

January 8, 2015

The Honorable Marilyn Tavenner Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Room 445—G Hubert H. Humphrey Building, 200 Independence Avenue SW Washington, DC 20201

RE: Proposed Rulemaking on Conditions of Participation for Home Health Agencies: Revision of Requirements

Dear Administrator 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') request for Public Comment on the proposed rule updates, **Conditions of Participation for Home Health Agencies: Revision of Requirements.** ¹ Thank you for the opportunity to provide comments on the Proposed Rule.

About the Alliance for Home Health Quality and Innovation

The Alliance is a non-profit 501(c)(3) organization with the mission to lead and support research and education on the value of home health care to patients and the U.S. health care system. Working with researchers, key experts and thought leaders, and providers across the spectrum of care, we strive to foster solutions that will improve health care in America. The Alliance is a membership-based 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. For more information about our organization, please visit: http://ahhqi.org/.

We appreciate the opportunity to provide comments on the Proposed Rule, and offer recommendations and considerations to CMS regarding: (1) support for the overall direction of the updates to the conditions of participation; (2) requests for further clarity and guidance on compliance and enforcement of the conditions of participation; (3) engaging primary care practitioners; and (4) request for an appropriate timeline to enable home health providers to update their systems and procedures.

¹ Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies, 79 Fed. Reg. 61,163 – 213 (October 9, 2014) (herein after "Proposed Rule"), http://www.gpo.gov/fdsys/pkg/FR-2014-10-09/pdf/2014-23895.pdf

I. Support for Revised Home Health Conditions of Participation

The Alliance supports CMS's efforts to update the Home Health Conditions of Participation (CoPs), especially in focusing greater attention on patient rights and value-based and outcomes-driven care. In addition, the Alliance appreciates CMS's overall recognition of issues related to health care disparities. CMS is clearly recognizing that there is evolution in the health care system in this area and the Alliance appreciates that CMS is seeking to lead home health care toward improvement quality.

Furthermore, the Alliance supports CMS's changes that are meant to update the conditions of participation in areas where the existing requirements might simply be outdated. An example of such an area is the new CoPs involving infection prevention and control. The modifications in this area bring the CoPs into alignment with today's standards and the Alliance supports such changes.

Overall in the Conditions of Participation, the Alliance urges CMS to bear in mind the role and value of home health care in the overall health care system as it makes changes to the conditions of participation. Home health care is a high-value asset to the healthcare system, working within the continuum to improve patient outcomes through efficient and lower-cost care, which is patient preferred. In particular, home health agencies are specialists in serving patients who need post-acute care and/or need community-based care management to address chronic conditions. Home health agencies provide high-quality care to vulnerable patients who need it the most and are key players in the effective delivery of health care to an aging population.

In particular, the Alliance supports the focus on patient-centered care in the proposed rule. The emphasis on informing patients of their rights, and patient safety in general, is directionally important and appropriate for the Conditions of Participation. Earlier this fall, the Alliance cosponsored a workshop with the Institute of Medicine and National Research Council on the future of home health care. A major theme of the workshop was the drive toward more patient-centered care.

The ability to receive care in the home is preferred by a majority of patients (73 percent of those with disabilities and 58 percent of the total population over 50).² Furthermore, care provided in the home allows for a shift in care customization, allowing patient goals to play a great role in the care plan.²

Moreover, the Alliance supports the interdisciplinary approach to care as a key component of the delivery of care in the future, including further engagement of physicians and caregivers. The Alliance supports CMS's efforts to advance this approach to health care delivery. In order

² Alliance for Home Health Quality and Innovation, *The Future of Home Health Care Project (May 2014)*, p. 4 http://ahhqi.org/images/pdf/future-whitepaper.pdf

² Eric Dishman, *Personal Health, Going Home and Beyond (October 2014)*http://www.iom.edu/~/media/Files/Activity%20Files/Aging/Future%20of%20Home%20Health/DISHMAN.pdf

to achieve that ideal future state of health care delivery, team members from across the spectrum of care, working in tandem with patients and caregivers as members of the team, will need to develop an interdisciplinary approach.

