

Health Care Law

The Benefits and Risks of Self-Disclosure Under the Self-Disclosure Protocol

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Self-Disclosure Protocol

The Provider Self-Disclosure Protocol was published by the Office of the Inspector General of the United States Department of Health and Human Services in an effort to encourage health-care providers to play a cooperative role in identifying and voluntarily disclosing noncompliance with federal health-care programs. The SDP makes possible the resolution of potential violations of federal criminal, civil or administrative laws for which exclusion or civil monetary penalties may be imposed. On the other hand, if a physician discovers mere overpayments or billing errors which do not involve a violation of law, such matters should be brought directly to the attention of the entity that processes claims.

This article provides an overview of the SDP and analyzes the benefits and risks a physician must carefully consider in determining whether to voluntarily disclose to the OIG a violation of law related to a federal health-care program.

Overview of OIG's Provider

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The SDP requires that a physician provide certain information to the OIG upon their initial disclosure, including a full description of the nature of the matter, including the type of claim, transaction or other conduct giving rise to the matter, the entities and individuals involved, and the relevant time periods, the reasons why a violation of federal law may have occurred and a certification that the submission contains truthful information and is based on a good-faith effort to bring the matter to the government's attention for the purpose of resolving any potential liabilities to the government.

The OIG later published "An Open Letter to Health Care Providers," clarifying and expanding the information that must be included in a physician's initial submission to the OIG. The disclosure must include: (i) a complete description of the conduct; (ii) a description of internal investigation conducted or a commitment regarding when it will be completed; (iii) an estimate of the damages to the federal health-care programs and the methodology used to calculate that figure or a commitment regarding when such estimate will be completed; and (iv) a statement of the laws potentially violated by the conduct.

Upon initial disclosure of the matter, the physician will be expected to conduct an internal investigation, including identification of the potential causes of the violation, the impact on, and risks to, health, safety or quality of care, and disclosure of all individuals involved. The physician should also report to the OIG how the violation was discovered and the measures taken to address the problem and prevent future violations. During the internal investigation, the OIG will generally agree to forego its own investigation of the matter.

In addition to the foregoing, the physician is also expected to conduct a self-assessment, or internal financial assessment, to estimate the monetary impact of the violation on the federal health-care programs. Based on factors such as cost, number of claims affected and duration, the assessment should consist of a review of either (i) all of the claims affected by the disclosed violation for the relevant period or (ii) a statistically valid sample of such claims. The physician should submit to the OIG a work plan describing the self-assessment process, including the objective of the review and the review procedure; identification of the claims being reviewed and an explanation of how the claims were chosen; a description of the source of the information upon which

the review will be based; and identification of the names and titles of the individuals conducting the self-assessment.

The internal investigation and self-assessment must be completed within three months. Once the reports are produced to the OIG, the OIG will begin to verify the information disclosed. The OIG will require access to all work papers and supporting documents.

In 2006, in "An Open Letter to Health Care Providers," the OIG announced an initiative to encourage the use of the SDP to resolve civil monetary penalty liability under the self-referral (Stark) law and antikickback statute for financial arrangements between hospitals and physicians, in particular, situations involving a financial benefit knowingly conferred by a hospital upon physicians. The OIG announced that for self-referral violations, the calculation of civil monetary penalties would be based on the number and dollar value of improper claims. For kickbacks, the penalties calculation would be based on the number and dollar value of improper payments or remuneration.

Recent Changes to SDP

On March 24, the OIG, in "An Open Letter to Health Care Providers," narrowed the scope of the SDP by announcing that they would no longer accept disclosure of matters that involve only liability under the self-referral (Stark) law, in the absence of an antikickback statute violation. The OIG's focus would be on kickbacks intended to induce or reward a physician's referrals. In addition, the OIG established a minimum settlement amount. For kickback self-disclosures under the SDP, the OIG will require a minimum \$50,000 settlement amount to resolve the matter.

Benefits of Self-Disclosure

If a physician discovers a violation of law in their practice relating to a federal health care program, the physician should consider whether voluntarily disclosing the violation under the SDP would be beneficial to the physician and their practice. The following are some of the benefits to self-disclosure under the SDP.

In general, the intent of the OIG in promulgating the SDP is to encourage physicians to conduct self-evaluations of their compliance with federal health care program requirements and to self-disclose violations. Therefore, the OIG may be more willing to reduce penalties for physicians who cooperate in identifying and voluntarily disclosing violations.

One of the main benefits to self-disclosure is that if the physician has an effective compliance program and demonstrates trustworthiness, the OIG will waive its authority to exclude the physician from federal health-care programs, which could result in a slow death to a physician's practice. The OIG has stated that detection and prompt disclosure of potential fraud are evidence of an effective compliance program. Moreover, the OIG will consider such compliance measures as a mitigating factor in determining a resolution to the violation, and will not generally require the physician to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement.

Another benefit to self-disclosure under the SDP is that the OIG has stated that it will generally settle SDP matters for an amount near the lower end of the continuum for calculating civil monetary penalty damages.

Finally, by self-disclosing, physicians may be able to avoid costly and protracted government investigations that would likely be disruptive to their practice. In addition, it gives physicians the ability to disclose what happened in the best possible light, which may result in a more favorable settlement for the physician.

Risks of Self-Disclosure

Although the OIG encourages voluntary self-disclosure and there are certain benefits, as discussed above, to participating in the SDP, a physician's decision to self-disclose a violation of federal criminal, civil or administrative laws relating to federal health-care programs is not without risk.

The OIG has specifically stated that it "cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will

enure to the disclosing entity." Further, the OIG "is not obligated to resolve the matter in any particular manner." Therefore, there is no guarantee that by self-disclosing the violation, the physician will be given any leniency in resolving the matter.

Disclosure of a potential violation to the OIG does not shield the physician from additional claims and penalties from other governmental agencies. The OIG, after reviewing the disclosure, may determine that the matter should be referred to the United States Department of Justice ("DOJ") for consideration under its civil and/or criminal authorities. The OIG's agreement to resolve a matter disclosed under the SDP is not binding on the DOJ. Further, the physician must agree in writing that settlement of the matter does not affect the government's ability to pursue criminal, civil or administrative remedies or to obtain additional fines, damages or penalties for the violation.

Similarly, additional violations uncovered by the OIG during its review of the physician's disclosure, which are outside the scope of the matter disclosed to the OIG, may be treated as new matters outside the SDP. In other words, the OIG may discover additional violations for which they can hold the physician liable.

Finally, under the most recent changes to the SDP, once a violation is submitted to the OIG under the SDP, the minimum settlement amount is \$50,000. Physicians must carefully consider the minimum settlement amount in light of the nature and extent of the violations being disclosed.

Conclusion

The most important lesson for physicians from the OIG guidance on self-disclosure is that they should implement an effective compliance plan designed to educate their office staff and set out a procedure for early discovery of non-compliance with federal health-care plan requirements and the steps to determine how to address such violations. It is imperative that physicians consult with their health-care counsel as soon as a violation is discovered so that the benefits and risks of self-disclosure can be assessed and disclosure made in a timely manner, if appropriate. ■