

HEALTH LAW

Update

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The OIG's Newest Open Letter Regarding The Self-Disclosure Protocol: What's a Stark-Only Violator To Do?

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The Provider Self-Disclosure Protocol (the "Self-Disclosure Protocol"), which has been in place in one form or another since 1998, allows health care providers to voluntarily disclose evidence of potential fraud and abuse to the Office of Inspector General of the Department of Health and Human Services (the "OIG"). Although self-reporting will not result in an absolute reprieve, the OIG has indicated that voluntary disclosures under the Self-Disclosure Protocol may mitigate the severity of penalties and avoid the costs and disruptions of a full-scale audit and investigation by the federal government. For example, providers who have self-reported in the past have often been able to avoid entering into a Corporate Integrity Agreement and have also been able to negotiate damages based on the improper benefit given to the referral source instead of the aggregate amount of claims attributable to the referral source.

On March 24, 2009, the OIG released an Open Letter to Health Care Providers (the "2009 Open Letter") making two important changes to narrow the scope of matters eligible for the Self-Disclosure Protocol. First, the OIG said it will no longer accept self-disclosure of matters only involving liability under the federal physician self-referral law (the "Stark Law") unless the improper arrangement also includes a "colorable" violation of the federal anti-kickback statute.¹ Second, the OIG now requires a minimum settlement amount of \$50,000 to resolve any kickback-related matter that is self-disclosed. Each of these changes is discussed in more detail below.

No More Stark-Only Violations

The OIG's refusal to accept Stark-only violations into the Self-Disclosure Protocol is a reversal of the position announced just three years ago in the OIG's Open Letter of April 24, 2006 (the "2006 Open Letter"), in which the OIG encouraged the use of the Self-Disclosure Protocol as a vehicle for providers to resolve Stark Law violations.² As a result of the OIG's new policy, providers are left with relatively limited options for self-reporting Stark-only violations, such as reporting to the Medicare fiscal intermediary (FI) or carrier (now known as the "Medicare Administrative Contractors" or "MACs"), the Office of the U.S. Attorney, or possibly the Department of Justice. Each of these routes has drawbacks –

¹ OIG Open Letter to Health Care Providers, March 24, 2009.

² OIG Open Letter to Health Care Providers, April 24, 2006.

the FIs and carriers (now the MACs) may not have as much flexibility to negotiate damages as the OIG, and neither the FIs or carriers, nor the U.S. Attorney's Office, may be as familiar with Stark-only cases as the OIG. In addition, providers will continue to face legal exposure, including qui tam lawsuits, if they do not enter into some sort of settlement agreement with the government.

As a practical matter, many Stark Law violations may also present "colorable" violations of the anti-kickback statute, so another option could be to attempt to gain access to the Self-Disclosure Protocol by raising an anti-kickback issue. However, many providers are wary of including statements that could potentially be construed as an admission under an intent-based statute (the federal anti-kickback statute requires "knowing and willful" violations). Moreover, since the Stark Law is a strict liability statute, there may be instances of technical violations of the Stark Law (e.g., no signed contract) that in no way amount to even a "colorable" violation of the anti-kickback statute. For these types of violations, providers will have to weigh the remaining limited options carefully with their counsel.

The Ante Is Now \$50,000

Pursuant to the second change to the Self-Disclosure Protocol, the OIG now requires a minimum payment of \$50,000 to settle and resolve any matter that is self-disclosed under the federal anti-kickback statute. The OIG appears to have established this \$50,000 threshold based on the Civil Monetary Penalty Statute (CMP), which gives the OIG authority to assess a penalty of *not more than* \$50,000 per kickback plus up to three times the total payment offered, paid, solicited or received under the illegal arrangement.

It is unclear whether this refinement to the Self-Disclosure Protocol means that the OIG will not accept into the Self-Disclosure Protocol any anti-kickback related disclosures that do not involve at least \$50,000 of damages, or whether the OIG will accept cases with less than \$50,000 of damages but will require a minimum settlement payment of \$50,000. The OIG said it will continue to analyze the facts and circumstances of each self-disclosure and determine the appropriate settlement amount near the lower end of the damages continuum.

Rationale for the Changes

The OIG noted that the decision to narrow the scope of the Self-Disclosure Protocol was being made for "resource purposes" so as to reduce the overall number of disclosures submitted to the agency and to allow the agency to prioritize and allocate work in a more efficient manner. The 2009 Open Letter thus underscores the OIG's belief that the success of the Self-Disclosure Protocol requires prompt resolution by the agency of matters that are self-disclosed. Just one year ago, in an Open Letter issued on April 15, 2008 (the "2008 Open Letter"), the OIG discussed changes to the initial submission process and the agency's internal review procedures designed to increase the efficiency of the Self-Disclosure Protocol. The OIG emphasized that the Self-Disclosure Protocol was intended to facilitate resolution of potential fraud matters and not merely billing errors or overpayments that should be addressed to the appropriate Medicare contractor. In the wake of the 2008 Open Letter, the OIG saw a noticeable increase in the number of Stark-only self-disclosures. The difficulty in valuing Stark-only conduct under the CMP, and in finding a quantifiable financial benefit to the physician, apparently were factors in the OIG's decision to allocate limited resources and focus its efforts on conduct that causes greater harm to the Medicare program. Continuing in that vein, the most recent changes in the 2009 Open Letter seek to further ensure use of the Self-Disclosure Protocol for significant, fraud-related matters.³

³ OIG Open Letter to Health Care Providers, March 24, 2009.

Conclusion

Although the Open Letter does not offer any guidance regarding self-disclosure of Stark Law violations that are not coupled with a "colorable" anti-kickback statute violation, the OIG cautioned providers against inferring that the federal government will curb its enforcement of the Stark Law or that kickbacks of less than \$50,000 will be overlooked. Accordingly, health care providers should carefully consider their options in deciding whether and how to self-disclose anti-kickback statute and Stark violations. In the meantime, perhaps CMS will feel the pressure to resolve the quandary in which providers now find themselves.

If you have any questions about the Self-Disclosure Protocol or other matters discussed in this *Health Law Update*, please do not hesitate to contact any of the attorneys in our Healthcare Practice Group listed below.

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