JOHN MUIR HEALTH

John Muir Medical Center
Walnut Creek Campus

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A not-for-profit organization

September 21, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of **John Muir Health** in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services.

The CARE tool contains over 300 items divided into 11 major sections: Administrative Items, Admission Information, Current Medical Items, Cognitive Status, Impairments, Functional Status, Engagement, Frailty/Life Expectancy, Discharge Status, Other Useful Information, and Feedback. Of those 300 items, 100 items are common to all settings, 163 are required upon discharge from acute care, 155 are required upon admission to a post-acute setting (SNF, IRF, LTCH, HHA), 160 are required upon discharge from a post-acute setting, and 139 are required for interim assessments every 14 days in post-acute settings. CMS estimates that the CARE tool will take 35-60 minutes to complete, depending on the setting and complexity of the case.

My comments and concerns regarding the CARE tool are presented below:

1. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient classification and reimbursement.
    a. The rationale for the inclusion of the additional 210-220 items is not clear.
    b. The forced use of the CARE tool will create an unnecessary burden on staff and increase costs to acute and post acute care providers.
    c. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources that will be needed to comply with these changes.
    d. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
    e. Given the complexity of the form and the time needed to correctly complete the form, Acute Care facilities will need to significantly increase FTEs to accommodate this requirement.

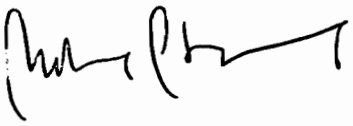
2. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.
    a. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim.

b. Rehabilitation facilities will need to develop new assessment forms, worksheets, and documentation procedures for each of the 140-160 CARE tool items.
c. Each of two acute care hospitals will require at least two trained PPS/CARE coordinator to collect and submit CARE tool data.
d. The CARE tool may increase therapy, nursing, and physician documentation time by as much as 20 percent, necessitating an increase in staff.
e. Staff time, which should be focused on providing direct patient care and therapy, will instead be redirected toward the paperwork and documentation needed to meet the data requirements of the CARE tool.
f. All case management, discharging physician, rehabilitation, and home health staff will need to be trained in the use of the new CARE tool at a considerable expense.
g. JMH will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. JMH has already developed automated documentation systems (electronic medical records), which will need to be revised.
h. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.

In light of the above observations, JMH is recommending the following:

1. The CARE tool should be refined and condensed to no more than 50 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
2. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
3. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

I am grateful for the opportunity to provide comments on this important demonstration project.
Sincerely,



Andrea P. Segura RN MSN CNAA BC
Director Nursing Practice/Operations
John Muir Medical Center, Walnut Creek Campus
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Catholic Healthcare West
CHW

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:

On behalf of our 42 hospitals in Arizona, California and Nevada, Catholic Healthcare West (CHW) appreciates the opportunity to respond to the Proposed Continuity and Assessment Record and Evaluation (CARE) instrument. Eleven of our hospitals have inpatient rehabilitative facilities and we have over nine-hundred skilled nursing beds system-wide. As the eighth-largest non-profit hospital system, we are committed to our mission of providing compassionate, high quality health care to all.

Please see below our comments on the proposed CARE instrument:

Background

CHW agrees the development of the CARE tool is an important step in creating uniform patient assessments and believes the focus of the project is appropriate, particularly because inpatient rehab facilities and skilled nursing facilities, as well as long term care hospitals and home health care agencies, play and integral role in the provision of medical rehabilitation services and transitional services for patients going from hospital to home and community settings. Creating a single tool to record patient assessments and data would 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).

CHW appreciates and agrees with the current project's focus on the post acute continuum of care. Inpatient rehabilitation facilities and skilled nursing facilities, as well as 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 relevant data regarding patient characteristics, clinical assessment, treatment needs, and outcomes of care provided in post acute settings. We also support the continued refinement of patient

assessment processes and tools combined with reimbursement mechanisms that recognize the time required to establish patient status and recovery potential, consistency in assessment standards, maximize communication across and between levels of care, and to ensure patient access to appropriate services. However, we have serious questions regarding the proposed CARE tool and its implementation, beginning with the time required to administer it, its ability to collect reliable and valid information, and its impact upon treatment planning and patient access.

Process and Implementation

CHW is concerned the requirement to complete the CARE tool will add an additional burden to clinical staff and Health Information Management (HIM). Although CMS estimates an average 20-60 minutes to complete the form, a survey of providers suggests it would take an individual discharge planner 60 – 90 minutes per CARE tool to complete CARE tools, further limiting our time at the bedside with patients and families and imposing a delay in efforts to coordinate arrangements for the next level of care. This is in part due to the requirement to provide certain data elements that may not be readily available. For example, some information may be readily available in a patient's medical record; other information is only available though patient interview or direct observation. If the patient is unable to provide the information necessary, the staff will be required to locate family or others to obtain the information. In addition, this type of data collection requires the coordination and communication with multiple hospital departments and staff and will necessitate an increase in time away from direct patient care to coordinate responses with all providers. As a result, CHW is concerned the CARE tool will require departments to hire additional personnel responsible for filling out the form, though CMS will not provide additional reimbursement. **For these reasons, CHW strongly urges CMS to redevelop the tool to minimize the time necessary to complete it.**

Availability and Accuracy of Data

CHW is concerned about the limited availability of required information within the designated time frame for the tool to be completed. For example, ICD-9-CM coding information requested in Section III is usually not available until several days, sometimes weeks, after discharge, following the completion of the physician discharge summary and medical record coding. Accessing and reporting this information at or before the patient's discharge will be time consuming, cumbersome and administratively challenging. In addition, the two day assessment window for some data is problematic, especially in acute care settings when short lengths of stay and immediate patient needs can make assessment difficult. For example, a stroke patient would typically be in an acute care hospital for three to four days post onset before being discharged to a post acute facility or home. This three to four day "window" does not provide adequate time to fully assess functional status and potential for rehabilitation, or a complete picture of the patient's clinical and functional need as s/he transitions to a community or post-acute setting. This requirement will be additionally onerous for Mercy Mt. Shasta, CHW's only Critical Access Hospital (CAH), because of the requirement to maintain lengths of stay under 96 hours. **For these reasons, CHW urges CMS to reconsider its requirement on patient assessments.**

Reliability and Validity of Data

CHW uses established assessment tools in the post acute care continuum, including the IRF-PAI, OASIS and the MDS, which have a demonstrated track record of effective use. **CHW strongly urges CMS to incorporating existing assessment tools in the development of the new CARE tool, thereby building upon current practices that have been validated.** Reducing the redundant assessment processes does not lead to improved understanding of patient need or aid in guiding the arrangement of continued care.

Staff Training and Qualifications

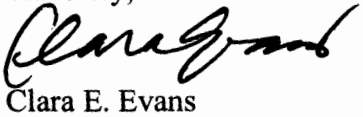
Current communications from CMS do not specify guidelines for administration or for staff training or qualifications, particularly since many data items in the CARE tool appear to require subjective, clinical observations done by a trained evaluator. **CHW seeks further guidance on this issue.**

Other Reporting Functions

CHW must comply with other reporting requirements regularly, including quality data and reimbursement reporting. The assessment form is incredibly complex and most certainly interdisciplinary. The amount of time and number of personnel involved in its completion and complexity of the information required is enormous. **CHW strongly CMS to consider this value of this information and its use.** Furthermore, it is unclear if the CARES tool will fulfill some already-existing reporting requirements or if it will be in addition to what is already required. If it is an additional requirement, it would be helpful to understand the value of the data collected. **Given the high cost of data collection, CHW requests consideration of the nexus of other reporting and give specific guidance on how the new CARES tool fulfills these requirements.**

Thank you again for the opportunity to comment on the proposed tool. While CHW supports the development of an effective tool to aid in continued care arrangements, we encourage CMS to look closely at the tool, its usefulness, planned implementation and the administrative burden this process places on the entire professional care team, negatively affecting our ability to provide care to our patients. If you have any questions, please feel free to contact me at (916) 851-2007 or at clara.evans@chw.edu.

Sincerely,



Clara E. Evans
Director, Public Policy & Fiscal Advocacy
Catholic Healthcare West

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Re: CMS CARE tool and PAC-PRD Demonstration

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My comments and concerns regarding the CARE tool are presented below:

1. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient **classification and reimbursement.**
    a. **The rationale for the inclusion of the additional 210-220 items is not clear.**
    b. The forced use of the CARE tool will create an unnecessary burden on staff and increase costs to acute and post acute care providers.
    c. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources that will be needed to comply with these changes.
    d. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
    e. Given the complexity of the form and the time needed to correctly complete the form, Acute Care facilities will need to significantly increase FTEs to accommodate this requirement.

2. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.
    a. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim.
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    f. All case management, discharging physician, rehabilitation, and home health staff will need to be trained in the use of the new CARE tool at a considerable expense.
    g. JMH will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. JMH has already developed automated documentation systems (electronic medical records), which will need to be revised.
    h. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.

In light of the above observations, JMH is recommending the following:

1. The CARE tool should be refined and condensed to no more than 50 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
2. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
3. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

I am grateful for the opportunity to provide comments on this important demonstration project.

Sincerely,

Eileen Kahn RN MS

Eileen Kahn, RN, MS
Cross Campus Director Case Management & Social Services
John Muir Health: Walnut Creek and Concord Campuses

NEW ENGLAND
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A FIVESTAR QUALITY CARE HOSPITAL

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September 26, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of **New England Rehabilitation Hospital** in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005. The CARE tool will be used to (1) standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals, (2) document medical severity, functional status, and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post-acute treatment, and (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization. For the PAC-PRD demonstration project, CMS intends to use 150 selected providers plus 238 volunteer acute care and post-acute care providers in 10 demonstration sites, including 44 inpatient rehabilitation facilities, to test the CARE tool over a 3-year period beginning in January 2008. CMS plans to develop a uniform assessment tool to be used across all post-acute settings, including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), and home health agencies (HHAs), replacing its current assessment instruments. Providers participating in the demonstration project will be asked to complete the CARE tool in addition to the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), Minimum Data Set (MDS), and Outcome and Assessment Information Set (OASIS) on approximately 30,000 patients (150,000 assessments). Following completion of the PAC-PRD demonstration project and refinement of the CARE tool, CMS plans to develop a single payment system for all post-acute settings.

The CARE tool contains over 300 items divided into 11 major sections: Administrative Items, Admission Information, Current Medical Items, Cognitive Status, Impairments, Functional Status, Engagement, Frailty/Life Expectancy, Discharge Status, Other Useful Information, and Feedback. Of those 300 items, 100 items are common to all settings, 163 are required upon discharge from acute care, 155 are required upon admission to a post-acute setting (SNF, IRF, LTCH, HHA), 160 are required upon discharge from a post-acute setting, and 139 are required for interim assessments every 14 days in post-acute settings. CMS estimates that the CARE tool will take 35-60 minutes to complete, depending on the setting and complexity of the case.

