Voluntary Disclosure:

Risks and Benefits

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This article is the second installment of a two-part series on mandatory and voluntary disclosure. The first installment, published in the June issue of *AHLA Connections*, discussed the Affordable Care Act of 2010 (ACA) and the establishment of mandatory obligations to report and return overpayments. This article discusses the processes, benefits, risks, and other considerations in making a voluntary disclosure to the government.

OIG Self-Disclosure Protocol

The decision whether to make a voluntary disclosure is now, in many ways, more difficult and more nuanced than whether a mandatory disclosure is required. In 1995, the Department of Health and Human Services Office of Inspector General (OIG) issued its first voluntary disclosure mechanism for health care providers. As set forth below, the current operative OIG self-disclosure protocol was updated in 2013.[1]

The OIG protocols provide a roadmap to self-disclosure. For starters, a disclosing party is expected to conduct an internal investigation as to the matter at issue and report its findings to the OIG. It is critical to maintaining credibility with OIG, and to obtaining the full benefits of any self-disclosure, that the findings of the internal investigation reported to OIG are thorough and forthright. OIG will expect that these findings include discussion of the causes of the problem; the individuals involved, including those who knew or should have known about the problem and failed to detect it; disciplinary actions taken; scope and duration of the problem; and financial and patient impact, if any, of the problem.

Who may disclose?

Any health care provider, supplier, or other individual or entity subject to the OIG's civil monetary penalty (CMP) authorities found at 42 C.F.R. Part 1003 may make a voluntary disclosure to the OIG.

What conduct is eligible for disclosure?

The OIG Self-Disclosure Protocols are available for any potential violations of federal criminal, civil, or administrative laws for which CMPs are authorized. For example, mere mistakes would not qualify. Also, the protocols are not available for disclosure of issues solely pertaining to the Stark Law. There is a separate disclosure protocol for Stark-only violations, discussed in the next section.

What are the basics of a self-disclosure to the OIG?

On a more nuts-and-bolts level, the protocols require that a disclosure include the following information in the narrative submission:

- name, address, type of health care provider, provider ID numbers and tax ID numbers of the disclosing party, and the government payers to which the disclosing party submits claims
- an organizational chart if there are related or parent entities or networks of entities
- contact information for the disclosing party's designated representative, and if different, the name of an individual authorized to enter into a settlement agreement
- a concise statement of the details relevant to the disclosed conduct, including types of claims, time frame, names or individuals, and entities implicated
- a statement of the federal criminal, civil, or administrative laws that are potentially violated by the conduct
- the federal health care programs affected by the disclosed conduct
- an estimate of damages
- a description of the corrective action undertaken
- a statement of whether the matter is under current inquiry by the government, and whether there is any other conduct of the disclosing party that relates to a federal health care matter and is under investigation
- a certification that the submissions contain truthful information and is based on a good faith effort to bring the matter to the government's attention for the purpose of resolving potential liability to the government and to assist the OIG in its resolution of the disclosed matter.

What are the benefits of OIG Self-Disclosure?

The primary benefits are reduced civil liability and decreased risk of criminal prosecution. More specifically, the OIG's Self-Disclosure Protocols provide, generally, for a multiplier of 1.5 times the single damages, as opposed to typical Department of Justice (DOJ) settlements in the 2–3 times range. Another major benefit of resolving matters through the OIG protocols is avoidance of an Integrity Agreement with the OIG. The protocols contain a presumption against requiring an Integrity Agreement. This is a major benefit, as Integrity Agreements are expensive, time consuming to maintain, and create risk for the subject of the Integrity Agreement. Lastly, disclosure may toll the 60-day period for return of an overpayment pending resolution of the self-disclosure.

In addition, a number of benefits to self-disclosure are hard to quantify but quite meaningful, including:

- The opportunity to shape, direct, and frame the subject matter of the disclosure and subsequent dialogue with the government; and
- The ability to embark on a cooperative, rather than adversarial process, with government enforcers.

While a self-disclosure will result in some form of payment to the government,[2] it presents an opportunity to reduce the size of that payment and to minimize the internal disruption and outside legal spend that a government investigation of the same conduct through subpoenas and other investigatory resources would require.

> The OIG Self-Disclosure Protocols are not a vehicle for relief or a release from a qui tam action under the False Claims Act.

What are the risks of OIG Self-Disclosure?

The OIG Self-Disclosure Protocols are not a vehicle for relief or a release from a qui tam action under the False Claims Act. Situations in which a whistleblower has filed a qui tam action are not well suited to these protocols as the government may already be aware of the issues and DOJ may decide not to join the self-disclosure process and not to provide a release for the False Claims Act liability. This is more of a limitation of the protocols than a true downside of making a disclosure.

