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Disclose Smart: Strategic Considerations in Making a Government Disclosure

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A former deputy chief in the U.S. Department of Health and Human Services' Office of Counsel to the Inspector General weighs in on the growing need for self-disclosure by health industry entities

After years of significant federal government attention to health care fraud, some prosecutors are starting to wonder whether the industry has indeed embraced a new culture of compliance. Just last month, Zane David Memeger, the U.S. Attorney for the Eastern District of Pennsylvania in Philadelphia, put it directly when he said, “the expectation is that you will have a strong compliance program”^[1] now as a result of the large number of False Claims Act (FCA) cases and settlements over the past 20 years. “But at the end of the day, I suspect that at some point, entities may push the envelope again.”

No part of the health care industry has been spared scrutiny, especially among pharmaceutical and device manufacturers and hospitals. The numbers speak for themselves: the \$2.3 billion in health care fraud recoveries in fiscal year 2014 marks five straight years of more than \$2 billion recovered in cases involving false claims against federal health care programs such as Medicare and Medicaid.^[2] The pharmaceutical industry accounted for a substantial part of that \$2.3 billion and hospitals paid a total of \$333 million.

So how do organizations show that they have strong compliance programs? The Office of Inspector General of the Department of Health and Human Services (OIG) states that disclosing and resolving problematic conduct are “indications of a robust and effective compliance program” in the Provider Self-Disclosure Protocol^[3] (SDP), reissued in 2013. Perhaps because of the industry’s enforcement history, OIG explicitly encouraged pharmaceutical and device manufacturers to use the SDP to report potential violations of the anti-kickback statute.

At this point, making smart decisions about disclosure is arguably more important than ever. Even OIG recognizes that an organization with a robust and effective compliance program can discover problems—the act of disclosing and resolving those problems is what makes the compliance program robust and effective. And once an organization is considering an affiliation, merger, or acquisition, the door opens to either discovering

the potential problems of other entities or becoming connected to those problems if they continue after the transaction.

Regardless of how an issue is discovered, the organization should have a clear process in place for reviewing issues and determining how to respond. It is critical to make an informed and reasoned decision about whether to disclose the issue to the government, who to make the disclosure to, and how to present the information to the government to help facilitate the best resolution possible.

Whether to Disclose

Whether an issue is appropriate for government disclosure requires careful investigation and deliberation to make the best decision. Taking the time to appropriately examine the issue and consult with internal and external experts to decide whether disclosure is the right call ultimately is in the organization's best interests. Acting quickly is important, but acting too quickly can create more problems. This process is not a sprint, but also is not a Sunday stroll in the park. Moving forward on an internal investigation and review in a reasonable and diligent manner is key for a variety of reasons, including maintaining credibility when explaining to the government that you *did* act in a timely way and complied with the 60-day rule.^[4] While the proposed rule^[5] from the Centers for Medicare & Medicaid Services (CMS) may have left the health care community with unanswered questions, CMS acknowledged in the preamble that the 60-day clock would not start running until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment "with all deliberate speed" after receiving information concerning a potential overpayment. CMS proposed to define "identify" as "actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate indifference of the overpayment" to "give providers and suppliers incentive to exercise reasonable diligence to determine whether an overpayment exists."

Disclosing and then concluding, after further review, that factual or legal reasons exist to suggest that the issue did not require disclosure puts the organization in a difficult position. At this point, you are in front of the government and are now in the position of trying to explain why you want to withdraw the matter. It is hard to unring the bell at this point. Or you have refunded claims to the contractor and now may be unable to rebill.

To help make the decision about whether to disclose:

- Conduct a thorough review of the facts surrounding the issue.
- Research the billing rules completely and contact the appropriate contractor or billing expert with any questions or to clarify areas of uncertainty.
- Consult experienced counsel on any legal issues that may impact the conclusion of whether there is conduct to report, including statutory or regulatory interpretation questions and an assessment of possible defenses.
- Conduct at least a preliminary overpayment estimate.

Under the formal disclosure pathways created by the SDP and CMS in the Self-Referral Disclosure Protocol^[6] (SRDP), the government invites the disclosure of “actual or potential violations.” However, there is no legal duty to report conduct that only potentially violates the law or potentially resulted in an overpayment. Part of making a disclosure decision is assessing where the situation falls on the potential violation risk spectrum. Clear cut answers in health care generally are the exception and not the norm. If you conclude there is an actual overpayment, then there is a legal duty to at least refund that overpayment. If there are reasonable and defensible arguments to say that there is no overpayment or violation, then making the disclosure decision requires exercising judgment and making a reasoned risk assessment.

Where to Disclose

After making the decision to refund or disclose, the next step is to decide where to go. Several avenues exist and choosing the right one for the issue is important.

Contractor

First, there is the applicable contractor. Depending on the amount of the overpayment and other facts, this may be the most appropriate avenue. For example, if the overpayment amount is relatively small for the organization, the conduct lasted for a short period of time, or the investigation concluded that the cause of the conduct was an inadvertent error, then it may be reasonable to conclude there is little exposure risk under the fraud laws, other than needing to return the overpayment and take corrective action going forward. Refunding, without further disclosure, is likely an appropriate disclosure method for a number of situations. While the organization does not obtain releases under the fraud authorities, it has likely neutralized potential liability under the FCA for retaining the overpayment.

