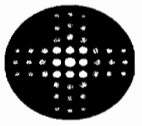

September 21, 2007

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

Subject: CMS-R-249, CMS-10238, CMS-102,105, CMS-10243 and CMS-10244

Dear Ms. Harkless,

Thank you for the opportunity to comment on the proposed changes to the Medicare home health OASIS document and the CARE tool. Gentiva Health Services (Gentiva) is the nation's largest provider of comprehensive home health services, delivering annually to approximately half a million patients in 36 states. Gentiva strongly supports the efforts of the Centers for Medicare & Medicaid Services (CMS) to refine the current OASIS tool and to include process measures, where appropriate and useful for ensuring better overall care to our patients as well as a minimal burden to our clinicians.

Gentiva has been a strong advocate for further development of evidence-based home health-specific measures as the next evolution to the OASIS tool. As better clinical processes and treatments are applied uniformly to the care of our patients, the end result should focus on achieving better overall outcomes for the patient. Furthermore, the transition to evidence-based measures will likely also help to break down the healthcare "silos" between providers and establish patient-centric care, ensuring the best care possible by each setting. Therefore, we applaud the effort by CMS to undertake the implementation of process measures and the potential development of a CARE-like tool for all post-acute care providers.

With regards to the outlined process measures for the 2009 OASIS tool, Gentiva would like to recommend a change to the M1140.

Gentiva's recommendation is to reword the OASIS question M1140 to say, "Has this patient had a Fall Risk Assessment?" and the answers be re-worded to offer responses of:

- "Yes, and it does not indicate that the patient is at risk for falls";
- "Yes, and it indicates that this patient is at risk for falls", and
- "No falls risk assessment conducted".

The rationale for our recommendation is that there are valid and reliable fall risk assessment tools that consider multiple factors by evaluating function through direct observation rather than by asking a series of questions. An example is the Timed Up and Go test, an assessment tool commonly used by physical therapists to screen for fall risk. Additionally, we have found that training nurses to perform the Timed Up and Go test improves the accuracy of their assessments of ambulation, dyspnea, pain and cognitive ability because of the direct observation required when performing this assessment.

We cite the Timed Up and Go test merely as an example of a valid measurement test though there may also be others. We feel the goal should be gaining results which identify patients at risk rather than specifying features of the assessment tool that should be used.

Finally, Gentiva is very interested in monitoring the PAC demonstration project as it is implemented in 10 sites across the country. If the demonstration is successful, we are hopeful that it will result in better overall patient care with a focus on an exchange of patient information from the onset.

Gentiva does not have any specific changes to recommend for the proposed CARE tool. However, we would like to offer these few basic and overarching recommendations.

1. **Utilize health information technology**. Gentiva believes strongly that the development of evidence-based home health criteria is integral with the use of health information technology. In order for clinicians to focus their time and energy on excellent patient care, their paperwork burden should be reduced as much as possible. We believe it is imperative for the PAC demonstration to include an electronic format that allows providers to access and complete their data in a timely fashion. The use of an electronic format will also reduce the burden to all clinicians by eliminating current wasteful and cumbersome use of paper formats. It is important to note that vendor selection for this aspect of the project may become a project in itself. Another important consideration is that the vendor be required to meet the standard. An assumption is made here that IT standards are developed, and that they potentially be able to support multiple platforms.
2. **Provider Information Exchange**. With the goals of the PAC demonstration project to seek uniformed data sets and payments for post-acute care providers to achieve better patient care, it seems one of the most critical areas is with the hospital data. In order to improve care coordination, Gentiva is urging that the demonstration project ensure that hospitals (and in fact all providers) release detailed information contained in the PAC to the next care provider as soon as they begin planning the patient's transition. Incomplete data when planning the admission of the new patient to a home health agency leaves gaps in the treatment reduces efficiency and is a barrier to providing the highest quality care.

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NFCA®

September 24, 2007

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

Re: Comments on Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument
Document Identifier/Form # - CMS-10243
OMB # - 0938-NEW
Federal Register – vol. 72, No. 144, pgs, 41328-41329 (July 27, 2007)

Dear Ms. Harkless:

The National Family Caregivers Association (NFCA) appreciates the opportunity to comment on the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. NFCA commends CMS for this effort to standardize assessment for hospital discharge and post acute care. We believe that use of the CARE instrument will improve hospital discharge planning and post-acute care and outcomes for Medicare beneficiaries with chronic conditions.

We urge CMS to add a caregiver assessment to the CARE instrument. Such an assessment is essential when the feasibility of a patient's discharge plan depends on a family member or friend to provide the care. It is important to remember that 80% of all long-term care is provided by family caregivers and not in institutions by professionals. More than two thirds of seniors needing care get it solely from a family caregiver.[1] Despite this a caregiver assessment is not needed in all hospital discharge and post acute care situations. The Post Acute Care Payment Reform Demonstration, that will use the CARE instrument, provides a unique and immediate opportunity to determine which questions within the CARE instrument can be used to identify the hospital discharge and post acute care situations in

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[1] Health and Human Services, *Informal Caregiving: Compassion in Action*. Washington, DC: Department of Health and Human Services. Based on data from the National Survey of Families and Households (NSFH), 1998 and [1] National Family Caregivers Association, *Random Sample Survey of Family Caregivers*, Summer 2000, Unpublished and [1] National Alliance for Caregiving and AARP, *Caregiving in the U.S.*, 2004.

which a caregiver assessment is essential and to develop a protocol for this purpose.

The National Family Caregivers Association is the nation's only organization for family caregivers reaching out to all family caregivers regardless of their loved one's diagnosis. NFCA provides an authentic understanding and viewpoint of the family caregiving experience and is a powerful spokesperson for family caregivers. NFCA offers a broad range of programs and services for people family caregivers of persons with chronic conditions and as their voice to Congress.

Hospital discharge is often a very difficult process for caregiving families because there is a lack of understanding of the role that family caregivers play and a desire on the part of hospitals to keep hospital stays as short as possible. Family caregivers are improperly informed, educated and trained even though they must manage complex medical treatments and prescribed medications, diet, exercise, and other care for their loved one. A study by the United Hospital Fund clearly points this out.[2] Here is a comment from a family caregiver who participated in the study.

> *'I was terrified of it[an electronic feeding tube)...It's broken twice. When we left the hospital they showed me 1,2,3, and that's it.' They said, 'Don't worry, you'll learn it.'*

The National Family Caregivers Association strongly urges CMS to add a caregiver assessment to the CARE instrument and to use the Post Acute Care Payment Reform Demonstration, which will incorporate the CARE instrument, to determine which questions within the CARE instrument can be used to identify situations in which a caregiver assessment is essential.

In 2005, the Family Caregiver Alliance conducted a national consensus conference on caregiver assessment.[3] One outcome of the conference was consensus that caregiver assessment should be conducted in situations where the feasibility of a patient's discharge plan depends on a family member/friend. Conference participants agreed that caregiver assessment should be part of hospital discharge planning for Medicare beneficiaries, but that not all hospital discharges require such an assessment. They agreed that a protocol should be developed to determine when Medicare should require a caregiver assessment as part of a "safe and effective discharge."

The CARE instrument includes many questions that instrument could be used to identify the hospital discharge and post acute care situations in which a caregiver assessment is essential. It is possible that a few additional questions should be added and some existing questions should be adjusted to assure that caregiver assessment is conducted in the discharge and post acute care situations in which it is essential, but the total number of additional questions should be limited to avoid unnecessary burden for the person, the family, and hospital and post acute care staff members.

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[2] Levine, Carol, Rough Crossings: Family Caregivers' Odysseys through the Health Care System. New York: United Hospital Fund (2000) 9, 11-13.

[3] Family Caregiver Alliance. *Caregiver Assessment: Principles, Guidelines, and Strategies for Change: Report from a National Consensus Development Conference.* (San Francisco, CA: Family Caregiver Alliance, April 2006).

Section IX now includes a question about whether the patient currently has one or more caregivers who are both "willing and able to provide the necessary care." Instructions for assessors should state that this question must be asked explicitly of the caregiver(s) rather than being answered on the basis of the patient's comments or staff observation. In addition, the question might be made more specific by referencing patient care needs that are identified earlier in the CARE assessment, for example, need for assistance with medical items from Section III, functional impairments from Section V, or activities of daily living from Section VI. The caregiver could be asked, for example, whether he or she is willing and able to provide assistance with wound care, toileting, or medication management, if the assessment indicated that the patient needed such assistance.

Reports from the Family Caregiver Alliance Consensus Conference include valuable information about the domains that should be included in a caregiver assessment and how the assessment should be conducted. We would be happy to work with CMS to select an assessment instrument to be added to the CARE instrument for evaluation in the Post Acute Care Payment Reform Demonstration.

The opportunity created by the Post Acute Care Payment Reform Demonstration to develop and test a protocol to identify hospital discharge and post acute care situations in which a caregiver assessment is needed should not be wasted. We hope CMS will act quickly to make use of this opportunity.

