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**BY OVERNIGHT MAIL**

Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development – C  
Attention: Bonnie L. Harkless  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244 - 1850

**RE: *Type of Information Collection Request: New collection; Title of Information Collection: Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument***

Dear Ms. Harkless:

The Acute Long Term Hospital Association (“ALTHA”) is the Washington-based trade association of Long Term Acute Care Hospitals (“LTACs”). LTACs are hospitals which provide patients with acute care for extended inpatient stays, on average 25 days or more. Access to these hospitals is crucial to a small but critically-ill population of patients. ALTHA works to protect patient access to quality LTAC care. ALTHA represents over three hundred LTACH hospitals across the United States, constituting over two-thirds of this provider community nationwide.

We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS”) notice on the Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. ALTHA supports the comments submitted by the Federation of American Hospitals (“FAH”).

In 2005, ALTHA developed the following four principles which we believe should guide development of rational policy in the post-acute space:

First, ALTHA believes each provider in the post-acute sector plays a critical and distinct role in meeting the needs of the post-acute patient population. Policy should seek clearer definitions of those distinct roles but should recognize that a certain amount of overlap is inevitable and necessary to ensure continuity of patient care across settings.

Second, ALTHA supports CMS' efforts to explore and evaluate development of a comprehensive post-acute assessment tool. Development of such an instrument is an important prerequisite to integrating care, and possibly payment, across the post-acute setting. However, development of a common instrument is a very complicated and important task. The range, depth, and content of clinical information necessary to evaluate and treat LTCH patients is more comprehensive than is captured in the assessment instruments used by other post-acute providers. Policy makers should proceed carefully in developing a common instrument and ensure active participation by clinicians involved in treating patients across the post-acute continuum.

Third, ALTHA supports the principle that patients should be cared and paid for in the appropriate setting. MedPAC's recommendations and CMS's current research on revised certification criteria for LTCHs are designed to achieve this goal. While determination of appropriate setting is a complicated decision requiring extensive input from treating physicians in consultation with patients, ALTHA agrees with the premise of MedPAC's recommendation that the decision should be made based primarily on patients' clinical characteristics and needs. Patients who can be safely and effectively cared for in SNFs should not be treated and paid for in LTCHs or IRFs. Conversely, severely ill, medically complex patients with multiple co-morbidities should have access to the intensive interventions only available in LTACs.

Fourth, ALTHA believes that public policy should also require not only that patients be placed in the appropriate setting, but that providers in the post-acute sector have the capacity to meet the needs of the patients. Staffing levels, staff skill mix, availability of diagnostic tests, sophistication of technology and intensity of service vary significantly across post-acute settings. While it is tempting for public policy to encourage patients to be placed in the least intensive and least costly setting, this decision must be made in light of patient needs and quality of care, as measured by the providers' capacity to effectively treat patients with certain clinical conditions.

We support CMS's efforts to advance policy according to these principles. At the same time, we are concerned that policy may be proceeding without adhering to these principles. We urge CMS to consider ALTHA's comments carefully in light of the fact that two of ALTHA's member LTACs were pilot sites in the creation of the CARE instrument and can provide insight into the utility of the instrument for LTACs. In general, ALTHA is concerned that the instrument, as currently constructed, does not adequately capture the unique clinical and functional characteristics of typical LTAC patients, particularly the medical instability of these patients upon admission to the LTAC. In addition, ALTHA cautions CMS against drawing conclusions about the utility of the CARE instrument, particularly as a predictor of resource use, based on a small number of LTAC pilot sites and approximately 50 patients. Finally, ALTHA does not believe that CMS has adequately specified the fundamental purpose(s) of the CARE instrument, which we believe is an important prerequisite to designing and testing the instrument.

## **The Purpose of the CARE Instrument Should be Clearly Identified**

ALTHA believes that CMS has not identified clearly enough the purposes for which the CARE instrument is being constructed. Without clear specification, the instrument ultimately created can be inadequate to serve any purpose very well. There are several potential purposes for such an instrument. These purposes should be explicit and guide the instrument development process before proceeding with the demonstration:

- Determining appropriate placement of patients following an acute episode;
- Facilitating smooth transition between service sites;
- Developing an initial and ongoing care plan within service sites;
- Generating quality indicators, both for internal use in quality improvement and for external use by regulators and consumers;
- Predicting resource consumption for purposes of organizing care delivery systems, determining staffing levels, etc.
- Determining appropriate payment levels;
- Evaluating medical necessity and continued stay and determining appropriate discharge destination.