My comments and concerns regarding the CARE tool for all post-acute settings are presented below. They are organized into sections as follows:

1. The necessity and utility of the proposed information collection for the proper performance of the agency's functions
2. The accuracy of the estimated burden
3. Ways to enhance the quality, utility, and clarity of the information to be collected
4. The use of automated collection techniques or other forms of information technology to minimize the information collection burden

1 & 2: The necessity and utility of the proposed information collection for the proper performance of the agency's functions and the accuracy of the estimated burden

1. The CARE tool has not been tested or validated as a reliable measure of variance in costs, lengths of stay for inpatient rehabilitation, burden of patient care, or outcomes of patients treated in rehabilitation facilities.
    a. The CARE tool, which borrows items and content domain largely from the MDS (version 2) and some limited items from the IRF-PAI and OASIS, has not been previously approved, tested, or reviewed by the field of rehabilitation providers.
    b. There is no data available on the reliability, validity, or psychometric scaling properties of the CARE tool.
    c. The MDS-PAC, used in a prior attempt to develop an assessment tool for all post-acute settings, failed as a reliable predictor of costs and outcomes and would have placed an undue burden on providers to collect unnecessary data.
    d. It is unlikely the CARE tool as proposed will be able to adequately measure the true burden of patient care, medical complexities, and acuity differences among patient populations treated in the various post-acute settings.
    e. There was no attempt to stratify the selection of rehabilitation facilities, based on facility type (private, county, or teaching facility) or specialized regional centers (spinal cord injury, traumatic brain injury, or neurological programs), or by the number of rehabilitation facilities per capita. The proposed sample is not representative of IRFs nationwide.
    f. The burden of patient care is a key issue that must be addressed in managing patients effectively and efficiently across post-acute care venues. The FIM™ instrument is used to estimate burden of patient care, defined as hours/minutes of assistance needed per day from another person for personal care. It is not readily appreciated that a person with a disability, who needs daily help from another person to perform personal care tasks, presents a burden of patient care that could exceed the capacity of accompanying persons to provide help needed in the home. Often, the consequence is that the patient may require either short-term hospital or institutional care for rehabilitation or long-term residential care. Quantification of burden of patient care is necessary to appropriately manage the care of patients with limitations in ability to perform daily living tasks independently. Studies have been conducted in homes with individuals who had stroke, spinal cord injury, multiple sclerosis, and head injury (research references can be provided) in which the actual time needed for assistance was highly correlated with the FIM™ instrument rating. For example, a total FIM™ rating of 80 (total ratings range from 18 to 126) corresponds with 2 hours or less of personal care needed per day, a total FIM™ rating of 100 amounts corresponds with 0 to less than 30 minutes per day needed for personal care, and a total FIM™ rating of 60-70 indicates functional deficits too severe for care at home in most cases. A total FIM™ rating of 60 is common for stroke patients at the time of admission to a rehabilitation program. In practice, on average, a patient who has sustained a stroke is admitted with a total FIM™ rating of 65-70 and is discharged with a total FIM™ rating of 85-90, resulting in a reduction in the amount of help needed per day from 3-4 hours to 1-2 hours. Quantifying the amount of personal care needed helps to triage patients to appropriate venues and serves to estimate the amount of care needed and the costs of that care. The time needed in the previous examples of burden of patient care may appear minor on the basis of a day or a week; when viewed over a month, several months, or a year, the

time and subsequent costs are substantial. Remember that dependence can last for several years. The FIM™ instrument is not restricted to use for inpatients only, but it is currently known to be used by SNF and LTCH care settings, and it is sometimes appropriate for use with outpatients with more severe disabilities or for those at risk for incurring progressive disability.

g. The stated goals for the PAC initiative and for patient care would be better served with a known, reliable, and functional measurement tool. Reliability of functional measurement, as well as the other domains, has not been tested using the CARE tool. This is especially troubling given that training followed by testing and credentialing of staff is not a key component of the PAC-PRD, thus introducing a high risk of uncontrolled variability in accurately measuring function across the different settings. High variability in the data will greatly reduce the effect size capable of being detected with the sampling scheme, thus rendering the demonstration conclusions invalid because of a high Type II error. In short, there may be a difference in functional outcomes between settings, but the lack of training and the subsequent allowance for great variability may prevent real differences from being detected even though they may exist. The FIM™ instrument is a much more reliable tool for functional assessment because of the associated training, testing, and credentialing required of clinical staff members who use the tool.

2. Premature use of the CARE tool, which has been neither tested nor validated for patient classification and the prospective payment system for Medicare patients, will result in denied access to acute rehabilitation for patients with more severe impairments.
   a. Based on studies over the past 10 years by the Center for Disease Control (CDC), healthcare planners, and consultants, an estimated 20% to 60% of patients with a significant impairment—such as stroke, brain injury, spinal cord injury, amputation, multiple trauma, or neurological conditions—could require rehabilitation services in one or more of the post-acute settings (SNF, IRF, LTCH, or HHA).
   b. The relative weights for each case-mix group in the IRF PPS were developed using the FIM™ instrument and the IRF-PAI, not the CARE tool. The FIM™ instrument has been proven to measure the true burden of patient care and the expected costs of rehabilitation services for patients with designated impairments.
   c. If forced to use the CARE tool as a discharge planning tool to determine the most appropriate post-acute setting for a patient with ongoing needs, acute care discharge planners and case managers may overlook critical factors, including medical complexities and risk factors affecting functional recovery, and fail to identify patients who may require both close daily supervision by physicians with experience in rehabilitation medicine and 24-hour rehabilitation nursing care.
   d. Despite its length, the CARE tool is extremely complex and uninformative in terms of two key components: measurement of burden of patient care and clarity of medical necessity. If the acute care hospital discharge report fails to accurately identify these two critical issues, patients can be placed into inappropriate post-acute settings, resulting in higher returns to acute care, higher (and unnecessary) healthcare costs, and higher (and equally unnecessary) risk to the patient, all of which will lead in turn to a need for tracking mechanisms to identify and correct these circumstances in a timely manner.
   e. Case-mix management will become the preferred survival strategy of established SNFs and IRFs, and therefore not all patients with disabilities will have equal access to inpatient rehabilitation. IRFs will most likely screen out severely impaired and medically complex cases due to insufficient reimbursement.

f. There are significant differences and regional variations in the medical capabilities, training, and expertise of the various post-acute settings (SNFs, IRFs, LTCHs, and HHAs) and their ability to handle patients with complex medical conditions and to prevent further medical complications that will result in unnecessary readmission to acute hospitals.
g. Access to required and needed rehabilitation services must be preserved.
h. The CARE tool presents coding issues. The instructions do not provide specific guidance regarding the assignment of ICD-9-CM codes. Currently, the official guidelines result in a different set of codes at the acute facility and at each of the post-acute care facilities for the same patient due to the circumstances of the admission. The code for the primary diagnosis is optional, as the instrument states "if available." It is easier to provide this code than it is to provide the code for the reason for admission to the prior facility. The use of V-codes is problematic, as (a) several V-codes do not have associated medical conditions and (b) the use of certain codes as additional codes would amount to double-reporting of the same condition. What the additional code represents is not clear, and the tool does not indicate whether the additional code applies to both the primary diagnosis and the secondary condition.

3. The proposed rating scale for the items in section VI, Functional Status, is inconsistent with the FIM™ instrument, and the proposed scale has not been tested for psychometric scaling properties.
   a. The proposed 6-point scale for the self-care and mobility items eliminates the Modified Independence level from the FIM™ instrument (requires an assistive device or aid, extra time, or there are safety consideration), separates setup from supervision (both of which require a helper to safely carry out the activity), and combines contact guard or touching assistance with supervision.
   b. The tool includes a proposed 3-point rating scale for the communication and cognitive items instead of the 7-point FIM™ instrument scale, and the definition of each rating is unclear.
   c. Instrumental ADLs are assessed on a 4-point scale.
   d. The CARE tool bases functional assessments on the most usual performance, not the lowest level of performance, over a 2-day assessment period upon admission to a post-acute setting, within the interim period (every 14 days), and upon discharge from a post-acute setting.
   e. The different rating scales for the various items, the lack of tested psychometric scaling properties, and the inconsistency with the FIM™ instrument, which has been widely used and fully tested in several million applications for over 20 years, is likely to be confusing to providers and will not yield reliable and valid measures of burden of patient care as reflected in the various post-acute settings.
   f. There is some redundancy among the items in section IV, Cognitive Status; section V, Impairments; and section VI, Functional Status.
   g. Using the AlphaFIM® instrument in acute care settings, the FIM™ instrument in SNF, IRF, and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) in HHAs would be a more appropriate approach. The AlphaFIM® instrument uses 6 FIM™ items to project a patient's full FIM™ rating; the OmegaFIM™ instrument also uses 6 FIM™ items to project a full FIM™ rating for higher-functioning patients. These FIM™ instrument items, which have been fully tested and validated, can be easily supplemented with additional items, such as Instrumental Activities of Daily Living (IADLs) or other similar items.

h. A consistent rating scale, such as the 7-point scale used in the FIM™ instrument, provides the best way to measure the true burden of patient care. Burden of care is not well appreciated as a concept, but it is the most important factor in determining the long-term care needs of an individual with disability.

4. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient classification and reimbursement.
   a. The rationale for the inclusion of the additional 210-220 items is not clear.
   b. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
   c. Many of these items are totally irrelevant to IRF patient populations, including IV-A, Comatose; B-1, Brief Interview for Mental Status (BIMS); VI-C, IADLs; and VIII-A2, *Would you be surprised if the patient were to die within the next 12 months?* Although these items may be appropriate for patients in SNFs or LTCHs, they should not be required in IRF settings.
   d. The forced use of the CARE tool will create an unnecessary burden on and cost to rehabilitation providers. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources IRFs will need to comply with these changes in the PPS.
   e. Given an average of 250 Medicare admissions per facility, the existence of 1,123 IRFs nationwide, and a rate of approximately 280,750 admissions per year, the following tables present more realistic estimates of the time requirements for IRF-PAI assessments and CARE tool assessments in the IRF setting.

IRF-PAI	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	20 minutes	100%	93 hours	105,000
Discharge assessment	20 minutes	100%	93 hours	105,000
TOTAL TIME	**40 minutes**	-	**186 hours**	**210,000**

CARE Tool	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	120 minutes	100%	500 hours	561,500
Interim assessment (day 14)	**60 minutes**	60%	150 hours	168,450
Discharge assessment	90 minutes	100%	375 hours	421,125
TOTAL TIME	**270 minutes**	-	**1,025 hours**	**1,151,075**

Given these more realistic time estimates, nearly 7 times more staff time per patient will be required to complete the CARE tool. This represents a significant increase in assessment time. The difference is nearly 840 hours per facility per year.

f. Assuming that the CARE tool must be completed by a clinician (licensed therapist or nurse) who is familiar with the assessment tool—a condition currently required for the IRF-PAI—the cost of completing the CARE tool will be $35,875 per IRF per year (at $35 per hour), but the cost of completing the IRF-PAI will be only $6,510. This represents an increase of $29,365 per IRF per year. However, these are not the only costs associated with the proposed CARE tool, as explained below.

5. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.
   a. Rehabilitation facilities will need to develop new assessment forms, worksheets, and documentation procedures for each of the 140-160 CARE tool items.
   b. Functional assessment techniques will need to be altered to reflect the 6-point rating scale for the proposed self-care and mobility items and the 3-point scale for the proposed communication and cognitive items.
   c. An interim assessment will be required on or around day 14, to include 140 items.
   d. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim (where warranted).
   e. Each facility will require at least one trained PPS/CARE coordinator to collect and submit CARE tool data.
   f. The CARE tool may increase therapy, nursing, and physician documentation time by as much as 20 percent, necessitating an increase in staff.
   g. Staff time, which should be focused on providing direct patient care and therapy, will instead be redirected toward the paperwork and documentation needed to meet the data requirements of the CARE tool.
   h. All rehabilitation staff will need to be trained in the use of the new CARE tool at a considerable expense.
   i. Each facility will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. Many providers have already developed automated documentation systems (electronic medical records), which will need to be revised.
   j. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.
   k. Given an average hourly rate of $35 per hour for a PT, OT, or RN, each IRF would need to pay $29,365 in additional staff expenses just to complete the CARE tool. The estimated costs of additional staff assessment time, the hiring of a new CARE tool coordinator, additional training, new software, new program interfaces, and revised documentation are shown in the following table.

Estimated Cost of Implementing the Care Tool	Annual Cost
Additional staff time (PT,OT, ST, RN) and assessment time	$29,365
PPS coordinator (full-time clinician) for data collection, entry, and transmission	$54,600
Annual cost of CARE tool software (UDS-PRO® software, eRehab)	$11,250
CARE tool training costs (12-16 hours per staff member), Year 1	$18,750
Program interfaces (ADT, medical records, billing, etc.), Year 1	$56,250
Documentation revision and development of CARE tool worksheets, Year 1	$11,250
TOTAL PROJECTED COST (first year)	**$181,465**

TOTAL PROJECTED COST (subsequent years)	$95,215

6. Nationwide, the average cost per IRF for implementing the CARE tool and changes in PPS are expected to be $181,465 for the first year and $95,215 (about $8,000 per month) for each subsequent year. (Costs may vary significantly by state, but a significant increase is certain.) This additional cost will place an undue burden on these facilities and most likely will result in denied or restricted access to needed rehabilitation services in an IRF setting. The eventual financial burden of the CARE tool on IRFs alone will be about $107 million—a number that doesn't begin to consider the added costs for nearly 29,000 PAC and post-acute and acute care venues.

