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January 5, 2015

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

***Re: CMS 3819-P, Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies; Proposed Rule, Oct. 9, 2014.***

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including almost 1,000 that have home health services, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services'(CMS) proposed rule to revise the Conditions of Participation (CoPs) for home health agencies (HHAs).

**We support the proposed rule. We applaud CMS for continuing to update CoPs for health care providers and to ensure that regulations are current, reflect the best and most recent knowledge about care delivery, and embody high expectations for quality of care.** CMS's proposals for HHA regulations embrace the right quality of care concepts and reflect many of the activities our members already undertake to promote patient safety. We are pleased that CMS proposes to modernize the regulatory framework to include ongoing quality assessment and performance improvement and formalized infection control and prevention programs, and that the agency emphasizes patient-centeredness, outcomes and care coordination.

CMS does not propose a timeline for implementing the proposed requirements once they are finalized. **We ask CMS to adopt an effective date that is one year after the release of the final rule**. This timeframe would allow HHAs sufficient opportunity to incorporate new policies, procedures and practices effectively. We also understand that many states have modeled their HHA regulations on the Medicare CoPs. A one-year implementation timeframe would, in theory, give state health departments the time they need to align with federal standards.

Further, a one-year timeline would allow CMS to prepare and pilot test interpretive guidance before the new standards go into effect. We urge CMS to consider using an open and transparent

process for developing the interpretive guidance for the finalized regulations. CMS could, for example, post the draft guidance electronically for a period of 30 to 60 days and provide an email address for stakeholders to offer comments. We appreciate the fact that CMS provides flexibility with regard to many of the proposed standards and believe that interpretive guidance will be important in terms of defining adequate compliance with those requirements.

While the AHA supports the proposed rule, we note that CMS estimates the economic impact of the proposed standards to be $148 million in year one and $142 million in year two and thereafter. Hospital-based HHAs will absorb these costs, along with the recent rebasing cut of 14 percent over four years, while experiencing markedly negative margins. According to the March 2014 Medicare Payment Advisory Commission (MedPAC) report, the average Medicare margin for hospital-based HHAs in 2012 was *negative* 15 percent. Further, MedPAC's March 2013 report notes that, in some counties, hospital-based agencies are the sole source of home health services. As we have previously communicated to CMS, **we are concerned that the combined impact of these factors could lead to barriers to access in some areas, particularly rural areas.** We ask CMS to address these concerns in the final rule and to outline how the agency will help HHAs implement the proposals at a lower cost, such as providing the types of tools or resources described on the following pages. We believe this request is aligned with Executive Order 12866, which requires agencies to take into account the costs of cumulative regulations, and Executive Order 13563, which requires our regulatory system to identify and use the best, most innovative, and *least burdensome tools* for achieving regulatory ends.

Again, we recognize and thank CMS for developing a thoughtful and comprehensive update to the HHA regulations. We provide comments about selected proposed provisions below.

## QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

**As noted above, the AHA fully supports CMS's proposal for HHAs to develop and implement QAPI programs.** Further, we appreciate that the agency will provide flexibility in how these programs are implemented. We also acknowledge the resources CMS references in the proposed rule to aid HHAs in creating their QAPI programs, such as the Home Health Quality Initiative (HHQI). While we believe our HHA members by and large already conduct QAPI activities, **we encourage CMS to continue to find ways to help HHAs develop and implement QAPI programs**. For example, although the size and scope of QAPI programs will vary among HHAs, CMS could provide examples of what the agency considers to be model QAPI programs, via webinars and other avenues, *before the final rule takes effect*. In addition, CMS should ensure that Quality Improvement Organizations that support the HHQI continue to provide HHAs with relevant QAPI-related education and support.

**Also, we ask CMS to clarify that an HHA that is owned by a hospital or health system can fulfill the QAPI requirement by participating in a larger, system-based improvement program**, as long as it meets the requirements of proposed § 484.65. For example, a system that aims to reduce hospitalizations for chronic obstructive pulmonary disease patients might have a cross-cutting quality improvement team that involves the HHA staff and looks specifically at

how to improve the patient's ability to care for himself or herself in the home. These types of programs enable hospitals to share resources and expertise with HHAs and foster increased communication from HHAs back to hospitals.

