UMC HEALTH SYSTEM

UMC Health System
602 Indiana Avenue
Lubbock, Texas 79415

p 806.775.8200
f 806 775.9361
teamumc.com

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 University Medical Center of Lubbock, Texas 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 and the accuracy of the estimated burden
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

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	Assessments per facility	Total 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	Assessments per facility	Total 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.

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.

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 **(806) 775-9375.**

Sincerely,

Craig Bragg, PT, CWS
Program Director
Inpatient Rehabilitation
University medical Center

September 19, 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 **Sun Health Del E. Webb 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 and the accuracy of the estimated burden
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

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 [illegible]	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.

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.

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 **623-214-910-0058.**

Sincerely,

Patricia A. Heimann, RN, MS, CRRN

Patricia A Heimann, RN, MS, CRRN
Acute Rehabilitation Clinical Nurse Educator
Sun Health Del E. Webb Rehabilitation Center
14503 W. Meeker Blvd.
Sun City West, AZ 85375

National Hospice and Palliative Care
Organization

Centers for Medicare & Medicaid Services (CMS)
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 25, 2007

Re: Comments on Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument CMS-10243 (OMB#:0938)

The National Hospice and Palliative Care Organization ("NHPCO") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed implementation of the Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument.

NHPCO is the largest nonprofit membership organization representing hospice and palliative care programs and professionals in the United States. The organization is committed to improving end of life care and expanding access to hospice care with the goal of profoundly enhancing quality of life for people dying in America, and their loved ones. Though hospice and palliative care has not been named as a healthcare entity affected by the proposed CARE instrument, we envision that the data collected by other healthcare entities during post acute services will benefit the hospice provider who cares for the patient in their final days. NHPCO supports the implementation of the tool in the acute and post acute care settings and would offer our providers to work with other healthcare providers in communities where this is piloted.

There are times when a patient receiving hospice or palliative care services re-enters the acute and post acute care settings and returns to hospice or palliative care at home. Data that is collected during these admissions can be extremely valuable for appropriate care planning for end of life care.

The specific collection of data reflecting a beneficiaries' acuity at discharge from acute hospitals is essential for healthcare entities which provide services in an outpatient or home setting such as home health care, palliative care, and hospice.

1700 Diagonal Road • Suite 625 • Alexandria, Virginia 22314
703/837-1500 • www.nhpco.org • 703/837-1233 (fax)
Member Service Center 800/646-6460

Identification and documentation of a beneficiaries' medical severity and functional status will aid CMS, fiscal intermediaries, and providers to better identify what resources a beneficiary actually needs to transition to the next care level. The data collection from the CARE instrument will allow providers to implement more efficient care management for the beneficiary, hopefully reducing duplication and fragmentation of care services.

NHPCO has reviewed the CARE Instrument and has the following suggestions:

- Under B-3; Questions to be added under Caregiver?
  - Is there an available willing caregiver?
  - Has the healthcare care provider spoken with caregiver to confirm they are willing?
  - Is the caregiver available not only upon discharge, but also 30 days post discharge?

NHPCO supports the collection of this data and hopes that the data from the CARE Instrument will allow CMS to accurately view the care utilization and needs of the beneficiary in the acute and post acute care environments. We also hope this data will support a seamless transition between settings so that all healthcare providers are able to provide the best care possible for patients and their families.

Should you have any questions or need clarification regarding any comments, please do not hesitate to contact me, at (703) 837-3122 or jlundperson@nhpco.org.

Sincerely,

Judi Lund Person

Judi Lund Person
Vice President
Regulatory and State
Leadership

Sinai
NEW ENGLAND SINAI HOSPITAL

Lester P. Schindel
President and CEO

Richard K. Blankstein
Chairman of the Board

Lawrence S. Hotes, M.D.
Chief Medical Officer

September 24, 2007

CMS Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development - C
Room C-4 26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Attention: Bonnie L. Harkless

Subject: Demonstration on new hospital discharge instrument (CARE instrument)

Background: The proposed CARE tool would be added to the current hospital discharge process to collect the clinical and functional status of all Medicare beneficiaries leaving the acute hospitals. The tool will also be used by post-acute providers. The CARE instrument is designed to measure the differences in patient severity, resource utilization, and outcomes for patients in acute and post-acute settings.

