December 19, 2014 **Submitted Electronically**

Ms. Marilyn B. Tavenner

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

200 Independence Avenue, SW

Washington, DC 20201

**RE: CMS-3819 -P** Proposed Rule Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies

Dear Ms. Tavenner:

LeadingAge appreciates the opportunity to comment on this proposed regulation published in the October 9, 2014 Federal Register.

The members of LeadingAge and affiliates touch the lives of 4 million individuals, families, employees and volunteers every day. The LeadingAge community ([www.LeadingAge.org](http://www.LeadingAge.org)) includes 6,000 not-for-profit organizations in the United States, 39 state partners, hundreds of businesses, research partners, consumer organizations, foundations and a broad global network of aging services organizations that reach over 30 countries.  The work of LeadingAge is focused on advocacy, education, and applied research. We promote home health, hospice, community-based services, adult day service, PACE, senior housing, assisted living residences, continuing care communities, nursing homes as well as technology solutions and person-centered practices that support the overall health and wellbeing of seniors, children, and those with special needs.

**We provide comments below on the following sections of the proposed rule:** §484.2 Condition of Participation: Definitions (i) Standard: Physician; Section III C Patient Rights Proposed § 484.50; § 484.50 Condition of participation: Patient rights. (12)(d) Standard: Transfer and discharge; § 484. 50 Condition of Participation: Patient rights. (c)Standard: Rights of the patient. The patient has the right to—(4)(iii) Establishing and revising the plan of care, including receiving a copy of it; § 484.50(c)(10), Consumer Information; §484.55 Condition of Participation: Comprehensive assessment of the patient’s initial assessment visit 1) b) Standard: Completion of the comprehensive assessment*;* §484.65 Quality Assessment and Performance Improvement; §484.70 Condition of participation: Infection prevention and control; § 484.80 Condition of participation: Home health aide services; (b) Standard: Content and duration of home health aide classroom and supervised practical training; §484.110 Condition of participation: Clinical records. (a) Standard: Contents of clinical record; Section III D4. Personnel Qualifications (Proposed § 484.115) -Administrator; and Section § 484.2. the elimination of subunit designation.

LeadingAge is pleased to see the release of the Proposed Rule, Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies. Since the proposed rule for the Home Health Conditions of Participations issued in 1997 was never finalized, there are many changes needed to update the Home Health Conditions of Participation to address the changes in our health care delivery system due to health care reform. Also, the proposed rule adds more specificity in areas of the current Conditions of Participation that are broad or vague.

We believe that CMS has successfully incorporated the principles of patient centered plans of care that are outcome oriented and data driven. To reflect that we no longer can work in silos of care based on our specific provider licensing and regulations, the proposed rule emphasizes integration and interdisciplinary care planning. We are pleased that the proposed rule eliminates the 60 day summary to physician, Professional advisory committee (PAC) and Quarterly record review. These three requirements would be a duplication of processes and documentation that are proposed in other sections of the proposed rule.

We also are pleased that the proposed rule significantly expands patient rights, especially the right to participate in the care planning process. This change correlates with final rules for Medicaid that were released by CMS that also stresses the need for a person centered plan of care and the patient’s participation in the care plan process.

**ISSUE: §484.2 Condition of Participation: Definitions (i) Standard: Physician.** The definition of a physician is not consistent with the specialties of physicians who may certify and establish the plan of care for home health services.

**COMMENTS:** The definition of a physician noted at 42 CFR 410.20(b) is not consistent with the specialties of physicians who may certify and establish the plan of care for home health services in the regulation at 42 CFR 424.22(a)(1)(iii). For example, the proposed definition includes doctors of dental surgery, doctors of optometry, and chiropractors. **§424.22,** (iii) states that a plan for furnishing the services has been established and is periodically reviewed by a physician who is a doctor of medicine, osteopathy, or podiatric medicine. There are no additional references to doctors of dental surgery, doctors of optometry, and chiropractors.

**RECOMMENDATIONS:** LeadingAge recommends that the definition of a physician in 42 CFR **§**424.22(a) (1) (iii) is a person who meets the qualifications and conditions noted in section 1861(r) of the Act and applied at 42 CFR 410.20(b).