Thank you for your consideration of our suggestions. If we can be of any further assistance, please feel free to contact me at 301 942 6430 or suzanne.mintz@thefamilycaregiver.org

Sincerely,

Suzanne Mintz
President/Co-founder

American Congress of Rehabilitation Medicine

6801 Lake Plaza Dr., Suite B-205 • Indianapolis, IN 46220

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September 24, 2007

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

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

Dear Ms. Harkless:

We are writing on behalf of the American Congress of Rehabilitation Medicine (ACRM) to comment on the proposed CARE Tool for a Uniform Post-acute Patient Assessment Instrument. Founded 84 years ago, ACRM is a national membership organization whose primary mission is to advance research and evidence-based practice in post-acute rehabilitation across all settings of care. Our membership is comprised of researchers, academicians, administrators, and clinicians, most of whom are associated with an academic or clinical care setting. Many work in both.

A significant number of our members have conducted years of research related to functional status measurement, rehabilitation outcome measurement, patient classification systems, and prospective payment systems. These topics and others like them are also front and center in our annual meetings and publications.

ACRM is also one of the original sponsors of the Functional Independence Measure (FIM) that is currently embedded in the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) and used as the basis for Medicare's prospective payment system (PPS) for inpatient rehabilitation facilities. In the mid 1980s, ACRM joined forces with the American Academy of Physical & Rehabilitation Medicine

(AAPM&R) in cosponsoring the task force that created today's FIM. Hence, ACRM and its members remain major stakeholders in the FIM's future use and its possible successor.

Although the FIM continues to serve as an important post-acute measurement tool, ACRM believes that a more robust patient assessment tool is needed to measure more adequately the medical needs and functional status of patients served across post-acute settings. As researchers and clinicians, many members are keenly aware of the FIM's relative strengths and limitations and believe that the time is right to move on to a new generation of patient assessment technologies although there are features of the FIM that are well worth incorporating into a new patient assessment instrument. Thus, we applaud CMS's commitment to develop a new post-acute patient assessment instrument.

We believe that a new tool can aid greatly in enhancing post-acute placement, quality monitoring, outcome assessment, and payment. That said, we believe that there are several risks in the development of a new uniform patient assessment instrument such as the proposed CARE tool as well as several potential shortcomings. These risks and shortcomings need to be mitigated and are not insurmountable.

The greatest risk is that the tool will become much too large and unwieldy. It is an instrument that is designed to:

- Assist in post-acute placement
- Assist in care planning
- Determine payment
- Monitor quality
- Evaluate outcomes

Moreover, it is an instrument that is intended be used

- In both acute and post-acute care
- Across all post-acute settings
- Across all diagnostic groups
- Across a variety of medical and functional domains

Combined, these multiple purposes comprise an enormously tall order for any one patient assessment instrument.

The developers of the CARE tool have wisely reached out to all the current stakeholders who individually and collectively have invaluable insights. Where possible, the project development team has attempted to build on current tools used in post-acute care. Each of today's three legacy tools (i.e., MDS, OASIS, IRF-PAI) represents years of development, arises from a distinct professional and institutional culture, and reflects additional years of investment in information systems technology, database development, training, and quality monitoring systems. There is much to be said for building on the best of what each legacy tool of care

provides now. Our fear, however, is that in doing so, CMS will try to please all and satisfy none. The great risk is that we will develop an unwieldy one-size-fits-all tool that tries to cover all the bases.

In discussions with the CARE tool project team, ACRM learned that the application of the tool will include a degree of modularity and many skip patterns to minimize respondent burden and cost of administration. We believe that modularity and skip patterns will not be enough and that more thought needs to be given to the use of computer adaptive testing technologies that can calibrate patient function and status more quickly. We understand that many acute and post-acute facilities may not be adequately computerized and thus will not be able to take full advantage of these assessment technologies. Nonetheless, we believe that CMS needs to make a commitment from the outset to migrate the tool from a paper-based one to an entirely electronic one within three years if the tool is going to succeed. CMS will also have to provide hospitals and facilities both technical assistance and the resources to implement such an ambitious system.

Ten criteria for a more adequate and robust patient assessment tool

Our organization and its members individually can provide commentary on each of the major domains used in the CARE tool, the various scales and measurement instruments embedded in the tool, and the wording of individual data elements, and the like. This we will continue to do informally with the developers of the CARE tool. More importantly, we believe there is a need to remain focused on the criteria that should inform the tool's development and implementation. We offer here a tentative list:

1. The tool must be valid for each of the purposes it is intended.
2. The tool's various components must be reliable across settings and raters.
3. The tool should maximize continuity of care.
4. The tool should minimize opportunities for gaming.
5. The tool should minimize administrative complexity.
6. The tool should minimize respondent burden.
7. The tool should encourage a rational organization of medical and rehabilitation capacity.
8. The tool should be allowed to evolve and mature over time as experience is gained and as measurement technologies evolve.
9. The tool and the system underlying it should be made inter-operable with other electronic platforms such that multiple users can easily gain access to the resulting database with due protection for patient privacy.
10. The tool and the system underlying it should foster transparency, i.e., public disclosure of quality and outcomes in order to encourage best practice and evidence-based policy.[1]

[1] The first 7 criteria listed come from a Delphi survey of post-acute stakeholders reported in a paper by Sherri Tepper, Gerben DeJong, Deborah Wilkerson, Ruth Brannon (1995) entitled "Criteria for the Selection of a Payment Methodology for Inpatient Medical Rehabilitation." ***Archives of Physical Medicine and Rehabilitation***, 76 (April), 349-354. While meant to apply to the development of a post-acute payment system, these criteria have equal

We believe that, over the long run, these criteria are mutually reinforcing. We invite others to add or modify this list. We believe that, to the extent to which we keep these criteria in mind, we can achieve a more parsimonious patient assessment instrument and a more rational post-acute care system that can better meet the needs of the diverse patients seen in post-acute care.

Criteria 8, 9, and 10 warrant additional commentary.

With respect to Criterion 8, we believe that the CARE tool should be allowed to evolve over time. We believe that this is possible while maintaining the comparability of new data with historic patient-level data collected earlier in the tool's life despite changes made in wording of individual scales. There is a need to refine the scales and measurements embedded in the tool as we gain experience with them. Item banking and computer adapted technologies can assist in doing so. We need to avoid "instrument lock-in" and should not make retooling an over-burdensome task. Once an opportunity for improvement emerges, post-acute providers should not remain stuck with an instrument or scale, or portion of the CARE tool indefinitely because the tool was not sufficiently robust to accommodate new insight, new scaling technologies, new patient populations, and new experiences resulting from its application across the patients and settings.

Criterion 9, interoperability, is important in order to encourage innovation in the use of the data. In the IRF industry, for example, eRehabdata has taken the use of patient assessment data to an entirely new level that is user friendly to its subscribers. While there is a need for a common electronic platform supported by CMS, we should not preclude 3rd parties from applying new information technologies that can lead to new and better uses of the data in enhancing patient care, research, and policy development.

Criterion 10, transparency with respect to quality and case-mix adjusted outcome, is important in order to aid patients, family members, and the public to make informed choices about their post-acute placement. We believe that such transparency will encourage providers to work toward best practice and can also serve as the foundation for a rational and transparent pay-for-performance system. As an organization committed to research, evidence-based practice, and evidenced based policy, ACRM believes that Criterion 10 should be a key feature of the new post-acute patient assessment system.

In closing

ACRM applauds CMS's attempt to bring greater rationality to the nation's diverse, disparate, and sometimes disorganized post-acute care system. There certainly is a need for developing a uniform patient assessment for post-acute care. The desire to develop a one-size-fits-all instrument should not undermine diversity of the current post-acute system. Our current post-acute system is indeed dysfunctional and suboptimal but its diversity should also be viewed

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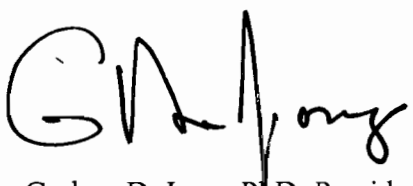
relevance here. Interestingly, these criteria have also been invoked in other commentary submitted to CMS regarding the CARE tool.

as a national strength not merely as a system failure. We believe that the nation can develop a more rational system for post-acute care and, with the right tools, do so without regards to today's artificial post-acute boundaries. ACRM is prepared to assist the CARE tool team in any way it can.

Thank you for this opportunity to comment on the proposed CARE tool.

Sincerely,



Gerben DeJong, PhD, President
American Congress of
Rehabilitation Medicine

Gregory Worsowicz, MD, Chair
Ad-hoc Committee on Post-acute Patient Assessment
American Congress of
Rehabilitation Medicine

cc: ACRM Board
ACRM Research Policy & Legislation Committee

September 24, 2007

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

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

Dear Ms. Harkless:

The National Association for the Support of Long Term Care (NASL) is a trade association representing providers of both ancillary services and products to the long-term care industry. Our member companies provide speech-language pathology; physical, occupational and respiratory therapy; portable x-ray/EKG and ultrasound; pharmacy; long term care (LTC) software systems; and other ancillary services. NASL members also provide products such as complex medical equipment; parenteral and enteral supplies, equipment and nutrients; and additional specialized supplies for post-acute care settings nationally.