Comments: This proposed tool was tested on several LTAC inpatients at New England Sinai Hospital. While this assessment tool is quite comprehensive, it is time consuming to complete and duplicates many existing assessment processes in the hospital.

In general, most of the items of the CARE are captured during pre and post admission assessments performed by various members of the interdisciplinary team. On average, each application of the CARE instrument took 80 minutes to complete by an experienced RN case manager. This 80 minute segment excluded any time which would be required to interview patients and assess cognitive status. That interview process could easily take an additional 20 minutes of time.

A licensed nurse or RN case manager is best qualified to use the CARE instrument. The additional RN resources need to complete this CARE instrument at the time of admission, and again at discharge, do not currently exist in our hospital. The administrative and financial burdens associated with this tool are considerable. Using a conservative estimate of 80 minutes per admission and discharge for 100 Medicare discharges per month, Sinai would need to hire a licensed nurse for 32 - 40 hours per week to manage this process. Approximately twenty-seven (27) hours per week would be dedicated solely to data collection; the remaining time would be spent on data input and collection, as well as completion of staff logs.

With regard to the tool's coding requirements, the types of required responses are somewhat inconsistent. In some cases, a "check mark" is required; in other cases a numerical code is required. A more standardized approach to data collection would

President and CEO
New England Sinai Hospital

NATIONAL PRESSURE ULCER ADVISORY PANEL

1255 Twenty-Third Street NW
Suite 200
Washington, DC 20037-1174
Tel: 202-521-6789
Fax: 202-833-3636
Web: www.npuap.org
Email: npuap@npuap.org

September 25, 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.

* * * * * * * * * *

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

HANYS Healthcare Association of New York State

Proud to serve New York State's Not-For-Profit Hospitals, Health Systems, and Continuing Care Providers

Daniel Sisto, President

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: CMS–10243 (OMB#: 0938–NEW): Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

Dear Ms. Harkless:

The Healthcare Association of New York State (HANYS), on behalf of our more than 550 hospitals, nursing homes, home health agencies, and other health care providers, submits the following comments on the Continuity Assessment Record and Evaluation (CARE) Instrument. Our comments include suggestions for the addition of three specific assessment items and the importance of using information technology standards to reduce the burden of and facilitate interoperability of the tool.

Assessment of Pneumococcal and Influenza Vaccines

HANYS recommends that assessment of patients' pneumococcal and influenza vaccine history be added to the form as a part of Section III., Current Medical Items.

The importance of preventive pneumococcal and influenza vaccines is well documented by multiple entities such as Centers for Disease Control and Prevention, National Institutes of Health, and the Centers for Medicare and Medicaid Services (CMS). All agree to the importance of these vaccines in maintaining an individuals' health status as well as the public health of all Americans. HANYS supports the addition to the CARE instrument of an assessment of an individual's pneumococcal and influenza vaccine history.

Assessment of Stage 1 Pressure Ulcers

HANYS urges that CMS add assessment of Stage 1 pressure ulcers to the CARE tool, Section III. - Current Medical Items, G. - Skin Integrity.

Numerous clinical experts on skin integrity have long supported the assessment of individuals for Stage 1 pressure ulcers as a means of early detection and prevention of advanced stage pressure ulcers. In fact, every CMS assessment mandated for the post-acute participants in the payment demonstration using the CARE instrument, requires clinicians assess patients and residents for Stage I pressure ulcers. HANYS believes that CMS' CARE instrument skin integrity assessment requirements should be consistent with existing CMS setting-specific assessment requirements, as well as industry-wide health care standards. HANYS urges CMS to add assessment of Stage 1 pressure ulcers to the Skin Integrity section of the CARE instrument.

Reducing the Burden with Information Technology

HANYS recommends CMS adopt information technology standards that facilitate the interoperability of the CARE tool across demonstration settings and reduce the burden of its use on providers.