## INFECTION PREVENTION AND CONTROL

**We support CMS's proposal to require HHAs to have infection prevention and control programs as integral parts of their QAPI programs.** HHAs currently conduct infection control activities and may already meet the proposed standards, especially if they are accredited. We ask CMS for additional examples of infection control activities that it would consider to be best practices for HHAs. For instance, CMS could provide examples of *surveillance* activities that the agency would consider effective and appropriate, especially as HHAs may not see their patients every day. The proposed rule does not address surveillance in detail, and HHAs would welcome additional clarification from CMS as to its expectations for surveillance in the home versus surveillance in the community.

## PATIENT RIGHTS

**We support CMS's proposal to strengthen and reorganize the patient rights requirements.** Overall, the proposed regulation provides a very robust and comprehensive set of patient rights, and CMS correctly emphasizes the importance of ensuring that patients are aware of their rights.

We agree with CMS's proposal to require both written and verbal notice of patient rights. However, **we ask CMS to clarify what constitutes adequate verbal notice.** As we understand it, verbal notice should cover the content of the notice of rights. CMS estimates that it would take about five minutes per patient for HHAs to describe the content of the notice of rights and obtain the patient's signature confirming that he or she received a copy.

We are not convinced that timeframe will be adequate for every patient, and we ask CMS to provide flexibility to HHAs to tailor the length of the verbal notice depending on the circumstances and what each patient needs to gain an understanding of his or her rights. This type of clarification also would align with The Joint Commission's standard that each patient has the right to receive information that he or she understands. We note that the HHA admission process involves a large amount of paperwork and information and can take from two to four-and-a-half hours to complete. Some patients can be overwhelmed by the time required and the amount of information, especially elderly patients. Therefore, we ask CMS to share its thoughts about the best ways to address this "information overload" to ensure patients truly obtain and understand the information they need. For example, CMS could consider whether there is any information it believes could be provided in the second visit.

**We also suggest that CMS create a consumer website to provide information about patient rights in layperson's terms in multiple languages.** The new and enhanced patient rights information will need to be conveyed to patients in an understandable format. A CMS-sponsored website would ensure message consistency and standardization as the regulatory language is

translated for dissemination to a wide audience. Further, having the information readily available on a website would allow a patient or family member to refer easily to the statement of rights if a question arose during the course of care after treatment begins.

Providing this content also would decrease burden for providers in at least two ways. First, HHAs could use CMS's description of the notice of patient rights as the basis for the written notification. Second, it could help reduce costs associated with language services. Translation services are necessary, and they are expensive. For example, an HHA can spend as much as $800 a month on language services for a single HHA patient. If CMS can provide resources like the notice of rights in multiple languages, then the agency will reduce costs overall. Instead of thousands of HHAs taking the time to translate the written notice of rights into multiple languages, the time and cost will be reduced to those needed by the agency that sets the standards. CMS also could provide similar resources, such as templates in multiple languages, for other requirements, including templates about discharge and transfer policies.

## REVISIONS TO PATIENT CARE AND DISCHARGE PLANS

**We ask for clarification regarding the communication of changes in patient care plans**. The AHA agrees that HHAs should provide each patient with a copy of his or her individualized care plan. In the preamble to the proposed rule, CMS explains that an HHA would need to notify a patient, representative (if any), caregivers and the physician responsible for the HHA plan of care when the individualized plan of care is updated due to a *significant* change in the patient's health status. However, the text of the proposed regulation does not include the word "significant," making it appear as if slight changes in patient status that result in tweaks to the plan would require notice to all stakeholders. **We ask CMS to include the word "significant" in the final regulation and to allow the HHA flexibility in how it provides notice to ensure it is effective in each circumstance.**

**We urge CMS to make a revision in the regulatory language related to the individuals who would receive a revised patient care and discharge plan.** In the proposed rule, any revision to the plan of care due to a change in patient health status, and any revisions related to the plans for the patient's discharge, also would need to be communicated to the physician responsible for the home health plan of care. Some HHAs provide services to veterans who receive care through the Veterans Administration (VA). VA patients may be cared for by a group of physicians, and they do not necessarily have a single physician who is responsible for the plan of care or who signs the revised plan of care. **We ask CMS to change the wording of the regulation to state that the revised plan of care should be provided to the physician or physician group responsible for the plan of care**.

## CLINICAL MANAGER

**The AHA supports the proposed requirement for HHAs to have a clinical manager to oversee patient care services and personnel, but we ask CMS to provide additional clarification and change the wording of the regulation.** We have received numerous questions

about this provision. For example, HHAs use many different terms and titles to describe their personnel. A clinical manager in one organization may be called something else in another organization. In addition, an HHA staff member who is currently called a "clinical manager" may have different responsibilities than outlined for clinical managers in the proposed rule. We ask CMS to identify in the regulation the *functions* that it expects the clinical manager to perform without using that title. Thus, CMS could change the title of § 484.105(c) to "Standard: Oversight of Patient Care Services and Personnel" and require that "a designated HHA staff member" who is a qualified licensed physician or registered nurse fulfill the described oversight duties. In addition, we ask CMS to clarify that the administrator and clinical manager can be the same person.

