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OIG Open Letter Regarding the Self-Disclosure Protocol: Further Refinements

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On March 24, 2009, the Office of Inspector General (OIG) of the Department of Health and Human Services released an "Open Letter" to healthcare providers containing what the agency has described as refinements to the OIG's Self-Disclosure Protocol (SDP).[1] In the 2009 Open Letter, the OIG announced two policy changes that serve to (1) clarify when the SDP should be used to address potential physician self-referral (Stark Law) violations; and (2) narrow the applicability of the OIG's April 24, 2006 Open Letter. In that guidance, the OIG encouraged providers to utilize the SDP to voluntarily disclose potential violations under both the physician self-referral law (Stark Law) and the anti-kickback statute (AKS). The 2009 Open Letter, on the other hand, encourages providers to resort to the SDP for potential Stark Law violations only if there are also potential AKS violations. In the 2009 Open Letter, the OIG also announced that it will impose a minimum civil monetary penalty (CMP) of $50,000 for non-compliance with the Stark Law and AKS reported under the SDP.

The 2009 Open Letter is the OIG's latest step aimed at providers' voluntary compliance in the healthcare sector. It comes at a time when other developments, along with political and economic conditions, have made the stakes higher than ever for providers' compliance programs. On the federal level, both relators and the government are becoming more aggressive and expansive in their interpretation of the scope of the Stark Law and AKS and how they can be predicates to False Claims Act violations. More state agencies are also increasing their Medicaid fraud enforcement activities. For example, there are now Medicaid voluntary disclosure protocols in Texas[2] and New York.[3]

Operation Restore Trust

The Clinton Administration initiated Operation Restore Trust (ORT) in May 1995 as a two-year demonstration project. ORT was concentrated in five states: California, Florida, Illinois, New York, and Texas, which had 40% of the country's Medicare beneficiaries. ORT included an invitation to providers to voluntarily disclose potential non-compliance.

Because there were barriers to entry and not many assurances that providers would obtain tangible benefits from voluntarily disclosing under ORT, providers did not accept the invitation.

Refining the Scope of the SDP

Following the limited success of the voluntary disclosure aspect of ORT, the OIG released the SDP in October 1998.[4] The OIG intended that the SDP would be a more open-ended process that did not set limitations on the conditions under which a healthcare provider could disclose potential non-compliance to the OIG. Thereafter, the OIG has issued three Open Letters addressing voluntary disclosures, each of which has provided further guidance on the OIG's aims and policies relating to the SDP.

As of March 31, 2006, the OIG reported that it had received 295 voluntary disclosures under the SDP. As of that same date, the OIG further reported that there were 60 recoveries and 63 settlements, totaling $104.2 million collectively in receivables.[5] Although some of the reported disclosures under the SDP have involved Stark Law violations, prior to 2006 they tended to be coupled with potential AKS violations. Although the OIG would waive a damages assessment on occasion, more recently the OIG insisted on a full review and report of potential exposures as provided for in the SDP (i.e., the volume and reimbursement value of potentially tainted claims) before moving forward with settlement discussions on a Stark Law voluntary disclosure.[6] The cost of such a review, together with potentially substantial settlement payments, the risk of disclosing without any guarantees as to the outcome, and the possibility of a Corporate Integrity Agreement (CIA) or Certificate of Compliance Agreement (CCA)[7] likely dissuaded many providers from attempting to avail themselves of the SDP for what were exclusively or primarily Stark Law issues, particularly if they involved relatively small dollar amounts of remuneration or were perceived as "technical" violations (even where the law did not distinguish in the potential penalties based on such "technicalities").

In its 2006 Open Letter, the OIG encouraged providers to use the SDP to disclose Stark Law violations.[8] As part of this initiative, the OIG announced two attractive incentives to encourage providers to disclose potential non-compliance through the SDP: (i) a general pledge of leniency by the agency towards healthcare providers who disclosed using the SDP (e.g., in some cases shortly before the 2006 Open Letter, OIG was amenable to penalties roughly equivalent to the amount of the problematic remuneration paid to physicians in appropriate cases—similar to the approach in the 2006 Open Letter); and (ii) a representation that the agency could view use of the SDP as a positive mitigating factor in determining whether to impose a CIA or CCA in connection with a voluntary disclosure.

