July 8, 2014

Ms. Patrice Drew

Office of Inspector General

Department of Health and Human Services

Attention: OIG-403-P2

Cohen Building

330 Independence Avenue SW

Room 5541C

Washington, DC 20201

***RE: OIG-403-P2: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities***

Dear Ms. Drew:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities*, 79 *Federal Register* 26,810 (May 9, 2014) (the “Proposed Rule”). AHCA is the nation’s leading long term care organization. AHCA and our membership of 11,000 non-profit and proprietary facilities are 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 of our nation’s frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

As you know, the Affordable Care Act (ACA) expanded the Department of Health and Human Services, Office of Inspector General’s (OIG) authority for exclusion and authorized the use of testimonial subpoenas in investigations of exclusion cases. In the Proposed Rule, the OIG incorporates the statutory changes enacted by the ACA, revises the definitions applicable to exclusions, proposes early reinstatement procedures and offers a number of proposed policy changes as to when and how exclusions may occur. As authorized, in part, by the ACA, the Proposed Rule would significantly expand the exclusion regulations applicable to persons or entities that receive, directly or indirectly, funds from the federal health care programs.

AHCA is pleased that the Proposed Rule offers certain mitigating factors to be considered when the OIG imposes permissive exclusions. However, as detailed below, we are concerned that certain aspects of the Proposed Rule would subject providers to limitless exclusion exposure for long-past conduct and set unfair and unrealistic standards for determining the duration of exclusion and the ability for reinstatement. Accordingly, AHCA respectfully requests that the OIG modify specific provisions of the Proposed Rule to reflect the operational realities of providers participating in federal health care programs.

**Proposed Alternative Reinstatement Process**

AHCA supports the OIG’s proposed early reinstatement process, which, under certain circumstances, would considerably shorten the time for an individual to be reinstated in order to participate in federal health care programs. Under current law, the OIG can and does exclude individuals whose state health care license has been revoked or suspended by a state licensing authority, or who have otherwise lost or surrendered a license or the ability to apply for or renew a license for reasons bearing on professional competence, performance or financial integrity. Many of these individuals lose their licenses permanently, move to a different state or choose not to obtain a new license. As a consequence, such exclusions effectively result in a permanent exclusion even if the individual was not charged or convicted of a criminal offense, or in situations where the exclusion is simply the result of administrative or clerical lapses (*e.g.,* a name change, missing a renewal deadline) that have no bearing on the individual’s trustworthiness.

AHCA understands that the early reinstatement process would supplement, rather than replace, the existing reinstatement regulations. Specifically, the individual would still have to, among other things, provide reasonable assurances that the actions that formed the basis for the exclusion have not recurred and will not recur, pay any fines and debts due and owing (including overpayments), obtain a determination from the Centers for Medicare & Medicaid Services (CMS) that the individual met the applicable conditions of participation or supplier conditions, and show that he or she has not submitted any claims to federal health care programs while excluded. AHCA supports the reinstatement requirements contemplated by the OIG, as we believe that they would help protect federal health care programs and our members’ patients.

However, as we interpret the Proposed Rule, an individual who is not seeking a health care license and has been excluded for less than five years would need to overcome the presumption against reinstatement. AHCA questions if this presumption is misplaced; and requests that the OIG not impose a higher bar for someone who is seeking a non-licensed position, especially since a person in a non-licensed position generally has a less direct or indirect role in furnishing or billing for items or services paid by federal health care programs.

**Aggravating Factor Monetary Threshold**

AHCA is concerned that the Proposed Rule does not meaningfully increase the monetary amount of financial loss leading to an individual or entity triggering an “aggravating factor”. As you know, the OIG utilizes aggravating factors to determine the length of exclusion from federal health program. The current aggravating factor regulations set a financial loss floor $5,000 and were last updated in 2002. The regulations for certain affirmative exclusions set a financial loss floor of $1,500 and were last updated in 1998. The Proposed Rule would update the financial loss floor triggering an aggravating factor to only $15,000. In the Proposed Rule’s preamble discussion, the OIG states that “[w]e believe this updated amount . . . provides a realistic marker for determining whether someone is untrustworthy.”[[1]](#footnote-1) However, AHCA urges the OIG to set a higher financial loss floor that the agency would consider an aggravating factor. Given the realities of health care billing, actions that cause or were intended to cause a financial loss of $15,000 or more would encompass many, if not most, actions. As a consequence, the proposed amount likely would not accomplish the OIG’s intended purpose of determining trustworthiness.