NASL has been following the implementation of the Post-Acute Care (PAC) Payment Reform Demonstration program since it was mandated by the *Deficit Reduction Act of 2005*. We recognize that the CARE Tool issued through this Information Collection Request is intended for use in a short-term and relatively small demonstration program that is voluntary in nature. However, since it represents an initial step in the agency's plans for developing a uniform patient assessment instrument that could be used across all acute and post-acute settings, NASL would like to offer the following comments. Our comments include general concerns about the CARE Tool and specific concerns about information technology interoperability.

General Comments

NASL supports the development of a global approach for assessing patient severity, resource utilization and outcomes across acute and post-acute settings, but a single assessment tool requires careful balance between maximizing the collection of comparable information while minimizing the reporting burden. The CARE Tool must be viewed as merely the first step in a cooperative and evolutionary process of developing this global approach to patient assessment, but the agency needs to better articulate its goals for the CARE tool. Is it intended to be a hospital discharge placement tool, a payment tool and an outcomes measurement tool all in one?

Stakeholder groups from industry and health care professional organizations are concerned that the agency intends to adopt the CARE Tool as its "one size fits all" assessment instrument. This would be an unrealistic approach that raises clinical, reimbursement and data analysis concerns.

The CARE Tool has several key flaws, ranging from a lack of a definition of terms to a lack of consistency in the rating scales used in determining functional status. Therapy services are an essential component in the provision of patient care in post-acute settings. Therapy professionals specialize in improving functional capabilities in patients, and the CARE Tool should be refined to further recognize the importance of functional status in assessing patient needs. We understand that therapy professional organizations will be submitting comments with specific recommendations for improving the CARE Tool, and we hope that the agency will be receptive to these comments.

Current therapy assessments are generally discipline specific. NASL is leading an effort to document therapy use and intensity for the individual and combined disciplines. The data being studied for this initiative encompasses approximately 12 percent of the total population that received Medicare Part B therapy in SNF settings during 2004. We would be pleased to share our results with CMS upon completion of our current research project.

Another pressing concern that must be addressed by the agency is how a patient's needs will be assessed during the continuum of treatment. The CARE Tool only calls for completion at admission and discharge. However, the current MDS allows for reassessment five times during 100 days to account for a beneficiary's changing resource needs, while the home health care OASIS allows for reassessment every 60 days.

Periodic reassessment is an essential ingredient in measuring resources and outcomes. In issuing Transmittal 52 regarding the therapy cap exceptions process last year, CMS outlined requirements for documenting medical necessity and a plan of care. In that transmittal, CMS went in great detail on the need to document evaluations, subsequent re-evaluations and progress reports. How will the CARE Tool accommodate reporting requirements already established by CMS regarding the interim progress and needs of patients?

Health Information Technology

NASL notes with approval that the system is being developed as an interoperable data system meeting CHI standards and allowing for the CARE tool to be merged with other components of a provider's record system. However, we are concerned that CMS has decided to develop its own separate software reporting tool rather than simply establishing specifications that could be met by the industry. The use of this separate tool set outside the rest of the industry solutions could result in a set of data that is not compatible with industry standards and existing automation strategies.

Conclusion

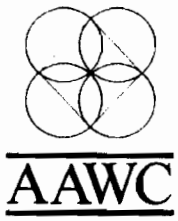
NASL recognizes that in order for CMS to conduct the PAC Demonstration project, it must move forward with an assessment tool. However, we urge CMS to proceed with the initial use of the CARE Tool in a cooperative spirit in full recognition that further refinements and improvements are vital to the agency's goal of developing a global patient assessment tool.

Thank you for your consideration of these comments. We welcome the opportunity to work with CMS on the issues concerns we have raised in this document. Please feel free to contact me by telephone at (703) 549-8500, or by e-mail at clendenin@nasl.org with any questions that you may have regarding these comments.

Sincerely,

Peter C. Clendenin

Peter C. Clendenin
Executive Vice President



ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE

September 19, 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

Dear Ms. Harkless:

AAWC appreciates having the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the draft Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. AAWC is a non-profit, 501c3 organization, dedicated to the multidisciplinary approach to wound care.

With nearly 1800 members from diverse medical specialties, AAWC exists to build a collaborative community to facilitate optimal care for the millions of patients who suffer with wounds.

Section II. Admission Information

- **Section A2: Admitted From.**

  AAWC suggests the following additions:
  - "Short stay (less than 24 hours)"
  - "Emergency Department with admission to the hospital"
  - "Emergency Department visit without admission to the hospital".

Section III, Current Medical Items

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

  AAWC strongly recommends adding Enteral Tube Feeding to this section. Enteral Feeding Tubes are medical devices and, as such, must be monitored for complications that could impact wound healing.

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

  AAWC recommends use of the NPUAP pressure redistribution nomenclature as is found at www.npuap.org which differentiates between "reactive" and "active" surfaces.

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

  AAWC recommends that "Complex Dressing Changes" be changed to "Complex Wound Management". Examples include, but are not limited to, wounds that require advanced wound interventions/modalities (growth factors, bioengineered skin substitutes, advanced wound dressings, negative pressure wound therapy, etc.) or wounds requiring significant clinical caregiver time/resources.

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

  - AAWC strongly recommends that "compression therapies" be added to the list of treatments.

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

  AAWC 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 valid and reliable risk assessment tool. Specifying a score with this tool would help serve as a reference point for other assessment tools that may be used.

  Additionally, 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 are at high risk for the development of a pressure ulcer. AAWC recommends that clinicians be directed to consider patients with non removable medical devices as high risk and be coded a "2" on Item G1.

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

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

  AAWC suggests that all the stages of pressure ulcers be included as 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.

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

  Deep tissue injury is a new label of pressure ulcers defined as a "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).

- **Section G2a. Stage 2**

  AAWC believes it is important to distinguish in the description of Stage 2 pressure ulcers that are true pressure ulcers and those that are a result of a skin tear, tape stripping, or incontinence associated dermatitis. AAWC recommends the description of a Stage 2 pressure ulcer include wording to ensure true Stage 2 ulcers only are recorded in this section.

- **Section G2c. Stage 4**

  AAWC recommends modifying the definition of a Stage 4 pressure ulcer to "Full thickness tissue with exposed bone, tendon, or joint capsule. Necrotic tissue may be present on some parts of the wound bed. Often includes undermining and tunneling." (NPUAP, 2007)

- **Section G2d. Unstageable**

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

- **Section G3.**

  AAWC 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.**

  AAWC recommends adding "undermining" in this data element. Our suggested wording would be "Indicate if any unhealed stage 3 or stage 4 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. In addition, venous leg ulcers are the result of chronic underlying etiologies related to chronic venous insufficiency. AAWC also suggests 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**

  AAWC recommends removing Item E "None of the above apply".

AAWC 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. If you have any questions, please do not hesitate to contact us through our Executive Director, Tina Thomas at 610-560-0500, ext. 223.

Sincerely,

John Macdonald, MD, FACS
President

William Ennis, DO
President Elect

Cc: Joanne Lynn, MD

HEALTHPOINT
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September 24, 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 leadership of the Medical and Clinical Affairs Department at Healthpoint Ltd. 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. Healthpoint, Ltd. is an operating company of DFB Pharmaceuticals, Inc. As a specialty pharmaceutical company, Healthpoint is uniquely committed to the prevention and treatment of diseased and traumatized skin and related soft tissue. We recognize that people suffering with wounds are eager to return to a better quality of life. We are steadfastly committed to helping patients with wounds by bringing new technology and education to the community.

As the primary author of this letter, I, Diane Cooper, have spent over thirty years caring for, studying, and conducting research related to wound healing, most particularly the treatment of chronic wounds. Most recently, I participated in writing the Wound Healing Society's Clinical Guidelines for Chronic Wounds. My two colleagues in the Department, both physicians, obviously have not only tended to individuals with wounds but, in their positions here at Healthpoint, work closely in formulating future research endeavors related to wound healing, as well as in educating key opinion leaders and clinicians using our products. Our interests span the gamut of the classically recognized chronic wounds (i.e., pressure ulcers, diabetic foot ulcers and venous stasis ulcers). Additionally we have a growing interest in an emerging diagnosis within healthcare, namely moisture associated skin damage (MASD). We view the latter diagnosis as an unmet medical need and definitely a need that will grow as the population ages. Recent publications support the reality of this diagnosis as unique and as requiring focused efforts to rectify it. The CARE Instrument affords CMS and all those concerned about tissue injury at any level the opportunity to ensure that assessments are thorough and that wounds of multiple etiologies are not overlooked. The Medical and Clinical Affairs Department at Healthpoint commends CMS for undertaking this very important and critical effort. Our comments emanate from the OMB 7/17/2007 draft of the instrument.

Comments:

Section G2. Add Stage I, as well as erosion as an etiology.

