December 2, 2014

Ms. Patrice Drew

Office of Inspector General

Department of Health and Human Services

Attention: OIG-403-P3

Cohen Building

330 Independence Avenue SW

Room 5269

Washington, DC 20201

***RE: OIG-403-P3: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing***

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 Safe Harbors Under Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing*, 79 *Federal Register* 59,717 (Oct. 3, 2014) (the Proposed Rule). AHCA is the nation’s leading long term care organization. AHCA and our membership of 12,000 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 care centers, assisted living communities, subacute centers and centers for individuals with intellectual disability and developmental disabilities.

AHCA applauds the U.S. Department of Health and Human Services, Office of Inspector General (OIG) for issuing the Proposed Rule which would codify certain changes enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and Affordable Care Act (ACA), would effectuate technical corrections to an existing regulation and would result in new safe harbors that the OIG believes would present low risk to the federal health care programs. As you know, the Proposed Rule represents the first time in seven years that the OIG has either issued any significant changes to or proposed any new safe harbors under the federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a–7b(b). It also has been nearly 20 years since the OIG first attempted to promulgate regulations addressing the gainsharing civil money penalty (CMP).[[1]](#footnote-1) We commend the agency for addressing some of the significant matters emerging in the ever-changing health care profession. AHCA also believes, however, that in certain instances the Proposed Rule falls short of providing the necessary flexibility to health care organizations to accomplish the ACA’s laudable goals of access and cost-efficiency, and is otherwise unnecessarily narrow.

Specifically, the OIG proposes a new safe harbor to protect free or discounted local transportation services provided to certain federal health care program beneficiaries—“established patients”)—to obtain medically necessary items or services. AHCA is concerned, however, that the OIG offers no definition for the meaning of “established patients,” and the one example given in the preamble discussion does not apply in the context of post-acute provider organizations.  In fact, the OIG does not seem to consider the normal operations of long-term care facility organizations—where a patient or resident may not be considered formally admitted until the patient, resident or his or her representative signs an admission agreement when the patient or resident is already physically present at the facility—in its “established patient” requirement. AHCA urges the OIG to define “established patients” to include patients being discharged from a hospital, and receiving complimentary, local transportation to a skilled nursing facility (SNF) or other long-term care facility, who have not yet signed an admission agreement but who have expressed an interest in going to that SNF or other long-term care facility.  This would address the situation where a patient may not have completed all of the admission paperwork while at the hospital and therefore would not be an “established patient”.  Interpreted otherwise, the Proposed Rule’s “established patient” definition could prohibit safe harbor protection for SNFs and other long-term care facilities providing free, local transportation to patients who have not yet been formally admitted to the facility, which may impede access to federal health program beneficiaries who may otherwise benefit from transportation services protected by this safe harbor.

Furthermore, AHCA urges the OIG to expand safe harbor protection to free or discounted local transportation services furnished to friends and family members of SNF or other long-term care facility patients or residents. In Advisory Opinion 09-01,[[2]](#footnote-2) the OIG opined favorably upon a SNF’s free, local transportation to friends and family members of its residents.  However, in the Proposed Rule, the OIG appears to take a more restrictive approach, limiting “eligible entities” provision of free or discounted transportation to “someone to assist the patient” to obtain medically necessary items or services (if needed).  AHCA encourages the OIG to reconsider and expand the proposed safe harbor to protect the provision of free or discounted local transportation to friends and family members of SNF and other long-term care facility patients and residents. As you know, strong community ties, including relationships with family and friends, can health improve health and well-being. Safe harbor protection for the provision of free or discounted local transportation services—while meeting the safe harbor’s specified criteria—could help SNF and long-term care facility patients and residents maintain strong community ties and social connections. This is consistent with obligations under federal law for SNFs and nursing facilities to provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being for their residents.

The Proposed Rule also would codify the ACA exception to the definition of “remuneration” that protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care program.” The ACA included an exclusion from prohibited remuneration for the offer or transfer of items or services for free or less than fair market value to financially needy individuals.  The OIG notes in the Proposed Rule’s preamble discussion that “financial need” would not be limited to “indigence” but could result from any reasonable measure of financial hardship.  AHCA is concerned that the OIG does not define the term “reasonable measure of financial hardship,” and respectfully requests the OIG to better define and provide examples of that phrase.

On behalf of our members, AHCA thanks you for the opportunity to submit these comments regarding the proposed revisions to the safe harbors under the AKS, and civil monetary penalty provisions regarding beneficiary inducements and gainsharing. If you have specific follow-up questions to these comments, please contact Dianne De La Mare at 202-898-2830 or email at ddmare@ahca.org.

Sincerely,



Mike Cheek

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

1. The gainsharing CMP is set forth at 42 U.S.C. § 1320a–7a(b). [↑](#footnote-ref-1)
2. U.S. Department of Health and Human Services, Office of Inspector General, OIG Advisory Opinion No. 09-01 (Mar. 13, 2009), *available at*  http://oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-01.pdf. [↑](#footnote-ref-2)