In its 2008 Open Letter, the OIG clarified the second incentive from the 2006 Open Letter and indicated that providers using the SDP to disclose potential non-compliance would not automatically be required to sign either a CIA or a CCA.[9] The 2008 Open Letter also clarified that the SDP is only intended to facilitate resolution of matters that potentially violate laws for which exclusion or civil monetary penalties are authorized. According to the 2008 Open Letter, the SDP is not intended to be a mechanism for reporting billing errors or overpayments, which should instead be resolved through a repayment to the Medicare contractor.

In the 2009 Open Letter, the OIG has narrowed the instances in which providers may use SDP by announcing that it will no longer accept self-disclosures of circumstances that might give rise to CMP liability without any evidence of an AKS violation. In a transition to its pre-2006 position, the OIG's 2009 Open Letter also indicates that the OIG will no longer accept self-disclosures involving only potential liability under the Stark Law without any AKS implications. The OIG will, however, continue to accept disclosures of matters that only involve "colorable violations" of the AKS or involve situations where "colorable violations" of both the Stark Law and the AKS are present. The 2009 Open Letter emphasizes that despite the sharper focus of the SDP in relation to Stark Law violations, the Government remains committed to enforcing the Stark Law, and the continued string of Stark-related False Claims Act cases bears out that point. As discussed below, the 2009 Open Letter may have many implications, but a decrease in enforcement activity is not one of them.

In addition, the 2009 Open Letter establishes a minimum settlement amount. Effective March 24, 2009, the OIG will require a minimum of $50,000 to settle any kickback-related submissions that it accepts through the SDP. The OIG has indicated that the minimum settlement amount is consistent with the OIG's statutory authority to impose a penalty of up to $50,000 for each kickback violation (in addition to treble damages).[10] On the positive side from the provider's perspective, however, the OIG also noted in the 2009 Open Letter that it will continue to look at the facts and circumstances of each disclosure "to determine the appropriate settlement amount consistent with our practice, stated in the 2006 Open Letter, of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred."[11]

OIG Commentary on the 2009 Open Letter

Speaking to the American Health Lawyers Association (AHLA) Medicare & Medicaid Institute on March 24, 2009, Tony R. Maida, Deputy Chief of the Administrative and Civil Remedies Branch of the Office of Counsel to the OIG, stated that the decision to exclude Stark Law-only matters from the SDP was based on the difficulty inherent in determining

the value of such infractions. Deputy Chief Maida noted that in Stark Law-only situations there often is not a quantifiable value paid to a physician, making Stark Law-only violations more difficult to value than AKS violations.[12]

Deputy Chief Maida explained the imposition of a minimum settlement amount on the basis that it would allow the OIG to efficiently and effectively utilize its resources to resolve matters entailing potential kickbacks that pose serious risk to the integrity of the healthcare system, rather than using its limited resources to handle minor AKS infractions. The minimum penalty, however, may dissuade providers from disclosing matters that they may have otherwise brought to the OIG's attention through the SDP. Deputy Chief Maida concluded his address to the AHLA conference attendees by stating that the OIG does not believe, and the release of the 2009 Open Letter should *not* be read to suggest, that:

1. Kickbacks involving under $50,000 are safe;
2. Stark Law enforcement is not important; or
3. The Department of Justice is bound by the OIG's positions.

A violation of the Stark Law can result in civil penalties and exclusion from Medicare, Medicaid, and other federally-funded healthcare programs. Sanctions for violation of the Stark Law include denial of payment for the services provided in violation of the prohibition; refunds of amounts collected in violation; a civil penalty of up to $15,000 for each service arising out of the prohibited referral; exclusion from participation in the federal healthcare programs; and a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition. Under a currently expanding legal theory, knowing violations of the Stark Law may also serve as the basis for liability under the False Claims Act.

Options for Voluntary Disclosure After the Open Letter

Even though the OIG has narrowed the scope of potential Stark Law violations that can be disclosed under the SDP, enforcement activity continues unabated. Providers discovering potential Stark Law violations now have a more limited menu of options for how to address them. In addition to enacting effective measures to remedy past noncompliance and to prevent similar occurrences in the future, the options for additional corrective action are, in effect, the same options that providers had prior to the 2006 Open Letter:

1. Use the SDP to file a voluntary disclosure with the OIG and cast the conduct in question as a potential violation of both the Stark Law and the AKS. As in the past, providers will be walking a fine line between making the threshold statements necessary to show that there was a potential AKS violation without necessarily admitting that there

was definitely an AKS violation. As noted above, the 2009 Open Letter refers to "colorable violations" of the Stark Law and AKS as the threshold for accepting a voluntary disclosure under the SDP. In that regard, it is important to note that if the provider is not accepted into the program, the disclosures it makes could be used against the provider and other parties in any ensuing investigation or litigation. Moreover, with the $50,000 minimum penalty, it will be hard to argue that there was a technical violation for which the provider should not pay any penalty at all.

