CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

September 25, 2007

Centers for Medicare and 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, Maryland 21244-1850

Re: Agency Information Collection Activities: Proposed Collection: Comment Request, CMS-10243, 4. *Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument,* 72 F.R. 41328-41329, July 27, 2007

Dear Ms. Harkless:

The California Hospital Association (CHA) respectfully submits comments on the Continuity Assessment Record Evaluation (CARE) tool. CHA submits comments on behalf of its nearly 500 hospital and health system members. Our membership includes approximately 70 inpatient rehabilitation facilities (IRFs), over 100 distinct part hospital based skilled nursing facilities (SNFs), and several long term acute care hospitals (LTCHs). In addition, many of our members provide home health and other community based services. Our member facilities represent a broad range of provider types, from large urban facilities and academic medical centers to small rural and critical access hospital (CAHs).

The diverse nature of our membership provides an effective framework for the review and evaluation of the CARE tool. Since the publication of the draft document on July 27, 2007, CHA has solicited comments from the various constituency groups within the organization's membership. The comments presented here reflect input from individuals of each of these levels of care and types of providers.

I. Background

We understand that the CARE tool is a uniform patient assessment instrument developed in association with the Centers for Medicare and Medicaid Services (CMS) Post Acute Care Payment Reform Demonstration (PAC-PRD) project. The stated goal of the CARE tool is to measure differences in patient severity, treatment needs and outcomes for patients in both acute and post acute settings. The tool is to be administered at discharge in acute care settings and at admission and at discharge for each of four post acute care providers; including SNF, IRF, LTCH, and Home Health Agencies (HHAs). The CARE tool is being designed to eventually replace portions of existing assessment tools, including the Minimum Data Set (MDS), IRF

Patient Assessment Instrument (IRF-PAI) and the Outcome and Assessment Information Set (OASIS).

CHA appreciates and agrees with the current project's focus on the post acute continuum of care. Inpatient rehabilitation facilities, skilled nursing facilities, long term acute care hospitals, and home health care agencies play an essential role in the provision of medical and rehabilitation services and in the transition of patients from hospital to home and community. We support CMS's goal of collecting data regarding patient characteristics, treatment needs, and outcomes in post acute care. We also support the continued refinement of patient assessment and reimbursement mechanisms to provide consistency in assessment standards, maximize communication across and between levels of care, and ensure patient access to appropriate and effective services.

We have serious questions, however, regarding the proposed CARE tool and its implementation. Overall, our members have concerns about the amount of time the instrument would take to administer, the tool's ability to collect reliable and valid information, and its impact upon treatment planning and patient access. Taken together, the comments summarized in this letter raise serious questions about the ability of the CARE tool to achieve its stated goals.

II. Comments on Process and Implementation

A. Time Burden/Staff Resources

Providers from all levels of care commented that the time required for the administration of the CARE tool would far exceed the CMS estimates. They questioned the ability of facilities to administer the proposed tool with existing staff, and noted that they would be unable to add additional staff without a corresponding increase in reimbursement.

This issue was raised by providers of all types and from all levels of the continuum of care, but was most pronounced from members representing acute care settings.

Discharge planners in the acute care setting are charged with the development and initiation of discharge plans within very short time frames for large numbers of patients. The implementation of the CARE tool represents a significant, and unrealistic, addition to their job duties. It is not unusual for an individual discharge planner in the acute care setting to have responsibility for thirty patients or more. The authors of the CARE tool have estimated that the instrument will take 20-45 minutes per patient to complete, depending on the discharge disposition of the patient. Based on this estimate, an individual discharge planner would devote 1-2 full days per week to CARE tool completion, a time commitment increase of twenty to forty percent of a full time equivalent (FTE). Current staffing levels in acute care facilities do not support such a significant increase in time commitment and it is unrealistic to expect that facilities will be able to absorb this new activity. Addition of staff to complete these new duties will not be possible without a related adjustment to associated reimbursement levels.