Suggest adding that, in addition to pressure as the cause, Stage I ulcers can also evolve because of shear, friction and erosion. Skin damage, secondary to urinary or fecal incontinence, is increasing as the public ages and control of bodily functions become compromised. Although historically these moisture associated skin damage wounds have been placed under the staging systems for "true pressure" ulcers (i.e., those directly attributable to pressure or a combination of pressure and shear, pressure and friction, pressure and moisture), there is a growing need for a separate diagnostic term for skin breakdown not caused by pressure but solely by moisture and, most often, not over a boney prominence. A separate diagnostic term is seriously wanting for MASD. Without it, confusion reigns, treatments are not focused, and clinicians are inappropriately held accountable for skin damage that is not related to a lack of relief of pressure. The diagnosis of MASD should be singled out, defined clearly and treatment algorithms formulated to improve identification of this unique problem and for MASD to assume its rightful place in the litany of skin and soft tissue injuries.

Most ideally MASD would be singled out with clear definitions of the extent of partial-thickness skin injury, location etc. There might be a directive requesting that the individual assessing the patient evaluate skin damage that is not over a boney prominence and is clearly present as a result of ongoing urinary and/or fecal incontinence, so that this untoward occurrence does not go unrecognized.

- **Section G2a. Stage 2**

Suggest that MASD be removed from the pressure ulcer classification. The CARE Instrument creates the opportunity to deal with an, as yet unaddressed issue, namely referring to all skin damage (i.e., partial thickness and full thickness) as pressure ulcers. Continuing to misname unique wound types when, in fact, clinicians are well aware that etiologies vary, only continues to avoid the issue. The CARE document could be the Instrument that moves clinical practice forward, where specific etiologies and targeted treatments for unique wound types are acknowledged.

If the decision is to continue with including many tissue injury types under the traditional staging classification, our recommendation would be to add:

Stage I ulcers can also evolve because of shear, friction and <u>erosion</u>. Skin damage secondary to urinary or fecal incontinence is increasing as the public ages and control of bodily functions becomes compromised. Although historically these MASD have been placed under the staging systems for "true pressure" ulcers (i.e., those directly attributable to pressure or a combination of pressure and shear, pressure and friction, pressure and moisture), there is a growing need for a separate diagnostic term for skin breakdown not caused by pressure but solely by moisture and, most often, not over a boney prominence. A separate diagnostic term is seriously wanting for MASD. Without it, confusion reigns, treatments are not focused, and clinicians are inappropriately held accountable for skin damage that is not related to a lack of relief of pressure. The diagnosis of MASD should be singled out, defined clearly and treatment algorithms formulated to improve identification of

this unique problem and for MASD to assume its rightful place in the litany of skin and soft tissue injuries.

* * * * * * * * * *

The Medical and Clinical Affairs leadership at Healthpoint appreciate 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,

Diane M. Cooper

Diane M. Cooper, PhD
Director of Clinical Affairs

Frank Strobl MD

Frank Strobl, MD, PhD
Senior Director of Medical Affairs

UNIVERSITY of VIRGINIA HEALTH SYSTEM

The DEPARTMENT *of* UROLOGY

September 24, 2007

CMS Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attn: Bonnie L. Harkless
Room C4-26-05
7500 Security Blvd
Baltimore MD 21244-1850

RE: Medicare Continuity Assessment Record and Evaluation (CARE Document)

To Whom It May Concern:

I am writing to provide comments for CMS Proposed Care document. Section G on page 14 covers skin integrity. It appropriately begins with an evaluation for presence of pressure ulcers. Currently it requires documentation of Stage 2 to 4 ulcers and it provides the possibility of an unstageable ulcer. However, two absolutely essential issues are missing in this section on skin integrity. The first is moisture-associated skin damage, which is not mentioned in this document. Moisture-associated skin damage can be defined as dermatitis and/or skin erosion associated with excessive moisture. Common clinical manifestations include incontinence-associated dermatitis, sometimes called perineal dermatitis, and intertrigo affecting skin folds and especially skin folds in the perineal area and groin. The inflammation and erythema created by incontinence-associated dermatitis is often confused with a Stage 1 pressure ulcer and many of these lesions are also associated with erosion, particularly when exposed to friction or when fecal incontinence is present with associated exposure of the skin to digestive enzymes. Differential of incontinence-associated dermatitis as compared to Stage 2 pressure ulcer is essential because each of these lesions has distinctive pathophysiology and each is treated differently. In the case of a Stage 2 pressure ulcer, pressure redistribution and topical therapies are indicated, whereas incontinence-associated dermatitis is based upon principles of cleanse, moisturize, and protect the skin from further irritantion with a skin protectant. In addition, a significant number of cases of incontinence-associated dermatitis are accompanied by cutaneous infections, especially candidiasis, which also requires unique treated compared to pressure ulcer management. Differential diagnosis of these conditions also forms an essential component of a pressure ulcer prevention program. Specifically, incontinence and/or the broader concept of moisture are included in all of the major pressure ulcer risk assessment tools, including the Braden, Waterlow and Norton Scales. Multiple studies have associated urinary and fecal incontinence with increased pressure ulcer risk and with slower healing of existing ulcers.

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The second issue that is not included in the CARE document is the presence of deep tissue injury, which is included in the National Pressure Ulcer Advisory Panel's latest staging system. While the pathophysiology of these lesions and their assessment continues to evolve, the presence of deep tissue injury is being documented by the NPUAP and the clinical reality of these lesions and their importance to pressure ulcer prevention is widely acknowledged among clinicians.

I have provided several references for incontinence-associated dermatitis and moisture-associated skin damage below. Thank you for your consideration of these matters. I believe the document can serve a very significant role and it will be strengthened by consideration and inclusion of these essential disorders affecting skin integrity.

Sincerely,

Mikel Gray, PhD, FNP, PNP, CUNP, CCCN, FAANP, FAAN
Nurse Practitioner and Professor of Nursing

Gray M. Bliss DZ. Doughty DB. Ermer-Seltun J. Kennedy-Evans KL. Palmer MH. Incontinence-associated dermatitis: a consensus. *Journal of Wound, Ostomy, & Continence Nursing. 34(1):45-54; quiz 55-6, 2007 Jan-Feb.*

Zimmaro Bliss D. Zehrer C. Savik K. Thayer D. Smith G. Incontinence-associated skin damage in nursing home residents: a secondary analysis of a prospective, multicenter study. *Ostomy Wound Management. 52(12):46-55, 2006*

Junkin J. Selekof JL. Prevalence of incontinence and associated skin injury in the acute care inpatient. *Journal of Wound, Ostomy, & Continence Nursing. 34(3):260-9, 2007*

Bliss DZ. Zehrer C. Savik K. Smith G. Hedblom E. An economic evaluation of four skin damage prevention regimens in nursing home residents with incontinence: economics of skin damage prevention. *Journal of Wound, Ostomy, & Continence Nursing. 34(2):143-52; 2007*

Anthony D. Barnes E. Malone-Lee J. Pluck R. A clinical study of Sudocrem in the management of dermatitis due to the physical stress of incontinence in a geriatric population. *Journal of Advanced Nursing. 12(5):599-603, 1987*

Gray M. Bohacek L. Weir D. Zdanuk J. Moisture vs pressure: making sense out of perineal wounds. *Journal of Wound, Ostomy, & Continence Nursing. 34(2):134-42, 2007*

Magee Rehabilitation
Jefferson Health System

September 24, 2007

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

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

Dear Ms. Harkless,
These comments are provided by senior therapy, nursing, case management and administrative staff at Magee Rehabilitation Hospital (Magee). Magee is a free standing Inpatient Rehabilitation Facility currently celebrating 50 years of providing inpatient rehabilitation services . Magee Rehabilitation Hospital comprises the rehabilitation portion for one of 14 federally designated Model Systems for Spinal Cord Injury care, and we serve approximately 1400 inpatients per year. Diagnostic groups served by Magee include brain injury, stroke and amputee patients, as well as spinal cord injury patients.

Thank you for the opportunity to provide comment on the proposed CARE tool referenced above. It is clearly a Herculean task to design a tool that can appropriately assess and objectively assign patients to the appropriate level of post acute care. The following comments are provided in the spirit of collaborating with CMS in order to assure that Medicare beneficiaries receive the appropriate level of care at the appropriate time and in the appropriate setting. Comments regarding the CARE tool are provided under the headings of **operational concerns**, **efficacy concerns**, **reliability and validity concerns** and **philosophical concerns**.

Operational Concerns:
Many portions of the proposed tool require report of information that is captured in the existing pre-admission, admission and discharge assessments for this IRF. Reproduction (data entry) of this information for purposes other than the design and implementation of care is a poor use of skilled professional resources. Using a lower level of worker to complete the tool is not an option, given the clinical assessment required by most items.

The time required for completion of the tool will vary widely, given both the complexity of the patient and the patient's ability to participate in the assessment. In our setting, we would anticipate a minimum of 1.5 hours of professional staff time involved in completion of each type of assessment, with interim and discharge assessments requiring at least an additional half hour. These time estimates are for time required in addition to the current process of evaluation and documentation. Provision of an admission, interim and discharge evaluation

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for each Medicare beneficiary served annually in our setting would require staff time equivalent to one full time employee beyond current staffing patterns. We are concerned about directing resources that would otherwise be used for direct patient care to the completion of a tool that is redundant with tools currently utilized for the planning and provision of that care.

