September 25, 2007

Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

RE: CMS – 10243 (OMB#: 0938 – NEW), Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 72, No. 144), July 27, 2007

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems, and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) Continuity Assessment Record and Evaluation (CARE) patient assessment instrument, which the agency proposes to use in a three-year demonstration project. We applaud CMS’ effort to better understand the distinct clinical characteristics of patients needing post-acute care and to work towards a post-acute payment that is based on those characteristics rather than the setting of care. We understand that the agency intends to ultimately deconstruct the current post-acute payment silos and replace them with a unified post-acute care payment system that uses CARE assessment data in determining Medicare payments. As an advocate of 158 long-term care hospitals, 1,230 inpatient rehabilitation hospitals and units, 1,183 hospital-based skilled nursing facilities and 1,388 hospital-based home health agencies, we believe this goal must be pursued with great care and input from stakeholders to ensure that patient access to medically necessary care is maintained under a unified post-acute structure.

The CARE assessment has the potential to ultimately streamline hospital discharge planning across hospitals, improve consistency of patient data across settings, smooth patient transfers among general acute hospitals and post-acute providers, and provide for meaningful analysis of resource use by clinical condition and treatment. The CARE assessment also has the potential to assist in care-planning for patients who need post-acute care by identifying post-acute care that is most clinically appropriate for the patient. However, to achieve these potential benefits requires not only resources for providers facing this new, expanded process, but also requires that CMS address the significant concerns discussed below.
If the CARE tool becomes the mandatory patient assessment instrument for all post-acute admissions and discharges, it would have a major impact on post-acute care providers. But, the CARE process, as proposed, also would have major ramifications for general acute hospitals. CMS proposes to require that all general acute hospitals conduct a CARE assessment on every Medicare beneficiary being discharged. The tool would impose a huge resource burden on hospital nurses and other clinical and support staffs and, in many cases, the assessments would delay the discharge of hospital patients adding unnecessary burden to patients and cost and disruption to hospitals.

To better understand the impact the CARE assessments would have on general acute hospitals and post-acute providers, we solicited input from both our hospital and post-acute members. Our comments on the CARE instrument reflect these two distinct perspectives.

**Discharge Planning Overview**
Discharge planners are mostly registered nurses or clinical social workers who assist patients as they transition from the general acute hospital to home or another residential or health care setting. For the 48 percent of Medicare beneficiaries who are referred for follow-up care after hospital discharge, discharge planners assist in identifying and securing care options that take into account the patient’s clinical and functional capabilities; post-acute goals for improvement; the referring physician’s recommendation for post-acute care; the availability of post-acute services in the local community; the patient’s insurance coverage and financial wherewithal to pay for follow-up care; the patient’s available support from family or others; physical barriers in the home such as stairs; and other factors. This multi-faceted process is more challenging for patients who have medically complex needs following hospital discharge.

The list below summarizes the information typically provided to patients who need post-acute care after discharge:
- A written list of instructions that are specific to a patient’s diagnosis or procedure and recuperative needs, such as when to resume normal activities.
- Follow-up appointment and contact information for physicians, physical therapy and other providers.
- Medication information including dosage, method, time, dietary considerations and possible side effects.
- Information on signs of potential complications and how to deal with them; and
- Contact numbers for additional advice or information.

**Implementing CARE Discharge Assessments**
Most troubling to general acute hospitals is CMS’ intention to apply the CARE instrument to all Medicare beneficiaries discharged from this setting. With more than 11 million beneficiaries being discharged from hospitals every year, this new mandate would require general acute hospitals to reallocate limited patient-care resources from direct patient care to the CARE process, which does not directly contribute to quality care for hospital patients, but rather is primarily designed to influence patient referrals to post-acute care. To require general acute hospitals conduct a CARE assessment for all Medicare discharges is excessive and unnecessary.
Hospital discharge planners already face tremendous pressure to discharge patients quickly in response to demand for inpatient beds. Adding the CARE assessment to this scenario would place further stress on busy nurses and other clinical and support staff by complicating and slowing down the discharge process. It is unreasonable for CMS to expect that general acute hospitals should substantially expand the current discharge planning processes without accounting for the nursing, technology, coding, therapy and other resources that would have to be dedicated to the new tool’s requirements, and in many cases diverted from other patient-focused functions.

Also troubling, while several disciplines would contribute to CARE assessments, an individual would be needed to oversee their final completion in a comprehensive and timely manner. Without sufficient additional oversight, it would be unlikely that all of the distinct elements of the assessment – pharmacy, medical treatments, lab, functional assessments, cognitive assessments, coding, etc. – would be pulled together in a reliable way to benefit the millions of Medicare beneficiaries who receive post-acute care.

The AHA urges CMS, at a minimum, to restrict use of the CARE tool to post-acute discharges only.

