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August 11, 2012

Mr. Kenneth D. Kraft  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-1301-N  
Cohen Building, Room 5541B  
330 Independence Avenue, S.W.  
Washington, DC 20201

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

Dear Mr. Kraft:

The American Healthcare Association (AHCA) appreciates the opportunity to briefly comment on the Department of Health and Human Services (HHS), Office of Inspector General (OIG) *Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol* (77 *Federal Register* 36281 [June 18, 2012]).

AHCA is the nation's leading long term care (LTC) organization representing more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million or our nation's frail, elderly and disabled citizens who are in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities. The vast majority of AHCA's member providers participate in the Medicare and/or Medicaid programs. Accordingly, AHCA and its members have a direct interest in the OIG's solicitation to improve the Self-Disclosure Protocol (SDP) "to address relevant issues and to provide useful guidance to the health care industry."

OIG's SDP was first published in 1998 and was drafted to establish a process for healthcare providers to disclose potential fraud involving federal health care programs. OIG's SDP provides guidance on how to investigate conduct; quantify the damages; and report the conduct to OIG to resolve a provider's liability exposure under OIG's Civil Monetary Penalty (CMP) authorities.

OIG has issued three open letters (in 2006, 2007 and 2008) about the SDP since the original 1998 publication. Each letter provides more detail about the required contents of a provider's disclosure. In 2006, OIG announced an initiative to encourage disclosure of conduct creating liability under the Anti-Kickback Statute and Physician Self-Referral Law. In 2008, OIG issued additional guidance and requirements for SDP submissions, including new requirements for the initial submission and specific time commitments for providers. The 2008 guidance also announced the presumption that OIG would refrain from requiring a compliance agreement as part of settling a cooperative and complete disclosure. In 2009, OIG determined it would no longer accept disclosure of a matter that involved only liability under the Physician Self-Referral Law in the absence of a "colorable" Anti-Kickback Statute violation. The 2009 guidance also announced a minimum \$50,000 settlement amount for kickback-related submissions.

AHCA believes that improvements to the SDP could enhance its value. While originally intended to expedite resolution of potential fraud matters by shifting the investigative burden to disclosing providers, self-disclosures under the SDP often are anything but "speedy," even though OIG states that the SDP can "diminish the time it takes before the matter can be formally resolved." In many instances, other self-disclosure options, such as disclosures to the Centers for Medicare & Medicaid Services (CMS), State, US Attorneys' offices or Department of Justice have emerged as more effective and user-friendly. OIG should consider putting additional resources into the SDP program or prioritizing disclosures to make the process more effective.

AHCA members use the SDP program most often to disclose difficulties with individuals listed on OIG's List of Excluded Individuals and Entities (LEIE). Since OIG first released its *Special Advisory Bulletin on the Effect of Exclusion from participation in Federal Health Care Programs* in 1999, OIG has published significant new guidance for implementing its permissive exclusion authority under the Social Security Act §1128(b)(15), which specifically authorizes the agency to exclude an owner, officer or managing employee of a sanctioned entity, from participation in Federal health care programs.


AHCA recognizes that OIG has suggested that a provider will be worse off if the government detects the fraud prior to a Federal health care program provider self-disclosing. However, in the case of a provider who employs or contracts with an excluded individual, absent any fraud on the part of the provider, we understand that the provider is frequently required to repay the salary and benefits of the excluded individual plus a multiplier of 1.5 to 2. Therefore, AHCA strongly urges the OIG to consider, in cases absent fraud, that a provider who self-discloses is given a flat repayment without the imposition of a multiplier. We believe that the OIG's strict liability position on this issue will have the opposite effect desired by OIG and actually create a chilling effect on the self-disclosure process.

AHCA also believes that OIG should and could improve the value of the SDB by:

- Providing a clearer explanation of which types of disclosures are appropriate for OIG and which disclosures should be submitted to the MAC using the voluntary refund process;
- Eliminating repetitive or outdated questions and updating the list of topics to be addressed in the initial disclosure, report of the internal investigation and the self-assessment;
- Establishing a time frame for OIG's assessment of completed submissions under the SDP;
- Offering guidance on the scope of OIG's internal investigations and, particularly, the appropriate length of a look-back period;
- Clarifying whether OIG will require certification of compliance agreements for resolutions under the SDP;
- Providing guidance on whether, and in what circumstances, OIG would impose CIA obligations on self-disclosing entities;
- Creating a more streamlined disclosure and proportional settlement approach for matters involving employment of excluded persons; and
- Producing standards for the range of multipliers that OIG will apply to matters self-disclosed under the SDP.

On behalf of our members, AHCA thanks you for the opportunity to submit these comments, and we look forward to reviewing the revised and updated SDP.

Sincerely,

A handwritten signature in black ink that reads "Dianne J. De La Mare". The signature is written in a cursive, flowing style.

Dianne J. De La Mare  
Vice President, Legal Affairs

CC: Dr. Peter Budetti, CMS/CPI, Deputy Administrator for Program Integrity  
Gregory Demske, OIG/Chief Counsel to IG