The time needed to complete the CARE tool will also be affected by timely access to required data. While some of the required information may be readily available in the medical record (e.g., lab results), other information may be available only through patient interview or observation, or other sources (e.g., memory). In order to complete the tool accurately, discharge planners will be required to initiate additional time-consuming coordination and communication with multiple hospital departments and/or team members.

Based on these factors, we question the Centers' estimate of time required for tool completion in the acute care setting. Several CHA members reported that they attempted to fill out the tool on a trial basis. Some members reported taking as long as two to three hours to complete a single assessment.

The challenges presented by the tool in the hospital setting are especially problematic in the case of rural and critical access hospitals (CAH). In these facilities, staff nurses are responsible for a broad range of patient care activities, including discharge planning. Other team members may be available on a limited basis only. The time required for accurate data collection and completion is unrealistic for these settings. In addition, Procedures for completing the CARE for patients residing in swing beds during a portion of their stay are not clear.

In California, resource availability is particularly impacted by two factors unique to the state: the presence of statutorily-mandated nurse staffing ratios, and a national nursing workforce shortage that is exacerbated in California by nurse staffing ratios and other state labor policies. Both of these phenomena will curtail larger acute care facilities' ability to shift nursing staff from direct patient care to discharge planning, making it extremely difficult for these institutions to compensate for the much larger administrative burden the CARE tool will impose upon the discharge planning process.

The time demand for CARE tool administration is also a concern to post acute care providers. The authors of the CARE tool have stated that it will eventually supplant some portions of the MDS, IRF-PAI and OASIS tools, so that implementation of the CARE tool will result in some "trade-off" of the time dedicated to administration of these current tools. Further review, however, indicates that the CARE tool will result in a need for increased staff time in post acute settings.

For example, MDS administration in the SNF setting is required during the first several days of a patient's stay and at specific intervals. Introduction of the CARE tool will require additional time –consuming assessments to be completed at discharge. The CARE tool requirement for interim assessment will also mandate additional assessments in SNF, IRF and HHA settings. Current assessment procedures will need to continue for non-Medicare patients, even after introduction of the CARE tool. This issue will be especially problematic during the pilot program, when providers will be required to complete the CARE tool while also maintaining current documentation and data collection systems. Providers who may otherwise be interested in participating in the pilot program will be unable to do so, secondary to their inability to hire additional staff. We question whether additional

reimbursement or recognition of the increased expenses would be provided to support provider participation.

In summary, our review indicates that implementation of the CARE tool will result in significant increases in required staff time at all levels of the continuum of care. Our member providers are universal in their concern that current staffing levels are not sufficient to absorb this activity.

B. Availability and Accuracy of Data

A related issue is that of the limited availability of required information within the designated time frame. For example, the ICD-9 codes requested in Section III are frequently unavailable until several days after patient discharge, following the completion of the physician discharge summary and the medical record coding process. Accessing and reporting this information at or before the patient's discharge will be cumbersome and of questionable accuracy.

Similarly, the two day assessment window for some data items is problematic. In the acute care setting, short lengths of stay and patient factors interact to make accurate and consistent assessment of behavior and functional areas difficult. For example, a patient who has suffered a stroke may be in the acute care hospital for only three to four days prior to being discharged to a post acute facility or to home. During the two day assessment "window", this same patient's functional status will vary considerably in terms of mobility, self care and other items. Data reflective of a two day "window" will not present an accurate picture of the patient's clinical and functional needs as he/she transitions to a post-acute setting.

Critical Access Hospitals are required to keep their lengths of stay to less than 96 hours. The short lengths of stay will exacerbate problems with the required assessment/data collection period and the time required for instrument completion.

We also have concerns that the requirement for extensive data collection will also lead to increased costs and inappropriate utilization of patient care services. For example, facilities may initiate therapy consults for the purpose of completing the CARE tool in the absence of clinical indications for the service.

C. Staff Training and Qualifications.

The current communication from CMS does not include information regarding guidelines for administration or for staff training or qualifications. Additional information regarding these issues would be helpful in assessing the CARE tool and its implementation.