To evaluate risk of a self-disclosure to the OIG, one must weigh the likelihood of the government learning of the problem versus the certainty of having to make a financial settlement with the government in the wake of a self-disclosure. Risks of disclosure also include inviting the government to inquire into different and broader areas, and in a context of cooperation it is difficult to refuse these inquiries. These inquiries could lead to different and more serious issues than those disclosed, thus turning a confined disclosure into an open-ended high risk situation in which all government tools, including criminal prosecution, are on the table. Also, if the OIG or another government agency finds that the self-disclosure omitted other known problems, the benefits of the disclosure could be eviscerated and the government could launch a broad investigation into the disclosed and non-disclosed issues.

Lastly, the self-disclosure is to the OIG; there is no guarantee that the DOJ will agree with the OIG's decision in response to the self-disclosure.

> Unlike the OIG and CMS voluntary disclosure protocols there is no protocol of formal guidance for voluntary disclosures to the DOJ.

CMS Self-Referral Disclosure Protocol

As an outgrowth of the ACA, the Centers for Medicare & Medicaid Services (CMS), in 2010, implemented a self-disclosure protocol for Stark Law violations.[3] This protocol is strictly and only for Stark Law violations. Disclosures involving Stark issues and other kinds of issues must be made to the OIG through its self-disclosure protocols. Given the strict liability nature of the Stark Law, the CMS Self-Referral Disclosure Protocol was seen as attractive by the provider community; however, the data show that it has been relatively lightly used with only 233 disclosures settled from 2011 through 2016.[4] This protocol also has an "expedited" process for one specific type of Stark Law violation.[5] This expedited process only applies to matters involving the Stark Law requirement that physician-owned hospitals disclose that the hospital is owned or invested in by physicians on any public website of the hospital and in any public advertisement. On March 28, 2017, CMS issued a new Voluntary Self-Referral Disclosure Protocol.[6] The new protocol's usage is mandatory as of June 1, 2017. The new protocol, which CMS describes as "streamlined," requires the following: (1) SDRP Disclosure Form; (2) Physician Information Form; (3) Financial Analysis Worksheet; and (4) Certification.

Who is eligible?

All health care providers and suppliers may participate in the CMS protocol.

What must be disclosed?

The CMS protocols set out the technical requirements for the disclosure. Under the new protocol, the disclosing party must detail the pervasiveness of non-compliance, submit a Physician Information Form, and include a financial analysis worksheet quantifying overpayments for each physician at issue. Disclosing parties also must cooperate with CMS through the process, including the production of any requested documents.

What are the benefits of disclosure?

The Stark-only CMS program is particularly well suited to self-disclosure because of the statute's strict liability standard and the potential for significant damages for highly technical violations. Under this self-disclosure protocol, CMS has significant discretion to determine settlement amounts, and may do so with reference to the following factors:

- nature and extent of illegal practice;
- timeliness of the self-disclosure;
- the cooperation with CMS post-disclosure;
- the litigation risk of the disclosed matter; and
- the financial conditions of the disclosing party.

Similar to the OIG self-disclosure protocols, the submission of a self-disclosure to CMS tolls the 60-day period to return an overpayment pending the resolution of the disclosed matter with CMS.

Lastly, in terms of benefits, in connection with a self-disclosure, CMS may release the discloser from administrative liabilities under Section 1877(g)(1) of the Social Security Act. However, it may not release the discloser from CMPs as these are the province of the OIG. However, the CMS protocol states that it may use a disclosing party's submission to recommend to the OIG and the DOJ resolution of False Claims Act, CMP, or other liability.

What are risks/detriments of disclosure?

In addition to the release limitations noted above, and the types of risks identified for the OIG self-disclosures, the other primary drawback is that the process generally is regarded as somewhat slow. Another drawback is that CMS settlement offers are not negotiable, creating a situation in which the offer either has to be accepted, or the provider has to drop out of the voluntary disclosure program, a near impossibility given that under the new protocols the provider has already certified non-compliance with the Stark law.

Voluntary Disclosure to DOJ

Unlike the OIG and CMS voluntary disclosure protocols discussed above, there is no protocol of formal guidance for voluntary disclosures to the DOJ. There are two initial threshold questions that must be resolved before making a voluntary disclosure to the DOJ: (1) what should be disclosed; and (2) to which DOJ component should disclosure be made. The question of "what" to disclose informs the question of to whom the disclosure should be made. For example, if a criminal matter is at issue, the disclosure generally should be made to a U.S. Attorney's Office, whereas for a civil matter, disclosure to the DOJ Civil Division may be more appropriate.