TIME ESTIMATES FOR CARE ASSESSMENT COMPLETION
Preliminary testing of the CARE tool by Chicago-area hospitals and post-acute providers indicates that a CARE assessment requires approximately 15 to 20 minutes for low-complexity patients and approximately 60 to 90 minutes for high-complexity patients. We conservatively estimated that to conduct the CARE assessment on all beneficiaries discharged from general acute hospitals over a 12-month period would require 2,678 full-time equivalents. We based our estimate on an average of 30 minutes for all assessments and an annual discharge population of 11,138,692. (2006 MEDPAR Data) This new staff requirement would be augmented by other new costs required to implement the CARE tool, such as staff training and re-engineering of documents and information systems to interface with CARE instrument protocols.

Furthermore, review of the CARE tool by many general acute hospitals and post-acute providers raises doubts about the accuracy of CMS’ preliminary time estimates for CARE assessments. If you consider the array of staff needed to complete the lengthy assessment, it quickly becomes apparent that a 15-minute assessment for even the most basic patient is highly improbable. The amount of time estimated by CMS is currently not available among the nurses, therapists, coders, physicians, and others who would be called upon to redirect their efforts from their existing core activities to a CARE assessment. As a result, many providers would need to hire additional staff, but many would not have the resources to do so. This expectation would be particularly burdensome for rural hospitals facing workforce shortages. For the minority of hospitals that could afford to hire additional personnel to conduct CARE assessments, nursing and therapist shortages would present problems.
To replace current patient assessment instruments with the CARE tool would require additional investment by hospitals and post-acute providers. For example, inpatient rehabilitation facilities would face an increase of approximately 150 assessment elements with the CARE tool beyond their current patient assessment instrument. And their new time requirement is estimated to be more than seven times greater than the current 40-minute average for an admission and discharge assessment. Given the hourly costs of the additional personnel who would be required to implement this major change, it is unclear at this point if the relative gains justify this significant additional resource investment.

The AHA recommends that CMS streamline the CARE tool to make it more manageable for nurses and other clinical and support staff.

HOSPITAL DISCHARGE TO POST-ACUTE SETTINGS

The CARE instrument’s design does not appear to yield an indication of a patient’s level of medical necessity for post-acute care, which diminishes the eventual role the assessment would play in helping to determine the most appropriate post-acute services for each patient. If the CARE assessments do not specifically produce a composite indication of a patient’s level of medical necessity based on key post-acute indicators of clinical and functional status relative to Medicare’s coverage guidelines, then post-acute providers would have to conduct a separate medical necessity assessment using tools other than the CARE instrument.

It also remains unclear how CARE assessments by hospitals would be integrated with a physician’s referral for post-acute care. We strongly feel that the physician’s expert clinical judgment should be given controlling weight in determining post-acute medical necessity for patients being discharged from general acute hospitals, and should be a primary determinant in post-acute referral process.

Furthermore, CMS and the Medicare Payment Advisory Commission have recognized that medically complex patients often face challenges in securing post-acute care since some providers can be reluctant to treat these demanding and costly patients. The CARE assessment will provide a readily available and detailed listing of patients’ primary diagnosis, comorbidities, medications and other indicators of medical complexity. Therefore, it may be even easier for certain post-acute facilities to deny these patients, delay hospital discharge and/or result in less-than-preferred post-acute care.

IMPACT ON PHYSICAL THERAPY RESOURCES IN HOSPITALS

Both hospitals and post-acute providers have speculated that the ability of physical therapists to conduct the CARE tool’s functional assessment will result in an increase in hospital orders for physical therapy assessments to accurately assess patients’ rehabilitation needs in order to complete the CARE tool.

INFORMATION SYSTEMS

We are concerned about how CMS intends for hospitals to integrate the CARE tool with their existing information technology. As of 2006, only one out of 10 hospitals nationwide had fully
implemented electronic health records. And only 10 percent had computerized physician order-entry systems for prescriptions. In 16 percent of hospitals, laboratory and other tests were ordered electronically at least half of the time. Therefore, a significant amount of patient information needed for a CARE assessment would have to be accessed from patients’ paper medical records and other varied hospital systems. Today, this would be a time-consuming process that involves the acquisition of a wide array of information from dispersed sources. CMS must not overlook the reality that 32 percent of hospitals have no electronic health record and 55 percent of the smallest hospitals, those with 50 or fewer beds, have no electronic health record. CMS needs to understand the diversity of information systems in hospitals and hospitals’ varied ability to integrate the CARE tools into their electronic protocols for those hospitals that have electronic systems.