II. Further Clarity and Guidance on Compliance and Enforcement

The Alliance seeks further clarity and guidance on how providers should comply and how CMS will enforce certain aspects of the conditions of participation. The following are the specific areas where further guidance is needed.

a. Sec. 484.50 Patient Rights

Documentation Examples. The Alliance recommends that CMS provide examples of how to document satisfaction of the requirement that the patient understands his or her rights and responsibilities, taking into consideration the need to balance the intent of the new requirements with the potential burden on providers. Alliance members are concerned about the potential challenges associated with achieving compliance given that some patients are limited English proficient, and many may have literacy and cognitive limitations. We encourage CMS to issue guidance that strikes a balance between the need to support patient rights with the need to provide streamlined and realistic compliance guidance for home health agencies. Furthermore, the Alliance encourages CMS to permit use of technology where possible to simplify documentation and compliance.

Patient involvement with the plan of care. The proposed rule specifies that the patient participate in "establishing and revising the plan of care, including receiving a copy of it." In practice today, changes to the plan of care may appear in writing, but may be made orally. Then the changes are transcribed and sent to the physician for signature. Such changes occur frequently, even though the changes to the plan of care may be very minor in nature. The Alliance agrees with the intention of the proposed rule to include the patient (or representative) in the plan of care, but is concerned that including the patient in even minor changes to the plan of care would be burdensome for both the home health agency and the patient. Given the frequency of revisions to the plan of care, for even minor changes, the Alliance recommends that CMS modify its CoP requirement so that patients (or their representatives) need only participate in major revisions to the plan of care. For example, a change in the goal of care, the number of visits, or discharge date would be considered a major change in the plan of care that would necessitate patient involvement.

Furthermore, the Alliance recommends that for LEP patients, translation of the plan of care should be permitted *orally*, rather than requiring translation of the plan of care in writing. Alliance members are concerned that requiring written translations for each plan of care would be impractical because each plan of care is unique to the individual patient. The Alliance supports the need for meaningful patient engagement, but is concerned about unnecessary burden in this regard.

Permitting electronic transmissions. Finally, the Alliance recommends permitting electronic transmission of the plan of care information to patients, and allowing

flexibility on the means one might use to support patient participation. Enabling multiple means of transmission, rather than only permitting paper-based transmissions, would support ease of compliance and efficiency.

b. Sec. 484.55 Comprehensive assessment of patients

The Alliance recommends greater clarity involving the requirement that each patient must receive, and an HHA must provide, a patient-specific comprehensive assessment. The question raised by the proposed change in section 484.55 is whether CMS plans to establish the minimum content required to satisfy what "comprehensive assessment" is for all of home health care, regardless of payer. Greater clarity on what will be required for all payers would support provider compliance with these proposed provisions.

c. Sec. 484.60 Care Planning, coordination of services and quality of

The Alliance supports the overall direction and instruction related to care planning, care coordination, and quality of care. The Alliance recommends that CMS provide greater clarity and specific guidance on exactly what is needed to demonstrate that patient-centered goals have been set. In addition, examples of effective interdisciplinary teams would be useful in enabling effective compliance with the CoPs.

The Alliance is concerned, however, about the requirement that verbal orders must include the "time" of the order. Home health agency systems typically have the ability to record signatures and dates, but times normally are not obtained. In general, the time of day is not a critical piece of information in home health care practice. The Alliance recommends that signing and dating the orders should be required, but that the time of day not be required in the CoPs.

d. Sec. 484.65 Quality Assurance and Performance Improvement (QAPI) programs

The Alliance supports CMS's changes to the CoPs in this section. The section provides flexibility and brings home health into alignment with other parts of the health care system.

e. Sec. 484.70 Infection prevention and control

The Alliance supports CMS's changes to the CoPs in this section. The inclusion of language involving education of patients and caregivers is an appropriate and needed aspect of infection prevention and control.

f. Sec. 484.75 Skilled professional services

The Alliance supports CMS changes to the CoPs in this section. In particular, the Alliance supports enabling occupational therapists to open a case.

g. Sec. 484.80 Home health aide services

The Alliance has no comments on this section of the CoPs.

h. Sec. 484.100 Compliance with Federal, State and local laws and regulations related to the health and safety of patients

The Alliance has no comments on this section of the CoPs.

i. Sec. 484.105 Organization and administration of services

The Alliance supports the creation of a "Clinical Manager" position as a condition of participation. Ensuring oversight of all patient care services and personnel under this position is appropriate and consistent with efforts to ensure coordination of patient care.

j. Sec. 484.110 Clinical records

The Alliance supports the overall direction that CMS proposes in section 484.110 on clinical records. Exchange of health information is a critical goal for the U.S. health care system. Incomplete information hinders the ability to achieve care coordination and achieving improvements in care transitions throughout our health care system. The electronic exchange of standardized data between and among eligible providers and professionals and long-term and post-acute care (LTPAC) providers is critical to improving care coordination across the spectrum of care.

