

**WHEN TO HOLD YOUR TONGUE -
THE BENEFITS AND RISKS OF SELF-DISCLOSURE**

WHAT IS A PHYSICIAN PRACTICE TO DO?

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OIG's Provider Self-Disclosure Protocol – Why Established?

On October 30, 1998, the Office of the Inspector General (“OIG”) of the United States Department of Health and Human Services published its Provider Self-Disclosure Protocol¹ (“SDP”) in an effort to encourage health care providers to play a “cooperative role in identifying and voluntarily disclosing” non-compliance with federal health care programs. The SDP is designed to facilitate resolution of potential violations of federal criminal, civil or administrative laws for which exclusion or civil monetary penalties (“CMPs”) are authorized. The OIG’s reason for issuing the SDP is that “health care providers must be willing to police themselves, correct underlying problems and work with the Government to resolve these matters”.

The OIG may seek CMPs for many types of conduct. For example, the OIG may seek CMPs against any person who:

- Presents or causes to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent².

¹ 63 FR 58399 (October 30, 1998); Available at <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>.

² 42 USC 1320a-7a(a)(1)(A) and (B).

- Violates the anti-kickback statute by knowingly and willfully: (1) offering or paying remuneration to induce the referral of federal health care program business; or (2) soliciting or receiving remuneration in return for the referral of federal health care program business³.
- Presents or causes to be presented a claim that the person knows or should know is for a service for which payment may not be made under the physician self-referral or Stark Law⁴.

The OIG is authorized to seek different amounts of CMPs and assessments based on the type of violation at issue. For false or fraudulent claims, the OIG may seek a penalty of up to \$10,000 for each item or service improperly claimed, and an assessment of up to three times the amount improperly claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim. For a kickback, the OIG may seek a penalty of up to \$50,000 for each improper act and damages of up to three times the total amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. For a Stark Law violation, the OIG may seek a CMP of up to \$15,000 for each improper service and an assessment of up to three times the amount improperly claimed for each such item or service. In each case the OIG may exclude the person from participation in the federal health care programs.

³ 42 USC 1320a-7a(a)(7).

⁴ 42 USC 1395nn(g)(3).

The Role of the SDP Over Time

On April 24, 2006, in An Open Letter to Health Care Providers⁵, the OIG announced an initiative that promoted the use of the SDP to resolve civil monetary penalty liability under the Stark Law and anti-kickback statute for financial arrangements between hospitals and physicians. In particular, the SDP could be used to resolve situations involving a financial benefit knowingly given to a physician by a hospital. The civil monetary damages calculation for Stark Law violations is based on the number and dollar value of improper claims. The damages calculation for kickbacks are based on the number and dollar value of improper payments or remuneration. The OIG did state that they would generally settle self-disclosed violations for an amount near the lower end of these continuums, i.e. a multiplier of the value of the financial benefit conferred by the hospital upon the physician.

Recent Changes to the SDP

Earlier this year, on March 24, 2009, the OIG, in An Open Letter to Health Care Providers⁶, narrowed the scope of the SDP by announcing that they would no longer accept disclosure of matters that involve only liability under the Stark Law, in the absence of a “colorable” anti-kickback statute violation. The OIG’s focus would be on kickbacks intended to induce or reward a physician’s referrals. The OIG’s decision to exclude Stark-only violations was based on the difficulty inherent in determining the value of such violations. Therefore, the SDP is no longer an option for physician practices to disclose a Stark Law violation.

Moreover, 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

⁵ Available at <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>.

⁶ Available at <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

resolve the matter. This minimum settlement amount is consistent with the law that imposes a penalty of up to \$50,000 for each kickback violation. The OIG reaffirmed its commitment to generally resolve matters near the lower end of the damages continuum if disclosure is in accordance with the SDP.

Overview of the SDP

Step 1 – Elements of Initial Disclosure

If a physician practice has discovered a potential violation of law related to federal health care programs, and determines, after careful consideration of the pros and cons discussed below, to voluntarily disclose such violation to the OIG, the following items should be included in the disclosure:

1. Name, address, provider identification number and tax identification number of the disclosing physician practice.
2. Whether the matter and/or the physician practice is under current inquiry by a Government agency or contractor.
3. 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 an explanation of their roles, and the relevant periods involved.
4. Type of physician practice, provider billing numbers and the federal health care programs affected.
5. Reasons why a violation of federal criminal, civil or administrative law may have occurred.

6. Certification by an authorized representative on behalf of the practice that, to the best of the individual's knowledge, 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 disclosure must be submitted in writing to the Assistant Inspector General for Investigative Operations at the OIG.