3. Ways to enhance the quality, utility, and clarity of the information to be collected

In light of the previous observations, I recommend the following:

1. The FIM™ instrument has been widely used for over 20 years and has more than 20 years of science behind it. The bibliography of publications focused on the instrument exceeds 600. More than 10 million assessments have been performed using the instrument, which is the only instrument used in post-acute settings that has the capacity to predict average length of stay and costs for purposes of prospective payment. As a result, I recommend that the AlphaFIM® instrument be used in acute care settings, the FIM™ instrument be used in SNF, IRF and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) be used in HHAs. These instruments, which have been fully tested and validated, can be easily supplemented with additional items such as Instrumental Activities of Daily Living (IADLs) and similar items.
2. IRFs should continue to use FIM-CMGs until the CARE tool has been fully tested and validated as a good predictor of length of stay and costs for rehabilitation patients.
3. The CARE tool should be refined and condensed to no more than 100 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
4. Rationales should be provided for the inclusion of each additional CARE tool item beyond the 100-item limit mentioned above.
5. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
6. The CARE tool should use the 7-point rating scale used in the FIM™ instrument to measure true burden of patient care. Use of a consistent 7-point scale will help avoid "ceiling effects" in measurement.
7. A consistent time frame should be established for assessing all CARE tool items that apply to each post-acute setting. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

4 The use of automated collection techniques or other forms of information technology to minimize the information collection burden

The system now used by most IRFs is an extensive, Internet-based, real-time data collection and reporting system offered by UDSMR. It could easily be modified to accommodate the PAC-PRD demonstration, and it offers access to multiple users.

I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at 781-935-5050

Sincerely,

Joel Rudin
Chief Executive Officer

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

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, Maryland 21244–1850

September 17, 2007

Dear Ms. Harkless:

I have just become aware of and voice my objection to the CMS Post Acute Care (PAC) Payment Reform Demonstration project slated to begin in early 2008. Under the current project specifications, almost 90% of Medicare patients discharged from my facility will meet the criteria for inclusion in this study. The burden of completing a 35-page Continuity Assessment Record and Evaluation (CARE) instrument will impact my ability to efficiently discharge patients.

Case Managers/Discharge Planners already function under heavy workloads, and the time and resources that will be necessary to collect the information for the CARE tool is an unreasonable addition. The estimate is that the form will take 20-45 minutes per Medicare discharge to complete. This appears to be a modest estimate after viewing the tool and gauging the time it will take to abstract this information from the medical record.

My greatest concern is that the time taken from our nursing case managers will lead to increased ER visits, increased length of stay, readmissions and an overall decline in healthcare services for all our patients. I respectfully request that you reconsider this demonstration project or redesign the methodology to be less burdensome on those of us that are trying to provide the highest quality care in the most efficient manner.

Sincerely,

Mary Tarpley, RN
Manager, Case Management
Sutter Lakeside Hospital
5176 Hill Road East
Lakeport, CA 95453

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, Maryland 21244–1850

September 20, 2007

Dear Ms. Harkless:

I have just become aware of and voice my objection to the CMS Post Acute Care (PAC) Payment Reform Demonstration project slated to begin in early 2008. Under the current project specifications, almost 90% of Medicare patients discharged from my facility will meet the criteria for inclusion in this study. The burden of completing a 35-page Continuity Assessment Record and Evaluation (CARE) instrument will impact my ability to efficiently discharge patients.

Case Managers/Discharge Planners already function under heavy workloads, and the time and resources that will be necessary to collect the information for the CARE tool is an unreasonable addition. The estimate is that the form will take 20-45 minutes per Medicare discharge to complete. This appears to be a modest estimate after viewing the tool and gauging the time it will take to abstract this information from the medical record.

We are a small rural hospital, and lack adequate community resources to handle many of our patients' routine needs; it is a daily challenge to provide many of our patients with a safe, effective discharge plan. My greatest concern is that the time taken from our nursing case managers will lead to increased ER visits, increased length of stay, readmissions and an overall decline in healthcare services for all our patients. I respectfully request that you reconsider this demonstration project or redesign the methodology to be less burdensome on those of us that are trying to provide the highest quality care in the most efficient manner.

Sincerely,

Lisa M Valdez

Lisa M Valdez, RN
Sutter Lakeside Hospital
5176 Hill Rd East
Lakeport, CA 95453

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, Maryland 21244–1850

September 17, 2007

Dear Ms. Harkless:

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Sincerely,

Benna Clemmons MSW

Case Manager

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—C
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Room C4–26–05,
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Sincerely,

Nancy Heldarger RNC/OCP

Case Manager

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—C
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Sincerely,

James Pretorius MD

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, Maryland 21244–1850

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Sincerely,

Lora Robinson RN

Case Manager

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,
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Sincerely,

Nicole Lagle, RN

CRN, RN

Anne Marie Austin, RN

Med / Surg Meeting

1.) [illegible] RN MS
2- Mona Mata CNA N/S
3) Steve Bosley RN MS
4) DEB ARD
5) Lorri Hennessy M/S
6.) C Roth, RN
7) ~~D. Hedden~~
8) Lisa Leonard
9) Miguel Cabrera CNA.
10) Stefanie Edwards CNA
11) Dawn Bryant CNA
12) Concepcion Mendez

LABAMA
OSPITAL
SSOCIATION

September 25, 2007

CMS, Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development—C,
Room C4–26–05, 7500 Security Boulevard,
Baltimore, Maryland 21244–1850.

Attn: Bonnie L. Harkless

I am writing on behalf of the Alabama Hospital Association's Rehabilitation Constituency Section concerning the proposed Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. Our Section is comprised of hospitals with inpatient rehabilitation units and hospitals that are stand-alone rehabilitation facilities, and we appreciate having the opportunity to comment on the new tool.

Specifically, we would like to ask that the following concerns be addressed:

- Focus needs to be given to ensuring the reliability and accuracy of observed measures. A measure that is observed can be considered reliable only if it can be reproduced by a diverse group of observers. Another variation can occur when someone observes a fixed event and is oblivious to other previous incidents. In addition, we are concerned about the variety of settings, the differences in legacy definitions of items, and staff with different care philosophies and levels of expertise and training. We urge CMS to publish a description of the reliability and validity studies that will be undertaken with respect to the tool and the items in the tool.
- There are some concerns among our members about the sample size, that it might not be large enough to provide results that can be generalized. In addition, since there is no reimbursement for participation in the demonstration, the final sample may be heavily skewed toward larger facilities and thus not provide information on patients in smaller, rural hospitals.
- Facilities participating in the study should be exempt from the 75 percent rule. Due to the implementation of the rule and the increasing prevalence of medical necessity audits, the inpatient rehabilitation volume has significantly decreased and staffing patterns are in a state of flux. Therefore, we believe to get a true picture of inpatient rehab, the demonstration sites should have the option of waiving the 75 percent rule for the duration of the demonstration.
- Providers believe the tool will be very time consuming, more so than the initial estimates, and that it will be particularly difficult for acute care hospital discharge planners who are not accustomed to capturing information on function, cognitive or impairment status, etc. Thus, the information provided could be incomplete or, in the worst case scenario, inaccurate simply based on the knowledge level of the recorder.

500 North East Blvd. • Montgomery, AL 36117 • phone: (334) 272-8781 • fax: (334) 270-9527 • web: www.alaha.org

- CMS in developing its system for capturing this information should ensure that the information technology can be easily linked to existing systems being used by rehab providers. There are a number of systems that provide excellent information for daily operations, and providers would not want to have another tool that did not interface with them.

Thank you for allowing our comments.

Sincerely,

Rosemary Blackmon, Staff Liaison

AlaHA Rehabilitation Constituency Section

Marin General Hospital
A Sutter Health Affiliate

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Greenbrae
Box 8010
San Rafael, CA 94912-8010
(415) 925-7000

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, Maryland 21244–1850

September 17, 2007

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I respectfully request that you reconsider this demonstration project or redesign the methodology to be less burdensome on those of us that are trying to provide the highest quality care in the most efficient manner.

Sincerely,

HPagilagan RN-CM

Case Manager

Eden Medical Center
A Sutter Health Affiliate

Case Management Department

20103 Lake Chabot Road
Castro Valley, CA 94546
(510) 889-5040
(510) 538-8136 Fax

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, Maryland 21244–1850

September 24, 2007

Dear Ms. Harkless:

I have just become aware of and voice my objection to the CMS Post Acute Care (PAC) Payment Reform Demonstration project slated to begin in early 2008. Under the current project specifications, almost 75% of Medicare patients discharged from my facility will meet the criteria for inclusion in this study. The burden of completing a 35-page Continuity Assessment Record and Evaluation (CARE) instrument will impact my ability to efficiently discharge patients.

Case Managers/Discharge Planners already function under heavy workloads, and the time and resources that will be necessary to collect the information for the CARE tool is an unreasonable addition. The estimate is that the form will take 20-45 minutes per Medicare discharge to complete. This appears to be a modest estimate after viewing the tool and gauging the time it will take to abstract this information from the medical record. In what acute care setting has this been tested so accurate time estimates can be made? Aside from giving CMS data to study, what have you *proven* will be the benefit for the Medicare beneficiary? For the hospital staff required to complete this?

As the Director of Case Management I expect my staff to use their clinical skills and expertise in providing services to our patients. Your data collection tool will have the opposite effect. Until every hospital has an electronic medical record, the CARE process should be placed on hold.

Sincerely,

Lyssa Wieland, RN
Director, Case Management

American Physical Therapy Association

1111 North Fairfax Street
Alexandria, VA 22314-1488
703 684 2782
703 684 7343 fax
www.apta.org

September 25, 2007

Bonnie L. Harkless
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

Subject: Comments regarding the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

Dear Sir or Madam:

On behalf of our 70,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the Center for Medicare and Medicaid Services (CMS) Information Collection Request regarding Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument, published in the July 27, 2007, *Federal Register*.

The CARE instrument is a patient assessment instrument designed to measure differences in patient severity, resource utilization, and outcomes for patients in acute and post-acute care settings. Physical therapists furnish services to Medicare beneficiaries in acute care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies. Therefore, the CARE tool would have a significant and direct effect on physical therapists and the patients to whom they provide services.

General Comments

In the data collection notice, CMS specifies that the CARE tool will be used to 1) standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals; 2) document medical severity, functional status and other factors related to outcomes and resource utilization at admission, discharge and interim times during post-acute treatment; and 3) understand the relationship between severity of illness, functional status, social support factors and resource utilization. The CARE instrument will be used in the Post-Acute Care (PAC- Payment) Reform Demonstrations Program and will ultimately be used to develop a setting neutral post-acute care payment model.

APTA supports the concept of having a uniform assessment tool and agrees that patients should be placed into the appropriate setting to meet their needs based on their clinical characteristics. However, we do not believe that the CARE tool as proposed will accurately document medical severity, functional status and other factors related to outcomes. The questions lack sensitivity and therefore the type of information about the patient needed to measure outcomes and severity is not being collected by this instrument. It would be premature to establish a new payment system without having accurate measures of these factors. To do so could create access problems for Medicare beneficiaries.

APTA also has concerns that the accuracy of the data will differ depending on the individual who completes the CARE tool. Although a nurse may be able to complete a majority of the tool, the Functional Status section (VI) should be completed by rehabilitation professionals from the appropriate discipline. An individual who is not specifically educated and trained as a physical therapist would probably include different answers to the functional assessment items than a therapist.

CMS also needs to consider the administrative and financial burden this instrument will have on providers. Most hospitals, skilled nursing facilities, and home health agencies have gone to great lengths to ensure that their staff is well trained and consistent when performing admission, interim, and discharge assessments. These settings will need to provide new training for their staff. Facilities will most likely need to hire additional staff to be responsible for these assessments. In addition, the use of a new tool will require major modifications to documentation systems and related software.

APTA's specific comments and questions on each section of the CARE instrument are included below. We recommend that CMS include a detailed glossary of the terms used in the instrument to provide further clarity.