The expertise and background of individuals responsible for patient assessment and discharge planning varies greatly among and between providers both within a single level of care and between different levels of the continuum of care. Many data items contained on the CARE tool appear to require a subjective assessment by the evaluator, and will inevitably be affected by the setting and by the reviewer's background and experience. It is unrealistic to expect that a single individual will

have all the requisite experience to complete the tool accurately. At the same time, completion by multiple individuals will lead to inconsistencies and variability in the reported data. Such unavoidable variations will limit the validity of the information collected and its value for future policy decisions and planning.

D. Reliability and Validity of Data

The changes in methodology from current assessment instruments to the CARE tool will cause significant problems with the consistency and accuracy of collected data. For example, the proposed CARE tool uses a 6 point scale for rating functional activities such as self care and mobility. While the CARE tool's scale is very similar to the 7 point FIM scale that is used by rehabilitation professionals, it also contains some significant differences. This change will undoubtedly create confusion and lead to inaccurate reporting of patient characteristics.

It is not realistic to expect that clinicians in the various settings will adjust to totally new assessment standards with the implementation of the CARE tool. It is equally unrealistic to expect individuals responsible for CARE tool completion to recognize when existing documentation must be converted to the new assessment scales created for CARE tools. As a result, data reported will be inaccurate and will not support comparisons across settings.

We also question the advisability of changing data reporting from established assessment tools to a new instrument instead of building on the body of experience, evidence, and research that is available from decades of data from current documentation systems. The FIM tool, for example, has been used for decades to measure burden of care as well as patient gain in functional activities. There are established mechanisms for training and inter-rater reliability. Moreover, there is a lengthy history and a wealth of data and related research that would be invaluable in future efforts to refine and improve patient outcomes in the post-acute continuum of care.

E. Integration with Documentation

Many of our members expressed concern about the construction of the CARE tool and its relationship to/integration with existing clinical documentation systems. Most providers have developed and implemented documentation systems that correspond to current reporting requirements and that facilitate data retrieval for current tools such as the IRF-PAI and the MDS. To the extent that implementation of the CARE tool initiates new rating scales and assessment requirements, documentation forms and systems will need to be changed, at great expense to the provider. Moreover, the need to maintain duplicate systems to accommodate other functions and payers will be onerous.

Providers have questions regarding the integration of the CARE tool with electronic medical records and computerized documentation systems. CHA Members are at various stages of automation and electronic medical record collection; while some are using or preparing to use elaborate electronic documentation systems, others

utilize medical record systems that remain totally paper-based. The ability to access and obtain data from current documentation would improve the data collection for the project.

F. Related Documentation Functions

We are concerned that the CARE tool will not fulfill reporting requirements currently performed by existing assessment instruments, which will lead to costly duplicative reporting or documentation systems. For example, in addition to determining reimbursement, the MDS tool is used in the SNF setting to report information that is used for quality initiatives and for facility licensing and certification. Specifically, we note that the CARE tool does not request information regarding the patient's need for restraints or the use of strategies to limit restraint use. This is a crucially important item for the evaluation of quality in the SNF setting, and is monitored actively by the QIOs on behalf of CMS. Similarly, many IRFs use the IRF-PAI to meet requirements for Joint Commission performance measurement.

G. Implications for Demonstration Project

Based on our review, we are concerned that the cumulative effect of these factors will have a significant effect on the results of the demonstration project. The expense and resources required by additional assessments will undoubtedly limit the number and variety of facilities that are able or willing to participate in the demonstration project. Those that are will not be representative of the broader provider community. The need to continue with parallel and duplicative assessment systems with different-but-similar data elements and rating systems will result in data inaccuracies and confusion. We believe that the data collected during the pilot will ultimately be compromised and of questionable value for use in planning effective payment reform.

We also question the use of this tool to objectively compare outcomes across various settings, when each of those settings must comply with regulatory requirements that may affect patient access, selection, and resource use, such as the 75% rule and LTCH length of stay requirements.