**ISSUE Section III C Patient Rights** **Proposed § 484.50**. In the proposed rule, CMS ask how requiring patient rights to be explained to a patient in the language and manner that he or she understands, would address the needs of vulnerable populations and contribute to eliminating health disparities; Ways to assure that patient choice is respected and upheld, while also balancing the need to assure patient safety.

**COMMENTS:** Vulnerable populations may include groups of people who have systematically experienced greater obstacles to receive quality health care services based on their race or ethnicity; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion. We are aware that other populations at risk may include pregnant women, infants, persons with limited English proficiency (LEP), and persons with disabilities (for example, visual, hearing, cognitive or perceptual impairments) or special health care needs. Under current federal and state regulations HHAs are already required to provide translation services for individuals with limited English proficiency (LEP). There are also requirements in place to ensure that persons with disabilities (for example, visual, hearing, cognitive or perceptual impairments) or special health care needs are aware of their rights and have access to services. We believe that eliminating health disparities go beyond explaining patient’s rights to a patient in the language and manner that he or she understands. As required by the Affordable Care Act a Vulnerable Care study was completed to assess what diagnosis, functional levels and service codes do not produce adequate payment to cover the cost of quality care. CMS has still not addressed how they will use recommendations from this study to reduce the incidences of providers not caring for a vulnerable high risk individual because it will result in a loss of revenue. Risk due to socioeconomic factors has to be incorporated into the home health payment methodology.

**RECOMMENDATION:** LeadingAge recommends CMS move forward on addressing the findings of the Vulnerable Care study.

**ISSUE : § 484.50 Condition of participation: Patient rights. (12)(d) Standard: Transfer and discharge** CMS proposes that all patients and representatives (if any), have the right to be informed of the HHA’s policies governing admission, transfer, and discharge, and lists the criteria by which an HHA could discharge or transfer a patient. The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d) (5) (i) through (iii) of this section, that the patient’s (or other persons in the patient’s home) behavior is disruptive, abusive, or non-cooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired.

**COMMENTS:** We find that the list is not comprehensive, especially in regards to behaviors that may necessitate a discharge from home health. These three behaviors limit the definition of reasons an agency may transfer or discharge for cause and are up to interpretation as to when a patient may be exhibiting the behaviors. Patients may exhibit other behaviors or have extenuating circumstances that are not clearly defined as disruptive, abusive, or uncooperative that prevents an agency from effectively caring for the patient or might be a threat to the agency staff.

**RECOMMENDATION:** LeadingAge recommends that CMS allow stakeholders to submit additional types of behaviors that may necessitate a discharge from home health. Reasons for cause should not be limited to the three listed behaviors. Rather, use these as examples for when it would be appropriate for agency to transfer or discharge a patient. Agencies should be permitted to transfer or discharge a patient for any reason related to cause that affects their ability to provide adequate care and /or threatens the safety of the staff.

**ISSUE: § 484. 50 Condition of Participation: Patient rights. (c)Standard: Rights of the patient. The patient has the right to—(4)(iii) Establishing and revising the plan of care, including receiving a copy of it.** The patient and representative (if any), have the right to be informed of the patient’s rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

**COMMENTS:** Providing patients with a copy of the initial POC and at each revision would be burdensome for the agency in terms of maintaining compliance and the associated costs with providing copies of the POC and all revisions for each patient, particularly for patients that have frequent changes. It is unclear if the agency is required to provide the written POC and revisions in the patient’s preferred language; if so, it could be unmanageable for the agency to implement this requirement. This requirement will be in addition to the requirement that agencies provide a written notice when services are to be reduced or terminated, and prior to discharge. When multiple written notices are provided to patients it becomes overwhelming.

**RECOMMENDATION:** LeadingAge recommends that CMS only require a copy of the initial plan of care to be given to patients, and that any additional changes to the plan of care would be verbally given to the patient, and the interaction with the patient then would be in the patient’s chart noted by the home health staff. This minor change would eliminate the patient from receiving a volume of documents that may lead to confusion. Of course if the change of plan of care involves teaching the patient skills to improve their medical treatment, the home health staff could leave information flyers that would help the patient remember and follow what they were taught by the home health staff.