As noted above, HANYS' membership includes all of the provider types that will be using the CARE instrument as part of the Post-Acute Care (PAC) Payment Reform Demonstration program. As also noted earlier, these providers are also required by CMS' conditions of payment to each complete their own setting-specific assessment tool. Each of these tools uses unique and different definitions, coding requirements, and assessment timeframes, making information sharing impossible. A uniform, single assessment tool, that allows electronically-shared patient information between settings, can bring value and efficiency in efforts to improve patient safety, delivery and outcomes of care, and patient transitions between care settings.

Across New York, HANYS' members have participated in multiple efforts to develop data and communication standards to be used in the exchange of information between partners. Our members have worked with payers, providers, advocacy organizations, and the New York State Department of Health. A primary focus of these activities has been on interoperability between systems.

HANYS recommends that CMS adopt information technology standards in the demonstration that facilitate interoperability and encourage the development of products meeting these standards. In subsequent phases of this Demonstration program, CMS should consider integrating these same standards, once approved, for use in the production version of the released product. The industry is using XML as one of its tools to facilitate information sharing between multiple providers' communication applications. HANYS urges CMS and its contractor to consider its use going forward. CMS could then integrate the CARE tool functionality into existing or proposed local solutions for capturing and sharing information between systems.

HANYS supports CMS' plan as outlined in the CARE Tool Abstract for its application as a Web-based tool promoting use on an interoperable data system meeting CHI standards.

HANYS appreciates the opportunity to comment on the CARE instrument. If you have any questions regarding our comments, please contact me at (518) 431-7702 or at dlebarro@hanys.org.

Sincerely,

Debora LeBarron
Director, Continuing Care

DL:cp

amda
American Medical Directors Association

A national organization of long term care physicians committed to quality care

American Medical Directors Association

10480 Little Patuxent Parkway
Suite 760
Columbia, MD 21044
(410) 740-9743

Washington, DC
(301) 596-5774

Toll Free
(800) 876-AMDA

FAX
(410) 740-4572

www.amda.com

September 24, 2007

CMS Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development-C
Attention: Bonnie L. Harkless, Room C-4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Harkless:

The American Medical Directors Association (AMDA) is pleased to submit these comments on the Continuity Assessment Record and Evaluation (CARE) tool as requested through a comment request in the *Federal Register* on July 27, 2007. AMDA is the national professional association committed to continuous improvement of quality patient care by providing education, advocacy, information and professional development for medical directors, attending physicians, and other professionals who practice in the long-term care continuum. We represent more than 7,000 physicians who provide hands-on care in nursing homes and for community-based patients.

General Comments

AMDA applauds CMS for the development of the CARE tool and the efforts the agency has made to inform the public on the tool and receive feedback. We especially found the Special Open Door Forum to be informative. Given the scope and variety of patients coming to postacute care, it makes sense to standardize various instruments across settings. We also believe that it is important to have an instrument that improves upon the weaknesses of other previously developed tools such as the Minimum Data Set (MDS), and provides a more balanced context for the medical complexities of postacute patients in addition to their functional and psychosocial issues.

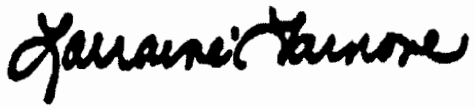
Thus, we recognize and appreciate the intent behind the CARE tool. It appears to reflect the right intentions, and it incorporates many of the elements that have been identified as important to providing care for those with recent illness and injury. However, we do have specific comments to identify and suggest ways to make the content more precise and accurate, which we believe would make the tool more effective.

detailed considerations will occur very often, making the conclusions suspect. We recommend removing or revamping this question to something more objective; for example, "What is the total anticipated daily (or monthly) cost of the medications on which the patient is to be discharged?"

We recommend changing the language and the criteria, as suggested above, to make this more precise and objective.

We are willing to work on the various revisions we suggested at your request.

Sincerely,



Lorraine Tarnove
Executive Director

We recognize that the tool seeks to get more information about important medical conditions and symptoms, yet it does not quite get at enough critical information to enable meaningful conclusions about key physical problems such as impaired gas exchange, altered breathing pattern, ineffective airway clearance, decreased cardiac output, activity intolerance, excess fluid volume, fluid volume deficit, and medical instability. Our comments provide recommendations to attain that critical information.

