June 10, 2013

The Honorable Daniel Levinson
Inspector General
Office of the Inspector General

Ms. Patrice Drew
Office of Inspector General

Department of Health and Human Services
Attention: OIG– 404–P
Room 5541C, Cohen Building
330 Independence Avenue SW.
Washington, DC 20201

RE: Proposed Rule - Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute

Dear Mr. Levinson and Ms. Drew:

I am writing on behalf of the Alliance for Home Health Quality and Innovation (the "Alliance") in response to the **Office of Inspector General's (OIG's) Proposed Rule – Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute.**[1] Thank you for this opportunity to provide comments.

In addition to our comments on this proposed rule, we are also submitting comments on the complementary proposed rule issued by the Centers for Medicare & Medicaid Services on the Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements.[2]

The Alliance is a non-profit 501(c)(3) organization with the mission of supporting research and education on the value home health care can offer to patients and the U.S. health care system. Working with researchers, key experts and thought leaders, and providers across the health care continuum, we strive to foster solutions that will improve health care in America.

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[1] 78 Fed. Reg. 21,314 (April 10, 2013) [hereinafter Proposed Rule]. Available online at: https://oig.hhs.gov/authorities/docs/2013/EHR_Safe_Harbor_Proposed_Rule.pdf.
[2] 78 Fed. Reg. 21,308 (April 10, 2013). Available at: http://www.gpo.gov/fdsys/pkg/FR-2013-04-10/pdf/2013-08312.pdf.

We are a member organization comprised of not-for-profit and proprietary home health care providers and other organizations dedicated to improving patient care and the nation's healthcare system. Within our membership, our Health Information Technology Working Group works to bridge interoperability gaps across care settings to facilitate health information exchange, with the goal of aligning home health care providers with interoperability initiatives necessary to achieve health care reform.

At the outset, the Alliance appreciates the OIG's support for "the public policy goal of promoting electronic health records."[3] Our comments, below, focus on three areas of the Proposed Rule: (1) the role of home health within the care continuum as it relates to developing electronic health records; (2) support for the proposal to extend the sunset provision; and (3) the types of providers considered eligible donors under the safe harbor.

1. **Home health care providers are a necessary partner in achieving the goal of promoting electronic health records and interoperability in the health care system. The 2006 Final Rule correctly extends safe harbor protection to home health as a provider that has a substantial and central stake in achieving health information exchange across settings.**

In order to "significantly further the important public policy goal of promoting electronic health records," the 2006 Final Rule adopted a bright line test that extended safe harbor protection to "any donor" that provides patients with health care items or services "covered by a Federal health care program" including Medicare and Medicaid.[4] The rule further explained that the donors under the safe harbor must be "individuals and entities with a ***substantial and central stake*** in patients' electronic health records" (emphasis added).[5]

The 2006 Final Rule correctly categorized home health agencies as entities that have a "substantial and central stake" in patients' electronic health records as front line, not ancillary, providers of health care services within the health care continuum. Home health agencies provide skilled, clinical health care services to patients on the front line of care. In fact, federal regulations mandate that home health services can only be provided where the patient needs "intermittent skilled nursing care", "physical or speech therapy", or "occupational therapy"[6] provided by skilled home health care professionals. These regulations require that home health's services be clinical in nature. Patients and the overall U.S. health care system benefit when home health providers collaborate well with other providers and settings of care as home health agencies are working directly to coordinate care with acute care hospitals, physicians and the patient's primary care providers.

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[3] Proposed Rule at 21,318 (citing 71 Fed. Reg. 45110, 45128 (Aug. 8, 2006)).
[4] Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute [hereinafter 2006 Final Rule], 71 Fed. Reg. 45,110, 45,127 (Aug. 8, 2006). Available at: http://www.gpo.gov/fdsys/pkg/FR-2006-08-08/pdf/06-6666.pdf.
[5] *Id.*
[6] 42 C.F.R. § 424.22 (Oct. 1, 2004) (stating that home health services must include either skilled nursing care or other skilled health care services). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2004-title42-vol2/pdf/CFR-2004-title42-vol2-sec424-24.pdf.

The Department of Health and Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) have publicly acknowledged the importance of equipping long-term and post-acute providers with EHR technologies to enable cross-setting health information exchange.[7] In fact, the recent HHS/ONC Request for Information (RFI) on Advancing Interoperability specifically asked home health agencies to provide information on how regulatory tools can be used to encourage health information exchange between home health and other care settings.[8] The RFI is an example of the government's recognition that home health is an important provider in the health care continuum. The safe harbor's inclusion of home health, among other long-term and post-acute care providers, is a critical piece in achieving a longitudinal, electronic care record.

Additionally, innovation in health care delivery models requires strong partnerships with home health providers. CMS's various innovation programs have recognized the importance of home-based care in achieving interoperability. For example, the IMPACT Project, funded through a CMS Challenge Grant, has done extensive work to create a cross-setting, electronic transfer of care document, with its foundation built from home health's OASIS assessment tool.[9] Several projects from CMS's Centers for Medicare and Medicaid Innovation (CMMI), and required or authorized by statute in the Patient Protection and Affordable Care Act (PPACA), envision the home as a setting of care including: the Independence at Home demonstration project, the Bundled Payments for Care Improvement Initiative (Models 2 and 3 involve home health), and the Medicare Shared Savings Program (which allows home health to be involved). The Alliance asks that the OIG support this vision by continuing to include home health as a key partner in achieving interoperability initiatives.