A disclosure to DOJ generally should include the types of information that are called for in the OIG and CMS voluntary disclosures; namely, a detailed description of the wrongdoing, the laws implicated, the individuals involved, the financial impact to the government, the investigation performed, and the remediation steps taken. As with any disclosure, a complete and candid description of the events is paramount; however, when dealing with DOJ, with its full array of investigative tools and prosecuting options, this requirement cannot be overemphasized. A less than full or candid disclosure can lead to a grand jury investigation after which criminal charges may be brought, with no benefit provided for the voluntary disclosure.

Benefits of DOJ Disclosure

The primary benefit for a voluntary disclosure of clear criminal conduct is that the discloser may avoid a long, risky, and expensive investigation, and that the prosecutor will exercise discretion and either decide not to pursue a criminal charge (or to try some more desirable alternative to prosecution such as a deferred prosecution agreement, a non-prosecution agreement, or pretrial diversion).

In the event that the government does bring a criminal case, a voluntary disclosure, coupled with cooperation can yield substantial benefits under the Federal Sentencing Guidelines. Section 8C2.5(g) of the Federal Sentencing Guidelines states:

> *Self-Reporting, Cooperation, and Acceptance of Responsibility*
>
> If more than one applies, use the greatest:
>
> 1. If the organization (A) prior to an imminent threat of disclosure or government investigation; and (B) within a reasonably prompt time after becoming aware of the offense, reported the offense to appropriate governmental authorities, fully cooperated in the investigation, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract 5 points; or
> 2. If the organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract 2 points; or
> 3. If the organization clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract 1 point.

The benefit of a 5-point reduction can be very significant in terms of the fine imposed on a corporate defendant. The impact of a 5-point reduction can result, in some instances, in a fine reduction of approximately 50%.

Lastly, if the disclosure included issues implicating the False Claims Act, the DOJ does have the power to provide a release for such conduct.

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Risks of DOJ Disclosure

A voluntary disclosure to DOJ will inherently require cooperation with DOJ. At present, under the so-called Yates Memo[7] that cooperation obligation includes providing information on all "individuals responsible for the misconduct. . . ." This may raise the bar on what the government expects in terms of "cooperation." In addition, as noted above, a voluntary disclosure to DOJ follows no formula or protocol, and thus is more unpredictable than the other disclosures discussed herein. There are no guarantees or assurances that DOJ will not launch its own investigation on the disclosed matters, or other matters. This is one reason why familiarity with the office and the prosecutors to whom disclosure is made is vital when making a voluntary disclosure to DOJ.

Other Issues to Consider in Connection with Voluntary Disclosures

What about private payers?

The federal health care fraud statute[8] prohibits defrauding public and private insurers. Many states have enacted statutes that prohibit kickbacks with respect to private health care plans.[9] Thus, even if an entity discovers fraud purely with respect to private insurers, there are serious issues to consider in terms of voluntary disclosure due to the potential of federal and state criminal liability in that context.

The decision whether to make a voluntary disclosure is now, in many ways, more difficult and more nuanced than whether a mandatory disclosure is required.

Employment actions

Corporate criminal and civil liability arises because of actions taken by individuals who are usually employees of the corporation. Employment actions taken by companies against individuals may have significant impact with respect to voluntary disclosures. For example, while the False Claims Act prohibits retaliating against a whistleblower, the government may look favorably on the termination of an employee involved in illegal conduct. There is no one-size-fits-all approach to employment actions in this context. Instead, the action or inaction must be carefully considered in the context of the voluntary disclosure(s) contemplated.

Conclusion

The decision whether to make a voluntary disclosure is nuanced and must be made by balancing the potential benefits of alerting the government to a problem on your own terms with the risks inherent in a governmental investigation. While the facts of each case will prove determinative, use of the voluntary disclosure process has resulted in positive outcomes and reduced penalties for potentially fraudulent behavior. Nonetheless, there is no guarantee that this will be the case; a discrete disclosure on a specific issue could turn into an open-ended examination of an unrelated problem. A keen assessment of these risks and benefits must be performed to use these processes effectively. C

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Endnotes

1 The current (2013) OIG Self Disclosure Protocols are *available at* https://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-protocol.pdf.

2 Certain settlements with the government may be tax deductible, including amounts paid in False Claims Act settlements that are "compensatory" as opposed to "punitive." *See Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 69 (1st Cir. 2014).

3 https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html.

4 https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html.

5 *See* 42 C.F.R. § 411.362(b)(3)(ii)(C).

6 CMS Voluntary Self-Disclosure Protocol, *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol.pdf.

7 *Available at* https://www.justice.gov/dag/file/769036/download.

8 18 U.S.C. § 1347

9 *See, e.g.,* Mass. Gen. Laws ch. 175H, § 3.