**ISSUE: Under § 484.50(c)(10),** Consumer Information. Patients would be advised of the names, addresses, and telephone numbers for relevant Federally and State-funded consumer information, consumer protection, and advocacy agencies. HHAs should select agencies that have a public service mission and provide assistance free of charge, such as area Agencies on Aging, Aging and Disability Resource Centers, legal service programs, State Health Insurance Programs, and Adult Protective Services.

**COMMENT:** Theavailability ofFederally-funded and State funded, State and local consumer information, consumer protection, and advocacy agencies would vary from one area to another area of the country. We agree that it is important for the patient to have this information, but we are concerned that surveyors will not have enough guidance to know what organization contact information should be on the list given to the patients.

**RECOMMENDATION:** LeadingAge recommends that the home health agency should be able to compile a list based on their patient population, and availability of these organizations in the service area. We also recommend that CMS obtain provider feedback on what other organizations may be appropriate to include on the list; for example, the local Center for Independent Living, transportation broker, housing authority, etc.

**ISSUE: §484.55 Condition of Participation: Comprehensive assessment of the patients**

**(a) Initial assessment visit** 1) **b) Standard: Completion of the comprehensive assessment***.* The requirement for the RN to conduct the initial and comprehensive assessments when nursing and therapy are both ordered results in the waste of valuable resources (extra RN visits that are not reimbursable) in cases where the plan of care requires that the therapist visit prior to the RN.

**COMMENT:** CMS does maintain the requirement for the registered nurse (RN) to conduct the initial and comprehensive assessment, except in therapy **only** cases. The requirement for the RN to conduct the initial and comprehensive assessments when nursing and therapy are both ordered results in extra RN visits that may not be needed. The regulation increases costs to the agencies, and is a barrier for the agency to assign RNs where they are needed the most.

**RECOMMENDATION:** Permit either the RN or the therapist to conduct the initial and the comprehensive assessment when both disciplines are ordered at the initiation of care.

**ISSUE : §484.65 Quality Assessment and Performance Improvement** The addition at § 484.65 of the Quality Assessment and performance improvement (QAPI) is critical to ensure that home health providers are using the same process to measure, analyze and improve quality as other health care providers, such as nursing homes, hospice and hospitals.

**COMMENTS:** CMS, in the preamble, states: “We believe small and mid-size HHAs would be able to effectively implement this condition as easily as larger HHAs. The proposed QAPI CoP would provide HHAs with enough flexibility to implement the quality assessment and performance improvement process without inordinate expenditure of capital or human resources.” LeadingAge disagrees. LeadingAge strongly supports the requirement that home health agencies implement a comprehensive QAPI program. Our concern is that the cost of the home health agency to develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program will initially be a major expense for agencies that are not currently accredited through a nationally recognized accreditation organization or are not an affiliate of a large parent organization that has providers that are already involved in Quality Assurance Performance Improvement.

**RECOMMENDATION:** It is important that surveyors and home health agencies have sufficient time to understand this new condition of participation. We suggest that the implementation of the rule be at least six months after the rule is finalized.

**ISSUE : §484.70 Condition of participation: Infection prevention and control.** The addition at § 484.70 Infection Control is already in place for home health agencies that are accredited under Joint Commission and Community Health Accreditation Program, as well as HHAs in states that already mandate these infection control regulations.

**COMMENT:** Variation exists among home health agencies with regard to elements of an infection control program. This addition is necessary, but will require additional resources for agencies**.**

**RECOMMENDATION:** It is also important that surveyors and HHA have sufficient time to understand this new condition of participation. We suggest that the implementation of the rule be at least six months after the rule is finalized.

**ISSUE: § 484.80 Condition of participation: Home health aide services. (b) Standard: Content and duration of home health aide classroom and supervised practical training**. CMS has added several new requirements under home health aide training requirements.

**COMMENT:** LeadingAge supports that CMS has added several new requirements under home health aide training requirements. We find that our home health members are already including many of the skills that are mentioned in the proposed rule, such as skin assessments.