2. <u>The Alliance fully supports the proposal to extend the sunset provision to December 31, 2016 in order to allow providers necessary time to adopt EHR technologies.</u>

The long-term and post-acute care community, including home health, faces continuing obstacles in achieving interoperability despite a strong desire to engage in health information exchange. Although home health and other long-term and post-acute providers are not included under the Medicare and Medicaid EHR Incentive Programs (known as the Meaningful Use program)[10], many providers have sought out community-led interoperability initiatives such as the Standards and Interoperability Framework (S&I Framework) and the LTPAC Health IT Collaborative. These initiatives demonstrate that the long-term and post-acute care community want to fully engage in health information exchange. Home health providers, and the Alliance membership in particular, are pursuing interoperability goals despite the lack of regulatory standards to govern the harmonization of technologies between Meaningful Use providers and those not included in the Meaningful Use Program.

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[7] *See* Advancing Interoperability and Health Information Exchange, 78 Fed. Reg. 14,793 (Mar. 7, 2013). Available at: http://www.gpo.gov/fdsys/pkg/FR-2013-03-07/pdf/2013-05266.pdf.
[8] *See id.* at 14,797, Question 6.
[9] *See* the IMPACT Project homepage, available at http://mehi.masstech.org/what-we-do/hie/impact/land-and-see.
[10] *See* Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44314, 44314 – 44588; *also at* 42 C.F.R. 412, 415, 422 *et al*, Medicare and Medicaid Programs, Electronic Health Record Incentive Program; Final Rule.

Even though we are confident that home health will achieve health information exchange with other care providers, home health (like many other health care providers) needs more time to implement interoperable EHR systems. A recent survey of the Alliance's health care providers revealed that the Alliance membership overwhelming supports health information exchange and the use of regulatory tools to facilitate such exchange. All responding providers reported that their organizations had the ability to capture clinical information, that their patients have corresponding electronic records, and that each organization could receive data from other providers. The majority, although not all, of the Alliance's provider members can send electronic information to other providers either through their existing EHR systems or through a state-based HIE.

Like many health care providers[11], home health needs more time in order to fully engage in this space. While roughly one-third of our current membership reports can exchange structured and narrative data with other settings, others still rely on Portable Document Formats (PDFs) or facsimile as the primary method of data exchange. Many existing EHRs have been built in a different language and architecture than the systems used by acute-care settings like hospitals and physicians, issues that are being addressed through the Health IT Policy Committee, ONC, and the S&I Framework.

For this reason, the Alliance fully supports the extension of the safe harbor until December 31, 2016 because it allows providers the time and means to bridge the gap between current systems and the standards for long-term and post-acute care currently under development.

3. **All home health care providers should be included as eligible donors under the safe harbor because home health, like other long-term and post-acute care providers, is a critical partner in achieving cross-continuum interoperability goals.**

The Proposed Rule considers narrowing the safe harbor by excluding "independent home health agencies" from the definition of protected donors.[12] All home health providers who provide skilled services in the home as required under Medicare (see footnote 6) should be included in the safe harbor. Furthermore, the distinction between "independent" home health agencies and other providers of home-based care is not relevant.

As stated above, there are several PPACA-mandated or authorized programs that envision the inclusion of home health providers, and provide incentives to better coordinate or integrate care across the health care continuum. If home health agencies are excluded from the safe harbor, progress toward ultimate coordination and integration will be hindered, in terms of both health information exchange and health care delivery system reform. Such limitations will punish those that are in progress toward the goals set by policy makers to improve health care delivery. Moreover, the ability to exchange health information (and thereby enable seamlessly coordinated care) is a policy goal in itself that is greatly facilitated by the safe harbor. Excluding any home health providers will only hinder achievement of these goals.

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[11] *See e.g.* Adam Wright, et al., Early Results of the Meaningful Use Program for Electronic Health Records, 368 New Eng. J. Med. 779-80 (Feb. 21, 2013) (stating that as of May 2012, only 12.2% of eligible physicians were prepared to meet the requirements of the Meaningful Use program). Available at http://www.nejm.org/doi/full/10.1056/NEJMc1213481.

[12] Proposed Rule at 21,318.

Finally, the rule does not provide a definition of "independent home health agencies," nor is it defined in the Office of Inspector General's Compliance Program Guidance for Home Health Agencies.[13] The Compliance Guidance does refer to "independent home health agencies" in a footnote and describes them as "small" and "with limited financial resources and staff."[14] As stated above, the Alliance would argue that this distinction that is not relevant as an agency's affiliation with other care providers is not related to its ability to comply with the requirements of the safe harbor and other federal laws.

All home health providers are front-line providers of skilled care and are a key part of the health care continuum. They should be on equal footing with other types of health care providers for purposes of the electronic health records safe harbor such that all home health providers are included as potentially eligible donors.

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The Alliance greatly appreciates the opportunity to comment. Should you have any questions about the Alliance's comments, please contact the Alliance's Director of Strategic Initiatives and Communications C. Grace Whiting at (202) 239-3983 or gwhiting@ahhqi.org.

Sincerely,

/s/
Teresa L. Lee, JD, MPH
Executive Director

[13] Office of Inspector General's Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410 (Aug. 7, 1998). Available at: http://oig.hhs.gov/authorities/docs/cpghome.pdf.
[14] *Id.* at 42,412.