Each of these purposes requires a distinct set of data points. As discussed below, the CARE instrument is not currently designed to yield information that can be used for all of these purposes, yet CMS implies that the instrument will be used for many reasons. ALTHA recommends that CMS be clear about the intent of the CARE instrument before specifying its contents and testing it.

## **CARE Instrument Fails to Adequately Capture the Characteristics of LTAC Patients**

LTACs typically admit and treat severely ill, medically complex patients. As acknowledged by various researchers, these patients defy easy categorization. However, one defining characteristic of LTAC patients is medical instability, particularly as distinct from patients in other post-acute settings.<sup>1</sup> Most LTAC patients are admitted from the ICU or step-down units of acute care hospitals and their medical condition is still somewhat unstable and subject to frequent change. The CARE assessment does not assess this rate of change. The list of diagnoses, procedures, treatments and medications show only a point in time status, not changes that are happening or what medical interventions are required to maintain stability. For example, the medication list does not indicate how recent the medication is administered or how frequently the dose is being adjusted. Similarly, the physiologic factors ask for the most recent

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<sup>1</sup> ALTHA acknowledges, as documented in the RTI report on LTACs produced for CMS, that there may be a certain amount of substitution between some LTACs and Inpatient Rehabilitation Facilities (“IRFs”) and to a lesser extent SNFs. ALTHA strongly supports revised LTAC certification criteria to more accurately distinguish between patients that could be treated in IRFs and SNFs from those that are currently being treated in LTACs.

value, not how often the factor is being measured or the recent variability in the value. This gradient of stability of a patient greatly affects not only resource utilization, but is critical to determine whether a patient can be transferred to another post-acute setting or is at risk of re-hospitalization to an acute care hospital. The current CARE instrument does not adequately assess this and therefore may yield fundamentally unreliable results regarding the course of care or resource use for patients in LTACs.

Likewise, the CARE tool does not accurately assess functional status in LTAC patients and, more fundamentally, changes in functional status over time. Specifically, based on the experience of the ALTHA member hospitals who participated in the pilot, the functional assessment portion of the CARE instrument most often was answered as “unable to assess” because the patient lacked the function to perform the assessment, at least as the form is currently constructed. Yet, many LTAC patients, while severely ill, do have some level of function that is important to measure and to establish a baseline as part of charting a therapeutic course and predicting resource use. It is not clear how the tool will handle “unable to assess” data points. Will they be interpreted as the highest severity or as missing data? The missing data approach would severely diminish the tool’s ability to differentiate LTAC patients from less severe post acute patients. Moreover, over the long course of care experienced by many LTAC patients, the patient’s condition will gradually allow individual items to be assessed and appropriate rehabilitation plans put into place. These are gradual changes in condition, subtle in nature, that are not adequately captured in the current CARE instrument and are not amenable to a single or small number of interim assessments. Without those interim assessments, there will not be a consistent baseline against which to measure progress. Again, as applied to LTAC patients, the CARE instrument will yield limited information for any of the purposes outlined above, most particularly measuring appropriate patient placement or resource use.

### **Sample Selection of LTACs**

ALTHA also urges CMS to choose a larger sample of LTACs in which to evaluate the CARE Instrument. As CMS well knows, there is variation among LTACs in the range of patients treated in terms of medical complexity and severity of illness. ALTHA has consistently advocated defining the role of LTACs in the post-acute continuum as being appropriate for Medicare’s most medically complex, severely ill patients. LTACs who specialize in treating patients that could be safely and effectively treated in lower acuity post-acute settings would not be appropriate demonstration sites for testing the CARE instrument since appropriate distinctions between sites of care would be muted. Accordingly, we urge CMS to be purposeful in selecting demonstration sites by selecting LTACs that are appropriately admitting and treating medically complex, severely ill patients.

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Bonnie L. Harkless  
Centers for Medicare & Medicaid Services  
September 25, 2007  
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We appreciate the opportunity to comment on this notice and hope that the agency carefully considers the comments in this letter. If appropriate, we would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions, please feel free to contact me at (703) 518-9900.

Respectfully submitted,



**William M. Altman**  
Chairman, ALTHA Policy Committee  
Senior V.P., Kindred Healthcare



**Peter R. Baronoff**  
President, ALTHA Board of Directors  
CEO, Promise Healthcare



**William Walters**  
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