Discussion of Specific Items in CARE Instrument

Section I. Administrative Items

I.A1.
In this section, one of the reasons for assessment is "Interim." We are wondering what the reason for an interim assessment would be. There is no explanation as to when it would be appropriate.

Also, if a patient is admitted one day and discharged the next, is it necessary to complete an admission and a discharge CARE?

I.C2.
The patient's middle name is required in this field. Most other forms require a middle initial. Is there are reason?

I.C.7
It is unclear what a patient's identification/provider account number is. This term should be defined. If a social security number is included in box C-9, is it still necessary to complete box C-7?

Section II. Admission Information

II.A.2.
In the description of admitted "directly from the community," a long term care facility is included as an example. We are wondering why this was included in this category. Also, it would be helpful to define the meaning of long term nursing facility verses a skilled nursing facility. If the distinction is between a Part A and a Part B bed, it will be difficult for the person completing this assessment to know that information without contacting the facility.

II.A.3.
This section asks if the patient is admitted from a medical setting, what was the primary diagnosis in the previous setting. Is this section not applicable for an acute care hospital?

II.B.3
This section includes options regarding who the patient lived with prior to the illness. We recommend you add another option for "Paid help not living in the home."

II.B.5
There are three scoring options regarding prior functioning: independent; needed some help, and dependent. "Needed some help" is very subjective. It would make more sense if it read "needed assistance." Also, there is a very large difference between 1/Dependent and 2/needed some help for scoring.

II.B5.a
Toileting should be added to question related to self care.

II.B5.c and B5.d
These sections question whether a patient needs assistance with stairs or moving from room to room with a wheelchair. If a patient does not have stairs (B5c) or did not use a wheelchair (B5d), then the only option for coding would be "9" unknown, which is not accurate. We recommend that section B5 include a category titled "not applicable" so that this question can be answered more accurately.

We recommend that CMS add another mobility category in addition to B5.b, B5.c, and B5.d, titled "Mobility (Bed, Transfers)." In the alternative, CMS could make two additional categories: one for bed mobility and one for transfers.

II.B.6
This section identifies mobility devices and aides. It fails to include orthotics and prosthetic devices in the list. We recommend that these devices be added. For example,

an ankle foot orthosis (AFO) can make a significant difference in terms of functional independence and safety in patients with foot drop.

II.B.7
In this section, there should be a clarification regarding the meaning of "history of falls." The definition of "history" and "fall" are not clear. Perhaps that wording could be changed to read: "has the patient fallen within the past year" or "has the patient had two or more falls in the past year or any fall with injury in the past year."

II.B.8
The question posed is whether there is any "evidence of an acute change in mental status..." This is a wide open question subject to different subjective interpretation. A change in mental status could be gradual or acute.

Section III. Current Medical Items

III.A.
This section of the tool requests a list of diagnoses being treated, managed, or monitored in the setting. It would be helpful if CMS clarified whether diagnoses can be added to this list at any time during the length of stay (i.e. if the patient develops pneumonia during the stay).

III.C.
In this section, it is unclear as to the type of procedures that should be identified. A physical therapist completing this section might believe that he/she would need to include the specific physical therapy interventions in each line item (i.e. therapeutic exercise, manual therapy, ultrasound, etc.) that were performed during the admission.

III.D.
In this section regarding treatments, we are wondering what types of items are considered treatments. Perhaps CMS should consider establishing separate boxes for physical therapy, occupational therapy, speech therapy, barium swallow, and other.

This list includes a treatment, D9, titled "Continuous Cardiac Monitoring." This description should be modified to say "intermittent or continuous cardiac monitoring." Many patients in acute care may not need continuous monitoring, but may need intermittent monitoring during an activity (i.e. with physical therapy treatment).

The treatment, D20, "Complex Dressing Changes" seems very limiting. A better term would be "wound care," which would include dressing changes, debridement, etc.

III.G.2
This section relates to the presence of pressure ulcers.

We question why CMS is only interested in knowing if there is a Stage 2 or higher pressure ulcer, particularly in light of the fact that survey and certification requirements

in home health and skilled nursing facilities are holding providers accountable for Stage 1 pressure ulcers that patients are admitted with or developed while on caseload.

III.G.2e
CMS should also include Stage 3 and 4 pressure ulcers in this section. Also, it does not make sense to exclude unhealed Stage 2 ulcers that have been present for less than one month.

III.G.3a-3c
This section requests a recording of the measurements for the largest ulcer. It is unclear to us as to how providing measurements for only the largest wound is helpful to determine resource use, quality of care, or discharge destination. A patient could have 15 pressure ulcers, all no larger than 3 cm x 2cm x 0.3 cm. Having the measurements for only one of these 15 ulcers would not provide much useful information. Also, a measurement of depth is not requested in this section. Depth is an important indicator of the type of wound as well as the resources it might take to heal it.

III.G.4
CMS should consider undermining in addition to tunneling.

III.G.5a
We question why CMS did not also consider "healing" surgical wounds in addition to "non-healing" surgical wounds.

III.G5.b
We question why CMS did not include non-healing traumatic wounds in addition to trauma related wounds.

III.G5.c
We question why CMS did include a delineation for non-healing diabetic food ulcers.

III.G5.d
We question why CMS did not delineate non-healing vascular ulcer wounds.

III.G6
This section relates to turning surfaces. Turning surfaces is not a familiar term and it would be more meaningful to list the areas where the skin is not intact. It is possible that skin is not intact on a surface that is not a "turning" surface, but may be just as critical (i.e., wrist, elbow). If the skin is not intact on these surfaces, transfers and weight-bearing will be restricted. Surfaces which often develop pressure ulcers include: knees, heels, toes, elbows, scapula, spine, earlobes, and skull/occiput. These surfaces are not included on CMS's list. Therefore, the question would be answered, "none of the above apply." With such an answer, relevant information about the patient's condition would not be captured.

Section IV. Cognitive Status

IV.C1 and C2
This question regarding short-term memory is too vague. The terms, such as "seems," "memory OK," and "long past," need further definition.

IV.C.4
It would be difficult to assess the ability of an individual to make decisions regarding tasks of daily life in certain settings, especially at admission. In addition, there are not many opportunities for the patient to make his/her own decisions "about tasks of daily life" in hospitals, skilled nursing facilities, and certain other settings.

IV.D
The scoring system might flow better if 2 became 1—i.e. if
0-behavior not present
1-behavior present, fluctuates
2-behaviour, continuously present

IV.F2a
The Patient Health Questionnaire, F2a and F2b, asks if the patient has little interest or pleasure in doing things. However, if the patient has been in an acute care hospital or other facility during the past two weeks, he/she probably did not have an opportunity (or feel like) having interest or pleasure in anything. Therefore, the answer to this question may not be particularly valid.

IV.G
This category relates to pain. We recommend that pain be included in its own section rather than being placed under the Cognitive Status section.

G.3
This section of the tool asks for the patients rating of pain during the last 2 days on a scale of zero to 10. It instructs the provider to "enter 8 if the patient does not answer." This does not make sense because it would not be feasible to distinguish between a patient who has answered that his/her pain is rated as an "8" as opposed to the practitioner entering and "8" because the patient did not answer. CMS should use the number "11" or higher for a "patient does not answer" designation.

G.4
This rating of pain severity seems to be duplicative because the patient has already rated his/her patient in G.3.

Section V. Impairments

V.A1
This section seeks information regarding impairments in specified areas. This question is not inclusive of potential impairments (bladder or bowel management, hearing, vision, communication, range of motion, weight bearing, grip strength, respiratory status, or endurance). If the patient does not have any impairments in the areas identified in this

question, then this section is skipped. Overall, this section does not include impairments in the following areas; lower extremity range of motion trunk/neck range of motion, lower extremity strength, trunk strength, gait, balance, posture, etc. By omitting these impairments, appropriate data regarding the patient would not be captured.

V.D.1 and V.D.2
The purpose of these questions appears to be to ascertain hearing. However, some of these questions could be skewed by a person's cognitive deficits. The question should be prefaced differently to lead the questioner to address the right area.

V.E.
This question includes two categories to describe functional range of motion: 1) within normal limits; and 2) limited range of motion. We suggest the need for a third category for hypermobile range of motion.

V.E1a-E1d
The only gross motions assessed are shoulder and elbow, even thought this category includes upper extremity. This section should be changed to add wrist and fingers. In addition, lower extremity and trunk/neck range of motion needs to be included in addition to upper extremity range of motion.

V.F.
This section asks for information regarding the patient's weight-bearing restrictions. The only options are (1) Fully weight-bearing and (0) not fully weight-bearing. There should be two additional categories: (1) Partial weight-bearing and (2) unable to bear weight (such as the case of a new amputee who does not have a prostheses yet).

V.I.
This section pertains to endurance. With respect to mobility endurance, it should include mobility endurance during bed mobility and ADL's in addition to walking and wheeling. Sitting endurance requires the patient to sit on the edge of the bed to assess sitting endurance. However, if the patient does not have the balance or trunk strength/tone to support sitting balance, this would be coded as "no sitting endurance." In fact, it may not be an issue of endurance at all. There should be a category titled "unable to perform."

V.J.

This section identifies mobility devices and aides. It fails to include orthotics and prosthetic devices in the list. We recommend that these devices be added.

VI. Functional Status

VIA1.
Under Eating, there are two distinct activities in the category that should be separated: 1) using utensils to bring food to the mouth and (2) swallowing the food.

VI.B5a
This section asks the provider to code the longest distance the patient can walk. It sets forth certain distances (e.g. 150 feet, 100 feet, 50 feet). This will raise questions regarding how to score if the patient walks 101-149 feet or 51-99 feet, etc. It would be more helpful to use a range of distance. For example:

1)Walk greater than 100 feet up to 150 feet
2) Walk greater than 50 feet up to 100 feet
3) Walk greater than 10 feet up to 50 feet
4) Walk up to 10 feet.

Also, this question does not link the distance specifically to function in terms of the tasks that the patient can accomplish. Without such a link to function, it will not be feasible to measure appropriate outcomes.

It may be problematic to allow only one measure without further instructions. For example, a patient with an amputation might be able to ambulate 150 feet with a walker or crutches but only 50 feet with a walker without the prosthesis or 25 feet with prosthesis and cane, which is required for safe discharge home due to environmental barriers.

VI. Functional Status- Supplemental Items

CMS should reconsider when the supplemental items are completed. The instructions state to complete it on persons "who will need PAC or personal assistance following discharge." It is most likely unrealistic to think that a person who has been in the hospital for 2-3 days is going to have all these items assessed accurately. During the TEP, there was a discussion about only requiring completion of this section for a patient who had therapy as an inpatient. The section would then be repeated on admission to a PAC.

VI. C. Supplemental Functional Ability
We recommend that C3 (roll left or right) and C4 (sit to lying) be included in the Core Functional Mobility category B, rather than Supplementary Functional Ability category C.

Section VIII. Frailty/Life Expectancy

VIII.A.
This question, "would you be surprised?" is not worded well. It may have poor reliability depending on who is performing the assessment. The person completing the CARE instrument may not be the most appropriate person to answer this question.

Section IX. Discharge Status

IX.A2
With respect to discharge locations, we recommend that an explanation of the distinction between a long-term care facility and a skilled nursing facility be included. Most

individuals do not understand the difference and may be unaware of the type of setting it is, particularly given the fact that so many LTC/SNFs are now duly certified.

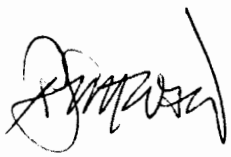
IX.B1
This questions asks who the patient lives with at discharge. It should be modified to include another option for "paid help not living in home."

IX.E8
This section addresses the reason for discharge delay. Reason number 4 is medical (patient condition changed). We are wondering whether the CARE instrument has to be redone if the patient's condition changes and the patient does not leave until 24 hours later.

Conclusion

Thank you very much for your consideration of our comments. We hope our concerns with the CARE tool will be addressed before it is used as a tool to determine severity, outcomes, and resource utilization. We look forward to working with CMS in the future as the Post-Acute Care (PAC- Payment) Reform Demonstrations Program demonstration is implemented. If you have further questions, please contact Gayle Lee at 703-706-8549 or gaylelee@apta.org.