The proposed system places free standing rehabilitation hospitals at a disadvantage as compared with hospitals that operate a rehabilitation unit within their physical plant, presuming that the latter have shared HIMs and documentation systems. Portions of the assessment that require detailed information from the referring acute hospital setting will be cumbersome for free standing hospitals to collect and report, as the free standing rehabilitation hospitals will not have the option of electronic transfer of that information. In particular, reports of ICD-9 codes from the preceding setting are not typically available at the time of discharge from that setting, and are not a portion of the clinical information reviewed in pre-admission evaluation. The clinical information that supports that coding **is** available, but the assignment of codes has not typically been completed at the time of transfer to the inpatient rehabilitation level of care. Again, freestanding hospitals will be at a disadvantage if it is necessary to request a change in work-flow at referring institutions in order to serve their Medicare beneficiaries.

Efficacy concerns:

One stated purpose of the CARE tool is to objectively identify the appropriate post acute care setting for a Medicare beneficiary who is in need of continued services. The current tool does not appear to provide information that would allow that determination. Specifically, there is no information concerning the plan of care for patients assessed by the tool. While deficits are reflected in some items and medical needs reflected in others, there is no portion of the tool that addresses the patient's potential for practical improvement or potential for reduction in the burden of caring for the patient. The need for medical intervention and monitoring is not thoroughly reflected in the tool. Though procedure codes are a portion of the data required by the tool, physician interventions provided in an inpatient rehabilitation setting are not reflected in procedure codes, which are primarily surgical and diagnostic in nature. While the list in section III.D. provides a snapshot of the medical resources required for the patient's care, it does not reflect the frequency or level of physician involvement. There is no aspect of the tool that addresses the patient's need for or ability to benefit from the provision of care by a communicating, multidisciplinary team.

Another stated goal for use of the CARE instrument is to identify post acute discharge placement. As currently designed, the instrument does not gather sufficient data on the social resources that often determine the medical safety of discharge to the community. This is a fundamental flaw in the design of the instrument, if it is to be effective in assignment of post acute discharge placement. Individuals with high medical needs and severe functional impairment can make gains through acute rehabilitation intervention that lessen the burden of care to a level that can be managed by some family and social systems outside of an institutional setting. A tool that does not measure each side of that equation will not accurately identify post acute placement, and will be biased toward institutional placement.

Reliability and validity concerns:

The CARE tool is comprised of portions of multiple other tools, and each of those tools has been devised for use in a particular care setting. Over years of use and development, each of

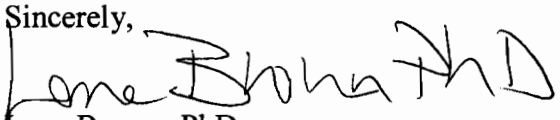
the component tools has a related data base and group of published studies outlining that tool's reliability, validity for its intended purpose, and limitations in that reliability and validity. The proposed combination of components from various tools and the alteration of those components from their source measures render all existing work on reliability and validity moot.
Though each brings limitations of its own, the component tools of the CARE have the requisite features to better support evidence based practice than a new tool (the CARE tool) that lacks even initial tests of reliability and validity. Existing data sets from the use of the component tools are also valuable resources for CMS and to the post acute field, in establishing evidence based practice. Rendering those data sets useless by a change in data collection tools seems a wasteful step backwards.

Philosophical concerns:
It is questionable whether a tool that is cobbled together from tools designed for disparate purposes can be used effectively for another purpose. While combination of existing instruments may be a reasonable starting place for the development of a new tool, there is intensive work to be done in assuring that the tool is in fact a good measure and predictor of the areas it is intended to measure and predict. Errors in assigning patients to the appropriate arena for post acute care are costly in terms of human potential and quality of life, as well as in financial terms. Medicare beneficiaries deserve the best tools to be used for that purpose.

The multiple intentions of the CARE tool are also of concern, as they are not necessarily parallel, and expectations for the predictive value of the tool are not conceptually sound. The Federal Register entry soliciting this comment states that the data from the CARE instrument will be "used to characterize patient severity of illness and level of function in order to predict resource use, post-acute care discharge placement and beneficiary outcomes." While there is some reason to expect that severity of illness and level of function could predict resource use, there is less reason to expect that the factors will predict appropriate setting or outcome, without data available concerning potential for improvement and more data concerning community resources. As noted above, the CARE instrument does not adequately assess these areas of potential for improvement and community support and resources.

It is our hope that CMS will take these comments into consideration in building the assessment tool for a setting neutral post-acute care payment model. Again, we appreciate the opportunity to review the proposed tool and to comment on it. We are willing to provide assistance and input as the process continues, and hope to have that opportunity.

Sincerely,



Lane Brown, PhD
Director, Case Management
Magee Rehabilitation Hospital
Philadelphia, Pennsylvania

Cc: Jack Carroll, President and CEO; Bob Kautzman, Vice President Clinical Services

American Hospital Association

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September 25, 2007

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

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

Dear Mr. Weems:

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

The CARE assessment has the potential to ultimately streamline hospital discharge planning across hospitals, improve consistency of patient data across settings, smooth patient transfers among general acute hospitals and post-acute providers, and provide for meaningful analysis of resource use by clinical condition and treatment. The CARE assessment also has the potential to assist in care-planning for patients who need post-acute care by identifying post-acute care that is most clinically appropriate for the patient. However, to achieve these potential benefits requires not only resources for providers facing this new, expanded process, but also requires that CMS address the significant concerns discussed below.

If the CARE tool becomes the mandatory patient assessment instrument for all post-acute admissions and discharges, it would have a major impact on post-acute care providers. But, the CARE process, as proposed, also would have major ramifications for general acute hospitals. CMS proposes to require that all general acute hospitals conduct a CARE assessment on every Medicare beneficiary being discharged. The tool would impose a huge resource burden on hospital nurses and other clinical and support staffs and, in many cases, the assessments would delay the discharge of hospital patients adding unnecessary burden to patients and cost and disruption to hospitals.

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

DISCHARGE PLANNING OVERVIEW

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

The list below summarizes the information typically provided to patients who need post-acute care after discharge:

- A written list of instructions that are specific to a patient's diagnosis or procedure and recuperative needs, such as when to resume normal activities.
- Follow-up appointment and contact information for physicians, physical therapy and other providers.
- Medication information including dosage, method, time, dietary considerations and possible side effects.
- Information on signs of potential complications and how to deal with them; and
- Contact numbers for additional advice or information.

IMPLEMENTING CARE DISCHARGE ASSESSMENTS

Most troubling to general acute hospitals is CMS' intention to apply the CARE instrument to *all* Medicare beneficiaries discharged from this setting. With more than 11 million beneficiaries being discharged from hospitals every year, this new mandate would require general acute hospitals to reallocate limited patient-care resources from direct patient care to the CARE process, which does not directly contribute to quality care for hospital patients, but rather is primarily designed to influence patient referrals to post-acute care. To require general acute hospitals conduct a CARE assessment for all Medicare discharges is excessive and unnecessary.

Hospital discharge planners already face tremendous pressure to discharge patients quickly in response to demand for inpatient beds. Adding the CARE assessment to this scenario would place further stress on busy nurses and other clinical and support staff by complicating and slowing down the discharge process. It is unreasonable for CMS to expect that general acute hospitals should substantially expand the current discharge planning processes without accounting for the nursing, technology, coding, therapy and other resources that would have to be dedicated to the new tool's requirements, and in many cases diverted from other patient-focused functions.

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

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

TIME ESTIMATES FOR CARE ASSESSMENT COMPLETION

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

Furthermore, review of the CARE tool by many general acute hospitals and post-acute providers raises doubts about the accuracy of CMS' preliminary time estimates for CARE assessments. If you consider the array of staff needed to complete the lengthy assessment, it quickly becomes apparent that a 15-minute assessment for even the most basic patient is highly improbable. The amount of time estimated by CMS is currently not available among the nurses, therapists, coders, physicians, and others who would be called upon to redirect their efforts from their existing core activities to a CARE assessment. As a result, many providers would need to hire additional staff, but many would not have the resources to do so. This expectation would be particularly burdensome for rural hospitals facing workforce shortages. For the minority of hospitals that could afford to hire additional personnel to conduct CARE assessments, nursing and therapist shortages would present problems.

To replace current patient assessment instruments with the CARE tool would require additional investment by hospitals *and* post-acute providers. For example, inpatient rehabilitation facilities would face an increase of approximately 150 assessment elements with the CARE tool beyond their current patient assessment instrument. And their new time requirement is estimated to be more than seven times greater than the current 40-minute average for an admission and discharge assessment. Given the hourly costs of the additional personnel who would be required to implement this major change, it is unclear at this point if the relative gains justify this significant additional resource investment.

