



CMS-1301-N

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number: OIG-1301-N]

**Solicitation of Information and Recommendations for Revising
OIG's Provider Self-Disclosure Protocol**

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and Opportunity for Comment.

SUMMARY: This *Federal Register* notice informs the public that
OIG: (1) intends to update the Provider Self-Disclosure
Protocol (63 FR 58399, October 30, 1998) and (2) solicits input
from the public for OIG to consider in updating the Protocol.

DATES: To ensure consideration, public comments must be
delivered to the address provided below by no later than 5 p.m.
on [Insert date 60 days after publication in the *Federal
Register*].

ADDRESSES: In commenting, please refer to file code OIG-1301-N.
Because of staff and resource limitations, we cannot accept
comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates,
please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: 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. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Kenneth D. Kraft, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff at (202) 708-9848.

All submissions must include the agency name and docket number for this *Federal Register* document. All comments, including

attachments and other supporting material received, are subject to public disclosure.

FOR FURTHER INFORMATION CONTACT: Kenneth D. Kraft, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 708-9848.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> after they have been received.

Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 708-9848.

BACKGROUND:

In 1998, OIG published the Provider Self-Disclosure Protocol (the Protocol) to establish a process for health care providers to disclose potential fraud involving the Federal health care programs. The Protocol provides guidance on how to investigate

this conduct, quantify damages, and report the conduct to OIG to resolve the provider's liability exposure under OIG's civil money penalty (CMP) authorities. Over the past 14 years, we have resolved over 800 disclosures, resulting in recovering over \$280 million to the Federal health care programs. Through our experience in resolving Protocol matters, we identified areas where additional guidance would be beneficial to the provider community and would improve the efficient resolution of Protocol matters. Specifically, we issued three Open Letters to Health Care Providers to address some of these issues. First, in 2006 we announced an initiative to encourage disclosure of conduct creating liability under OIG's anti-kickback and physician self-referral law CMP authorities. In 2008, we issued additional guidance and requirements for Protocol submissions to increase the efficiency of the Protocol, including new requirements for the initial submission and specific time commitments from the provider. This Open Letter also announced the presumption of not requiring a compliance agreement as part of settling a cooperative and complete disclosure. Finally, in 2009, we stated we would no longer accept disclosure of a matter into the Protocol that involved only liability under the physician self-referral law in the absence of a colorable anti-kickback violation. We also announced a minimum \$50,000 settlement amount for kickback-related submissions.

After over a decade of experience in resolving Protocol disclosures, we are considering revising the Protocol to provide additional guidance. We are soliciting comments, recommendations, and other suggestions from concerned parties and organizations on how best to revise the Protocol to address relevant issues and to provide useful guidance to the health care industry.

DATED: _June 8, 2012_____

Daniel R. Levinson

Inspector General

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