January 3, 2012

Mr. Daniel R. Levinson
Inspector General
Ms. Marilyn Tavenner
Acting Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1439-IFC
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

Re: Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule with Comment Period (CMS-1439-IFC)

Dear Mr. Levinson and Ms. Tavenner:

I am writing on behalf of the Alliance for Home Health Quality and Innovation (the "Alliance") in response to the Centers for Medicare and Medicaid Services ("CMS") and the Office of Inspector General ("OIG") interim final rule with comment period on the waivers in connection with the Medicare Shared Savings Program ("IFC").[1] The Alliance appreciates the opportunity to provide comments on the IFC.

Founded in 2008, the Alliance is a national consortium of home health care providers and organizations dedicated to improving individual patient care and the nation's health care system. The Alliance invests in research and education that demonstrates the value that home-based care can provide in the U.S. healthcare system. Home health providers offer cost-effective, patient-centered, and patient-preferred care by delivering high quality, skilled services to patients every day.

The Alliance has comments on the scope of the waivers set forth in section IV.B. of the IFC. ***Specifically, the Alliance recommends:***

I. **That CMS and OIG revise the structure of the ACO pre-participation waiver requirements to allow home health providers to engage in ACO pre-participation or "start-up" arrangements when a provider has a compliance program consistent with the OIG home health compliance program guidance.[2]**

II. **That CMS and OIG explicitly clarify that home health providers may be parties to arrangements described in the ACO participation waiver, the shared savings distribution waiver, the physician self-referral law waiver, and the waiver for patient incentives.**

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[1] Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67992, 67992 - 68010 (Nov. 2, 2011).

[2] *See* Publication of the OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410, 42410 - 26 (Aug. 7, 1998).

I. Scope of the ACO Pre-Participation Waiver

The Alliance urges CMS to reconsider the scope of providers that are eligible for inclusion in ACO pre-participation waiver arrangements to allow home health's inclusion. By excluding home health providers from eligibility, the Shared Savings Program will be less likely to leverage the high quality of care and efficiency that home health agencies provide to Medicare patients. ***The Alliance recommends that CMS and OIG allow home health agencies to participate in arrangements that are protected by ACO pre-participation waiver when the agency has in place a compliance program consistent with the OIG compliance program guidance for home health agencies.***

Compliant home health providers should be included as potential parties to ACO pre-participation arrangements in light of the following reasons: (1) home health offers a strong value proposition to the Medicare program; (2) excluding home health providers from the ACO pre-participation waiver provides a competitive disadvantage for those organizations that do not already have integrated home health agencies in their systems; and (3) issues of program abuse related to home health are isolated and localized, and a blanket exclusion of *all* home health providers unfairly punishes compliant home health agencies that are helping Medicare beneficiaries every day.

1. Home Health's Value Proposition

Home health offers a strong value proposition to the Medicare program, and more specifically to the Shared Savings Program. As the Medicare population grows and the baby boomers age, increasingly the emphasis will need to be on helping seniors to maintain independence at home. Published studies have shown that many patients can have improved quality of care when treated in the home as compared with facility-based care, with lower rates of hospital readmission and mortality over specific periods of time.

- When effective transitional care processes are linked with strong home care programs, one study showed that re-hospitalization was reduced by one-third in some less intensive models of care, and by one-half or more in some more intensive models.[3]
- Another study showed that home-based interventions for heart failure patients have been associated with reduced unplanned hospital readmissions and lower six-month mortality post-discharge as compared with other care settings.[4]
- Utilizing "hospital-at-home" technologies that are available today, a study conducted at Johns Hopkins University showed that patients treated at home for heart failure, chronic obstructive pulmonary disease and cellulitis had fewer clinical complications than those in the hospital.[5]
- Patients recovering from lower extremity joint replacements had a lower risk of mortality or re-institutionalization at 120 days post-discharge if they received home health as opposed to treatment in an independent rehabilitation facility or skilled nursing facility.[6]

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[3] Peter A. Boling, *Care Transitions and Home Health Care*, 25 Clinics in Geriatric Med. 135 (2009), *available at* http://www.sciencedirect.com/science/article/pii/S0749069008000712.

[4] Simon Stewart, et al., *Effects of a Home-Based Intervention Among Patients With Congestive Heart Failure Discharged From Acute Hospital Care*, 158 Arch. Intern. Med. 1067 (1998).

[5] Bruce Leff, et al., *Hospital at Home: Feasibility and Outcomes of a Program to Provide Hospital-Level Care at Home for Acutely Ill Older Patients*, 143 Annals Intern. Med. 798 (2005).

Moreover, home-based primary care programs that have been in operation for many years have experienced dramatic cost savings. Those close to the U.S. Veterans Health Administration have noted that the V.A.'s home-based primary care program has been in operation for thirty years, reporting reduced overall costs by 24%, hospital days by 80% and nursing home days by 90%.[7] Others have observed similar impact on care, relying on the home-based primary care initiative at Virginia Commonwealth University which has been in operation for 25 years and has reported reduced overall costs of 63% and reduced hospital days of 74%.[8]

The Alliance urges CMS and OIG to recognize the potential for high quality and efficient service delivery for patients through home health care, consistent with the purposes of the Shared Savings Program. Encouraging home health's participation through inclusion in the start-up arrangements protected by the ACO pre-participation waiver will help ACOs to achieve the triple aim of enhanced patient experience of care, improved population health, and reduced cost of care.