**Exclusion Based upon Conviction of “Obstruction” of an “Audit”**

AHCA understands that the ACA expanded the OIG’s ability to exercise its permissive exclusion authority, to exclude individual and entities based on a conviction of an offense in connection with the obstruction of an audit. In addition, AHCA recognizes that such permissive exclusion authority is a derivative exclusion authority and that, in order for the OIG to exclude an individual or entity under the provision, the individual or entity must first be convicted, under federal or state law, in connection with the interference with or obstruction of an audit. AHCA is concerned, however, that the OIG does not define “audit” nor does it explain in preamble discussion what constitutes an “audit.” For example, we assume that a state Medicaid survey or a state survey and certification survey for purposes of assessing compliance with the applicable conditions of participation would not be the sort of review or audit that would be within the OIG’s purview to seek exclusion under this provision. As a consequence, AHCA requests that the OIG further define “audit.”

**No Statute of Limitations for Exclusions for False or Improper Claims**

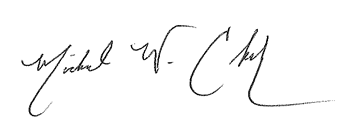
Finally, AHCA has significant concerns with the OIG’s assertion that there should be no statute of limitations within which the agency may seek affirmative exclusions imposed under section 1128(b)(7) of the Social Security Act for false or improper claims. This limitless look-back authority could place a tremendous burden on both providers and suppliers, since their conduct and compliance efforts could be second-guessed many years into the future, when supporting documentation and witnesses may be long gone.

This is the second time that the OIG has attempted to amend its regulations to provide that there would be no limitations on its ability to impose exclusions for submitting false or improper claims. In 2000, the OIG issued a proposed rule that would have resulted in no statute of limitations for such actions. At that time, commenters questioned the OIG’s proposed interpretation, pointing out that if an exclusion is based on the OIG’s determination that there has been a violation of another statute, the program exclusion action should be subject to the same limitations period that would apply to an action taken under the other statute. Otherwise, an individual or entity could be excluded for activities that occurred years before and that do not bear on current trustworthiness or integrity. Further, the commenters expressed concern that after the passage of significant time, evidence becomes difficult or impossible to gather, underscoring the need for limitations on program exclusions. Based upon these concerns, the OIG decided not to adopt the proposed revision in the regulations at that time.

Despite that history, the OIG is once again recommending this significant policy shift, and yet the concerns expressed by the commenters during the 2000-2002 rulemaking process remain valid today. Over time, the ability to retain evidence and the availability of witnesses significantly decreases. The OIG’s Proposed Rule could require health care providers to maintain records well beyond the time periods required by the Medicare and Medicaid programs. Further, the proliferation of civil False Claims Act cases over the past decade could lead to a similar uptick in exclusion actions. While the OIG states that in most cases “it makes sense” for the agency to decide whether to impose an exclusion based on the facts and circumstances at the time of the potential settlement, there is no requirement in the Proposed Rule that the OIG must wait until the settlement. The OIG could bring a parallel exclusion action at any time for conduct in the distant past. Finally, if the exclusion authority is in fact remedial, the OIG has not effectively demonstrated how imposing an exclusion for conduct occurring many years earlier, that likely involved different people, policies and procedures, furthers that policy goal.

On behalf of our members, AHCA thanks you for the opportunity to submit these comments.

Sincerely,



Mike Cheek

AHCA, Sr. V.P., Finance Policy & Legal Affairs

1. 79 Federal Register 26,810, 26,813 (May 9, 2014). [↑](#footnote-ref-1)