An appropriate postacute care instrument should reflect clinical realities and be pertinent to providing care and to the characteristics of the patients and the factors that influence results. One of those key realities is that there is often something other than a one-to-one relationship between symptoms, impairments, or risks and their causes. One symptom or impairment can have multiple simultaneous causes, and one condition can cause multiple problems and impairments concurrently. Therefore, one of the keys to understanding any patient is to correctly link causes and consequences. While we understand that this dataset will be used for various things other than the provision of care, we suggest various ways to improve on this dataset so that it will more accurately reflect the clinical realities of the patient, and minimize the likelihood of directing care and documentation in undesirable directions that are driven excessively by documentation or reimbursement issues.

Section II. Admission Information

A4. The options are lists of places, not of medical services.

We recommend rewording the question as "In what settings have the patient received services other than those identified in A2?

B4. A general question about the existence of possible structural barriers is relevant to discharge, but we do not see a reason for having a detailed list in this general dataset. There are many important aspects of care for which details belong in the medical record, not in a general dataset.

We recommend asking a general question such as the above, and leaving the details for the medical record, not this data set.

B8. We believe that this question is rather narrow, and not very clear, as written. It refers to "an acute change in mental status from the patient's prior status," prior to the current illness. If this is trying to identify delirium, it could have occurred prior to, during, or after the recent acute episode and/or hospital stay. What if the acute change constituted the current illness, rather than occurring prior to the current illness?

We recommend rewording this question to make it more precise and clinically pertinent.

Section III. Current Medical Items

The literature has identified the relevance of both medical diagnoses (comorbidities) and so-called "nursing" diagnoses (representing the consequences of illness and injury) to subsequent care and prognosis. (See Rosenthal GE, Halloran EJ, Kiley M et al. *Predictive validity of the nursing severity index in patients with musculoskeletal disease.* J Clin Epidemiol 1995 48(2):179-188). This dataset appears to

try to get at some of this information such as impaired gas exchange, altered breathing pattern, ineffective airway clearance, decreased cardiac output, and activity intolerance, excess fluid volume, fluid volume deficit, and medical instability.

This tool appears to try to gather more about important medical conditions and symptoms, which have often been minimized or overlooked in existing datasets. However, we are puzzled by some of its approaches. While Section V asks many detailed questions related to functional issues such as self-care deficit and impaired mobility, this Section appears to rely heavily on lists of procedures and test results as "proxies" for medical issues. While a complete list of diagnoses is requested, the approaches to other medical issues such as the ones mentioned above are much more uneven.

B. Other Diagnoses, Comorbidities, and Complications. The instructions say, "Include under-reported diagnoses (e.g., depression, schizophrenia, dementia, protein calorie malnutrition)." We have concerns about this statement. Among the thousands of medical conditions, there are many underreported diseases such as fibromyalgia and osteoporosis, and many overdiagnosed conditions such as "dehydration" (see, for example, Thomas DR, Tariq SH, Makhdomm S, Haddad R, Moinuddin A: *Physician misdiagnosis of dehydration in older adults*. J Am Med Dir Assoc 2003;4:251-254.) Recent and previous literature has challenged the extent to which depression is over diagnosed by being mistaken for apathy and by over-interpreting common symptoms such as sadness. We believe that singling out the mentioned diagnoses is purely arbitrary, reflects erroneous "conventional wisdom," and is more of a political statement than a clinically valid designation.

We recommend omitting the sentence entirely. The instructions should simply ask to list up to 15 diagnoses. This dataset should be neutral and should not bias interpretation or reporting by making or implying "political" statements about various diseases.

C - Procedures. C1 asks for up to 15 "diagnostic and therapeutic interventions." D then lists 32 different treatments. We can understand asking for a list of interventions as part of C. But we cannot discern a purpose for repeating many of the same things in D. Furthermore, where did the list in D come from, what is the point of this list, and what additional information or analysis is to be derived from it? Some of them are nursing procedures, and some are medical procedures. Even if it is useful to know that someone had a treatment or procedure frequently or came and went with the same treatment, the way the information is requested does not seem to make it very meaningful. Section III is entitled "Current Medical Items." But subsection D asks for "Admitted/Discharged With" and "Used Any Time During Stay." Thus, none of these requests is actually about "current" treatments (i.e., current at the time of completion). If there is one checkoff box for "admitted/discharged with," how could any subsequent analysis determine whether the patient had it at the beginning or the end of the stay? Without knowing that, and whether and how often the treatment or procedure was being given in between, what difference does it make just to check them off?