2. Make an informal voluntary disclosure to the local U.S. Attorney's Office. If the conduct is arguably only a potential Stark Law violation, disclosing to the Assistant U.S. Attorney (AUSA) in charge of healthcare matters in the Civil Division in the provider's district may provide some comfort that the government would not intervene in a later qui tam case under the False Claims Act, even if the disclosure was somehow not viewed as a public disclosure denying relator status. Such comfort, however, can come with a steep price and may involve substantial settlement payments. There is also a risk that the AUSA may view the conduct as potentially criminal and involve the Criminal Division in the matter.

3. If the potential violation is discovered in the context of due diligence for an acquisition, merger, or joint venture, a provider might consider filing advisory opinion requests with the OIG (for AKS issues),[13] and with the Centers for Medicare and Medicaid Services (CMS) (for Stark Law issues).[14] This approach may be appealing where there are reasonable arguments to support a position that there has been no violation or where there is the potential for abuse on the AKS side, but also safeguards in place to minimize those risks. If the advisory opinion request is rejected, or either CMS or OIG are unwilling to issue a favorable advisory opinion, the deal may be derailed at least until another disclosure avenue can be followed to completion. Of course, the OIG cannot issue advisory opinions on questions of intent, and neither the OIG nor CMS will opine on fair market value.

Conclusion

The 2009 Open Letter reflects a significant change in the scope and intended purpose of the SDP. By eliminating Stark Law-only violations from the scope of conduct that can be reported through the SDP, the OIG has narrowed the options available to providers who discover such violations. Aside from the SDP and the Open Letters, providers still do not have clear guidance from the OIG on the appropriate remedial steps to take upon discovery of such a violation, yet potential liability still persists. The 2009 Open Letter will reduce the burden on the OIG of administering the SDP, but it also may have the unintended consequence of leaving providers with limited options for dealing with comparatively minor Stark violations or with Stark violations that involve physicians who make significant referrals where the provider does not also face a "colorable" AKS risk. In

light of the continuing and potentially severe consequences of Stark Law-only violations, providers should carefully consider the other disclosure and advisory opinion options discussed above, as well as any potential state disclosure programs. Although one option may now be off the table, that does not necessarily diminish the potential exposures. Rather, it places a higher premium on effective compliance programs so providers can avoid what is now a more difficult decision of whether to disclose potential Stark Law violations and, if so, how and to whom.

The views set forth herein are the personal views of the authors and do not necessarily reflect those of the law firm with which they are associated.

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[1] The 2009 Open Letter is *available at* http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf.

[2] Texas Provider Self- Reporting Guidance, *available at* https://oig.hhsc.state.tx.us/ProviderSelfReporting/Self_Reporting.aspx (last visited Apr. 16, 2009).

[3] State of New York, Office of the Medicaid Inspector General, Self-Disclosure Guidance (Mar. 12, 2009), *available at* http://www.omig.state.ny.us/data....

[4] The SDP is *available at* http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.

[5] *See* OIG Semiannual Report, p. 18 (Spring 2006), *available at* www.oig.hhs.gov/publications....

[6] Many CIAs and CCAs are publicly available on OIG's website *at* http://oig.hhs.gov/fraud/cia/cia_list.asp.

[7] CIAs tend to be for a five-year period and included, among other provisions. Requirements for periodic reviews and certifications from Independent Review Organizations (IROs), whereas CCAs tend to be for three-year periods with more variation as to the level of any IRO involvement.

[8] The 2006 Open Letter is *available at* http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf.

[9] The 2008 Open Letter is *available at* http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf.

[10] 2009 Open Letter (citing 42 U.S.C. § 1320a-7a(a)(7)).

[11] *Id*.

[12] Deputy Chief Maida did not, however, provide any examples of Stark Law-only situations in which it was difficult to quantify the value of the alleged violation.

[13] *See* 42 C.F.R. Part 1008 (OIG advisory opinion procedures).

[14] *See* 42 C.F.R. §§ 411.370-411.389 (CMS procedures for Stark Law advisory opinions).