way in which the incident or practice was discovered and any corrective action that has been taken.

OIG has established guidelines that an organization must follow to conduct the self-assessment. Organizations should consider how the facts surrounding the incident or practice inform the monetary impact of the conduct on the federal health care programs. For example, when conducting the financial assessment of the underlying incident or practice, an organization should consider the nexus between the subject of the disclosure and federal health care program beneficiaries. The sources of data, the methodology for analyzing the data, and the presentation of the findings to OIG are considerations that should be discussed internally and with counsel. After the self-assessment is submitted, OIG will begin its verification and validation process, which may result in additional requests from

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Table 1

Category	CMS SRDP	OIG SDP
Protocol	New, untested*	In place for over a decade
Minimum Settlement Amount	No amount required	$50,000
Contents of Initial Disclosure	Must submit a full and complete disclosure that meets all of the enumerated elements in the CMS SRDP	At a minimum: • Basic Information required in the OIG SDP • Complete description of conduct being disclosed • Description of internal investigation or commitment regarding when it will be completed • Estimate of damages and methodology used to calculate or commitment regarding when it will be completed • Statement of laws potentially violated
Financial Analysis/Self Assessment	Must be submitted with initial disclosure	Must be submitted within three month of acceptance into the SDP
Corrective Action	Must resolve non-compliance before submitting disclosure	Must report any corrective action that has been taken (resolution of non-compliance not a requirement)
60 Day Overpayment Requirement	Confirmation of electronic submission will suspend 60 day overpayment requirement	Submission does not "officially" stay overpayment requirement

** As of the date this table was prepared, there have only been two settlements announced under the CMS SRDP.*

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the organization, including access to supporting documentation.

CMS SRDP

Similar to the OIG SDP, the CMS SRDP requires the provider to prepare a written submission detailing the actual or potential violations of law. The written submission must include, among other things, the provider's basic information. In addition, the provider must include a description of the nature of the matter being disclosed, including the types of financial relationships and the specific period of non-compliance. The written submission must also contain a statement regarding the type of designated health services at issue and the type of transaction or conduct that gave rise to the conduct. Because the CMS SRDP is focused on Stark Law violations, CMS specifically requires that the written submission include the names of the entities and individuals believed to be involved. As such, organizations should think strategically when preparing the submission and determine when and how to inform physicians who are potentially being named in the disclosure.

Unlike the OIG SDP, the CMS SRDP also requires a complete legal analysis, applying the Stark Law to the conduct at issue. The report should discuss any applicable Stark Law exception and detail the specific elements of the exception that were and were not met. In addition, CMS requires that the disclosing party include a description of pre-existing compliance programs and efforts taken to prevent the conduct from recurring. Unlike the OIG SDP, the non-compliance must be rectified before submitting a disclosure to CMS. Another difference between the OIG SDP and the CMS SRDP is that under the CMS SRDP the disclosing party must conduct and conclude a detailed financial analysis setting forth the entire monetary amount at issue and the amount of remuneration paid to each physician during the period of non-compliance at the time of the initial submission.

The CMS SRDP specifically sets forth the factors that CMS has the authority to consider when determining whether to reduce the settlement amount. These factors include: (1) the nature and extent of the improper or illegal conduct; (2) the timeliness of the self-disclosure; (3) the cooperation of the disclosing party in providing additional information; (4) the litigation risk associated with the matter disclosed; and (5) the financial situation of the disclosing party. Because CMS has the authority to consider these factors, although not required, the most effective disclosures will presumably address each of these elements.

SDP checklists

The general categories of information required under the respective SDPs are similar, but the specific elements under each category diverge slightly between the two protocols. In this regard, the following is a high-level checklist designed to assist health care providers and suppliers in preparing a self-disclosure under the OIG SDP or CMS SRDP. Although this checklist provides a roadmap for preparing a disclosure, it does not contain all of the elements that must be included in the disclosure.

OIG SDP

Basic information: The disclosing party must provide general background information on organizational structure and provider status. The written submission should describe the nature of the matter being disclosed, including the relevant time periods involved, and whether the provider has knowledge that the matter is under inquiry by the government.