Self-Referral Disclosure Protocol

Next, there is the SRDP. CMS created this pathway on September 23, 2010 as required by the Affordable Care Act for disclosure of actual or potential violations of the physician self-referral law (Stark Law). This protocol typically is more appropriate for “technical” Stark Law issues that do not create a significant concern of excessive financial benefits to a physician. The SRDP results in the disclosing entity and CMS entering into a settlement agreement to obtain a release under the Stark Law’s overpayment authority^[7] by paying a reduced overpayment amount as determined by CMS. There is limited, if any, negotiation over how much the overpayment amount is reduced once CMS has decided on the reduction amount, so it is critical to provide all of the information requested by CMS and to make the best case possible about any legal defenses or ambiguities and factual issues that should lead CMS to substantially reduce the overpayment. It appears that CMS takes a thoughtful approach to considering and resolving SRDP submissions, although there have been relatively few settlements in comparison to the number of submissions received. As of March 1, 2015, the CMS website listed 69 SRDP settlement summaries.^[8] According to Representative Jim McDermott’s August 13 2013 letter to former Administrator Marilyn Tavenner, CMS had

received almost 300 submissions at that time. The settlement amounts have been relatively low to date, with the two highest settlements coming in at \$584,700 and \$579,000. This pattern may indicate a desire by CMS to make the SRDP attractive by heavily discounting the overpayment amount. However, CMS has not provided meaningful detail on how it determines the discounted amount. Stories of disclosures pending for three or more years are not uncommon. Thus, some level of uncertainty exists in predicting what a possible resolution might look like.

Self-Disclosure Protocol

In contrast, OIG has provided considerable guidance on its typical resolution process of OIG's civil monetary penalty authorities. The revised SDP, issued on April 17, 2013, significantly updated the original protocol document issued in 1998. This revised document explains OIG's review and resolution process with greater detail and clarity, incorporating modifications to the SDP announced in past Open Letters as well as publically articulating agency practices for the first time. Significantly, OIG stated that it generally requires a 1.5 multiplier to obtain a release from OIG for the disclosed conduct, with minimum settlement amounts of \$50,000 for kickback-related conduct and \$10,000 for all other matters. Of course, OIG reserves the right to seek a higher multiplier in cases where it believes it is appropriate to do so. But, OIG's general policy helpfully enables executives, board members, and their counsel to be able to predict what their resolution will likely be with some level of comfort.

However, this comfort is tempered by OIG's discussion of its coordination with the Department of Justice (DOJ) on SDP resolutions. If DOJ decides to participate in the disclosure, OIG states it will advocate that the resolution be consistent with OIG's approach in similar cases—which implies that DOJ may take a different, and more aggressive, approach than OIG would have. Thus, there is some possibility that a SDP submission may change from an administrative case to an FCA case (with potentially a higher dollar value) without the entity choosing that outcome.

Department of Justice

Finally, organizations have the option of disclosing directly to DOJ. Disclosure is typically made at the local U.S. Attorneys' Office (USAO) level, although Main Justice also may become involved at some point. Choosing this pathway presents its own challenges in predicting potential outcomes. Factors to consider in making this decision include the strength of the entity's or counsel's relationship with the USAO, the potential monetary value of the conduct, and the potential for whistleblowers. This pathway generally is reserved for more complex or extensive conduct where having an FCA release provides the most comfort to the organization.

How to Disclose

Regardless of which disclosure pathway is chosen, there are some good practices to keep in mind to help position the organization for the best possible outcome. First, ensure the disclosure is complete and accurate to the best of your ability. The

reputation of the organization and their counsel are front and center when making a disclosure to the government. Government attorneys expect that the factual representations are accurate and made in good faith so that they can be comfortable relying on those representations in resolving the conduct without doing an independent investigation. Second, be prepared. Once the decision is made to disclose and where, take the steps necessary to prepare a complete submission and be ready to engage with the government. In some situations, a submission may need to include some questions to the government on how they would like you to proceed with certain issues in order to complete the submission. Being prepared also means timely responding to requests for additional information. If the goal is to obtain as fast a resolution as possible, don't let time slip by after being contacted by the assigned attorney or you risk that attorney getting pulled away on another more urgent matter. Finally, cooperation is key. Effective cooperation with the government's review process helps maintain the trustworthy reputation needed to help ensure a smooth resolution.

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[1] See http://www.law360.com/health/articles/620176?nl_pk=dddb0bf2-ae6c-428e-b972-ff8a32705342&utm_source=newsletter&utm_medium=email&utm_campaign=health (subscription required).

[2] See <http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014>.

[3] <http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>.

[4] Section 6402 of the Affordable Care Act created a new obligation to report and return overpayments within 60 days from the date the overpayment was identified or the date the cost report is due. 42 U.S.C. § 1320a-7k(d).

[5] 77 Fed. Reg. 9184 (Feb. 16, 2012). On February 13, 2015, CMS announced a one-year extension to its normal three-year deadline to finalize the proposed rule.

[6] http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

[7] 42 U.S.C. § 1395nn(g)(1).

[8] See <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html>.

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