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

HOSPITAL DISCHARGE TO POST-ACUTE SETTINGS

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

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

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

IMPACT ON PHYSICAL THERAPY RESOURCES IN HOSPITALS

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

INFORMATION SYSTEMS

We are concerned about how CMS intends for hospitals to integrate the CARE tool with their existing information technology. As of 2006, only one out of 10 hospitals nationwide had fully

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

REPRESENTATIVE SAMPLE NEEDED FOR DEMONSTRATION

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

DATA RELIABILITY

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

REDUNDANCY AND TIME INEFFICIENCY

The CARE tool will require many hospitals to re-institute manual and redundant data collection, which have been engineered out of internal protocols to promote efficiency and redirect staff

time to patient care. For example, the CARE instrument requires extensive medication and lab data, which for most hospitals would require very time-consuming manual data retrieval from separate internal data sources. For some hospitals such discharge information is already stored in multiple locations and the CARE tool would be yet another place this information is reported.

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

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

INCONSISTENT SCALES

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

CODING

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

FRAILTY/LIFE EXPECTANCY ASSESSMENT

Section VIII on Frailty/Life Expectancy asks reviewers "Would you be surprised if the patient was readmitted to an acute care hospital in the next 6 months?" And "Would you be surprised if the patient were to die in the next 12 months?" To respond to these unorthodox questions, discharge planners would, at least in part, have to rely on subjective judgment. The subjectivity

raises legal risks and potential ramifications for medical necessity determinations. If a patient were expected to "die in the next 12 months" would the hospital be questioned for providing extensive care? If the patient were expected to be "readmitted to an acute care hospital in the next 6 months" would the hospital be challenged for discharging the patient to a post-acute setting? Would patients have access to a hospital's life expectancy assessment? These sensitive questions should be addressed before they are implemented in the CARE tool.

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

Sincerely,

Rick Pollack
Executive Vice President

APTA
American Physical Therapy Association

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703 684 2782
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September 25, 2007

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

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

Dear Sir or Madam:

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

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

General Comments

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

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

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

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

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

Discussion of Specific Items in CARE Instrument

Section I. Administrative Items

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

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

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

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

Section II. Admission Information

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

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

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

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

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

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

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

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

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

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

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

Section III. Current Medical Items

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section IV. Cognitive Status

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

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

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

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

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

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

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

Section V. Impairments

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

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

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

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

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

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

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

V.J.

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

VI. Functional Status

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

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

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

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

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

VI. Functional Status- Supplemental Items

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

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

Section VIII. Frailty/Life Expectancy

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

Section IX. Discharge Status

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

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

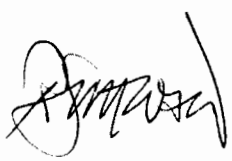
IX.B1
This questions asks who the patient lives with at discharge. It should be modified to include another option for "paid help not living in home."

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

Conclusion

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

Sincerely,



Scott Ward, PT, PhD
President

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 facilitate completion of the assessment. There also appears to be an abundance of questions about cognitive status. Perhaps this section could be streamlined.

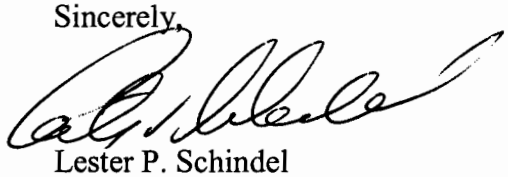
We do not anticipate any operational flow problems, other than as stated above, that this tool introduces new inefficiencies. Our experienced and highly qualified clinical and case management staff is currently able to determine the appropriate post-acute placement for patients without the use of a uniform assessment tool.

To the best of my knowledge, the proposed CARE tool would not interface with our existing information system and would require separate data collection and transmission.

It is unfortunate that the goal of measuring differences in patient severity, resource utilization and outcomes for post acute settings could not be achieved, in part, through use of the soon-to-be implemented MS-DRG methodology.

Thank you for this opportunity to comment on the proposed CARE instrument.

Sincerely,



Lester P. Schindel
President and CEO
New England Sinai Hospital

Curaspan
The eDischarge Company

70 Bridge Street, Suite 201 Newton, MA 02458 (781)492-8013

September 23, 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. Comments in support of the CARE tool.

Dear Ms. Harkless:

This letter is being writing 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 27, 2007, by the Centers for Medicare and Medicaid Services, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005.

I have been involved in Discharge Planning and continuity of care since the inception of the DRGs (1983) giving me 24 years of experience. In the mid 1980's there was an attempt by CMS, then referred to as HCFA, to have a Uniform Needs Assessment Instrument (UNAI). This effort was supported by the professional organization of which I was a member and individually myself and my nurse and social work colleagues. In fact, I still have a copy of the "Report of the Secretary's Advisory Panel on the Development of a Uniform Needs Assessment Instrument(s)" sent to Congress December 1992. A copy of the Draft UNAI is enclosed for reference.

My comments are in favor of the PAC-PRD, and in particular about the use of a CARE tool as outlined in the notice, are based primarily on the premise that it is time that patients be more accurately assessed for their continuing care needs as they move through this very complex health system. There are three main points in this letter:

1. The need for a 'predictive' assessment tool.
2. The need to address the requirements of PASARR /OBRA 1987 screening for MI/MR.
3. The use of information technology in the collection, transmission, and evaluation of data.

1. The need for a 'predictive' assessment tool:

The assessment of a patient for post-acute needs from a hospital is largely a process based on 'experience' (not evidence based, but practice based) on assumptions, availability and marketing.

- A discharge planner (DP), with or without years of experience, has no assessment tool to help 'predict' the most appropriate post-acute setting for a specific patient.
- The MDS, FIM, Oasis tools are not designed to 'predict' where the patient would best receive rehabilitation services.
- A hospital DP knows that a patient needs post-acute services, but is not have a way to make decision on which post-acute care setting other than a rough estimate based on number of hours of predicted therapy or nursing needs, or simply on what post-acute services are available at the time when the patient is ready for discharge, and in a geographic location that is suitable to the patient and family.
- Some states have forms that allow for the prediction of which RUGs (Resource Utilization Group) is likely to be assigned to a patient, but this is done only after the decision for discharge to a SNF (Skilled Nursing Facility) level has been decided. It an assessment could be used to predict which level is best for the individual patient prior to the decision it would be most helpful.
- Hospital DPs are driven by patient's best interest, and in attempting to manage length of stay. I believe DPs will applaud the ability to use a tool to help predict which of the many post-acute types of care would best suit the individual patient.
- **Recommendation:** keep up the good work!!! The categories in the tool that are assigned only as related to a specific level of care are well thought out, and I'm sure will be refined as the demonstrations move forward.

2. The need to address the requirements of PASARR (OBRA 1987 Section 4211 of the Omnibus Budget Reconciliation Act of 1987 (OBRA), which amended Title XIX of the Social Security Act to require screening for Mental Illness and Mental Retardation (MI/MR.) Because of PASSAR (Preadmission Screening and Annual Resident Review) requirements, the hospital DP must assess clinical eligibility requirements for the next level of care after the choice of which level is done.

- A PASARR Level I or Level II does not require an assessment for 'leveling' of the patient.
- Since PASARR contains mental health information about the patient, the need for privacy and confidentiality for transmission of the information would need to be considered.
- **Recommendation**: Review of the overlap of PASARR and CARE tools. If the PASARR requirement can be integrated into the CARE tool, collected and transmitted to each State agency, this would streamline the process of discharge even more.

3. The use of information technology in the collection, transmission, and evaluation of data.

I support the work of PAR-PRD) because the information technology support such a massive project. I believe the comments that will be submitted to CMS will be addressed at the *burden* of collecting the data because many DPs have not experienced web-based technology that streamlines work processes.

- The prototype powerpoint slide set was very informative and should be required viewing.
- The fact that known patient demographic fields will be pre-populated and other advances in data collection will be built into the tool will be important to DPs.
- The ability to track completion of the assessment form is a fantastic feature.
- My work with DPs in the collection and transmission of patient assessment data has spanned the last 8 years and I have seen first hand, that the more mature (age 45+/-) has a fear of technology. With hospitals moving to the EMR (electronic Medical Record) more DPs are comfortable with what automation can do.
- **Recommendation**: Any education how to use the CARE tool will need to start with even the most basic principles of 'point and click', and assurance that patient privacy will be honored.

Thank you for the opportunity to provide comment on such an important process.

Sincerely,

Jackie Birmingham, RN, MS

Jackie Birmingham, RN, MS, CMAC
VP Professional Services
jbirmingham@curaspan.com

Department of Health and Human Services
Health Care Financing Administration

DRAFT

ADDRESSOGRAPH:

ASSESSMENT OF NEEDS FOR CONTINUING CARE

I. SOCIODEMOGRAPHICS

Attach Admission Face Sheet. List the following information if not otherwise available.

