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August 17, 2012

Inspector General Daniel R. Levinson
c/o Kenneth D. Kraft
Office of Inspector General
Department of Health and Human Services
Attention: OIG-1301-N
Room 5541B, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Solicitation of Information and Recommendations for Revising OIG's Provider
Self-Disclosure Protocol [OIG-1301-N]

Dear Inspector General Levinson:

On behalf of the physician and medical student members of the American Medical Association (AMA), I write to you today in response to the Office of Inspector General (OIG) solicitation of input regarding recommended updates to the Provider Self-Disclosure Protocol. We appreciate the opportunity to submit the below recommendations.

The OIG should suspend the obligation to report and return overpayments from the time the provider has entered the Provider Self-Disclosure Protocol until such a time as a settlement agreement is entered, the provider withdraws from the protocol, or the provider is removed from the protocol.

Suspending the statutory obligation to report and return overpayments within 60 days would allow the submitting provider, and other providers who may be implicated in the disclosure, an opportunity to engage with the OIG protocol staff without running up against the 60-day due date for repayment. Because providers enter the Provider Self-Disclosure Protocol in part to settle outstanding potential overpayments, it is nonsensical for the 60-day period to run and expire during the course of the Provider Self-Disclosure Protocol. If the obligation to report and return overpayments is not suspended, providers may be discouraged from entering the protocol; conversely, if the obligation is suspended, providers may be encouraged to utilize the protocol.

Adoption of this policy would also be consistent with the Centers for Medicare & Medicaid Services' (CMS) recent overpayments proposed rule. In that rule, CMS proposed that the deadline for returning overpayments will be suspended when the OIG acknowledges receipt of a submission to the Provider Self-Disclosure Protocol until such time as a settlement agreement is entered, the person withdraws from the protocol, or the person is removed from the protocol.

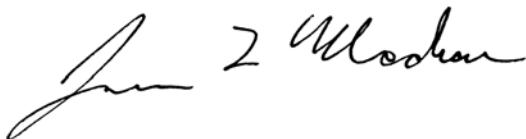
We also note that when a provider submits a potential violation to the CMS Self-Referral Disclosure Protocol, CMS sends the provider an email notification that the statutory obligation to report and return overpayments within 60 days is suspended until the conclusion of the Self-Referral Disclosure Protocol. We recommend that the OIG adopt the same policy and send an email notice when a provider submits a potential violation to the Provider Self-Disclosure Protocol.

The OIG should ensure the confidentiality of disclosures made through the Provider Self-Disclosure Protocol. Providers who are contemplating disclosing information to the OIG through the protocol should not be dissuaded from doing so because of confidentiality concerns. For the OIG to have the information that it needs to come to a meaningful and accurate assessment of a disclosed financial relationship or agreement, providers must be assured that they will not be penalized beyond the parameters of the Provider Self-Disclosure Protocol by the information that they disclose. For these reasons, at a minimum, the OIG should continue the current practice of redacting disclosures to prevent the release of any personally-identifiable information.

The OIG should consolidate guidance regarding the Provider Self-Disclosure Protocol. Since the Provider Self-Disclosure Protocol was introduced in 1998, the OIG has issued additional guidance in 2006, 2008, and 2009. As a result, providers and their legal counsel now have a piecemeal regulatory framework that they must review to understand the full ramifications of the Provider Self-Disclosure Protocol and how it may apply to their situation. To provide greater clarity, the OIG should consolidate the aforementioned guidance into one set of requirements.

We appreciate the opportunity to provide our comments on the Provider Self-Disclosure Protocol. Please contact Margaret Garikes, Director, Federal Affairs at: margaret.garikes@ama-assn.org or (202) 789-7409 if you have any questions about our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and a stylized "M".

James L. Madara, MD