Compliance Advisory:

Inspector General March 24 Open Letter

MEADE & ROACH LLP

March 2009

Inspector General Eliminates Providers' Ability to Self-Disclose Instance of "Stark Only" Non-Compliance: New Inspector General's "Open Letter to Health Care Providers" Announced March 24, 2009

The Inspector General released a new "Open Letter to Health Care Providers" on March 24, 2009 which refines his previously released Open Letters of April 24, 2006 and April 15, 2008. These Open Letters encouraged providers to utilize the OIG's Self-Disclosure Protocol ("SDP") to resolve matters giving rise to possible civil monetary penalties under the anti-kickback statute and the physician self-referral ("Stark") law.

The Inspector General's new Open Letter addresses two matters related to the SDP. First, the Open Letter limits a provider's ability to use the SDP to instances of Stark non-compliance in which there is also a "colorable anti-kickback violation." The OIG will no longer accept self-disclosure protocol submissions that involve only liability under the Stark law. Second, the Open Letter sets a new floor for resolution of anti-kickback violations that are disclosed pursuant to the OIG's SDP: for anti-kickback self-disclosures submitted after the date of the Open Letter, the minimum penalty assessed by the OIG in resolving any such self-disclosures will be $50,000.

In announcing the Open Letter, Tony Maida, Senior Counsel in the Office of Inspector General, cited an increasing number of "Stark-only" self-disclosures in recent months, and the difficulty that the OIG had experienced in calculating civil money penalties for Stark violations that do not involve "benefit conferred" on physicians. The OIG's anti-kickback CMP authority – the authority discussed in the 2006 Open Letter as the alternative remedy that the OIG would look to for Stark self-disclosures – allows the OIG to calculate a penalty that is equal to three times the amount of the financial benefit that was improperly conferred. Mr. Maida discussed instances where the only Stark non-compliance involved a missing signature on a contract as being an example of Stark non-compliance where there was no "benefit conferred" on the physician and where the OIG, therefore, had difficulty calculating a CMP penalty. Mr. Maida made the announcement at the American Health Lawyers Association's *Operationalizing Stark: From Complexity to Reality Conference in Baltimore*.

> In light of the new Open Letter, compliance with the Stark law is even more critical.

Mr. Maida also clarified that there are four things that the Inspector General does not intend to communicate by releasing the March 24, 2009, Open Letter:

- The Inspector General does not intend by this Open Letter to signal that kickbacks less than $50,000 are OK. Mr. Maida made clear that the OIG views any kickback no matter how small as creating risk of abuse to the Federal health care programs.
- In publishing the Open Letter the Inspector General also does not intend to communicate that Stark enforcement is unimportant. According to Mr. Madia, arrangements that violate the Stark law often create risk of abuse for the Federal health care programs.
- Mr. Madia noted that the Department of Justice is not bound by anything in the Inspector General's Open Letter, stating that the DOJ makes its own decisions about when and how to enforce violations of legal requirements.

- Finally, Mr. Madia clarified that the Open Letter should not be seen as a statement about the government's legal rights to seek remedies for violations of the Stark law. The government's legal remedies for Stark violations remain intact, in spite of the OIG's change of position in its willingness to accept self-disclosures of Stark violations.

Mr. Madia spoke on a Self-Disclosure panel that closed the AHLA's *Operationalizing Stark* conference. His co-presenters included several prominent Stark attorneys from around the country. They characterized the Open Letter as a discouraging development for health care organizations because it leaves providers who are attempting to resolve discovered instances of Stark non-compliance with limited alternatives. One speaker noted that the Department of Justice is now the only Federal agency that is able and willing to consider giving a False Claims release to providers who find instances of "Stark only" non-compliance.

Mr. Madia's co-presenters are correct. As a practical matter the Open Letter eliminates a provider's ability to use the self-disclosure protocol to resolve matters of Stark non-compliance, and makes unavailable to providers the alternative damages remedy (use of the CMP authorities to base a penalty on the "benefit conferred" on physicians) that was offered in the 2006 Open Letter. It leaves providers who wish to resolve issues of Stark non-compliance in a difficult position. CMS has made clear in its prior comments that it is unable to negotiate reasonable resolutions of Stark non-compliance. Intermediaries and Carriers will doubtless take the same position as CMS. And the OIG has now made itself unavailable to resolve non-compliance—while in its announcement making clear that the government's ability to seek legal remedies for instances of non-compliance remains unchanged. In other words, if the government decides to initiate an investigation, *or if a qui tam plaintiff files suit on the government's behalf* [1], all of the legal remedies that have existed remain intact.