II Comments on the CARE Tool

A. General Assessment Factors

We have concerns regarding the effect of certain patient characteristics on the administration of the CARE tool. Patients with mental health problems, cognitive impairment or communication difficulty may not be able to provide accurate or valid information. Homeless individuals or others who do not have caregivers to provide reliable information will also present a challenge. We recommend that the form be modified to allow for such contextual information to be provided in each of the appropriate data sections, so that reported data may be interpreted appropriately.

As previously stated, we also question the tool's changes in methodology and scoring procedures in several areas, such as functional activities or pain scales. Such changes will undoubtedly create confusion and lead to inaccurate reporting of patient characteristics.

B. Specific Assessment Items

Section I. Administrative Items

C12a "If not, is an interpreter available?" – This item raises concerns for providers regarding the need/requirement of the facility to provide a qualified interpreter for the completion of the assessment, and whether the results are valid if it is not. At a minimum, the response should include information as to whether the interpreter was a family member, trained interpreter, or other individual, and whether the interpreter was present on-site or accessed remotely.

Section II. Admission Information

A4. Skilled nursing facility (includes subacute SNF and transitional care unit – The use of the term "subacute" is confusing. In California, the term "subacute" refers to a category of MediCal certified SNF providers that are subject to specific staffing and patient admission requirements. Since the term may be used differently in other states, its use here should be clearly defined or omitted.

B4. If the patient lived in the community prior to the current illness, exacerbation or injury, are there any structural barriers in the patient's residence that could interfere with the patient's discharge? – How would a provider validate the accuracy of the information provided?

B6. Mobility Devices and Aids - Use of an electric wheelchair should be added as an option. Required bathroom equipment should also be included.

B8 Prior Mental Status – This question requires a subjective judgment by the evaluator. In cases of new admissions in the acute setting, assessment will be based on second hand information. As such, we question the reliability of the responses and their value for future program planning.

Section III. Current Medical Items

A,B,C. Diagnoses, Procedures - Most facilities do not complete and validate coding until several days after patient discharge. ICD-9 codes are then entered onto other patient assessment and billing documents. Entering them on a separate form in a separate time frame will lead to discrepancies and incomplete data.

C. Procedures - Additional information is needed regarding the definition of what constitutes a "diagnostic or therapeutic intervention". It is also unclear whether certain procedure(s) are to be recorded using a title (e.g., Respiratory Therapy) vs. a CPT code. The form does not request information regarding the volume or frequency of procedures, which will often provide significant information regarding

patient characteristics and/or treatment needs. Documenting a corresponding ICD-9 code to each individual procedure is confusing and cumbersome.

D. Treatments - The list does not include some frequently used items such as Continuous Passive Range of Motion (CPM), or Continuous Positive Airway Pressure (CPAP). Hyberbaric oxygen treatment and wound vac should also be included. A category of "other" should be added to accommodate new or unanticipated treatment modalities.

E. Medications – This list is duplicative of other documentation for medication reconciliation and may result in transcription errors. We would suggest that the facility be able to provide lists of medications from existing data sources.

Section IV. Cognitive Status

Many of the items in this section are subjective, and results will be influenced by the expertise and background of the evaluator and/or the setting. For example, an individual may appear to be able to "Make decisions regarding tasks of daily life" in the acute care setting under close supervision but be unable to function in less structured settings such as home health.

C3. Memory/Recall Ability – The rating *C3e "None of the above are recalled or unable to assess"* conflates two distinct clinical pictures. We suggest separating "unable to recall" from "unable to assess."

F2. Patient Health Questionnaire – In ratings *F2b* and *F2d* "0" is not necessary, as they do not follow from an affirmative answer from the immediately preceding questions.

G. Pain- We question why the assessment of pain is part of the Cognitive Status section of the assessment. We note also that the assessment scale used to assess pain is a four point scale, different from the established scales (in particular the widely used 10 point Baker scale).