2. Anti-Competitive Effect

Excluding home health providers from the ACO pre-participation waiver provides a competitive disadvantage for those hospital systems and other health care organizations that do not have integrated home health agencies. Although some hospitals and health systems already own home health agencies, many others do not. By excluding home health agencies from ACO start-up arrangements, these health systems will be less likely to leverage the use of home health care to improve quality and reduce cost of care in the ACOs they form.

Alliance members have reported that hospitals and physician practices have expressed unwillingness to discuss any home health agency participation or involvement in ACOs as a result of the IFC's exclusion of home health from ACO pre-participation waiver arrangements. Although it may be true that home health agencies may participate in arrangements pursuant to the other waivers enumerated in the IFC, this is not explicitly stated in the IFC.[9] As a result, home health providers have effectively been blacklisted by many in the health care system from being considered as potential partners in the formation and implementation of ACOs. In light of the considerable value proposition that home health agencies have to offer the Medicare program, this effect, however unintentional, is particularly distressing.

3. Addressing Fraud and Abuse

Finally, the IFC states that the pre-participation waiver does not cover arrangements involving home

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[6] Melinda Beeuwkes Buntin, et al., *Comparison of Medicare Spending and Outcomes for Beneficiaries with Lower Extremity Joint Replacements*, RAND Health Working Papers Series (2005), *available at* http://works.bepress.com/melinda_buntin/72005.

[7] *See, e.g.*, James W. Holsinger, Jr., *Holsinger: Veterans Health Care Program Could Be Model for Medicare*, Roll Call, Nov. 8, 2011, http://www.rollcall.com/issues/57_55/james_holsinger_veterans_health_care_program_model_medicare-210094-1.html.

[8] *See* Jim Pyles, *Independence at Home Act: A Chronic Care Coordination Program for Medicare That Has Proven Effective in Reducing Costs and Improving Quality For Highest Cost Patients*, N.Y. Acad. Med. (May 26, 2009), http://www.nyam.org/policy/testimony/aging-federal03.pdf

[9] For this reason, the Alliance is also asking for clarification on the IFC. *See* Heading II of this document.

health suppliers because they "have historically posed a heightened risk of program abuse."[10] It is important to note that issues of fraud and abuse related to home health are isolated and localized. A blanket exclusion of *all* home health providers unfairly punishes compliant home health agencies that are improving quality and providing efficient care to Medicare beneficiaries every day.

The Medicare Payment Advisory Commission's recommendations recognize the localized nature of the fraud and abuse risk areas for home health. In its *2010 Report to Congress*, MedPAC recommended that the "Congress give the Secretary the authority to suspend payment and the enrollment of new providers in areas that appear to be at high risk [of fraud]."[11] The Report emphasizes that fraud is "concentrated in certain regions" or "high-fraud areas" and clarifies that regulation should target these areas where "local trends" suggest fraud or abuse.[12] The *March 2011 Report to Congress* raised additional concerns about the unusually high patterns of utilization in twenty-five specific counties in the United States.[13] Both reports identify fraud and abuse as a localized, isolated problem in high-risk areas rather than an across-the-board issue for all home health providers.

The Alliance supports strong compliance programs consistent with the OIG compliance program guidance for home health agencies. Furthermore, Alliance members support the MedPAC approach of addressing fraud and abuse by targeting enforcement efforts where there are specific reasons to suspect fraud and abuse. Alliance members have also supported adoption of legislative provisions that would address the root causes of fraud and abuse and have been working through the Partnership for Quality Home Healthcare to advance these provisions with members of Congress.

A blanket exclusion of all home health providers from the ACO pre-participation waiver arrangements – regardless of their history with the Medicare program or location in areas of the country not identified as problematic – does nothing to address the concerns and perils of fraud and abuse. This exclusion does, however, greatly impede the success of ACO development and the quality and efficiency goals of the Shared Savings Program.

The Alliance urges CMS and OIG to enable home health agencies that have been following the OIG's compliance program guidance to be part of ACO pre-participation arrangements that are covered by the waiver.

II. Clarification of the Scope of the ACO Participation Waiver, the Shared Savings Distribution Waiver, the Physician Self-Referral Law Waiver, and the Waiver for Patient Incentives

In addition, the Alliance strongly recommends that OIG and CMS provide clarification that home health agencies can participate in ACOs and can potentially engage in arrangements that would be covered by the ACO participation waiver, the shared savings distribution waiver, the physician self-referral law waiver, and the waiver for patient incentives. The Alliance recommends that such

[10] 76 Fed. Reg. at 68002.
[11] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, 214 (March 2010), *available at* http://medpac.gov/documents/Mar10_EntireReport.pdf (emphasis added).
[12] Id. at 215.
[13] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, 179 (March 2011), *available at* http://www.medpac.gov/documents/mar11_entirereport.pdf.

clarification be published in the Federal Register. The clarification could also appear in a "frequently asked questions" (or FAQ) document posted on the CMS and OIG websites.

As stated above, Alliance members have been reporting that hospitals and physician practices have expressed unwillingness to discuss any home health agency participation or involvement in ACOs as a result of the IFC's exclusion of home health from ACO pre-participation waiver arrangements. It is therefore critical that CMS and OIG provide clarification to ensure that health care system stakeholders can clearly understand that home health agencies may be strong potential partners in ACOs. CMS and OIG should explicitly state that home health agencies may participate in arrangements pursuant to the other waivers enumerated in the IFC.

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Thank you again for the opportunity to comment on the shared savings program waivers interim final rule. Should you have any questions, please contact me at 202-239-3671 or tlee@ahhqi.org.

Sincerely,

Teresa L. Lee, JD, MPH
Executive Director

Cc: Vicki Robinson, Esq.
James Cannatti, III, Esq.