A. Name (Last, First, Middle Initial):	B. Address:	C. Phone No.

D. Birthdate:	E. Sex ☐ M ☐ F	F. Marital Status: ☐ Married ☐ Separated ☐ Single ☐ Widowed ☐ Divorced ☐ Unknown	G. Religious Preference: ☐ Catholic ☐ Jewish ☐ Protestant ☐ Other ☐ Unknown	H. Date of Admission:

I. Race ☐ American Indian/Alaskan Native ☐ Asian or Pacific Islander ☐ Black ☐ Hispanic ☐ White ☐ Other ☐ Unknown

J. Education: (Highest Level Attained)

K. Employment Status: ☐ Employed ☐ Unemployed ☐ Retired ☐ Unknown

L. Health Care Coverage: Medicare: ☐ Part A ☐ Part B ☐ Medicaid ☐ Private ☐ Private Insurer (Specify _____) ☐ Veteran with service connected disability

M. Does the Patient Speak English? ☐ Yes ☐ No If no, primary language: _____

II. HEALTH STATUS

A. Reason for Admission:	B. Diagnosis(es) (Principal and Secondary):	C. Surgical Procedure(s)

D. Current or Recent Health Problems/Risk Factors that May Affect Post-Discharge Care Needs

☐ Heart Disease	☐ Head Injury	☐ Arthritis	☐ Falls/Unsteadiness
☐ Lung Disease	☐ Alzheimers/Other Dementias	☐ Contractures	☐ Impaired Vision
☐ Renal Disease	☐ Parkinsons/Other	☐ Amputations	☐ Impaired Hearing
☐ Diabetes	Neurodegenerative Disease	☐ Pressure Ulcer	☐ Substance Misuse: _____
☐ Cancer	☐ Phychiatric Disorder	☐ Obesity	☐ Non-Adherence with Therapeutic Regimen
☐ CVA	☐ Chronic Pain	☐ Food/Fluid Intake Problem	☐ Other: _____

E. Level of Consciousness: ☐ Alert (awake, responsive) ☐ Semi-conscious (lethargic, drowsy, obtunded or stuporous) ☐ Comatose (unresponsive)

F. Check Those Cognitive/Behavioral Factors that May Affect Post-Discharge Care Needs:

- ☐ Impaired Orientation (unaware of person, place or time)
- ☐ Impaired Memory (forgetful to the point of being dysfunctional)
- ☐ Impaired Comprehension (difficulty in understanding spoken or written directions
- ☐ Impaired Expression (difficulty in communicating needs verbally or in writing)
- ☐ Impaired Judgment (unsafe self-direction; inconsistency in care decisions)
- ☐ Depression (appears sad, helpless, hopeless; has difficulty with concentration, sleep and/or appetite)
- ☐ Delusions and/or Hallucinations (perceives what does not exist; thoughts of persecution, paranoia or grandiosity)
- ☐ Wandering (does not understand territorial constraints, leading to unsafe situations)
- ☐ Agitation (anxiety; restlessness)
- ☐ Physically Assaultive (strikes self or other, causing dangerous condition)
- ☐ Suicidal (HX attempts; verbalizes thoughts/plan)
- ☐ Unusual Behavior (inappropriate verbalization; reclusiveness; hoarding)
- ☐ Other: _____

G. Additional Information Regarding Patient's Condition that Affects Post-Discharge Care Needs:

III. FUNCTIONAL STATUS

See manual for complete definitions and instructions. Rate observed or reported performance only. Rating assumes patient is able to function safely.

A. Rate Level of Independence for the Following:

(Minimal assistance defined as including the need for supervision, verbal cueing or minimal physical assistance. Moderate assistance implies the need for physical assistance.)

Activities of Daily Living	Independent	Minimal Assistance	Moderate Assistance	Dependent	Assistive Device(s) Needed to Perform Activity
Eating (act of bringing food to mouth, chewing and swallowing)					
Bathing (bathing body, excluding back and shampooing hair)					
Dressing (setting out clothing and dressing entire body, including necessary prothesis/orthosis)					
Toilet Use (use of toilet, urinal, bedpan; includes cleansing self after elimination and adjusting clothing)					
Bowel Management (intentional control of bowel movements; includes use of agents necessary for bowel control)					
Bladder Management (intentional control of urinary bladder; includes use of agents necessary for bladder control)					
Transfer (transferring to and from bed, chair or wheelchair; includes coming to a standing position)					
Locomotion (includes walking, once in a standing position; using a wheelchair indoors)					

Check most frequent mode of locomotion at discharge: ☐ Walking ☐ Wheelchair

B. Additional Assistive Devices Currently in Use:

☐ Glasses
☐ Dentures
☐ Hearing Aid
☐ Other _____ (Specify)

C. Instrumental Activities of Daily Living (complete only if considering return to a community residence):

	Independent	Needs Assistance	Unknown
Meal Preparation (includes cooking food and setting up meal)			
Medication Administration			
Telephone Use			
Housekeeping			
Shopping			
Handling Finances			
Transportation Use			

D. Communication

Comprehension (Ability to understand auditory or visual communication)
- ☐ Able to understand directions
- ☐ Can follow directions with minimal prompting, repetition
- ☐ Has difficulty following directions, needs constant prompting
- ☐ Unable to follow simple directions

Expression (Ability to communicate basic daily needs)
- ☐ Expresses needs clearly
- ☐ Expresses needs slowly or requires minimal prompting
- ☐ Expresses needs with difficulty, requiring much prompting
- ☐ Unable to express needs

Usual Mode(s) of Communication
- ☐ Speech
- ☐ Writing
- ☐ Gestures/Sounds
- ☐ Sign Language
- ☐ Communication Device

E. List Restrictions that Would Affect Ability to Perform Above Functions:

IV. ENVIRONMENTAL FACTORS IN POST-DISCHARGE CARE

A. Usual Living Arrangements:

- ☐ House/Apartment
- ☐ Rented Room
- ☐ Board and Care/Personal Care Facility/Retirement Home
- ☐ Nursing Facility
- ☐ Other _____
- ☐ Alone
- ☐ With Spouse
- ☐ With Others (Specify) _____

Are noninstitutional living arrangements available? ☐ Yes ☐ No

B. Environmental Barriers

	Yes	No
Are there barriers to building entry/exit?		
Are there internal barriers? (stairs, narrow doorway)		
Is toilet/tub/shower accessible?		
Is the patient able to access emergency assistance?		
Other Barriers (Specify):		

Comments:

V. NURSING AND OTHER CARE REQUIREMENTS

Check Anticipated Needs for Continuing Care:

A. Therapeutic Needs:

1. **Skin:** ☐ Pressure Ulcer Care: _____ Stage _____ Site ☐ Drainage/Culture Care: _____

☐ Wound Care: _____ Stage _____ Site ☐ Drainage/Culture Care: _____

2. **Nutrition:** ☐ Therapeutic Diet (Specify) _____
   ☐ Enteral Feeding: ☐ Nasogastric ☐ Gastrostomy Frequency: _____
   ☐ Parenteral Feeding: Frequency: _____
3. **Hydration:** ☐ Encourage Fluids ☐ Restrict Fluids
   ☐ Intravenous Hydration Route: ☐ Peripheral ☐ Central
   Frequency: _____
4. **Respiratory:** ☐ Oxygen: ☐ Continuous ☐ Intermittent Frequency: _____
   Delivery Method and Liter Flow: _____
   ☐ Tracheostomy: ☐ Temporary ☐ Permanent Frequency of Care: _____
   ☐ Suctioning: Frequency: _____
   ☐ Ventilator: ☐ Temporary ☐ Permanent
5. **Elimination:** ☐ Urinary Catheter: ☐ Indwelling ☐ Intermittent
   Size: _____ Insertion Date: _____ Irrigation and Frequency of Care: _____
   ☐ Ostomy: Type and Frequency of Care: _____
   ☐ Dialysis: ☐ Hemo ☐ Peritoneal ☐ CAPD Treatment Frequency: _____
6. **Administration/Management of Medications:**
   ☐ Oral
   ☐ Subcutaneous/Intramuscular: Frequency _____
   ☐ Intravenous: ☐ Antibiotics ☐ Chemotherapy ☐ Blood Products
   Frequency: _____
   ☐ Implanted Pump: Frequency: _____
   ☐ Other: _____
7. ☐ Skilled Nursing Observation: _____
8. ☐ Supervision/Evaluation: _____
9. ☐ Other Care Needs: _____

B. Patient/Family Educational Needs:

- ☐ Self-Care Activities
- ☐ Self-Management of Illness
- ☐ Diet Instruction
- ☐ Medication Administration
- ☐ Ostomy Care
- ☐ Wound Care/Dressing Change
- ☐ Tracheostomy Care/Suctioning
- ☐ Other _____

VI. FAMILY AND COMMUNITY SUPPORT

A. Source(s) of Support:

Primary Support	Relationship	Type of Support (physical, psychological, social and/or economic)	Availability	Limitations or Constraints
Name:				
Address:				
Phone:				
Other Caregiver:				
☐ No Known Support				

B. Community Services Utilized Prior to Admission:

Home Health Services	
Homemaker Services	
Equipment/Supplies	
Meals to Homebound	
Transportation	
Adult Day Care	
Mental Health Services	
Hospice	
Respite	
Case Management	
Other _____	
_____	
_____	