Sincerely,



Scott Ward, PT, PhD
President

NATIONAL PRESSURE ULCER ADVISORY PANEL

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September 17, 2007

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: Comment Request posted in the Federal Register, vol. 72, no. 144, July 27, 2007 by the Department of Health and Human Services for Document Identifier CMS-R-249, CMS-10238, CMS-102, 105, CMS-10243 and CMS-10244

Ms. Harkless:

The National Pressure Ulcer Advisory Panel (NPUAP) would like to take this opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the draft Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. NPUAP is an independent, not-for-profit organization dedicated to the prevention and management of pressure ulcers through education, research and public policy. Formed in 1987, the NPUAP Board of Directors is comprised of leading authorities representing various disciplines, including medicine, nursing, occupational and physical therapy, nutrition, biomedical engineering, research and education.

While our Panel's major focus is pressure ulcers, our members are recognized experts in wound care and hence our comments reflect all wound types across a wide range of facilities. Our comments are provided below and are focused on the OMB 7/17/2007 draft of the instrument.

NPUAP Comments:

Section II. Admission Information

- **Section A2: Admitted From.**

  NPUAP suggests adding other forms of admission to acute care in this section including:
  - "Short stay (less than 24 hours)"

- "Emergency Department with admission to the hospital"
- "Emergency Department visit without admission to the hospital".

These visits often indicate that the patient's condition has changed and likely will require a change in the plan of care. Pressure ulcers may also develop during these stays.

Section III, Current Medical Items

- **Section D. Treatments, Item D3, Total Parenteral Nutrition:**

  NPUAP recommends adding Enteral Tube Feeding as an added Item D3a. Enteral Feeding Tubes are FDA Class II medical devices and, as such, must be monitored for complications that could impact wound healing.

- **Section D. Treatments, Item D24, Specialty Bed:**

  NPUAP recommends differentiating between a "reactive support surface" and an "active support surface" for specialty beds. The consensus definition of these terms from NPUAP's Support Surface Standards Initiative and examples of each are as follows:

  - Reactive Support Surface: A powered or non-powered support surface with the capability to change its load distribution properties only in response to applied load. These include static air, foam, low air loss and air-fluidized surfaces.
  - Active Support Surface: A powered support surface, with the capability to change its load distribution properties, with or without applied load. These include alternating pressure surfaces.

  While many products fit into these two categories, the selection of the appropriate support surface must be individualized to the patient's needs and overall condition.

  We also recommend the addition of devices used to "float" the heel, such as boots and splints. Boots and splints are designed to suspend the heel from making contact with the bed surface and thereby eliminate pressure from the heel. Devices such as sheep-skin and heel protectors do not relieve pressure but can be used to prevent friction or rubbing. This protection for the heel is not provided by support surfaces and needs to be identified.

- **Section D. Treatments, Item D20, Complex Dressing Changes:**

  The intent of this data element is to capture the complexity of the patient's wound care needs. As written, however, the focus appears to be primarily on wounds that require two people for dressing changes. NPUAP believe this interpretation may be too narrow.

We recommend the wording "Complex Dressing Changes" be changed to "Complex Wound Management" and with examples for this being wounds that require advanced wound interventions/modalities (growth factors, bioengineered skin substitutes, advanced wound dressings, negative pressure wound therapy, etc.) wounds that require significant clinical caregiver resources or increased frequency of clinical intervention (e.g., perineal dermatitis or moisture associated skin erosion) as defined by a defined number of person-hours of clinical intervention per day.

- **Section D. Treatments – Other Comments**

NPUAP recommends that "compression therapies" be added to the list of treatments. Compression therapies are used to treat chronic venous insufficiency and venous leg ulcers that are common medical conditions of patients in post acute care settings. Examples of compression therapies include:

  - Multi-layer bandaging systems
  - Pneumatic compression systems
  - Unna's boot

- **Section G. Presence of Pressure Ulcers, Item G1:**

The formal name for the Braden tool is "Braden Scale for Predicting Pressure Sore Risk©", Copyright Barbara Braden and Nancy Bergstrom, 1988 All rights reserved. Likewise, the formal name for the Norton tool is "Norton Scale for Predicting Risk of Pressure Ulcer" (Citation: Norton, D. McLaren, R, Exton-Smith, A.N. 1962.) NPUAP recommends use of the formal name for these tools along with copyright citations.

NPUAP is also concerned that the definition of "high risk" varies by assessment tool. For example, the Braden Scale has the following risk scale:

- At Risk: Score of 15 -18
- Moderate Risk: Score of 13 -14
- High Risk: Score of 10 -12
- Very High Risk: Score of 9 or below

By contrast, the Norton Scale has the following risk scale:

- Maximum score 20
- Minimum score 5
- At risk for pressure ulcer if score <= 14

The Norton Scale does not provide a score for high risk; rather it provides only a score for patients at risk.

Because of the differences between risk assessment tools as to what constitutes "high risk", NPUAP recommends that CMS specify the level of risk /risk score

that would indicate a code of "2" in this section based on the Braden Scale alone. The Braden Scale is not only the most commonly used risk assessment tool, specifying a score with this tool would help serve as a reference point for other assessment tools that may be used.

Also, a factor not captured in the Braden, Norton and other risk assessment tools is the presence of non-removable medical devices such as casts, splints, Continuous Positive Airway Pressure (CPAP) devices, etc. Patients with these devices in place may not score as high risk on traditional risk assessment tools, but they are high risk for the development of a pressure ulcer nonetheless. NPUAP recommends that clinicians be directed to consider patients with non-removable medical devices to be high risk and be coded a "2" on Item G1.

The phrase "healed scar" is not clear, we suggest using the phrase "A scar over a bony prominence (for example, from a healed pressure ulcer or surgical repair of an ulcer)".

NPUAP continues to support the recommendation that each risk factor be appraised in determining risk and reducing risk in accordance with the F314 tag.

- **Section G2. Add Stage I.**

NPUAP uses Roman numerals for the categories of pressure ulcer stages. We used Roman numerals in our comments here.

NPUAP suggests that all the stages of pressure ulcers be included because each Stage of pressure ulcers requires specific care. The revised definition of Stage I pressure ulcers is "intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area" (NPUAP, 2007). Stage I pressure ulcers are important warning signs of potential pressure ulcer development and their presence does change the plan of care because off loading is required. In addition, since this assessment tool is tracking Stage I pressure ulcers it would indicate in which setting the ulcer started.

- **Section G2. Add Deep Tissue Injury.**

Deep tissue injury is a new label of pressure ulcers. Their definition is "purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear" (NPUAP, 2007). These pressure ulcers typically have a 48 hour prodromal period and may not appear until the patient has been transferred.

- **Section G2a. Stage 2**

NPUAP believes it will be important to distinguish in the description of Stage II

pressure ulcers those that are true pressure ulcers and those that are a result of a skin tear, tape tear, fecal or urinary incontinence associated dermatitis or partial thickness skin erosion. A major consideration in this distinction is whether the surrounding skin is moist or dry. Because of this limitation in the staging system, NPUAP recommends the description of a Stage II pressure ulcer include wording to ensure true Stage II ulcers only are recorded in this section.

- **Section G2c. Stage 4**

  NPUAP recommends modifying the definition of a Stage IV pressure ulcer to the following that was developed and endorsed at NPUAP's recent Consensus Conference. (Bi-Annual Consensus Conference of the National Pressure Ulcer Advisory Panel, San Antonio, February, 2007.): "Full thickness tissue loss with exposed bone, tendon, or joint capsule. Necrotic tissue may be present on some parts of the wound bed. Often includes undermining and tunneling."

- **Section G2d. Unstageable**

  Devices that prevent skin assessment should be included. We suggest the phrase read "dressing, *device* or cast".

- **Section G3.**

  NPUAP recommends modifying the description of how to measure a pressure ulcer should be changed to the following wording endorsed by the NPUAP:

  > "The longest (vertical) head-to-toe length (in centimeters) and the greatest (horizontal) side-to-side width (in centimeters). The measurement of the width is perpendicular to length. Depth is the greatest point of the ulcer. The length and width measurements encompass the entire wound."

- **Section G4.**

  We recommend adding "undermining" in this data element. Our suggested wording would be "Indicate if any unhealed Stage III or Stage IV pressure ulcer(s) has tunneling (sinus tract or undermining).

- **Section G5 a-e. Number of Major Wounds**

  The number and type of major wounds other than pressure ulcers is noted in this section. While this is appropriate, it is notable that the CARE tool does not require documentation of these types of wounds beyond their number and type. This is in contrasted to pressure ulcers which have eleven data elements in the tool. Diabetic foot ulcers, for example, are often classified using the Wagner Classification System:

Wagner Ulcer Classification System	
Grade	***Lesion***
0	No open lesions; may have deformity or cellulitis
1	Superficial diabetic ulcer (partial or full thickness)
2	Ulcer extension to ligament, tendon, joint capsule, or deep fascia without abscess or osteomyelitis
3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
4	Gangrene localized to portion of forefoot or heel
5	Extensive gangrenous involvement of the entire foot

Citation: Wagner, FW: The dysvascular foot: A system for diagnosis and treatment. Foot Ankle 3:64, 1981

In addition, venous leg ulcers are the result of chronic underlying etiologies related to chronic venous insufficiency. Like pressure ulcers, they can be difficult and expensive to heal, require advanced wound management therapies and dressings, require supportive measures such as compression to alleviate the underlying condition, are subjective to infection, and can be complicated by patient co-morbitities and nutritional status. Moreover, they often recur if supportive measures are not put in place between ulcer episodes. We also suggest separation of arterial and venous ulcers and adding a category of "mixed etiology". Finally, a "healing surgical wound" should also be identified.

- **Section G6. Turning Surfaces Not Intact**

  NPUAP recommends removing Item E "None of the above apply" since Item A "Skin for all turning surfaces is intact" implies that Items B, C and D do not apply.

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NPUAP appreciates the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the draft Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. We would welcome an on-going dialogue with CMS on this tool as it continues to develop.

Sincerely,

Joyce Black, Ph.D., RN, CWCN, CPSN
President

George Taler, MD
Chair, Public Policy Committee

2007 SEP 25 PM 4: 20

September 25, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
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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:

The Georgia Hospital Association (GHA) , on behalf of our 160 member hospitals and health systems 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 the agency's 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 CMS' intentions are 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. We believe this goal must be pursued with great care and input from providers 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 addresses 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.

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To better understand the impact the CARE assessments would have on general acute hospitals and post-acute providers, we requested input from a number of our member hospitals, both acute care *and* post-acute care. The following 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 large numbers of beneficiaries being discharged from hospitals every year, this new mandate would require 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.

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.

Recommendation: We urge 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 involved in the initial testing 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. 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.

Recommendation: We strongly recommend that CMS streamline to 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, we would be happy to work with the American Hospital Association 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 seem 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.

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 Karen Waters at 770 249-4540 or via email at kwaters@gha.org

Sincerely,

Vi Naylor

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Executive Vice President

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A not-for-profit organization

September 24, 2007

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Attn: Bonnie L. Harkless

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of **John Muir Health** in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services.

The CARE tool contains over 300 items divided into 11 major sections: Administrative Items, Admission Information, Current Medical Items, Cognitive Status, Impairments, Functional Status, Engagement, Frailty/Life Expectancy, Discharge Status, Other Useful Information, and Feedback. Of those 300 items, 100 items are common to all settings, 163 are required upon discharge from acute care, 155 are required upon admission to a post-acute setting (SNF, IRF, LTCH, HHA), 160 are required upon discharge from a post-acute setting, and 139 are required for interim assessments every 14 days in post-acute settings. CMS estimates that the CARE tool will take 35-60 minutes to complete, depending on the setting and complexity of the case.

My comments and concerns regarding the CARE tool are based on discussions with the management who are responsible for patient assessment, and are presented below:

1. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient classification and reimbursement.
    a. The rationale for the inclusion of the additional 210-220 items is not clear.
    b. The forced use of the CARE tool will create an unnecessary burden on staff and increase costs to acute and post acute care providers.
    c. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources that will be needed to comply with these changes.
    d. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
    e. Given the complexity of the form and the time needed to correctly complete the form, Acute Care facilities will need to significantly increase FTEs to accommodate this requirement.

2. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.

a. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim.
b. Rehabilitation facilities will need to develop new assessment forms, worksheets, and documentation procedures for each of the 140-160 CARE tool items.
c. Each of two acute care hospitals will require at least two trained PPS/CARE coordinator to collect and submit CARE tool data.
d. The CARE tool may increase therapy, nursing, and physician documentation time by as much as 20 percent, necessitating an increase in staff.
e. Staff time, which should be focused on providing direct patient care and therapy, will instead be redirected toward the paperwork and documentation needed to meet the data requirements of the CARE tool.
f. All case management, discharging physician, rehabilitation, and home health staff will need to be trained in the use of the new CARE tool at a considerable expense.
g. JMH will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. JMH has already developed automated documentation systems (electronic medical records), which will need to be revised.
h. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.

In light of the above observations, JMH is recommending the following:

1. The CARE tool should be refined and condensed to no more than 50 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
2. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
3. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

I am grateful for the opportunity to provide comments on this important demonstration project.

Sincerely,

Vicki C. Lee
Executive Director, Revenue Management
John Muir Health

September 20, 2007

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Attn: Bonnie L. Harkless

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of Glenwood Regional Medical Center in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005. The CARE tool will be used to (1) standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals, (2) document medical severity, functional status, and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post-acute treatment, and (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization. For the PAC-PRD demonstration project, CMS intends to use 150 selected providers plus 238 volunteer acute care and post-acute care providers in 10 demonstration sites, including 44 inpatient rehabilitation facilities, to test the CARE tool over a 3-year period beginning in January 2008. CMS plans to develop a uniform assessment tool to be used across all post-acute settings, including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), and home health agencies (HHAs), replacing its current assessment instruments. Providers participating in the demonstration project will be asked to complete the CARE tool in addition to the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), Minimum Data Set (MDS), and Outcome and Assessment Information Set (OASIS) on approximately 30,000 patients (150,000 assessments). Following completion of the PAC-PRD demonstration project and refinement of the CARE tool, CMS plans to develop a single payment system for all post-acute settings.

The CARE tool contains over 300 items divided into 11 major sections: Administrative Items, Admission Information, Current Medical Items, Cognitive Status, Impairments, Functional Status, Engagement, Frailty/Life Expectancy, Discharge Status, Other Useful Information, and Feedback. Of those 300 items, 100 items are common to all settings, 163 are required upon discharge from acute care, 155 are required upon admission to a post-acute setting (SNF, IRF, LTCH, HHA), 160 are required upon discharge from a post-acute setting, and 139 are required for interim assessments every 14 days in post-acute settings. CMS estimates that the CARE tool will take 35-60 minutes to complete, depending on the setting and complexity of the case.

My comments and concerns regarding the CARE tool for all post-acute settings are presented below. They are organized into sections as follows:

1. The necessity and utility of the proposed information collection for the proper performance of the agency's functions
2. The accuracy of the estimated burden
3. Ways to enhance the quality, utility, and clarity of the information to be collected
4. The use of automated collection techniques or other forms of information technology to minimize the information collection burden

1 & 2. The necessity and utility of the proposed information collection for the proper performance of the agency's functions and the accuracy of the estimated burden

1. The CARE tool has not been tested or validated as a reliable measure of variance in costs, lengths of stay for inpatient rehabilitation, burden of patient care, or outcomes of patients treated in rehabilitation facilities.
    a. The CARE tool, which borrows items and content domain largely from the MDS (version 2) and some limited items from the IRF-PAI and OASIS, has not been previously approved, tested, or reviewed by the field of rehabilitation providers.
    b. There is no data available on the reliability, validity, or psychometric scaling properties of the CARE tool.
    c. The MDS-PAC, used in a prior attempt to develop an assessment tool for all post-acute settings, failed as a reliable predictor of costs and outcomes and would have placed an undue burden on providers to collect unnecessary data.
    d. It is unlikely the CARE tool as proposed will be able to adequately measure the true burden of patient care, medical complexities, and acuity differences among patient populations treated in the various post-acute settings.
    e. There was no attempt to stratify the selection of rehabilitation facilities, based on facility type (private, county, or teaching facility) or specialized regional centers (spinal cord injury, traumatic brain injury, or neurological programs), or by the number of rehabilitation facilities per capita. The proposed sample is not representative of IRFs nationwide.
    f. The burden of patient care is a key issue that must be addressed in managing patients effectively and efficiently across post-acute care venues. The FIM™ instrument is used to estimate burden of patient care, defined as hours/minutes of assistance needed per day from another person for personal care. It is not readily appreciated that a person with a disability, who needs daily help from another person to perform personal care tasks, presents a burden of patient care that could exceed the capacity of accompanying persons to provide help needed in the home. Often, the consequence is that the patient may require either short-term hospital or institutional care for rehabilitation or long-term residential care. Quantification of burden of patient care is necessary to appropriately manage the care of patients with limitations in ability to perform daily living tasks independently. Studies have been conducted in homes with individuals who had stroke, spinal cord injury, multiple sclerosis, and head injury (research references can be provided) in which the actual time needed for assistance was highly correlated with the FIM™ instrument rating. For example, a total FIM™ rating of 80 (total ratings range from 18 to 126) corresponds with 2 hours or less of personal care needed per day, a total FIM™ rating of 100 amounts corresponds with 0 to less than 30 minutes per day needed for personal care, and a total FIM™ rating of 60-70 indicates functional deficits too severe for care at home in most cases. A total FIM™ rating of 60 is common for stroke patients at the time of admission to a rehabilitation program. In practice, on average, a patient who has sustained a stroke is admitted with a total FIM™ rating of 65-70 and is discharged with a total FIM™ rating of 85-90, resulting in a reduction in the amount of help needed per day from 3-4 hours to 1-2 hours. Quantifying the amount of personal care needed helps to triage patients to appropriate venues and serves to estimate the amount of care needed and the costs of that care. The time needed in the previous examples of burden of patient care may appear minor on the basis of a day or a week; when viewed over a month, several months, or a year, the time and subsequent costs are substantial. Remember that dependence can last for several years. The FIM™ instrument is not restricted to use for inpatients only, but it is currently known to be used by SNF and LTCH care settings, and it is sometimes appropriate for use with outpatients with more severe disabilities or for those at risk for incurring progressive disability.
    g. The stated goals for the PAC initiative and for patient care would be better served with a known, reliable, and functional measurement tool. Reliability of functional measurement, as well as the other domains, has not been tested using the CARE tool. This is especially troubling given that training followed by testing and credentialing of staff is not a key

component of the PAC-PRD, thus introducing a high risk of uncontrolled variability in accurately measuring function across the different settings. High variability in the data will greatly reduce the effect size capable of being detected with the sampling scheme, thus rendering the demonstration conclusions invalid because of a high Type II error. In short, there may be a difference in functional outcomes between settings, but the lack of training and the subsequent allowance for great variability may prevent real differences from being detected even though they may exist. The FIM™ instrument is a much more reliable tool for functional assessment because of the associated training, testing, and credentialing required of clinical staff members who use the tool.

2. Premature use of the CARE tool, which has been neither tested nor validated for patient classification and the prospective payment system for Medicare patients, will result in denied access to acute rehabilitation for patients with more severe impairments.
    a. **Based on studies over the past 10 years by the Center for Disease Control (CDC), healthcare planners, and consultants, an estimated 20% to 60% of patients with a** significant impairment—such as stroke, brain injury, spinal cord injury, amputation, multiple trauma, or neurological conditions—could require rehabilitation services in one or more of the post-acute settings (SNF, IRF, LTCH, or HHA).
    b. The relative weights for each case-mix group in the IRF PPS were developed using the FIM™ instrument and the IRF-PAI, not the CARE tool. The FIM™ instrument has been proven to measure the true burden of patient care and the expected costs of rehabilitation services for patients with designated impairments.
    c. If forced to use the CARE tool as a discharge planning tool to determine the most appropriate post-acute setting for a patient with ongoing needs, acute care discharge planners and case managers may overlook critical factors, including medical complexities and risk factors affecting functional recovery, and fail to identify patients who may require both close daily supervision by physicians with experience in rehabilitation medicine and 24-hour rehabilitation nursing care.
    d. Despite its length, the CARE tool is extremely complex and uninformative in terms of two key components: measurement of burden of patient care and clarity of medical necessity. If the acute care hospital discharge report fails to accurately identify these two critical issues, patients can be placed into inappropriate post-acute settings, resulting in higher returns to acute care, higher (and unnecessary) healthcare costs, and higher (and equally unnecessary) risk to the patient, all of which will lead in turn to a need for tracking mechanisms to identify and correct these circumstances in a timely manner.
    e. Case-mix management will become the preferred survival strategy of established SNFs and IRFs, and therefore not all patients with disabilities will have equal access to inpatient rehabilitation. IRFs will most likely screen out severely impaired and medically complex cases due to insufficient reimbursement.
    f. **There are significant differences and regional variations in the medical capabilities, training, and expertise** of the various post-acute settings (SNFs, IRFs, LTCHs, and HHAs) and their ability to handle patients with complex medical conditions and to prevent further medical complications that will result in unnecessary readmission to acute hospitals.
    g. Access to required and needed rehabilitation services must be preserved.
    h. The CARE tool presents coding issues. The instructions do not provide specific guidance regarding the assignment of ICD-9-CM codes. Currently, the official guidelines result in a different set of codes at the acute facility and at each of the post-acute care facilities for the same patient due to the circumstances of the admission. The code for the primary diagnosis is optional, as the instrument states "if available." It is easier to provide this code than it is to provide the code for the reason for admission to the prior facility. The use of V-codes is problematic, as (a) several V-codes do not have associated medical conditions and (b) the use of certain codes as additional codes would amount to double-reporting of the same condition. What the additional code represents is not clear, and the tool does not indicate whether the additional code applies to both the primary diagnosis and the secondary condition.

3. The proposed rating scale for the items in section VI, Functional Status, is inconsistent with the FIM™ instrument, and the proposed scale has not been tested for psychometric scaling properties.
    a. The proposed 6-point scale for the self-care and mobility items eliminates the Modified Independence level from the FIM™ instrument (requires an assistive device or aid, extra time, or there are safety consideration), separates setup from supervision (both of which require a helper to safely carry out the activity), and combines contact guard or touching assistance with supervision.
    b. The tool includes a proposed 3-point rating scale for the communication and cognitive items instead of the 7-point FIM™ instrument scale, and the definition of each rating is unclear.
    c. Instrumental ADLs are assessed on a 4-point scale.
    d. The CARE tool bases functional assessments on the most usual performance, not the lowest level of performance, over a 2-day assessment period upon admission to a post-acute setting, within the interim period (every 14 days), and upon discharge from a post-acute setting.
    e. The different rating scales for the various items, the lack of tested psychometric scaling properties, and the inconsistency with the FIM™ instrument, which has been widely used and fully tested in several million applications for over 20 years, is likely to be confusing to providers and will not yield reliable and valid measures of burden of patient care as reflected in the various post-acute settings.
    f. There is some redundancy among the items in section IV, Cognitive Status; section V, Impairments; and section VI, Functional Status.
    g. Using the AlphaFIM® instrument in acute care settings, the FIM™ instrument in SNF, IRF, and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) in HHAs would be a more appropriate approach. The AlphaFIM® instrument uses 6 FIM™ items to project a patient's full FIM™ rating; the OmegaFIM™ instrument also uses 6 FIM™ items to project a full FIM™ rating for higher-functioning patients. These FIM™ instrument items, which have been fully tested and validated, can be easily supplemented with additional items, such as Instrumental Activities of Daily Living (IADLs) or other similar items.
    h. A consistent rating scale, such as the 7-point scale used in the FIM™ instrument, provides the best way to measure the true burden of patient care. Burden of care is not well appreciated as a concept, but it is the most important factor in determining the long-term care needs of an individual with disability.
4. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient classification and reimbursement.
    a. The rationale for the inclusion of the additional 210-220 items is not clear.
    b. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
    c. Many of these items are totally irrelevant to IRF patient populations, including IV-A, Comatose; B-I, Brief Interview for Mental Status (BIMS); VI-C, IADLs; and VIII-A2, *Would you be surprised if the patient were to die within the next 12 months?* Although these items may be appropriate for patients in SNFs or LTCHs, they should not be required in IRF settings.
    d. The forced use of the CARE tool will create an unnecessary burden on and cost to rehabilitation providers. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources IRFs will need to comply with these changes in the PPS.
    e. Given an average of 250 Medicare admissions per facility, the existence of 1,123 IRFs nationwide, and a rate of approximately 280,750 admissions per year, the following tables present more realistic estimates of the time requirements for IRF-PAI assessments and CARE tool assessments in the IRF setting.