Section V. Impairments

We find that many items in this section are subjective, and reported information will vary significantly based on who is responsible for the data collection in that setting. For example, whether a moderately aphasic individual "understands" will likely been seen and rated differently by a speech/language pathologist who can test for language comprehension as compared to a staff nurse or discharge planner who may have had only conversational interactions with the patient.

B. Bladder and Bowel Management – This item uses reporting methodology that is significantly different than other tools, such as the IRF-PAI, and focuses on impairment rather than management or burden of care. We suggest that this item be changed to be consistent with existing tools.

D. Hearing, Vision and Communication Comprehension - These items are subjective and rating choices are overly broad and vague.

E. Upper Extremity Range of Motion - The terminology "functional range of motion within normal limits" is confusing. A patient could have functional range of motion without having full normal use. There is no distinction between active, active assisted and passive range of motion. Wrist and hand function should be included.

F. Weight-Bearing – This question would be more meaningful if it included options for partial weight –bearing and more information regarding "medical restrictions."

G. Grip Strength - The assessment is subjective.

H. Respiratory Status – This item is overly subjective. We recommend use of an accepted scale, such as Rate of Perceived Exertion or Dyspnea Scale.

I. Endurance – Item would be more useful if assessment noted if activity is supported or unsupported.

J. Mobility Devices and Aids Needed – Electric wheelchair should be included as an option. We also recommend clarification of threshold for "part-time/full-time" use of wheelchair or scooter.

Section VI. Functional Status

As discussed previously, a major concern relating to this area in the use of new coding scales that represent a significant change from previous practice.

For many years rehabilitation professionals have utilized the FIM score for assessment of burden of care. The FIM tool forms the basis for the current IRF PPS system for reimbursement. A change from the established 7 point scale to the 6 point scale described in Section VI is problematic from several standpoints.

The FIM scale distinguishes between an individual who needs supervision only (FIM score = 5) and one who needs minimal assistance, including "contact guard" or "touching/steadying assistance" (FIM score = 4). In the proposed scale for self care and functional ability, both of these levels of care receive a score of 4. We would argue that the distinction between visual supervision and hands –on physical support is an important one for care planning and resource use, and it is unclear to us why this distinction is eliminated in the current scale.

Similarly, the change from the patient's lowest level of performance as required by the FIM tool to the "most usual" performance will also lead to inconsistency in data collection, as the patient's performance will vary over the course of the day in different settings and with different caregivers. We also question the use of "most usual" when the lowest level of performance is most indicative of the patient's care requirements and need for ongoing care.

Changing from the familiar and well-established FIM scale to another similar scale will also cause inaccuracies in data collection. The FIM scale is widely used by

rehabilitation professionals in all settings. It is unrealistic to expect that reviewers will recognize when they need to "translate" the established rating to the CARE tool rating.

B. Core Functional Mobility – 4. Toilet Transfer- A patient's ability to transfer to a toilet vs. a commode may be different. We recommend changing this item to specify standard toilet.

C. Supplemental Functional Ability - This section also includes several items related to independent living skills, such as the ability to do light shopping, laundry, or to drive a car. These items are not routinely evaluated or observed in the hospital or post acute setting. It is unclear how these items would be assessed, and what implications this data has for treatment planning or resource use.

Section VII. Engagement

We question the value of this question and its implications for treatment planning. In the context of cognitive impairment or mental health issues, an individual's compliance with treatment and/or level of frustration may not be indicative of prognosis or ability to benefit from treatment, and may vary significantly in the course of normal neurological recovery. Characterizing this behavior as reflective of the patient's level of "engagement' in treatment is inappropriate, and may lead to harmful decisions to limit treatment for a "problem" patient, such as those with limited insight, cognitive impairment, or depression.

Section VIII. Frailty/Life Expectancy

Many of our member providers indicated that they would be uncomfortable asking these questions. The questions in this section relate specifically to medical prognosis, which is most appropriately assessed by a physician. In addition, several providers indicated that they would be reluctant to answer "yes" to either question, out of concern that an affirmative answer may limit the patient's ability to access additional care.

