January 6, 2015

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445—G
Attention: CMS-3819-P
Hubert H. Humphrey Building, 200
Independence Avenue SW
Washington, DC 20201

Submitted Electronically

RE: CMS-3819-P; Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies

Dear Administrator Tavenner:

On behalf of our 90,000 physical therapist, physical therapist assistant, and students of physical therapy members, the American Physical Therapy Association (APTA) appreciates the opportunity to submit the following comments in response to the Conditions of Participation for Home Health Agencies proposed rule. Physical therapy is a qualifying service under the Medicare home health benefit and comprises a large portion of the treatment furnished to patients in the home health setting. Therefore, our members and the patients they treat are impacted significantly by the proposed rulemaking and subsequent implementation.

In the home health setting, physical therapists provide services to patients through a plan of care to engage and optimize the patient’s participation in achieving shared goals of improved functional performance, reduced risk of injurious falls, and reduced risk of acute hospitalization thereby promoting long-term health and wellness. Physical therapists provide an examination that includes the history, systems review, and tests and measures to determine the patient’s therapeutic, rehabilitative, and functional status and any environmental factors that influence the patient’s activity and/or participation. Through the evaluative process, the physical therapist will develop a comprehensive plan of care to achieve the goals and outcomes of improved function.
In the proposed rule, the Center for Medicare and Medicaid Services (CMS) has identified four principles to guide development of the proposed new home health agency (HHA) COPs. They are to:

- **Develop a more continuous, integrated care process across all aspects of home health services, based on a patient-centered assessment, care planning, service delivery, and quality assessment and performance improvement.**
- **Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and their interactions with each other to meet the patient’s needs. Stress quality improvements by incorporating an outcome-oriented, data-driven quality assessment and performance improvement program specific to each HHA.**
- **Eliminate the focus on administrative process requirements that lack adequate consensus or evidence that they are predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients.**
- **Safeguard patient rights.**

APTA agrees with these principles in concept and we look forward to working with the agency to ensure proper implementation. While we believe that the draft rulemaking is a step in the right direction, there are several technical and programmatic revisions that are necessary to ensure that the final draft accurately and fully represents the breadth and depth of care provided to patients by HHAs. Therefore, we respectfully request that the following comments and recommendations be given full consideration.

§484.55 Conditions of participation: Comprehensive assessment of patients

Section 484.55 states in part, “(c) Standard: Content of the comprehensive assessment. The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

1. The patient’s current health, psychosocial, functional, and cognitive status;
2. The patient’s strengths, goals, and care preferences, including information that may be used to demonstrate the patient’s progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;
3. The patient's continuing need for home care;
4. The patient's medical, nursing, rehabilitative, social, and discharge planning needs;
5. A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.
6. The patient’s primary caregiver(s), if any, and other available supports;
7. The patient’s representative (if any);
8. Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.”
We recommend that CMS add an item to the comprehensive assessment that addresses the use of standardized tests and measures by home health clinicians. The inclusion of tests and measures is critical to the practice of physical therapy. The use of standardized tests and measures early in an episode of care establishes the baseline status of the patient, assists in the development of the plan of care, and provides a means to quantify change in the patient’s functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized. As the patient reaches the termination of physical therapist services and the end of the episode of care, the physical therapist objectively measures the outcomes of the physical therapist services.

Standardized outcome measures provide a common language with which to evaluate the success of physical therapy interventions, thereby providing a basis for comparing outcomes related to different intervention approaches. Measuring outcomes of care within the relevant components of function, including body functions and structures, activity, and participation, among patients/clients with the same diagnosis, is the foundation for determining which intervention approaches comprise best clinical practice.

§484.60 Condition of Participation: Care Planning, coordination of services, and quality of care

Section 484.60 states in part, “Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient’s medical, nursing, rehabilitative, and social needs in his or her place of residence.” Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training that the HHA will provide, specific to the patient’s care needs. Services must be furnished in accordance with accepted standards of practice.

(a) Standard: Plan of care.
... If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.
(2) The individualized plan of care must include the following:
(i) All pertinent diagnoses;
(ii) The patient’s mental, psychosocial, and cognitive status;
(iii) The types of services, supplies, and equipment required;
(iv) The frequency and duration of visits to be made;
(v) Prognosis;
(vi) Rehabilitation potential;
(vii) Functional limitations;
(viii) Activities permitted;
(ix) Nutritional requirements;
(x) All medications and treatments;
(xi) Safety measures to protect against injury;
(xii) Patient and caregiver education and training to facilitate timely discharge;
(xiii) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;
(xiv) Information related to any advanced directives; and
(xv) Any additional items the HHA or physician may choose to include.