On April 15, 2008, the OIG published an Open Letter to Health Care Providers⁷ expanding the information that must be included in the physician practice's initial submission to the OIG. The additional disclosures include:

1. A complete description of the conduct being disclosed.
2. A description of the physician practice's internal investigation or a commitment regarding when it will be completed.
3. An estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment regarding when the practice will complete such estimate.
4. A statement of the laws potentially violated by the conduct.

Cooperation with the OIG and complete disclosure of the facts and circumstances surrounding the violation are essential to participation in the SDP.

Step 2 – Internal Investigation and Self-Assessment

Upon disclosure of the matter, a physician practice will be expected to conduct an internal investigation and self-assessment of its practice. During this step, the OIG will usually

⁷ Available at <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf>.

agree to forego its own investigation of the matter for a period of time.

The internal investigation should be a comprehensive examination of the practice including a full examination of the violation, how it was discovered and the practice's response to the matter.

The disclosing practice is also expected to conduct a self-assessment. The self-assessment consists of an 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 violation for the relevant period or (ii) a statistically valid sample of the claims affected by the violation for the relevant period.

Step 3 – Report to OIG on Internal Investigation and Self-Assessment

The internal investigation and self-assessment must be completed within three months from the initial disclosure. Failure to complete same within three months may result in the physician practice's removal from the SDP. Once the internal investigation and self-assessment are complete, the physician practice must report on the results of same to the OIG.

The physician practice's report to the OIG on the results of its internal investigation is twofold. The report should first address the nature and extent of the improper or illegal activity, including:

1. Identification of the potential causes of the violation, such as intentional conduct, lack of internal controls or circumvention of corporate procedures or Government regulations.
2. Describes the incident in detail, including how the violation arose and continued.

3. Identification of the divisions, departments, branches or related entities involved and/or affected.
4. Identification of the impact on, and risks to, health, safety, or quality of care posed by the violation, with enough detail to allow the OIG to evaluate the immediacy of the impact and risks, the steps that should be taken to address them, and the actions taken by the physician practice.
5. Disclosure of the period during which the violation occurred.
6. Identification of corporate officials, employees or agents who knew of, encouraged or participated in the violation and any individuals who may have been involved in detecting the violation.
7. Identification of corporate officials, employees or agents who should have had knowledge of, but failed to detect, the violation.
8. Estimate of the monetary impact of the violation on the federal health care programs.

The report on the internal investigation should also address the circumstances under which the physician practice discovered the violation and the measures taken to address the problem and prevent future abuses. This part of the report should include the following:

1. How the violation was identified, and the source of the information that led to its discovery.
2. Details regarding the physician practice's efforts to investigate and document the violation, such as the use of internal or external legal, audit or consultative resources.

3. Chronology of the steps taken by the practice in its internal inquiry into the violation, including the following:
 - a. List of individuals interviewed and their positions and titles when the violation occurred and at the time of the disclosure. A summary of the interview should be provided. In addition, any individuals who refused to be interviewed must be disclosed, including the reason why.
 - b. Description of the files, documents and records reviewed.
 - c. Summary of the auditing activity and documents relied upon in support of the calculation of losses.
4. The practice's actions to stop the inappropriate conduct.
5. All efforts by the practice to prevent a recurrence of the violation, such as new accounting or internal control procedures, increased internal audit efforts, or increased supervision by higher management or through training.
6. Any disciplinary action taken against corporate officials, employees or agents.
7. Any notices provided to other Government agencies resulting from the violation, such as the Securities and Exchange Commission or the Internal Revenue Service.

The physician practice's report to the OIG regarding its self-assessment process should address the following:

1. Objective of the review and the review procedure(s) used to achieve the objective.
2. Identification of the population of claims to be reviewed and an explanation how the population was developed.
3. Description of the source of the information upon which the review will be based, including standards to be applied, sources of payment data and documents to be

relied upon.

4. List of the names, titles and qualifications of the personnel conducting the self-assessment, including statisticians, accountants, auditors, consultants and medical reviewers.

If the physician practice opts to review a statistical sample of claims, supplementary information must be provided to the OIG in its report.

Step 4 - OIG Verification

Once the physician practice's reports on its internal investigation and self-assessment are produced to the OIG, the OIG will begin verifying the information disclosed. The OIG will generally require unfettered access to all work papers and supporting documents. During this time, the OIG will usually not accept refunds of overpayments until its investigation is complete. However, the physician practice is encouraged to put the overpayment in an interest-bearing escrow account during such time.