One challenge, however, is that the goal of true health information exchange has eluded both the home health community and the larger health care system. The electronic exchange of standardized, interoperable clinical information between different IT platforms would be an essential tool for care integration between and among physicians, acute care providers and LTPAC providers. This standardized, interoperable exchange of clinical information among platforms, however, does not exist today. Furthermore, although there is an effort to standardize information critical in this regard, there has been little progress in moving such effort into everyday practice. Thus, today's health care system continues to transmit data in often the most archaic means, whether via fax or even via hard copy delivery of paper records.

Recognizing the challenges of transmitting and receiving health information among health care professionals and providers today, the Alliance recommends that CMS modify section 484.110(a)(6) by modifying the time for sending a completed discharge or transfer summary. The Alliance recommends changing the wording of this sub-section by deleting "calendar" days and inserting "business" days. This will permit adequate time to transmit the discharge or transfer summary to primary care providers and facilities.

k. Sec. 484.115 Personnel qualifications

The Alliance has no comments on this section of the CoPs.

III. Engaging Primary Care Practitioners

In addition, CMS is soliciting comments regarding methods to engage physicians caring for patients prior to admission to home health service. The proposed rule preamble states:

"Specifically, we are interested in ways to maximize the level of involvement of the physician who is most involved in the patient's care prior to admission to the home health agency, and who is responsible for overall treatment of the condition(s) that led to the need for home health care."

The Alliance recommends that CMS consider using its demonstration authority to develop a care delivery model that would test the use of Nurse Practitioners (NPs) as primary care practitioners for home health patients. NPs often function as the primary care practitioner for patients in the community and play a significant role in providing care for patients, including Medicare beneficiaries, who use home health services. Therefore, any initiative aimed at engaging physicians who care for home health patients will necessitate recognizing and engaging the NPs that care for these patients.

The current statute prohibits NPs from certifying patients for home health services or writing orders while patients are under a home health plan of care. However, the Alliance supports exploring whether revising the statute to lift this prohibition could improve continuity of care, particularly for patients with multiple co-morbidities and chronic conditions.

IV. Given the significant nature of the proposed changes, the Alliance recommends that CMS implement these changes to the conditions of participation on a timeframe that takes into account the requisite time and effort for home health agencies to put systems and procedures in place to comply.

Although the Alliance supports the themes that CMS advances in the proposed CoPs, many of the requirements are geared towards emerging standards of care and areas where home health providers are striving to advance but have not yet realized such advancements. For example, changes in use of the discharge summary will likely be important in the future, but at present such changes might not actually be utilized to their full extent due to limitations in how (and with whom) health information is actually exchanged today.

Moreover, the changes made in the CoPs will require considerable investment by home health providers in training and education, as well as investments in software and systems updates. In an environment where payment rates have been rebased consistent with the provisions in the Affordable Care Act, these changes would appear to increase home health provider operating costs and put further strain on said providers. The costs of putting these new requirements into effect should be considered in future Home Health Prospective Payment System rule-makings so that rate-setting can be adjusted to enable home health providers to operate effectively.

Given the significant time and effort required to invest in training, education and software, and systems changes to comply with the new CoPs, the Alliance urges CMS to take into consideration the recommended timeframes put forth by both Alliance members and the home health community at large in determining an appropriate timeline for implementation of the proposed changes and requiring actual home health provider compliance.

Recommendation: Given the time, effort, and investment required to implement the new CoPs, the Alliance recommends HHAs be given no less than 18 months to implement and comply with the changes following the issuance of the final rule.

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The Alliance greatly appreciates the opportunity to comment. Should you have any questions about the Alliance's comments, please contact me at (202) 239-3671 or tlee@ahhqi.org.

Sincerely,

Teresa L. Lee, JD, MPH Executive Director

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