IRF-PAI	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	20 minutes	100%	93 hours	105,000

Discharge assessment	20 minutes	100%	93 hours	105,000
TOTAL TIME	**40 minutes**	-	**186 hours**	**210,000**

CARE Tool	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	120 minutes	100%	500 hours	561,500
Interim assessment (day 14)	60 minutes	60%	150 hours	168,450
Discharge assessment	90 minutes	100%	375 hours	421,125
TOTAL TIME	**270 minutes**	-	**1,025 hours**	**1,151,075**

Given these more realistic time estimates, nearly 7 times more staff time per patient will be required to complete the CARE tool. This represents a significant increase in assessment time. The difference is nearly 840 hours per facility per year.

f. Assuming that the CARE tool must be completed by a clinician (licensed therapist or nurse) who is familiar with the assessment tool—a condition currently required for the IRF-PAI—the cost of completing the CARE tool will be $35,875 per IRF per year (at $35 per hour), but the cost of completing the IRF-PAI will be only $6,510. This represents an increase of $29,365 per IRF per year. However, these are not the only costs associated with the proposed CARE tool, as explained below.

5. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.
   a. Rehabilitation facilities will need to develop new assessment forms, worksheets, and documentation procedures for each of the 140-160 CARE tool items.
   b. Functional assessment techniques will need to be altered to reflect the 6-point rating scale for the proposed self-care and mobility items and the 3-point scale for the proposed communication and cognitive items.
   c. An interim assessment will be required on or around day 14, to include 140 items.
   d. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim (where warranted).
   e. Each facility will require at least one trained PPS/CARE coordinator to collect and submit CARE tool data.
   f. The CARE tool may increase therapy, nursing, and physician documentation time by as much as 20 percent, necessitating an increase in staff.
   g. Staff time, which should be focused on providing direct patient care and therapy, will instead be redirected toward the paperwork and documentation needed to meet the data requirements of the CARE tool.
   h. All rehabilitation staff will need to be trained in the use of the new CARE tool at a considerable expense.
   i. Each facility will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. Many providers have already developed automated documentation systems (electronic medical records), which will need to be revised.
   j. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.
   k. Given an average hourly rate of $35 per hour for a PT, OT, or RN, each IRF would need to pay $29,365 in additional staff expenses just to complete the CARE tool. The estimated costs of additional staff assessment time, the hiring of a new CARE tool coordinator, additional training, new software, new program interfaces, and revised documentation are shown in the following table.

Estimated Costs of Implementing the Care Tool	Annual Cost
Additional staff time (PT,OT, ST, RN) and assessment time	$29,365
PPS coordinator (full-time clinician) for data collection, entry, and transmission	$54,600
Annual cost of CARE tool software (UDS-PRO® software, eRehab)	$11,250
CARE tool training costs (12-16 hours per staff member), Year 1	$18,750
Program interfaces (ADT, medical records, billing, etc.), Year 1	$56,250
Documentation revision and development of CARE tool worksheets, Year 1	$11,250
TOTAL PROJECTED COST (first year)	**$181,465**
TOTAL PROJECTED COST (subsequent years)	**$95,215**

6. Nationwide, the average cost per IRF for implementing the CARE tool and changes in PPS are expected to be $181,465 for the first year and $95,215 (about $8,000 per month) for each subsequent year. (Costs may vary significantly by state, but a significant increase is certain.) This additional cost will place an undue burden on these facilities and most likely will result in denied or restricted access to needed rehabilitation services in an IRF setting. The eventual financial

burden of the CARE tool on IRFs alone will be about $107 million—a number that doesn't begin to consider the added costs for nearly 29,000 PAC and post-acute and acute care venues.

3. Ways to enhance the quality, utility, and clarity of the information to be collected

In light of the previous observations, I recommend the following:

1. The FIM™ instrument has been widely used for over 20 years and has more than 20 years of science behind it. The bibliography of publications focused on the instrument exceeds 600. More than 10 million assessments have been performed using the instrument, which is the only instrument used in post-acute settings that has the capacity to predict average length of stay and costs for purposes of prospective payment. As a result, I recommend that the AlphaFIM® instrument be used in acute care settings, the FIM™ instrument be used in SNF, IRF and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) be used in HHAs. These instruments, which have been fully tested and validated, can be easily supplemented with additional items such as Instrumental Activities of Daily Living (IADLs) and similar items.
2. IRFs should continue to use FIM-CMGs until the CARE tool has been fully tested and validated as a good predictor of length of stay and costs for rehabilitation patients.
3. The CARE tool should be refined and condensed to no more than 100 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
4. Rationales should be provided for the inclusion of each additional CARE tool item beyond the 100-item limit mentioned above.
5. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
6. The CARE tool should use the 7-point rating scale used in the FIM™ instrument to measure true burden of patient care. Use of a consistent 7-point scale will help avoid "ceiling effects" in measurement.
7. A consistent time frame should be established for assessing all CARE tool items that apply to each post-acute setting. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

4 The use of automated collection techniques or other forms of information technology to minimize the information collection burden

The system now used by most IRFs is an extensive, Internet-based, real-time data collection and reporting system offered by UDSMR. It could easily be modified to accommodate the PAC-PRD demonstration, and it offers access to multiple users.

I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at 318-329-3667.

Sincerely,

Cleta Munholland

Cleta Munholland
Director Inpatient Rehabilitation, Glenwood Regional Medical Center

September 21, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

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    h. A consistent rating scale, such as the 7-point scale used in the FIM™ instrument, provides the best way to measure the true burden of patient care. Burden of care is not well appreciated as a concept, but it is the most important factor in determining the long-term care needs of an individual with disability.
4. The CARE tool contains over 300 items, of which only about 80 to 90 are necessary for patient classification and reimbursement.
    a. The rationale for the inclusion of the additional 210-220 items is not clear.
    b. The CARE tool contains approximately 150 additional items not typically tracked by most IRFs.
    c. Many of these items are totally irrelevant to IRF patient populations, including IV-A, Comatose; B-1, Brief Interview for Mental Status (BIMS); VI-C, IADLs; and VIII-A2, *Would you be surprised if the patient were to die within the next 12 months?* Although these items may be appropriate for patients in SNFs or LTCHs, they should not be required in IRF settings.
    d. The forced use of the CARE tool will create an unnecessary burden on and cost to rehabilitation providers. CMS has grossly underestimated both the time required to complete the CARE tool and the additional resources IRFs will need to comply with these changes in the PPS.
    e. Given an average of 250 Medicare admissions per facility, the existence of 1,123 IRFs nationwide, and a rate of approximately 280,750 admissions per year, the following tables present more realistic estimates of the time requirements for IRF-PAI assessments and CARE tool assessments in the IRF setting.

IRF-PAI	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	20 minutes	100%	93 hours	105,000

Discharge assessment	20 minutes	100%	93 hours	105,000
TOTAL TIME	**40 minutes**	-	**186 hours**	**210,000**

CARE Tool	Time per assessment	% of patients	Hours per facility	Total hours nationwide
Admission assessment	120 minutes	100%	500 hours	561,500
Interim assessment (day 14)	60 minutes	60%	150 hours	168,450
Discharge assessment	90 minutes	100%	375 hours	421,125
TOTAL TIME	**270 minutes**	-	**1,025 hours**	**1,151,075**

Given these more realistic time estimates, nearly 7 times more staff time per patient will be required to complete the CARE tool. This represents a significant increase in assessment time. The difference is nearly 840 hours per facility per year.

f. Assuming that the CARE tool must be completed by a clinician (licensed therapist or nurse) who is familiar with the assessment tool—a condition currently required for the IRF-PAI—the cost of completing the CARE tool will be $35,875 per IRF per year (at $35 per hour), but the cost of completing the IRF-PAI will be only $6,510. This represents an increase of $29,365 per IRF per year. However, these are not the only costs associated with the proposed CARE tool, as explained below.

5. The CARE tool will require major modifications to documentation in the medical record, software and information systems, assessment techniques, and timing of assessments. These changes will require additional staff and resources, which will be diverted from patient care at a considerable cost to the facilities.
   a. Rehabilitation facilities will need to develop new assessment forms, worksheets, and documentation procedures for each of the 140-160 CARE tool items.
   b. Functional assessment techniques will need to be altered to reflect the 6-point rating scale for the proposed self-care and mobility items and the 3-point scale for the proposed communication and cognitive items.
   c. An interim assessment will be required on or around day 14, to include 140 items.
   d. Nursing documentation will need to be altered to accommodate new items and assessments reflecting three measurement times: admission, discharge, and interim (where warranted).
   e. Each facility will require at least one trained PPS/CARE coordinator to collect and submit CARE tool data.
   f. The CARE tool may increase therapy, nursing, and physician documentation time by as much as 20 percent, necessitating an increase in staff.
   g. Staff time, which should be focused on providing direct patient care and therapy, will instead be redirected toward the paperwork and documentation needed to meet the data requirements of the CARE tool.
   h. All rehabilitation staff will need to be trained in the use of the new CARE tool at a considerable expense.
   i. Each facility will need to purchase special software capable of collecting, analyzing, and submitting CARE tool data. Many providers have already developed automated documentation systems (electronic medical records), which will need to be revised.
   j. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.
   k. Given an average hourly rate of $35 per hour for a PT, OT, or RN, each IRF would need to pay $29,365 in additional staff expenses just to complete the CARE tool. The estimated costs of additional staff assessment time, the hiring of a new CARE tool coordinator, additional training, new software, new program interfaces, and revised documentation are shown in the following table.

Additional staff time (PT,OT, ST, RN) and assessment time	$29,365
PPS coordinator (full-time clinician) for data collection, entry, and transmission	$54,600
Annual cost of CARE tool software (UDS-PRO® software, eRehab)	$11,250
CARE tool training costs (12-16 hours per staff member), Year 1	$18,750
Program interfaces (ADT, medical records, billing, etc.), Year 1	$56,250
Documentation revision and development of CARE tool worksheets, Year 1	$11,250
TOTAL PROJECTED COST (first year)	**$181,465**
TOTAL PROJECTED COST (subsequent years)	**$95,215**

6. Nationwide, the average cost per IRF for implementing the CARE tool and changes in PPS are expected to be $181,465 for the first year and $95,215 (about $8,000 per month) for each subsequent year. (Costs may vary significantly by state, but a significant increase is certain.) This additional cost will place an undue burden on these facilities and most likely will result in denied or restricted access to needed rehabilitation services in an IRF setting. The eventual financial

burden of the CARE tool on IRFs alone will be about $107 million—a number that doesn't begin to consider the added costs for nearly 29,000 PAC and post-acute and acute care venues.

3. Ways to enhance the quality, utility, and clarity of the information to be collected

In light of the previous observations, I recommend the following:

1. The FIM™ instrument has been widely used for over 20 years and has more than 20 years of science behind it. The bibliography of publications focused on the instrument exceeds 600. More than 10 million assessments have been performed using the instrument, which is the only instrument used in post-acute settings that has the capacity to predict average length of stay and costs for purposes of prospective payment. As a result, I recommend that the AlphaFIM® instrument be used in acute care settings, the FIM™ instrument be used in SNF, IRF and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) be used in HHAs. These instruments, which have been fully tested and validated, can be easily supplemented with additional items such as Instrumental Activities of Daily Living (IADLs) and similar items.
2. IRFs should continue to use FIM-CMGs until the CARE tool has been fully tested and validated as a good predictor of length of stay and costs for rehabilitation patients.
3. The CARE tool should be refined and condensed to no more than 100 essential items necessary for PPS and comparisons among post-acute settings (SNFs, IRFs, LTCHs, and HHAs).
4. Rationales should be provided for the inclusion of each additional CARE tool item beyond the 100-item limit mentioned above.
5. The complete FIM™ instrument—including the rating scale, items, definitions, levels of function, training materials, and instructions—should be incorporated into the CARE tool.
6. The CARE tool should use the 7-point rating scale used in the FIM™ instrument to measure true burden of patient care. Use of a consistent 7-point scale will help avoid "ceiling effects" in measurement.
7. A consistent time frame should be established for assessing all CARE tool items that apply to each post-acute setting. A separate listing of items required in each setting (SNF, IRF, LTCH, and HHA) should be provided.