Overpayments/Errors Versus Fraudulent Claims

If a potential disclosure only involves overpayments or billing errors in the absence of a violation of law, the disclosure should be made to the entity that processes claims and issues payment on behalf of the Government agency responsible for the particular federal health care program. However, if the entity believes that the overpayment was the result of fraud or other violations of law, they may refer the disclosure to the OIG.

The OIG clarified the distinction between erroneous and fraudulent claims in its Compliance Program for Individual and Small Group Physician Practices (see detailed

discussion below). Physician practices are not subject to penalties under the law for innocent errors, or even negligence. The False Claims Act imposes penalties only for those offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim⁸. Further, the Civil Monetary Penalties Law has the same standard of proof⁹. Thus, innocent mistakes, errors or negligence in submitting claims will not subject a physician to penalties.

When errors result in overpayments, physician practices merely must return the funds, without the imposition of any penalties. However, if a violation of law is suspected, the physician practice must determine whether to voluntarily disclose the potential liability to the OIG under the SDP.

When to Disclose – The Benefits of Self-Disclosure

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 and healthcare organizations who cooperate in identifying and voluntarily disclosing violations. The OIG has stated that “opening lines of communication with, and making full disclosure to, the investigative agency at an early stage generally benefits the individual or company.”

By self-disclosing, physicians and healthcare entities may be able to avoid costly and lengthy government investigations. In addition, it gives physician practices the ability to disclose what happened in the best possible light.

⁸ 31 U.S.C. 3729.

⁹ 42 USC 1320a-7a.

One of the main benefits to self-disclosure is that the OIG will waive its authority to exclude the physician from federal health care programs if the physician practice has an effective compliance program and demonstrates its trustworthiness to the OIG. The OIG has stated that detection and prompt disclosure of potential fraud are evidence of an effective compliance program.

There is a presumption that a physician practice has adopted effective compliance measures if it submits a complete and informative disclosure, a quick response to OIG's requests for further information, and performs an accurate audit. The OIG will consider such compliance measures as a mitigating factor in determining a resolution to the violation, and will not generally require the practice to enter into a Corporate Integrity Agreement ("CIA") or Certification of Compliance Agreement ("CCA"). Further, if the OIG determines that a CIA or CCA are appropriate, they will consider a physician practice's self-disclosure as an important factor in determining whether they should enter into a less restrictive CCA, rather than a more extensive CIA.

The OIG has stated that they will generally settle SDP matters for an amount near the lower end of the scale for calculating civil monetary penalty damages. In other words, the OIG will calculate damages based on the value of the financial benefit conferred in violation of the law, and forgo other penalties.

Self-reporting also offers the opportunity to minimize the potential cost and disruption of a full-scale audit and investigation by the federal government, to negotiate a fair monetary settlement and to avoid possible exclusion from the federal health care programs.

When to Hold Your Tongue – The 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 practice'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 practice will be given any leniency in resolving the matter.

The costs and time commitment to investigating the violation may be prohibitive. The SDP requires extensive investigation and analysis which can be expensive.

Disclosure of a potential violation to the OIG does not insulate the physician practice 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 review 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. Upon settlement of an overpayment, the practice must agree in writing that the government's acceptance of the payment does not constitute the government's agreement as to the amount of losses suffered by the programs as a result of the disclosed violation, and does not affect in any manner the government's ability to pursue criminal, civil or administrative remedies or to obtain additional fines, damages or penalties for the violation.

Additional violations uncovered by the OIG during its review of the physician practice's disclosure submission, 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 practice liable.

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.

Finally, due to the fact that the OIG must verify the internal investigation report and self-assessment report submitted by the physician, they need access to the underlying documents. Therefore, physician practices may have to waive certain privileges and disclose the documents. These documents, which are no longer protected by privilege, may then be discoverable in other actions, such as claims by private insurers and qui tam actions. On the other hand, however, a practice's refusal to provide these documents may be viewed as lack of cooperation, which will be considered an aggravating factor when the OIG determines how to resolve the matter.

What Should a Physician Practice Do if They Discover a Stark Law Violation Without a Colorable Anti-Kickback Violation?

In light of the OIG's March 24, 2009 Open Letter to Health Care Providers, physician practices are at a loss as to what to do with violations of the Stark Law that they discover, in the absence of a "colorable" anti-kickback statute violation.

We recently spoke with the OIG regarding this issue and they indicated that it is not within their authority and thus referred us to the Centers for Medicare and Medicaid Services ("CMS"), Division of Technical Payment Policies. We were advised by CMS that they do not have an official process for how to deal with overpayments that involve only a violation of the

Stark Law since the March 2009 Open Letter provides that the SDP is no longer available. If a physician disclosed the violation to CMS, they could not assure a compromise. In addition, if the claim involves more than \$100,000, CMS does not have the authority to compromise on the claim¹⁰, but rather the violation would have to be referred to the Department of Justice. If a physician did disclose the violation to CMS, they would review and evaluate the claim to determine if a settlement was appropriate.

