AHCA AMERICAN HEALTH CARE ASSOCIATION
NCAL NATIONAL CENTER FOR ASSISTED LIVING

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***VIA ELECTRONIC SUBMISSION: http://www.regulations.gov***

Daniel Levinson, Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Ave. SW
Washington, DC 20201

***RE: Comments on OIG-0803-N, Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP***

Dear Mr. Levinson:

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represents more than 13,500 long term and post-acute care facilities, or 1.07 million skilled nursing facility (SNF) beds and more than 225,000 assisted living beds. With such a membership base, the Association represents the majority of SNFs and a rapidly growing number of assisted living communities.

AHCA/NCAL supports the Office of Inspector General's (OIG) efforts to identify new anti-kickback statute safe harbors to enable arrangements that promote care coordination and delivery of value-based care. New safe harbors are necessary to more fully realize initiatives by the Centers for Medicare and Medicaid Services' (CMS) to identify and eliminate unnecessary regulatory barriers to coordinated care.

As a sector, SNFs are highly invested in efforts to improve care coordination and adapt to shifts in the Medicare payment focusing on value over volume. Partnering with other service providers in the post-acute and long-term care spectrum is a critical element to successful care coordination. Partnering can take many forms, including joint ventures, financial or clinical integration, or informal networks.

In particular, SNFs have more actively explored viable relationships with ancillary service providers since the Balanced Budget Act of 1997 introduced the Medicare prospective payment system (PPS) and consolidated billing. Demands to control cost pressures and improve post-acute care coordination have continued for SNFs, accelerating over the past 10 years. In response to these pressures, SNFs have identified new opportunities to find efficiencies and improve quality delivering ancillary services such as therapy, laboratory services, and transportation.

Consistent with trends towards health care provider integration horizontally and vertically, SNF joint ventures for ancillary services are an ideal avenue to efficiently deliver services and improve care coordination in post-acute care. For example, numerous skilled nursing facility companies are exploring vertical integration opportunities to expand into population health, physician services, home health services, personal care services, institutional pharmacy services and outpatient rehabilitation services. Almost all of these services are currently provided by highly fragmented providers. In many instances, the skilled nursing facility providers do not have the requisite expertise to build a new platform to provide the services on their own and they are seeking to collaborate with existing providers in these areas. At the same time, MedPAC has advocated a unified payment system for all post-acute care services.

In order to position themselves to be a desired provider along the spectrum of post-acute care services, SNF providers are eager to create a vertically integrated network of services that include many, if not all, of the services identified above. To the extent that SNF providers can collaborate with existing providers for the services within a safe harbor under the federal Anti-Kickback Statute, we believe that this will lead to better coordinated care for residents, better quality outcomes, and an enhanced ability to negotiate collaboration agreements with acute care providers and third-party and governmental payers.

However, such arrangements could implicate the anti-kickback statute, unless they fit within an existing safe harbor. It can be challenging for a SNF joint venture for ancillary services to fit within any existing safe harbor, which has a chilling effect on these arrangements. For example, SNF joint ventures for ancillary services rarely meet all the standards for the investment interests safe harbor, in particular the 60-40 percent investment and revenue standards. However, most SNF joint ventures easily comply with the other elements of the current investment interests safe harbor. As a result of not falling squarely within the safe harbor, SNFs and other providers receiving Medicare PPS rates are unnecessarily constrained from meeting an underlying goal of a prospective payment system: for the providers to negotiate better deals and realize cost savings for the Medicare program.

**Therefore, AHCA/NCAL proposes a new safe harbor for ancillary service joint ventures with language as follows:**

> *If the joint venture entity possesses investment interests that are held either by active or passive investors, all of the following applicable standards must be met:*
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> 1. *Within one year after the commencement of the entity's operations (defined as the commencement of the provision of services to federal governmental health care program beneficiaries by the entity) 20% of the entity's customer base must be participants enrolled in an accountable care organization (ACO), Medicare or Medicaid Managed Care Organization (MCO) or other shared savings program.*
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> 2. *The terms on which an investment interest is offered to an investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity must be no different from the terms offered to other investors.*

3. *The terms in which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity, must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.*

4. *There is no requirement that an investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.*

5. *The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral rate agreement) to investors differently than to non-investors.*

6. *Within one year of the commencement of the entity's operations, at least 20% of the entity's gross revenue related to the furnishing of healthcare items and services must come from ACOs, MCOs or other shared savings program payer sources.*

7. *The governing documents of the entity must be set forth in writing and signed by all of the parties.*

8. *Each investor must contribute a commercially reasonable capital investment. The commercial reasonableness of the investment will be sufficient to address the entity's startup costs and anticipated working capital needs for the first year of its operations.*

9. *The entity must: (i) possess the requisite number employees or contractors to provide the services for which the entity was created and (ii) must own or lease sufficient office space and equipment to provide the services for which the entity was created.*

**AHCA/NCAL also proposes a Navigator/Care Coordinator safe harbor for promoting care coordination and value-based care.** This would address potential risks associated with navigator/care coordinator arrangements whereby one or more providers along the continuum of care for a given beneficiary may provide counseling and referral-type services for or on behalf of other providers along the care continuum. For example, hospitals, SNFs, home health agencies and hospices may participate in the same preferred provider network that is not an ACO. The navigator assists the beneficiary in identifying appropriate resources from members of the network to assure appropriate treatment and placement in the most appropriate setting. Additionally, the navigator may work with various providers and beneficiaries to collect and report on quality metrics such as readmissions and use of anti-psychotic medications. The services of the navigator may be paid by one or more provider participants in the preferred provider network.

AHCA/NCAL proposes the following language for the Navigator/Care Coordinator safe harbor:

*As used in section 112B of the Act, "remuneration" does not include any remuneration between a hospital, SNF, home health agency or hospice that are members of a preferred provider network for navigator/care coordination services provided to or on behalf of beneficiaries who receive services from the preferred provider network, if all of the following conditions are met:*

1. *There is a written agreement, signed by all the parties, establishing the preferred provider network, that includes the goals of promoting care coordination and value-based care.*

2. *The term of the agreement is for not less than one year.*

4. *The payment for the navigator service is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.*

5. *The agreement specifies the services to be provided in relation to each provider setting. The agreement must specify that the navigator shall not provide any service that is required under applicable licensure and certification requirements to be provided by an employee of the provider.*

6. *The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.*

7. *The parties to the agreement are required meet at least semi-annually to discuss the quality metrics collected by the navigator and consider measures to improve quality outcomes.*

    (a) *The meetings and documents concerning the quality metrics shall be considered joint quality assurance and peer review activities of the parties, and accorded all confidentiality privileges guaranteed under Federal and State laws; provided, however, that the parties agree to make available copies of agendas and sign-in sheets to federal and state governmental agencies upon request.*

8. *The aggregate services do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purposes of the services.*

Thank you for the opportunity to submit comments. Please contact Lillian Hummel at LHummel@ncal.org with any additional questions.

Sincerely,

Lillian Hummel
Senior Director, Policy and Program Integrity
American Health Care Association/National Center for Assisted Living