January 7, 2015

The Honorable Marilyn Tavenner  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-3819-P, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies; Proposed Rule

Dear Administrator Tavenner:

The Visiting Nurse Associations of America (VNAA) writes in response to the proposed Conditions of Participation (CoP) for home health agencies to participate in the Medicare and Medicaid programs. VNAA is a national association that supports, promotes and advances mission driven, nonprofit providers of home and community-based healthcare, hospice and health promotion services to ensure access and quality care for their communities.

VNAA agrees with the need for updated CoPs for home health agencies (HHAs) and applauds CMS’ emphasis on high quality, patient-centered and safe care. We appreciate inclusion of elements that support the use of an interdisciplinary team and a patient focus that incorporates the “social determinants” of health. Many of the changes proposed in the regulation align with recommendations that VNAA and its members have long-supported. However, we have concerns with several provisions and seek additional clarification on others. Our primary concern relates to the sharing of clinical summaries when a patient is either discharged or transferred to the care of another provider. VNAA and our members strongly support CMS’ efforts to improve care coordination, including through the sharing of clinical records. However, HHAs may be challenged to comply with the proposed regulations in instances of unplanned transfers during which the HHA is not immediately notified when the patient moves from the home to another care setting. We recommend several modifications to the proposed regulations that will better ensure that providers engaged in the patient’s care have the most complete and up-to-date information on the patient.

VNAA encourages CMS to allow sufficient time for home health providers to educate staff and develop the systems and processes necessary to comply with the new CoPs. We request that CMS implement the CoPs no earlier than 18 months after publication of the final rule and provide a one year transition period during which CMS will not sanction providers who are not in full compliance.

VNAA submits the following comments and requests for clarification:
Subpart A: General Provisions
VNAA supports the proposed changes to the definitions. We are particularly pleased that CMS intends to codify regulations allowing HHAs to recognize the role of representatives in the development and delivery of the plan of care. However, we request additional clarification on and have one recommendation related to Branch Offices:

- **Sec. 484.2: Definitions: Branch Office.**
  - We request that CMS acknowledge that some providers will need time to either apply for branch office status or meet the requirements as an HHA independently. To the extent CMS transitions in enforcement of the CoPs (as we recommend above), we are confident that all providers will be in compliance upon the initiation of enforcement action. Should CMS hold HHAs accountable for the CoPs on day one, we request special consideration for those providers who are transitioning their status to either a branch or parent office.
  - The preamble states that parent agencies “…provide supervision and administrative control of branches on a daily basis…” (FR 79 61167). VNAA requests that CMS provide additional guidance on what constitutes an adequate level of supervision on a “daily basis” in this context. For instance, is CMS requiring a minimum amount of daily communication and/or type of communication between branch and parent offices?

Subpart B: Patient Care
VNAA supports the changes made to the CoPs with respect to patient care, which largely codify current HHA practices. VNAA is particularly pleased to see the detailed provisions related to Quality Assessment and Performance Improvement (QAPI) and infection prevention and control. VNAA submits the following comments and requests for clarification:

- **§484.50 (a) (1) Patient Rights: Notice of Rights.** The proposed regulation would require the home health agency to give verbal notice of the patient’s rights in the primary or preferred language of the patient or representative during the initial evaluation visit and in advance of care and also to provide a written copy of the patient’s rights information in English or in the patient’s primary or preferred language. The definition of preferred language needs to be clarified. In many places, the diversity of languages and dialects is great. HHAs cannot realistically provide verbal translation and written documents in dozens of languages or more, even using an auxiliary translation service. VNAA suggests that the term “preferred language” be clarified and that Patient Rights forms be standardized and available for use by providers, in the multiple language that CMS deems necessary.

- **§484.50 (d) Patient Rights: Transfer and Discharge.** The section regarding discharge “for cause” is narrow and does not recognize the real risks that home healthcare workers can and do encounter in providing care in the home. While we believe that reasonable efforts should be made to resolve situations, we also believe there are situations in which no one should be expected to reenter a home after an initial dangerous event. Real-life examples include when a homecare worker experiences an attempted or actual assault or is threatened by a patient or caregiver with a deadly weapon. We strongly urge CMS to allow the agency to determine when “for cause” applies and permit agencies to discharge immediately if there is real and present danger or serious threat of danger.
• § 484.55 (d) Standard: Update of the comprehensive assessment. VNAA agrees with updating the comprehensive assessment as needed. We request clarification on the criteria HHAs should use to determine when a change in a patient’s condition warrants an update to the comprehensive assessment. We can imagine changes in patient condition that are so minor that an update to the assessment does not result in meaningful change in the care provided to the patient. We ask for CMS to confirm that the change must be sufficiently significant that it either warrants close monitoring by HHA staff or results in a revision to the care plan.

§ 484.60 (c) Standard: Review and revision of the plan of care. VNAA agrees that HHAs must alert the responsible physician to any changes in the patient’s condition that suggest that outcomes are not being achieved and/or that the plan of care should be altered. VNAA requests clarification on what CMS considers reasonable with respect to notification to the physician and patient. Communication with the physician and updates to the physician are done each time a new order is obtained for most patients and occurs several times during the episode of care. We suggest that HHAs inform patients (or their representative or caregiver, as appropriate) when new orders are needed from the physician and why.