CMS did inform us that they did not previously receive many disclosures of technical Stark violations. In fact, they candidly admitted that the penalty amounts were typically disproportionate to the amount of the overpayment. However, CMS typically does not stray from the Stark Law, which is a strict liability statute, and therefore does not often compromise on violations, even if they are small or “technical”. CMS advised us to contact our local Assistant United States Attorney (“AUSA”).

We then spoke with our local AUSA. We were advised that in general, they were not out looking for technical Stark violations. They are looking for conduct inconsistent with the purpose of the law. The AUSA did inform us that they would take into account whether the violation was an accident and if the physician came forward shortly after discovering the violation. They are not interested in prosecuting inadvertent technical violations and would investigate the matter to determine a fair resolution. However, if the physician wanted a release under the Stark Law or False Claims Act, the AUSA would need the approval of the Department of Health and Human Services.

¹⁰ 42 CFR 401.601(c).

How to Avoid Problems - Compliance Programs

The OIG has affirmatively stated that health care providers have “an ethical and legal duty to ensure the integrity of their dealings with [federal health care] programs. This duty includes an obligation to take measures, such as instituting a compliance program, to detect and prevent fraudulent, abusive and wasteful activities.”

One of the mitigating factors the OIG will consider in determining an appropriate resolution to a disclosed violation is if the healthcare entity has an effective compliance program. The OIG has stated that detection and prompt disclosure of potential fraud are evidence of an effective compliance program. Therefore, it is imperative that an appropriate compliance program be adopted and followed.

The OIG has issued compliance program guidance to a number of healthcare entities, including individual and small group physician practices¹¹. One of the core principals of an effective compliance plan is to respond appropriately to detected violations through the investigation of allegations and to develop corrective action, including disclosure of the incidents to appropriate Government entities. Benefits of a compliance program include minimizing billing mistakes, reducing the chance that an audit will be conducted by the OIG, and avoiding violations of the anti-kickback statute and Stark Law.

Physician practices are advised to have standards and procedures in place that encourage compliance with the anti-kickback statute and Stark Law. In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers and vendors are areas of potential concern. In addition, physician practices should implement measures to avoid offering inappropriate inducements to

¹¹ 65 FR 59434 (October 5, 2000); Available at <http://oig.hhs.gov/authorities/docs/physician.pdf>.

patients. The practice should develop its own set of monitors and warning indicators to determine when further investigation is warranted.

When a practice discovers a possible violation of law, it should develop a corrective action plan and determine how to respond to the problem. It is important that the practice investigate whether a significant violation of law or the requirements of the compliance program has occurred, and, if so, take decisive steps to correct the problem. These steps may include a corrective action plan, the return of overpayments, a report to the OIG or other Governmental agency, or referral to law enforcement authorities.

How has the SDP been Implemented by Physicians?

In 2007-2008, the American Health Lawyers Association conducted a Voluntary Disclosure Survey¹² to determine healthcare entities' experience with voluntary disclosure of a potential violation of administrative, criminal or civil law to a government agency or contractor. The nature of the self-disclosures ranged from overpayment or billing/coding errors (70%) to anti-kickback and Stark Law violations (28%) and excluded persons issues (12%).

Most (71%) of the voluntary disclosures were made through outside counsel on behalf of the healthcare entity. Almost half (46%) of the reported disclosures were made to the OIG, followed by government contractors (36%) and the U.S. Attorney's Office (25%). A significant number (49%) of the voluntary disclosures were resolved within a year of disclosure, but on the other hand 13% of disclosures took longer than three years to resolve.

The resolution of the disclosures varied greatly. A full overpayment refund was reported in 46% of the disclosures. Negotiated refunds were reported in 40% of the disclosures. Only

¹² Available at <http://www.healthlawyers.org/Members/PracticeGroups/FA/Surveys/Pages/VoluntarySurvey.aspx>.

12% of disclosures resulted in corporate integrity agreements. Criminal prosecution or guilty pleas were indicated by 2% of the respondents and exclusion/debarment by 1%.

The large majority (83%) of disclosures were made without any prior government impetus or involvement and 21% were made to due a concern about a potential whistleblower complaint.

Conclusion

The most important lesson for physicians from the OIG guidance on self-disclosure is that they should implement a compliance plan to effectively discover non-compliance with federal health care plan requirements, to address such violations, and the factors a practice must consider in determining whether or not to voluntarily self-disclose such violations. It is imperative that physicians consult with their healthcare 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.