## CLINICAL RECORD

**We encourage CMS to clarify and modify slightly a proposed requirement related to discharge summaries.** Under the proposed rule, the clinical record would need to include, among other items, a completed discharge or transfer summary. As required by proposed § 484.110(a), that summary would be sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within seven calendar days of the patient's discharge. Alternatively, if the patient's care will be continued immediately in a health care facility, a discharge or transfer summary would need to be sent to the facility within two calendar days of the patient's discharge or transfer. A member called to our attention that two calendar days might be difficult to meet given the staffing of HHAs. Further, we request that CMS clarify that the summary would be sent after a discharge or transfer by the HHA for the reasons described under proposed § 484.50(d).

In addition, CMS may want to consider including the requirement to send the discharge or transfer summary in § 484.60(e), *Discharge or transfer*, in addition to or instead of § 484.110 (a), *Contents of the clinical record*. This requirement is more aligned with care coordination than clinical records, and moving its placement could make it easier to find for HHA staff working on discharge policies.

## PERSONNEL QUALIFICATIONS

We seek clarification about the following discrepancies noted in the section of the rule pertaining to personnel qualifications.

***Occupational Therapist.*** In the proposed rule, the qualifications for occupational therapists are almost identical to current regulation. However, the current regulations allow therapists educated abroad to meet part of the necessary criteria by successfully completing a program that is substantially equivalent to occupational therapist *entry-level education* in the U.S. offered by one of four categories of organizations. In the proposed rule, the therapist must have successfully completed a program that is substantially equivalent to occupational therapist ***assistant*** *entry-level education* in the U.S. by one of the four categories of organizations. We are curious as to

why the word "assistant" appears here, since there is a separate set of qualifications for occupational therapy assistants.

***Occupational Therapy Assistant***. The qualifications outlined in the proposed rule for an occupational therapy assistant are almost exactly the same as those in current regulation. However, the proposed rule states that an occupational therapy assistant is a person who "[a]fter January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section." There is no paragraph (b)(6)(i) in the proposed rule text.

***Physical Therapist***. In current regulation, and in the proposed rule, physical therapists must be licensed (if applicable) and must meet one of several additional categories of qualifications. In current regulations, the first category requires physical therapists to have successfully completed a physical therapist education program **and** passed an examination for physical therapists approved by the state. In the proposed rule, the word "and" is dropped, and the text is renumbered in a way that could imply that either education or passage of an exam is acceptable. We ask for clarification.

Under current standards, the fifth category requires a physical therapist to have been admitted to membership by the American Physical Therapy Association (APTA); ***or*** admitted to registration by the American Registry of Physical Therapists; ***or*** have graduated from a physical therapy curriculum in a four-year college or university approved by a state department of education. In the proposed rule, the fifth option includes the above mentioned membership, registration ***and*** graduation from a physical therapy curriculum. We ask for clarification as to whether CMS intended to propose this change.

***Physical Therapy Assistant***. CMS would revise the qualifications for physical therapy assistants. Under the proposed rule, a physical therapy assistant is a person licensed, registered or certified as a physical therapy assistant, if applicable, by the state in which the assistant is practicing, unless licensure does not apply. In addition, the assistant must meet one of two other categories of criteria. In the first category, the assistant must meet the same specified education as listed in current regulations. In the second category, the assistant must have passed a national exam for physical therapist assistants before 2010, ***and*** he/she must meet one of the following criteria:

- Is licensed, or otherwise regulated in the state in which practicing; or
- In states where licensure or other regulations do not apply, graduated before 2010 from a two-year college-level program approved by APTA and after Jan. 1, 2010, meets the requirements of paragraph (b)(8) of this section.

It is unclear what is meant by the reference to (b)(8) of this section, as there is no (b)(8) in the proposed text.

## DEFINITIONS

In the proposed rule, CMS eliminates a definition for "nonprofit agency" without referencing that removal in the preamble. We ask CMS to clarify if it meant to remove this definition from regulation.

We appreciate the opportunity to comment on this proposed rule. If you have any questions, please contact me or Nancy Foster, vice president for quality and patient safety policy, at nfoster@aha.org, or Evelyn Knolle, senior associate director of policy, at eknolle@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President