Stark's remedies include the ability to base a settlement amount on the amount of payments that a provider received as a result of billing Medicare for services referred by a physician whose financial relationship with the provider is not consistent with a Stark exception. So, for example, if a provider pays a physician for medical director services but fails to memorialize the arrangement in a writing (or memorializes the arrangement, but fails to obtain signatures from both parties) the provider is not allowed to bill Medicare for anything the physician/medical director refers to the provider, *and the government's or qui tam plaintiff's recovery under the statute can be based on the amount of Medicare payments that were received improperly as a result of such an arrangement.* CMS has made it increasingly clear that technical failures as basic as a missing signature on a lease agreement, or the provision of non-monetary compensation to a physician that, even in small amounts, exceeds the non-monetary compensation exception's annual allowance, can result in "periods of non-compliance" where the provider is not allowed to bill Medicare and is required by the Stark regulations to return any amounts that have been received as the result of improper billing.

The March 24, Open Letter makes it more difficult to resolve instances of non-compliance. It also makes it ever clearer that ensuring compliance with the highly technical Stark regulations is essential for providers who want to avoid being stuck between a rock and a hard place.

1 See, e.g., United States ex. Rel. Karen Johnson-Pochardt vs. Rapid City Regional Hospital. The Rapid City case resulted in the first significant False Claims Act settlement that was based on theories of Stark liability and was initiated by a whistleblower using the False Claims Act's qui tam provisions. The plaintiff's theory of liability was based on an expired lease agreement between the hospital and its radiation oncologists. The Hospital paid $6 Million to settle liability arising from the expired lease.

If you have any questions about clinical research compliance, please contact:

Ryan D. Meade at 312.498.7004 or
RMeade@MeadeRoach.com

Michael C. Roach at 312.255.1773 or
MRoach@MeadeRoach.com

Steven W. Ortquist at 312.285.4850 or
SOrtquist@MeadeRoach.com

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

An Open Letter to Health Care Providers

March 24, 2009

This Open Letter refines the OIG's Self-Disclosure Protocol (SDP) to build upon the initiative announced in my April 24, 2006, Open Letter. The 2006 Open Letter promoted the use of the SDP to resolve matters giving rise to civil monetary penalty (CMP) liability under both the anti-kickback statute and the physician self-referral ("Stark") law. As part of our ongoing efforts to evaluate and prioritize our work, these refinements aim to focus our resources on kickbacks intended to induce or reward a physician's referrals. Kickbacks pose a serious risk to the integrity of the health care system, and deterring kickbacks remains a high priority for OIG.

To more effectively fulfill our mission and allocate our resources, we are narrowing the SDP's scope regarding the physician self-referral law. OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law. Although we are narrowing the scope of the SDP for resources purposes, we urge providers not to draw any inferences about the Government's approach to enforcement of the physician self-referral law.

To better allocate provider and OIG resources in addressing kickback issues through the SDP, we are also establishing a minimum settlement amount. For kickback-related submissions accepted into the SDP following the date of this letter, we will require a minimum $50,000 settlement amount to resolve the matter. This minimum settlement amount is consistent with OIG's statutory authority to impose a penalty of up to $50,000 for each kickback and an assessment of up to three times the total remuneration. See 42 U.S.C. § 1320a-7a(a)(7). We will continue to analyze 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.

These refinements to OIG's SDP are part of our ongoing efforts to develop the SDP as an efficient and fair mechanism for providers to work with OIG collaboratively. Further information about our SDP can be found at: http://oig.hhs.gov/fraud/selfdisclosure.asp. I look forward to continuing our joint efforts to promote compliance and protect the Federal health care programs and their beneficiaries.

Sincerely,

/Daniel R. Levinson/

Daniel R. Levinson
Inspector General