(3) If HHA services are initiated following the patient’s discharge from a hospital, the individualized plan of care must include a description of the patient’s risk for emergency department visits and hospital re-admission (low, medium, high) and all necessary interventions to address the underlying risk factors. [Emphasis added]

(4) All patient care orders, including verbal orders, must be recorded in the plan of care."

In the first paragraph, we recommend that the recent Jimmo v. Sebelius clarifications regarding coverage of skilled maintenance therapy be reflected. We believe that it is important that the plan of care not only focus on rehabilitation potential but also encompasses the goals and objectives required for skilled maintenance therapy when appropriate. As CMS has indicated in regulatory guidance, there is a clear distinction between restorative or rehabilitative therapy and maintenance therapy. In restorative or rehabilitative care, the primary goal is to decrease or reverse loss in function, and therefore assessing the potential for improvement is appropriate. We believe the language, as currently written in this provision, only speaks to restorative/rehabilitative services and therefore could unintentionally penalize HHAs who are providing skilled maintenance therapy when being surveyed and certified.

Secondly, we urge CMS to provide additional clinical instruction on how to assess for risk of hospital readmission. There is a wealth of information provided regarding reporting quality measures that address hospital readmissions. While this information is helpful, it would be beneficial to provide additional resources to HHAs in order to train them on appropriate risk factors to consider when determining the likelihood of a hospital readmission. There are several resources available through APTA as well other professional organizations and we would welcome the opportunity to work with CMS to develop such guidance.

§484.105 Condition of participation: Organization and administration of services

Section 484.105 states in part, "(c) Clinical manager. A qualified licensed physician or registered nurse must provide oversight of all patient care services and personnel. [Emphasis added]
Oversight must include the following--
(1) Making patient and personnel assignments;
(2) Coordinating patient care;
(3) Coordinating referrals;
(4) Assuring that patient needs are continually assessed;
(5) Assuring the development, implementation, and updates of the individualized plan of care; and
(6) Assuring the development of personnel qualifications and policies."
APTA strongly objects to the exclusion of physical therapists, occupational therapists and speech-language pathologists from the definition of clinical manager. We believe that a physical therapist is more than qualified to serve in this capacity. Physical therapists play essential roles in today’s health care environment, are recognized as vital providers of rehabilitation and habilitation services, and prevention, and risk reduction services. Per clinical training and education, physical therapists render professional expert opinion or advice by applying highly specialized knowledge and skills to identify problems, recommend solutions, or produce a specified outcome in a given amount of time on behalf of each patient. In addition, physical therapists, as a standard practice, consult with other providers, such as the physician, nurse, and physician assistant, to communicate the rehabilitation plan of care and to obtain services for the individual that are beyond the professional or personal scope of practice of the physical therapist.

Therefore, we believe that physical therapists are well suited to carry out oversight of the delineated tasks under this provision. Therefore, we strongly recommend that CMS revise this provision to include physical therapists, occupational therapists and speech-language pathologists as eligible professionals to serve as clinical managers for the HHA.

§484.110 Condition of participation: Clinical records

Section 484.110 states in part, “(6) A completed discharge or transfer summary, as required by §484.60(e), that is 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 7 calendar days of the patient’s discharge; or, if the patient’s care will be immediately continued in a health care facility, a discharge or transfer summary is sent to the facility within 2 calendar days of the patient’s discharge or transfer.” [Emphasis added]

We believe that the requirement to send the discharge summary to the facility responsible for care of the patient post-discharge from the HHA within 2 calendar days may be too restrictive for some HHAs to meet. In some instances, the HHA may have an unanticipated discharge, which causes a delay in obtaining all requisite information to draft a comprehensive discharge summary. Therefore, we recommend that CMS allow seven calendar days for receipt of the discharge summary regardless of whether the information is being sent to the primary care physician or a health care facility.

APTA thanks CMS for the opportunity to comment on the Conditions of Participation for Home Health Agencies proposed rule, and we look forward to working with the agency to construct patient-centered policies that reflect quality health care for all patients. If you have any questions regarding our comments, please contact Roshunda Drummond-Dye, Director, Regulatory Affairs at (703) 706-8547 or roshundadrummond-dye@apta.org.

Sincerely,

Paul Rocker Jr.
Paul Rockar, Jr. PT, DPT, MS
President

PR: rdd