4 The use of automated collection techniques or other forms of information technology to minimize the information collection burden

The system now used by most IRFs is an extensive, Internet-based, real-time data collection and reporting system offered by UDSMR. It could easily be modified to accommodate the PAC-PRD demonstration, and it offers access to multiple users.

I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at 318-329-3667.

Sincerely,

Kim Roberts, RN, CRRN

Kim Roberts, RN, CRRN
Head Nurse/PPS Coordinator Inpatient Rehabilitation, Glenwood Regional Medical Center

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September 21, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of **Lawnwood Physical Rehabilitation Center** in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005. The CARE tool will be used to (1) standardize program information on Medicare beneficiaries' acuity at discharge from acute hospitals, (2) document medical severity, functional status, and other factors related to outcomes and resource utilization at admission, discharge, and interim times during post-acute treatment, and (3) understand the relationship between severity of illness, functional status, social support factors, and resource utilization. For the PAC-PRD demonstration project, CMS intends to use 150 selected providers plus 238 volunteer acute care and post-acute care providers in 10 demonstration sites, including 44 inpatient rehabilitation facilities, to test the CARE tool over a 3-year period beginning in January 2008. CMS plans to develop a uniform assessment tool to be used across all post-acute settings, including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), and home health agencies (HHAs), replacing its current assessment instruments. Providers participating in the demonstration project will be asked to complete the CARE tool in addition to the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), Minimum Data Set (MDS), and Outcome and Assessment Information Set (OASIS) on approximately 30,000 patients (150,000 assessments). Following completion of the PAC-PRD demonstration project and refinement of the CARE tool, CMS plans to develop a single payment system for all post-acute settings.

The CARE tool contains over 300 items divided into 11 major sections: Administrative Items, Admission Information, Current Medical Items, Cognitive Status, Impairments, Functional Status, Engagement, Frailty/Life Expectancy, Discharge Status, Other Useful Information, and Feedback. Of those 300 items, 100 items are common to all settings, 163 are required upon discharge from acute care, 155 are required upon admission to a post-acute setting (SNF, IRF, LTCH, HHA), 160 are required upon discharge from a post-acute setting, and 139 are required for interim assessments every 14 days in post-acute settings. CMS estimates that the CARE tool will take 35-60 minutes to complete, depending on the setting and complexity of the case.

My comments and concerns regarding the CARE tool for all post-acute settings are presented below. They are organized into sections as follows:

1. The necessity and utility of the proposed information collection for the proper performance of the agency's functions
2. The accuracy of the estimated burden
3. Ways to enhance the quality, utility, and clarity of the information to be collected
4. The use of automated collection techniques or other forms of information technology to minimize the information collection burden

1 & 2. The necessity and utility of the proposed information collection for the proper performance of the agency's functions and the accuracy of the estimated burden

1. The CARE tool has not been tested or validated as a reliable measure of variance in costs, lengths of stay for inpatient rehabilitation, burden of patient care, or outcomes of patients treated in rehabilitation facilities.
    a. The CARE tool, which borrows items and content domain largely from the MDS (version 2) and some limited items from the IRF-PAI and OASIS, has not been previously approved, tested, or reviewed by the field of rehabilitation providers.
    b. There is no data available on the reliability, validity, or psychometric scaling properties of the CARE tool.
    c. The MDS-PAC, used in a prior attempt to develop an assessment tool for all post-acute settings, failed as a reliable predictor of costs and outcomes and would have placed an undue burden on providers to collect unnecessary data.
    d. It is unlikely the CARE tool as proposed will be able to adequately measure the true burden of patient care, medical complexities, and acuity differences among patient populations treated in the various post-acute settings.
    e. There was no attempt to stratify the selection of rehabilitation facilities, based on facility type (private, county, or teaching facility) or specialized regional centers (spinal cord injury, traumatic brain injury, or neurological programs), or by the number of rehabilitation facilities per capita. The proposed sample is not representative of IRFs nationwide.
    f. The burden of patient care is a key issue that must be addressed in managing patients effectively and efficiently across post-acute care venues. The FIM™ instrument is used to estimate burden of patient care, defined as hours/minutes of assistance needed per day from another person for personal care. It is not readily appreciated that a person with a disability, who needs daily help from another person to perform personal care tasks, presents a burden of patient care that could exceed the capacity of accompanying persons to provide help needed in the home. Often, the consequence is that the patient may require either short-term hospital or institutional care for rehabilitation or long-term residential care. Quantification of burden of patient care is necessary to appropriately manage the care of patients with limitations in ability to perform daily living tasks independently. Studies have been conducted in homes with individuals who had stroke, spinal cord injury, multiple sclerosis, and head injury (research references can be provided) in which the actual time needed for assistance was highly correlated with the FIM™ instrument rating. For example, a total FIM™ rating of 80 (total ratings range from 18 to 126) corresponds with 2 hours or less of personal care needed per day, a total FIM™ rating of 100 amounts corresponds with 0 to less than 30 minutes per day needed for personal care, and a total FIM™ rating of 60-70 indicates functional deficits too severe for care at home in most cases. A total FIM™ rating of 60 is common for stroke patients at the time of admission to a rehabilitation program. In practice, on average, a patient who has sustained a stroke is admitted with a total FIM™ rating of 65-70 and is discharged with a total FIM™ rating of 85-90, resulting in a reduction in the amount of help needed per day from 3-4 hours to 1-2 hours. Quantifying the amount of personal care needed helps to triage patients to appropriate venues and serves to estimate the amount of care needed and the costs of that care. The time needed in the previous examples of burden of patient care may appear minor on the basis of a day or a week; when viewed over a month, several months, or a year, the time and subsequent costs are substantial. Remember that dependence can last for several years. The FIM™ instrument is not restricted to use for inpatients only, but it is currently known to be used by SNF and LTCH care settings, and it is sometimes appropriate for use with outpatients with more severe disabilities or for those at risk for incurring progressive disability.
    g. The stated goals for the PAC initiative and for patient care would be better served with a known, reliable, and functional measurement tool. Reliability of functional measurement, as well as the other domains, has not been tested using the CARE tool. This is especially troubling given that training followed by testing and credentialing of staff is not a key component of the PAC-PRD, thus introducing a high risk of uncontrolled variability in accurately measuring function across the different settings. High variability in the data will greatly reduce the effect size capable of being detected with the sampling scheme, thus rendering the demonstration conclusions invalid because of a high Type II error. In short, there may be a difference in functional outcomes between settings, but the lack of training and the subsequent allowance for great variability may prevent

real differences from being detected even though they may exist. The FIM™ instrument is a much more reliable tool for functional assessment because of the associated training, testing, and credentialing required of clinical staff members who use the tool.

2. Premature use of the CARE tool, which has been neither tested nor validated for patient classification and the prospective payment system for Medicare patients, will result in denied access to acute rehabilitation for patients with more severe impairments.
    a. Based on studies over the past 10 years by the Center for Disease Control (CDC), healthcare planners, and consultants, an estimated 20% to 60% of patients with a significant impairment—such as stroke, brain injury, spinal cord injury, amputation, multiple trauma, or neurological conditions—could require rehabilitation services in one or more of the post-acute settings (SNF, IRF, LTCH, or HHA).
    b. The relative weights for each case-mix group in the IRF PPS were developed using the FIM™ instrument and the IRF-PAI, not the CARE tool. The FIM™ instrument has been proven to measure the true burden of patient care and the expected costs of rehabilitation services for patients with designated impairments.
    c. If forced to use the CARE tool as a discharge planning tool to determine the most appropriate post-acute setting for a patient with ongoing needs, acute care discharge planners and case managers may overlook critical factors, including medical complexities and risk factors affecting functional recovery, and fail to identify patients who may require both close daily supervision by physicians with experience in rehabilitation medicine and 24-hour rehabilitation nursing care.
    d. Despite its length, the CARE tool is extremely complex and uninformative in terms of two key components: measurement of burden of patient care and clarity of medical necessity. If the acute care hospital discharge report fails to accurately identify these two critical issues, patients can be placed into inappropriate post-acute settings, resulting in higher returns to acute care, higher (and unnecessary) healthcare costs, and higher (and equally unnecessary) risk to the patient, all of which will lead in turn to a need for tracking mechanisms to identify and correct these circumstances in a timely manner.
    e. Case-mix management will become the preferred survival strategy of established SNFs and IRFs, and therefore not all patients with disabilities will have equal access to inpatient rehabilitation. IRFs will most likely screen out severely impaired and medically complex cases due to insufficient reimbursement.
    f. There are significant differences and regional variations in the medical capabilities, training, and expertise of the various post-acute settings (SNFs, IRFs, LTCHs, and HHAs) and their ability to handle patients with complex medical conditions and to prevent further medical complications that will result in unnecessary readmission to acute hospitals.
    g. Access to required and needed rehabilitation services must be preserved.
    h. The CARE tool presents coding issues. The instructions do not provide specific guidance regarding the assignment of ICD-9-CM codes. Currently, the official guidelines result in a different set of codes at the acute facility and at each of the post-acute care facilities for the same patient due to the circumstances of the admission. The code for the primary diagnosis is optional, as the instrument states "if available." It is easier to provide this code than it is to provide the code for the reason for admission to the prior facility. The use of V-codes is problematic, as (a) several V-codes do not have associated medical conditions and (b) the use of certain codes as additional codes would amount to double-reporting of the same condition. What the additional code represents is not clear, and the tool does not indicate whether the additional code applies to both the primary diagnosis and the secondary condition.
3. The proposed rating scale for the items in section VI, Functional Status, is inconsistent with the FIM™ instrument, and the proposed scale has not been tested for psychometric scaling properties.
    a. The proposed 6-point scale for the self-care and mobility items eliminates the Modified Independence level from the FIM™ instrument (requires an assistive device or aid, extra time, or there are safety consideration), separates setup from supervision (both of which require a helper to safely carry out the activity), and combines contact guard or touching assistance with supervision.
    b. The tool includes a proposed 3-point rating scale for the communication and cognitive items instead of the 7-point FIM™ instrument scale, and the definition of each rating is unclear.
    c. Instrumental ADLs are assessed on a 4-point scale.

d. The CARE tool bases functional assessments on the most usual performance, not the lowest level of performance, over a 2-day assessment period upon admission to a post-acute setting, within the interim period (every 14 days), and upon discharge from a post-acute setting.
e. The different rating scales for the various items, the lack of tested psychometric scaling properties, and the inconsistency with the FIM™ instrument, which has been widely used and fully tested in several million applications for over 20 years, is likely to be confusing to providers and will not yield reliable and valid measures of burden of patient care as reflected in the various post-acute settings.
f. There is some redundancy among the items in section IV, Cognitive Status; section V, Impairments; and section VI, Functional Status.
g. Using the AlphaFIM® instrument in acute care settings, the FIM™ instrument in SNF, IRF, and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) in HHAs would be a more appropriate approach. The AlphaFIM® instrument uses 6 FIM™ items to project a patient's full FIM™ rating; the OmegaFIM™ instrument also uses 6 FIM™ items to project a full FIM™ rating for higher-functioning patients. These FIM™ instrument items, which have been fully tested and validated, can be easily supplemented with additional items, such as Instrumental Activities of Daily Living (IADLs) or other similar items.
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I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at **772-467-3577.**

Sincerely,

Kathryn Lowery, RN, BS

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Program Director,
Lawnwood Physical Rehabilitation Center