Internal investigation: The report to OIG should thoroughly describe the nature of the provider's internal investigation into the incident or practice that gave rise to the disclosure, including the specific steps that were taken to investigate the matter. More specifically, the provider should describe the genesis of the incident or practice and the areas of the organization that were affected by the disclosed incident.

The provider should describe any corrective action, including any disciplinary measures, taken in response to the incident or practice.

Financial assessment: The report should estimate the monetary impact pursuant to the self-assessment guidelines provided by OIG.

Certification: An authorized representative of the provider must provide a signed certification.

CMS SRDP

Basic information: The disclosing party must provide general background information on the organizational structure and provider status. The written submission should describe the nature of the matter being disclosed, including the relevant time periods involved (and, if applicable, the dates or a range of dates whereby the conduct was cured); whether the provider has knowledge that the matter is under inquiry by the government; and whether the provider has a history of similar conduct or any prior criminal, civil, and regulatory enforcement actions (including payment suspensions) against it.

Internal investigation: The provider should include a description of the actual or potential violations, the types of financial relationships, the parties involved, the type of designated health services at issue, the names of entities and individuals believed to be implicated, and an explanation of their roles in the matter. In addition, the provider should include a description of the circumstances under which the disclosed matter was discovered and the measures taken to address the actual or potential violation and to prevent future noncompliance. The disclosure should also describe the compliance program.

Legal analysis: In contrast to the OIG SDP, the CMS SRDP specifically requires that a legal analysis be included. The legal analysis must include a statement as to why the disclosing party believes a violation of the Stark Law may have occurred, including a complete legal analysis of the application of the Stark Law to the conduct and any physician self-referral exceptions that apply to the conduct and/or that the disclosing party attempted to use. The legal analysis should (1) identify and explain which element(s) of the applicable exception(s) were met and which element(s) were not met, and (2) provide a description of the potential causes of the incident or practice.

Financial assessment: The initial disclosure must set forth the total amount, itemized by year, that is actually or potentially due and owing, based upon the applicable period of non-compliance.

Certification: The CEO, CFO or other authorized representative must submit a signed certification.

Tips for disclosure

- Start preparing for the disclosure only after you have made the discovery and are committed to disclosing.
- Make sure that all of the elements are in the disclosure. If some elements are not in there, specifically address why or when you will complete the disclosure.
- Ask questions, if you have them.
- Document the process and any correspondence with the government.
- Identify all of the laws at issue.
- Consider the most effective, efficient, and accurate approach to quantifying the financial impact of the disclosed matter.
- Be prepared to fully cooperate. Both OIG and CMS may request access to documents.
- Be prepared to engage in a dialogue and think strategically about whom to appoint as the contact for the government. This person may be an internal employee or outside counsel.
- When offering a self-imposed deadline to the government, make sure you can meet it.

Conclusion

Determining when a voluntary self-disclosure to OIG or CMS is appropriate and deciding which

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entity to disclose to can be challenging. These business and legal decisions should be made reflexively, based on the particular facts at issue and the practical considerations attendant to the self-disclosure process. Compliance personnel and counsel should plan and prepare early and work to develop a collaborative rapport with OIG and CMS to effectuate the best result for the organization. ■

1. Patient Protection and Affordable Care Act, Pub. L. 111-148, as amended by Health and Education Reconciliation Act Pub. L. 111-152 (hereinafter referred to collectively as ACA).
2. ACA § 6402.
3. 63 Fed. Reg. 58399 (October 30, 1998).
4. DHHS, OIG, "An Open Letter to Health Care Providers" (April 24, 2006). Available at http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf
5. DHHS, OIG, "An Open Letter to Health Care Providers" (April 15, 2008). Available at http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf
6. DHHS, OIG, "An Open Letter to Health Care Providers" (March 24, 2009). Available at http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf
7. CMS, Voluntary Self-Referral Disclosure Protocol, OMB Control Number 0938-1106. Available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/e61df099-abb6-4dfd-bb3b-21ef30599199.cfm (last accessed November 9, 2011).