What is special about "negative pressure wound therapy" that it should be singled out? We are not aware that it is more important or difficult than the many other wound treatment options. What is a "complex dressing change," and what is the evidence that

the kind of "complex" dressing change listed there is more complex than various other kinds of dressing changes? "One-on-one supervision" could be anything from a sitter to intensive nursing monitoring. Why is "multiple antibiotic administration" more special than giving a single one? Many individuals get multiple antibiotics simply because of the site or organism, and many people who get just one antibiotic have been very ill. Just what are "IV anticoagulants" (most are given orally or subcutaneously), and why are they any more meaningful or relevant than those given orally or subcutaneously?

We strongly recommend having only one list, and omitting the second list to avoid singling out or prompting certain treatments. As mentioned above, a dataset such as this one should remain neutral, and not select or imply that various treatments are more important, meaningful, or worthy of reporting or listing separately. At most, we recommend using some of the items in the text of instructions as examples of Procedures that could be listed in Part C.

E - Medications. We can understand asking for a list of medications that the patient is receiving. We agree that medications present considerable risks, and are aware that the literature indicates that adverse consequences due to medications are common. But we are unclear about what it to be gained by requiring the dose, route, frequency, and planned stop date. For many postacute patients, medications and doses change frequently during their stay. All of this information is on the physicians order sheet, which is already updated monthly or more often. If there were some way to correlate medications and doses with changes in condition and various medical outcomes such as return to hospital, this might make some sense. We cannot identify any meaningful analyses that could arise from recording such detailed information intermittently, especially in what is often a dynamic situation.

We recommend getting a complete list of medications but not requiring dose, route, and frequency every time this tool is redone, unless there is a clearly identified way to derive meaningful conclusions from having such information.

F - Allergies and adverse drug reactions. Does this mean current, previous or both? ADRs often relate to medication combinations as well as to individual medications, and ADRs often consist of multiple simultaneous symptoms such as dizziness and falling, or dry mouth and increasing confusion. However, the current format does not appear to allow for that to be captured accurately or completely, as it seems to imply or presume that there is always a one-to-one relationship between a medication and a reaction. What is meant by "Patient Reactions,"? Does that mean to describe an ADR in detail?

We recommend changing the allowable entry format to be consistent with clinical realities related to medications and adverse consequences related to medications.

G - Skin Integrity. In G1, what is meant by "a formal evaluation?" How is it to be distinguished from an "evaluation?" Proposed answers 1 and 2 appear to relate to a question such as, "Was the patient identified as being at risk for developing pressure ulcers?" That is different from the existing question and from answer choice "0."

For G3, it is important in caring for wounds to record measurements. But, we are unclear about the purpose in this dataset of asking for measurements for the largest ulcer. What meaningful conclusions could be made from such limited information? We believe

that this dataset should not substitute for, or repeat unnecessarily, valid pressure ulcer documentation tools in the medical record.

In G5 (Major Wounds), why does it only ask for major wounds with complications? Is there a reason to omit major wounds without complications?

We recommend changing the wording of these questions to make them more precise and consistent, and removing the requirement for information that is not likely to lead to meaningful interpretation of results. We would be pleased to assist you in this wording should you choose to accept our comments.

H. Physiological Factors.

Regarding H5, vital signs and pulse oximetry are measured in patients repeatedly, sometimes many times per day or week. Appropriate clinical practice requires that vital signs and pulse oximetry be interpreted in the proper context, both relative to previous results and to the patient's overall status. We cannot identify a clinically valid purpose for asking everyone to record the most recent vital signs and pulse oximetry on every patient. These would be relatively static results in an often dynamic situation.