Section IX. Discharge Status -

C1. Will the patient be able to pay for their medications after discharge? If the patient answers "no" to this question, what is the facility's responsibility?

D. Discharge Care Options - We find this question to be confusing. The question asks that the completer indicate which discharge option(s) among several was "Deemed Appropriate by the Provider". Each of the listed options represents a specialized level of care, with specific clinical and reimbursement requirements. A patient's candidacy for a specific level of care is subject to certain conditions and/or additional evaluation. It is unrealistic and inconsistent with current practice to expect staff members at an individual level of care to assess patient candidacy for all possible levels of post acute care.

The tool notes only two possibilities for reasons the patient may not proceed to a specific post acute setting ("Refused by Patient/Family," "Not Covered by Insurance"). There are multiple other reasons why a patient may not proceed to a given level of care. For example, a patient may be able to proceed to a SNF level of care, except that they require a clinical service that is not offered by SNFs in that area (e.g., blood transfusions). This question should be modified to reflect other reasons for lack of access, and provide an option for "other".

Substance abuse services or facility should be added as an option.

III. Comments on Related Issues

A. Effect on Patient Disposition

The stated goal of the CARE tool is to collect information on patient characteristics, outcomes, and needs across care settings. The tool's authors have indicated that it is not designed as a predictive tool, or one that is aimed at determining an individual patient's discharge disposition. Regardless of the intent, we have concerns that the tool may be misused as a mechanism to determine post acute placement and may ultimately control or reduce patient access to appropriate services. We recommend that CMS take steps to guard against inappropriate use.

B. Impact of Other Programs

We are concerned that the data collected by the CARE tool will be skewed by other CMS initiatives. Since the inception of the Recovery Audit Contractor program in California, post acute providers such as IRFs have been forced to initiate changes in utilization and admissions in response to inappropriate claims review and denials. To the extent that the pilot project includes markets in California, we request that CMS address how these market issues will be take into consideration.

IV. Summary

Our review of the CARE tool leads to numerous concerns regarding the instrument and the burden associated with its administration. We believe that the limitations of the CARE tool will have a significant negative impact upon data collection and results of the post acute care payment reform demonstration project. The expense and resources required by the additional assessment will undoubtedly limit the number and variety of facilities that are able or willing to participate in the demonstration project. As noted above, we are particularly concerned with the new and onerous administrative requirements that the CARE tool will impose on discharge planners in acute care institutions.

We recommend that CMS review the construction of the current CARE tool and consider revising it extensively. An alternative approach to the current tool would be to select and incorporate portions of existing assessment instruments into a comprehensive data set. Such a tool would avoid many of the accuracy and transition problems noted in the current discussion, and would allow for researchers to utilize previously collected data.

We also recommend that CMS consider financial remuneration as a part of the demonstration project, to compensate participating institutions for the heightened administrative burden of duplicative record keeping (in the case of post-acute providers), or of a new administrative requirement (in the case of acute care institutions.) This remuneration could be in the form of an enhanced Medicare prospective payment, which would maintain incentives for provider efficiency, or in the form of an evaluation-related separate payment. We recommend that the amount of payment be predicated upon several factors, including: 1) the presence of a similar assessment tool (such as MDS, IRF-PAI, or OASIS), or in the case of acute care providers, the lack thereof; 2) the labor costs associated with completing the CARE tool, adjusted for facilities' area nursing wages; and, 3) allocated costs for benefits, supervision and management, data systems, and facility use.

Thank you for the opportunity to provide input on these important issues on behalf of our providers and the disabled individuals and senior citizens they serve. If you have any questions or would like to discuss our comments, please contact Pat Blaisdell at (916)552-7553, or pblaisdell@calhospital.org.

Sincerely,

Pat Blaisdell, Vice President
Centers for Medical Rehabilitation
& Continuing Care Services

Cc: Barbara Gage, PhD, RTI

PB/beo