**Representative Sample Needed for Demonstration**

The field-testing of the CARE tool in 10 markets will be a critical opportunity to determine if the preliminary time estimates for CARE application are accurate across hospital settings. It also will be important to understand how the time estimates vary across clinical categories (orthopedic, neurological, etc.). We encourage CMS to create a representative sample of hospitals and post-acute providers participating in the demonstration. The sample must not be over-representative of high-performing institutions, which would skew the findings and diminish their applicability to typical providers. To help achieve a balanced sample of providers for the next phase of testing, the AHA would be happy to assist in recruitment.

**Data Reliability**

A top concern of both hospitals and post-acute care providers is that the CARE tool accurately and reliably fulfills its intended role of measuring per-patient resource use in four post-acute settings: home health, skilled nursing, inpatient rehabilitation and long-term care hospitals. While many of the CARE measures come from existing post-acute patient assessment instruments, they have not been validated for use as a set or for the purpose of assessing patients’ clinical status at admission/discharge in multiple post-acute settings. Furthermore, the data elements have never been validated for the purpose of discharge assessment from a general acute hospital. In addition to a lack of validation of each distinct element, the ability of these measures to collectively provide an accurate assessment of resource use remains unknown. The ability of CARE assessments to achieve appropriate levels of inter-rater reliability also must be addressed through the development of a comprehensive training plan for key staff who would be responsible for conducting CARE assessments and the allocation of adequate resources to implement this plan. Until these matters are fully studied and data accuracy and reliability are confirmed, it would be highly inappropriate for CMS to proceed with using the CARE assessment data as a basis for policy analysis on resource utilization across post-acute settings, much less payment. It is essential for CMS to explain its views on these concerns and its plan and timeline for ensuring CARE assessment data meet the highest quality standards.

**Redundancy and Time Inefficiency**

The CARE tool will require many hospitals to re-institute manual and redundant data collection, which have been engineered out of internal protocols to promote efficiency and redirect staff
time to patient care. For example, the CARE instrument requires extensive medication and lab data, which for most hospitals would require very time-consuming manual data retrieval from separate internal data sources. For some hospitals such discharge information is already stored in multiple locations and the CARE tool would be yet another place this information is reported.

Having the ability to opt out of a section of the CARE assessment for patients who are within normal limits is an important time-saving option. While several large sections of the CARE tool offer this feature, such as the impairment section, the cognitive section does not, but it should. Furthermore, most hospitals and many post-acute facilities will not have the capacity to test all of the items in the supplemental functional status section for marginal patients, such as assessing the patient’s ability to drive a car or use public transportation, without relying at least partially on a patient’s self assessment. While Section III of the tool on Current Medical Items includes a “not tested” option for the reviewer, other measures also are appropriate for the “not tested” feature.

We are aware that at least one state, North Carolina, has introduced a post-acute assessment tool built on many of the same principles influencing the CARE tool’s design. At this time the North Carolina Medicaid program has placed a hold on this initiative due to providers’ implementation concerns. CMS should coordinate its efforts with this state and any others pursuing similar initiatives so that providers are not expected to satisfy competing and inconsistent post-acute admission and discharge requirements.

**INCONSISTENT SCALES**

Some of the proposed measurement scales are different than those currently used by post-acute providers. Such scales should be tested for accuracy and reliability when applied to post-acute patients in multiple settings. It is essential that these scales be able to capture the true burden of patient care so that resource utilization assessment is accurate and meaningful for policy makers and providers.

**CODING**

Many hospitals do not conduct concurrent coding, and for these hospitals, coding information is often not available until one week after discharge or later. The CARE assessment process must accommodate this reality by allowing this data element to be completed following discharge of the patient to prevent needless, costly and potentially extensive delays in discharge from the hospital. In addition, we urge CMS to explain its plan for reconciling the differences between the different sets of codes used in general acute hospitals and those used in the post-acute settings. Through the Coding Clinic, the AHA and others have raised these inconsistencies with CMS and the National Center of Health Statistics.

**FRAILTY/LIFE EXPECTANCY ASSESSMENT**

Section VIII on Frailty/Life Expectancy asks reviewers “Would you be surprised if the patient was readmitted to an acute care hospital in the next 6 months?” And “Would you be surprised if the patient were to die in the next 12 months?” To respond to these unorthodox questions, discharge planners would, at least in part, have to rely on subjective judgment. The subjectivity
raises legal risks and potential ramifications for medical necessity determinations. If a patient were expected to “die in the next 12 months” would the hospital be questioned for providing extensive care? If the patient were expected to be “readmitted to an acute care hospital in the next 6 months” would the hospital be challenged for discharging the patient to a post-acute setting? Would patients have access to a hospital’s life expectancy assessment? These sensitive questions should be addressed before they are implemented in the CARE tool.

We thank CMS for the opportunity to comment on the CARE instrument. We are committed to continuing to help identify experts to provide input, convene focus groups as needed, assist with recruitment and other activities that can produce useful findings for the demonstration. If you have any questions about our comments, please feel free to contact me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

Rick Pollack
Executive Vice President