• § 484.60 (d) Standard: Coordination of Care. VNAA agrees with CMS’ focus on coordinated delivery of care. While we do not recommend any modifications to the regulatory text, we welcome additional guidance from CMS on what constitutes an adequate level of coordination across all disciplines and the mechanism to conduct coordination. We note that HHAs have different levels of capabilities with respect to the electronic collection and sharing of patient information, which may create coordination challenges for some smaller agencies.

Subpart C: Organizational Environment
VNAA generally supports the proposed changes to this subpart. Our members are well-positioned to meet the proposed governance requirements. However, we have one significant concern with respect to the standard on clinical records, as described below. We also seek clarification on several other provisions.

- § 484.105(b) Administrator and § 484.105(c) Clinical Manager. Many smaller agencies may have a single individual who could serve as both the Administrator and the Clinical Manager. VNAA requests confirmation that the CoPs allow for a single individual to serve in both roles.

- §484.105(c) Clinical Manager. This requirement inappropriately excludes rehabilitation professionals from serving as a clinical manager. Rehabilitation professionals currently hold clinical manager positions in home health agencies and are successfully fulfilling the responsibilities included in this new standard. Rehabilitation professionals also hold high level positions such as clinical director and executive director at some home care agencies. Rehabilitation professionals are well educated with many holding Masters or Doctoral degrees as well as specialist certifications such as Board Certifications in Geriatrics through the American Physical Therapy Association. The oversight of services provided to patients as described in the standard is already being successfully met by therapists. This standard would limit the leadership potential in the home health industry for a highly skilled group of individuals who currently provide or oversee high quality patient care that results in improvement in patient outcomes and quality of life. We request that CMS revise the regulations to permit physical therapists, occupational therapists and speech therapists to serve as clinical managers.
VNAA has significant concerns with the CoP that requires HHAs to a) send a discharge summary within seven calendar days 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, and b) in the case where a patient’s care will be immediately continued in a health care facility, send a discharge or transfer summary to a health care facility within two calendar days. In principle, we strongly agree with the sharing of patient records in order to facilitate improved transitions of care. However, there are a number of challenges that we considered in developing our comments, which we discuss below.

In the home health context, many individuals contribute to the patient record, including nurses, therapists, and other providers. In many HHAs, not all materials are electronic, such as signed verbal orders, relevant files from other providers, and other content. Given the lack of both completely electronic records and robust electronic data exchange functionality across sites of care, HHAs would be challenged to meet the timeframes for sharing summaries with facilities included in the proposed CoPs. Therefore, we recommend changes to the number of days that home health agencies have to send discharge and transfer summaries to facilities.

We also considered the specific challenge of providing the records in a timely manner in instances of unplanned transfers. HHAs will often learn about patient transfers to hospitals days after they have occurred (transfers to other settings are rarely unplanned). CMS acknowledged this challenge in its report to Congress on a Plan to Implement a Medicare Home Health Agency Value-Based Purchasing Program: “…HHAs may not always be aware of all hospital or emergency room care their clients receive, depending when it occurs….“ When an HHA learns of an unplanned transfer, it must determine which hospital and unit a patient has been sent to prior to sharing the information. In some cases, the patient may have already been discharged home by the time the HHA learns of the admission. In developing our comments, we considered the helpfulness of sending the record at this point. We considered recommending that CMS change the requirement that for unplanned transfers, home health agencies not be required to send discharge or transfer summaries. We also considered recommending that for unplanned transfers home health agencies only send discharge or transfer summaries at the request of the hospital. Ultimately, we did not recommend either of these two approaches due to unresolved questions about whether the records would provide some value at that point.

Based on our comments above, VNAA recommends the following changes to the proposed regulation:

- Change the requirement to send discharge or transfer summaries to facilities from two calendar days to three (3) business days.
- Permit HHAs to send only the information critical to facilitate the highest quality care for the patient and not the entire patient record. We recommend that HHA share medications, diagnoses, disciplines providing services, problems/issues lists, and caregiver/representative information.
- Exclude the need to send a transfer summary to a hospital in instances where an individual has been both admitted to and discharged from the hospital prior to the HHA’s knowledge of the admission.

§ 484.110(a) Standard: Retrieval of Clinical Records. There are many situations in which records must be made available, including at the request of a patient, auditor, surveyor or others. Most
federal and state audit programs already have established timeframes for delivering records. We are not suggesting changes to the timeframes established by those programs. However, for purposes of the CoPs, VNAA requests clarity on the timeframe for making records available. We understand that situations may differ. In cases where individuals are onsite awaiting information, we request that CMS allow HHAs sufficient time to assemble records. In many HHAs, not all materials are electronic, including signed verbal orders, files from hospitals, and other content. HHAs may need several hours to compile the most up-to-date records. For other purposes, we recommend a minimum of four business days unless otherwise stated.

Thank you again for the opportunity to provide our comments. VNAA is committed to supporting its members in implementing the final Conditions of Participation. Please contact Molly Smith, Vice President for Policy and Regulatory Affairs, at VNAA should you have any questions on these comments. She may be reached at msmith1@vnaa.org or 571-527-1529.

Sincerely,

Tracey Moorhead
President and CEO