For H13-H18, we cannot discern a clinically valid purpose for requiring a WBC result, as it cannot be readily interpreted without other clinical information, including the patient's current clinical condition. This information belongs in the medical record, and it is unclear what purpose it serves to repeat it in this dataset.

- For H19 and H20, while albumin and prealbumin tests are popular among some clinicians, recent literature has challenged their value and pertinence in relation to managing nutritional status, especially in those with a recent or current acute illness. In acute illness, albumin is suspected to be a marker of inflammatory processes, much more than of nutritional status (see, for example, Covinsky KE, Covinsky MH, Palmer RM, Segal AR. *Serum albumin concentration and clinical assessments of nutritional status in hospitalized older people: Different sides of different coins*? Journal of the American Geriatrics Society, 2002;50:631- 637). What is the purpose for including them on this list, and what interpretation could be made from having them documented on this tool?

- For H21, what interpretations could be drawn from having an INR listed, without being able to correlate it with other things about the patient?

Very few laboratory tests by themselves permit clinically valid conclusions to be drawn, without adequate clinical correlation.

We recommend reducing the list of laboratory and diagnostic test results to those that legitimately reflect or can clearly help identify causes and consequences of a patient's symptoms and condition.

Section IV. Cognitive Status

We question whether the title of this Section is correct. Only some of the items in this section are about "cognitive status." This is a very imprecise term for this section.

We recommend changing it to "Cognition and Behavior" and moving some of the items, as noted below.

A. Comatose. A1 asks about "persistent vegetative state," which is not the same thing as "comatose." A patient can be comatose and not be in a PVS. This is imprecise language.

Levels of consciousness (alert, lethargy, stupor, and coma) are really neurological designations more than they are cognitive ones.

We recommend moving this item to Section III. Medical Items.

B. Brief Interview For Mental Status

- We were surprised that this dataset would include a specific tool to evaluate mental status, thus apparently requiring everyone to document it in addition to or instead of other valid and longstanding instruments such as the MMSE. We cannot discern the purpose of doing so, and cannot identify why this is needed in addition to the items in Section C.

We recommend asking questions about mental status in a way that does not imply or require using a specific instrument.

C. What is the meaning of "observational assessment of cognitive assessment?" There are various objective measures of recall and memory. So, why is this tool asking for subjective opinion ("seems or appears")? Why not just ask for information that can be used as an objective assessment of cognition?

We recommend clarifying the purpose of these questions and the basis for having a mix of questions based on subjective criteria that don't necessarily relate to other, more quantitative items on the topic.

D. Confusion Assessment Method. We question the coding designations, as they appear to all relate to "behaviors." However, disorganized thinking (D2) is about cognition, which is not generally referred to clinically as a "behavior." Altered level of consciousness (D3) is about level of consciousness, which is not generally referred to clinically as a "behavior."

We recommend that the terminology of the coding choices be changed to be more precise, and that questions about level of consciousness be combined (see above) and moved to Section III, as they primarily reflect neurological status.

E3. We are puzzled as to why this section is labeled as "Other disruptive or dangerous behavioral symptoms not directed towards others." Isn't this just an unnecessarily convoluted way of saying, "Dangerous self-directed behavior?" Behavior either affects self or others, or both.

Furthermore, since when does pacing by itself qualify as a "disruptive or dangerous behavior?" It is often specifically described as a behavior that should not be considered pathological unless it is intrusive into the lives of others or dangerous to the well-being of the individual or others.

We recommend changing the language to be more precise.

G. Pain. We are puzzled as to why questions about pain are in a Section entitled "Cognitive Status." It is more properly placed under "III. Medical Items."

G3. Pain severity. There are 2 conflicting instructions in this Section. The patient's pain severity is to be entered on a scale of 1-10. But "8" is to be entered if the patient does not answer. This would conflict with entering "8" if the patient's pain is 8 on a scale of 1-10. It would not be possible to distinguish the basis for the answer "8" in this box. There is no indication in this section about whether the level of pain control is compatible with the target for pain management for a patient. It is known that pain cannot always be completely resolved.