**RECOMMENDATION:** LeadingAge recommends that CMS establish a realistic timetable for when all the existing home health aides must complete their training. We also recommend that agencies be given the flexibility of using different methods of training to fulfill this requirement. Unlike institutional settings, home health staff is traveling to different parts of their service area. The flexibility is needed to ensure that there is not an interruption of services provided for the patient, as well as increase costs to the agency.

**ISSUE: §484.110 Condition of participation: Clinical records. (a) Standard: Contents of clinical record.** CMS proposes to prescribe a time frame for which a discharge or transfer summary must be provided to the receiving health care professional or facility. The agency must provide within 7 calendar days of the patient’s discharge a discharge summary to the receiving primary care practitioner. The agency must provide within 2 days a transfer summary to the receiving facility.

**COMMENT:** LeadingAge request that CMS clarifywhen the transfer summary would need to be provided. Unlike an institutional setting, home health provides skilled intermittent care, so the HHA may not be providing service every day for the patient. There may be times, especially if there is not a family caregiver that the agency may not be aware of the transfer for several days.

**RECOMMENDATION:** LeadingAgerecommends that CMS allow the transfer summary to be provided within 2 days of the notification of the transfer to accommodate when a patient may have transferred to a facility without the agency’s knowledge.

**ISSUE Section III D4. Personnel Qualifications** (**Proposed § 484.115**) Specifically, proposed § 484.115(a) would set forth the requirements that a HHA administrator would be required to be a licensed physician, or hold an undergraduate degree, or be a registered nurse. We also propose that an administrator would have at least 1 year of supervisory or administrative experience in home health care or a related health care program. The possession of an undergraduate degree would be a new option for establishing the qualifications of an administrator that does not exist in the current regulations. CMS believes that this new option will give HHAs additional flexibility in selecting an appropriate administrator. However, CMS does not believe it is necessary to specify which undergraduate degree would be necessary to qualify for this option. Rather, CMS proposes that the HHA’s governing body would specify which undergraduate degree an HHA administrator would have to possess. In the absence of state requirements, CMS is not proposing to add financial management training as a requirement for HHA administrators at this time since HHAs often employ or consult a chief financial officer and billing staff, and the provision may place an additional burden on current HHAs.

**COMMENTS:** Some Home Health Administrators have ten or more years of experience in operating quality Medicare Certified Home Health agencies even though they may not have a college degree or be an RN. There are Home Health Directors that are LPNs or have other qualifications. The proposed rule does not designate the type of undergraduate degree that the home health administrator must have to be eligible to serve as a Home Health Administrator. The individual could have a Bachelor’s degree in Fine Arts, Architecture or other degrees that have no connection to the skill set needed to be a Home Health Administrator.

**RECOMMENDATION:**

* LeadingAge recommends that CMS grand-father in existing administrators
* There should be an exception policy in place that equates years of experience in the Medicare certified home health field and approval to be a Home Health Administrator.

**ISSUE Section § 484.2**. **Elimination of subunit designation** .CMS proposes to eliminate the subunit distinction upon finalization of the rule. Any existing subunit will either have to apply to become a branch or operate as a parent where by the agency will need to independently meet all the CoPs without sharing a governing body or administrator.

**COMMENT:** CMS does not address a transition plan to convert subunits to a parent or a branch. This could be an issue for agencies located in states where the Medicare state survey agency is not approving branches due to workload prioritizations, CON process, moratoria, etc. Only the Medicare state survey agency is authorized to approve home health branches, and this authority is not granted to accrediting organizations.

**RECOMMENDATION:** LeadingAge encouragesCMS to provide sufficient time for agencies to convert a subunit to either a parent or a branch. If a subunit is converting to a branch, CMS should consider giving a priority to scheduling Medicare state survey activities for subunit converting to branch offices in order to expedite branch approval. Also a system needs to be in place to ensure that claim processing is uninterrupted.

LeadingAge appreciates the opportunity to comment on this proposed rule. Please do not hesitate to contact us if you have any questions or would like further discussion. We look forward to our continued work with you on this and related issues.

Sincerely,



Cheryl Phillips, MD Senior VP Public Policy and Advocacy