We recommend moving questions about Pain to Section III. Medical Items, and correcting the scale, as above. We recommend adding a question as follows, how does the current level of pain control compare to the pain management goals for this patient. For example, if this level of pain is consistent with the goal, there could be a check box for that and if this level of pain is not consistent with goal, there could be a check box for that.

Section V. Impairments

The title of this section is "Impairments." The questions appear to refer primarily to "functional impairments." There are other kinds of impairments, such as impairments of the heart, lungs, kidneys, etc.

We recommend changing the language to be more precise.

C. Swallowing. C2a, C2b and C2c are questions about food intake, not about swallowing. There are various other reasons besides a swallowing disorder for needing modified consistency diets or supervision with eating. There are various other reasons for having a feeding tube that have nothing to do with swallowing. They either don't belong here or they should not be labeled as questions just about swallowing.

These questions appear to reflect the current beliefs among many in various health care settings that equate symptoms or problems related to eating, chewing, or swallowing as somehow reflecting a swallowing disorder. That is incorrect, and there is substantial evidence in the literature to contradict this way of thinking, despite its prevalence (see, for example, Smith PA. *Nutrition, Hydration, and Dysphagia in Long-Term Care: Differing Opinions on the Effects of Aspiration*. J Am Med Dir Assoc 2006; 7:545-549). For example, any of these symptoms could reflect oral conditions, dental problems, or various problems related to adverse consequences of medications. These questions appear to perpetuate that limited viewpoint, and should be modified to be clinically correct.

We recommend changing the language to be more precise, and removing any hint of bias about the meaning, origins, or implications for appropriate interventions of various nonspecific symptoms.

D1. The heading is "Hearing, Vision, and Communication Comprehension." However, this does not cover D2, which is about expression.

We recommend changing the heading to reflect the scope of questions.

H1. Respiratory status. These choices describe medical symptoms related to an organ system, and really belong under "III. Current Medical Items."

We recommend moving questions about Respiratory Status to Section III. Medical Items,

I. Endurance. The questions relate to mobility and endurance and sitting endurance. But what about general endurance (i.e., ability to tolerate overall activity)? That is an important question, which should be asked either here or in "III. Current Medical Items."

We recommend making the language more precise and including questions about overall endurance (that would cover factors such as physical endurance and activity tolerance) in Section III. Medical Items,

Section VII. Engagement.

A1. Engagement. We are puzzled about the origins and validity of the scale used in A1. The entire scale appears to imply that there is a problem with someone who "questions the value of activities," and that the more they question, the more problematic they should be considered. This seems to contradict the reality that people have the right to question or not to agree with some or all of the proposed plan of care, and that the proposed plan of care is not always relevant or problem-free. Scores 3 and 4 seem to equate "questioning the value of activities" with "having difficulty with frustrations." What is wrong with expressing frustrations or disagreeing with care? A more valid issue is the "degree to which the individual participates or fails to participate in care," which could be due to any number of reasons ranging from medical condition effects to adverse consequences due to medications to a personality disorder. The choices offered here are imprecise and value laden, and appear to be based more on interpreting nonspecific behavior than on seeking the root cause for that behavior (i.e., "refusing care"). It is not uncommon for individuals who "refuse care" or won't take their medications to be referred for psychiatric consultations without adequately considering the source of the behavior. We do not believe that it is appropriate practice to imply such value judgments or draw erroneous conclusions about the intention or meaning of challenging or disagreeing with care.

We recommend changing the language, as suggested above, to make it more precise, removing these portions about questioning the care and reworking this entire section. If the issue is whether or not the individual participates in care consistently, then that can be reduced to a single question, without so many judgmental options.

Section VIII. Frailty / Life Expectancy

We suggest that these are not really questions about "frailty," but rather about prognosis. Studies over many years have revealed various factors that can help predict prognosis (mortality, return to hospital, etc.) and longevity. So, we wonder why these are the only questions dealing with prognosis.

We recommend changing the language, as suggested above, to make it more precise, and considering identifying other items such as those in Section III that are known to be relevant to prognosis.

Section IX. Discharge Status

C1. We are puzzled by this question, especially since it asks for a conclusion based on unclear criteria. There is a big difference between just asking the patient and actually evaluating the costs and options for obtaining medications. We doubt that such