C. Additional Assistance Needed (For Home Care):

_____

D. Physician Responsible for Follow-up Care (Name/Phone No.):

_____

E. Other Individual Responsible for Coordinating Care (Name/Phone No.):

_____

VII. PATIENT/FAMILY GOALS AND PREFERENCES

A. Patient's Goals and Preferences for Continuing Care:

B. Family/Caregiver's Preferences for Continuing Care:

C. Religious or Ethnic Practices that May Affect Needs or Preferences for Continuing Care:

D. Decision-Making Support:

	Already Has	Desires/Requires
Durable Power of Attorney for Health Care Decision-Making		
Living Will		
Guardian/Conservator		

E. Surrogate Decision-Maker (Name/Phone No.):

VIII. OPTIONS FOR CONTINUING CARE

A. Therapy/Service Needs:

- ☐ Nursing
- ☐ Respiratory Therapy
- ☐ Physical Therapy
- ☐ Social Work
- ☐ Occupational Therapy
- ☐ Mental Health
- ☐ Speech Therapy
- ☐ Other _____

B. Durable Medical Equipment/Supply Needs:

- ☐ Bed ☐ Siderails ☐ Trapeze ☐ Commode
- ☐ Walker ☐ Wheelchair ☐ Oxygen
- ☐ Other: _____
- ☐ Disposable Supplies: _____

C. The Following Options are Consistent with the Patient's Needs:

- ☐ Home (no additional services necessary)
- ☐ Relative's home
- ☐ Home with home care services (Specify Type _____)
- ☐ Outpatient (Specify Type _____)
- ☐ Adult day care
- ☐ Other community services (Specify Type _____)
- ☐ Rehabilitation facility
- ☐ Board and care/personal care facility/retirement home
- ☐ Nursing Facility
- ☐ Hospice

D. Needs/Options Have Been Discussed with: ☐ patient ☐ family/representative ☐ not discussed

Remarks:

Discharge Planner/Coordinator's Signature: | **Date:**

Providing healthcare and healing services with Christian compassion

Pella Regional Health Center

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www.pellahealth.org

Pella Medical Clinic
405 Monroe Street
Pella, Iowa 50219
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September 24, 2007

Bonnie L. Harkless
Center for Medicaid Services
7500 Security Blvd, Room C4-26
Baltimore, MD 21244-1850

To Whom It May Concern:

Pella Regional Health Center is a Critical Access Hospital serving the rural community of Southeastern Iowa. Having recently reviewed the presentation given on September 19, 2007 by feature staff and Barbara Gage, we felt the urgency to share with CMS concerns about the proposed new Continuity Assessment Record and Evaluation (CARE) tool.

Critical Access Hospitals were created by the 1997 Federal Balanced Budget Act to assure Medicare beneficiaries in rural areas have access to health care services which include acute, primary, emergency and long-term care. It was designed to allow more flexible staffing, simplify billing methods and enhance reimbursement, thus enabling small rural hospitals to continue to offer their services. This program was designed for an overall facility acute care average length of stay of 96 hours (3 days). In the Critical Access short stay setting a large amount of time is spent by nursing staff completing admission and discharge processes. It is our concern that this extensive evaluation tool would increase the amount of time needed for discharge and may delay a needed admission and or require transfers to other facilities related to bed unavailability. This could be very costly. It may also decrease the amount of time nurses have to spend educating and preparing patients for discharge. The depth of the questions on the tool indicate a professional nurse would be needed to complete accurately, resulting in staffing as well as financial challenge to smaller facilities. It would also require additional hours needed by hospital coding personnel.

Many patients are hospitalized less than 3 days, resulting in less than a 2 day admission and 2 day prior to discharge look-back period. Would these patients fit the criteria and would the evaluation be required?

We are concerned with the cost of software i.e. RAVEN and HAVEN. Would the CARE tool software be an additional cost to the facility?

We have completed the following questions per request of the American Hospitals Association (AMA):

- It would require 2-3 hours for a high-complexity patient.
- It would require 1-2 hours for a low-complexity patient
- We do not include the following in our discharge process; administrative items, admission information, current medical items exclude skin integrity, psychological factors, height and weight, laboratory studies, blood gases, cardiac studies, cognitive status, impairments, functions status, and frailty life expectancy.
- An additional 2.0 hrs would need to be added to our current discharge process to complete the new CARE tool.
- A Registered Nurse, Coder and Data Entry/Clerical personnel would be needed to complete the CARE tool.
- We routinely do not code until after discharge. Staff nurses have not been educated on coding. The only clerical person in each area is the unit secretary whose responsibility is patient care centered.
- Implementation of the CARE tool would delay discharges and possibly admissions, when limited in size to 25 beds. This could result in increased cost to Medicare related to transfers. It also could delay transfers to our skilled unit within our facility.
- During emergency transfers (this occurs frequently related to our critical access status and specialties hospitals within a 35 mile radius) they would not be done.
- The Case Managers already determine the appropriateness of discharge and or placement or services needed without use of the CARE tool.
- We are in the very early phases of interfacing with our documentation system and see many challenges ahead with financial a major concern.

We hope that the voice of current providers are active in your decision making process and would invite any opportunity to visit or share with you our concerns and or ideas for health care improvement in the future.

Sincerely,

Janet Naset-Payne M.S., R.N.
Director of Inpatient Services
Pella Regional Health Center
Pella, Iowa 50219
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jnaset-payne@pellahealth.org

Saint Luke's
Northland Hospital
SAINT LUKE'S HEALTH SYSTEM
saintlukeshealthsystem.org

September 24, 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 to respond to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) as well as the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released by CMS on July 17, 2007. I submit these comments on behalf of Saint Luke's Health System (SLHS) in the Kansas City Metropolitan Region. SLHS consists of eleven hospitals, several physician groups, and other medical services organizations in both Missouri and Kansas. Within these eleven hospitals, several post acute care services are offered, including three inpatient rehabilitation units, long term care services, and home care services.

The intent of CARE tool is to, 1.) standardize program information on Medicare beneficiaries' acuity at discharge from acute care settings, 2.) document medical severity, functional status, and other factors related to outcomes and resources utilization at admission, discharge, and interim times during post-acute treatment, and 3.) to understand the relationship between severity, functional status, social support factors, and resource utilization. We concur with the comments regarding the CARE tool and the intended uses as submitted by Carl V. Granger, M.D. with the Uniform Data System for Medicare Rehabilitation on September 17, 2007, and want to elaborate on a few points most concerning to SLHS. While we agree that a single tool is needed in the health care industry to quantify the post-acute care placement decision, unfortunately, this tool does not appear to be the best option. The playing field between inpatient rehabilitation units (IRFs), Skilled Nursing Units (SNUs), and Long Term Acute Care Hospitals (LTACHs) must be leveled. Unfortunately, this tool does not appear to accomplish that task.

First and foremost, the tool is being rolled out very quickly, with little time for the rehabilitation industry to review and respond to it in detail. Its implementation will have a significant impact on all facilities, and more time should be allowed for the health care industry to review this and discuss it.

Secondly, the form is much longer than needed, and will require increased personnel and other resources at each facility for its completion. Estimates throughout the industry vary, but it is apparent that when combined, the admission and discharge assessments will exceed a total of 2 hours per admission more than the current patient assessment instrument (PAI). For a facility with 250 admissions a year, that would be an additional 500 hours of time, or at least one quarter of a full time staff person (.25 FTE), which would be between $15,000 and $20,000 per year. Besides personnel, additional software integration with current electronic medical records will be required to avoid duplicate documentation. That additional cost remains undefined. Multiple form changes, staff training, etc. are also costs that have not been quantified.

Thirdly, the form appears to disregard the validity of the FIM, and even requests the most frequently identified performance, rather than the lowest performance. In FIM utilization, the FIM number represents the burden of care the patient presents, and provides a measure to all care providers—employed or family—regarding how much assistance is needed for an individual to safely function in a defined environment. It does no good for a patient to be discharged with a frequent performance of moderate assistance needed in transfers if maximal assistance of two is needed occasionally. When two people are needed, the most frequent performance is of no help to the wife that has been given the responsibility to care for her husband by herself. The most frequent performance does not capture the true burden that is needed to keep individuals, both the care provider and the patient, safe. Additionally, the FIM requires credentialing of staff to administer it appropriately; without a similar process once again, disparity throughout the industry will be created.

In addition, we are concerned with the lack of definition regarding the test sites for this initiative. Some materials describing the PAC-PRD and testing of the CARE tool indicate participation as a test site is voluntary. However, other materials indicate that some sites will be selected because of their location and other relevant factors. Clarification on this issue would be beneficial to the industry. Further, we encourage you to reconsider any action that would require participation in this study. The impact on facilities that are not prepared for this level of activity could be devastating to the provider and could create excessive hardship on that provider, such as a hospital struggling to operate and work through other regulatory burdens.

Again, we applaud the cause and support the initiative. Unfortunately more time is needed for all involved to review the CARE tool, efforts should be made to pare it down to a more manageable size, and usage of the FIM instrument would provide helpful outcome information and quantifiable comparisons between patients in different settings. This is a costly initiative for all involved, and it is imperative it be done accurately and correctly. We cannot afford to do otherwise.

Thank you for the opportunity to review and respond to the draft of the CARE tool and the demonstration project. Should you have any questions or would like additional information, please do not hesitate to contact me.

Sincerely,

Don Sipes
CEO, Saint Luke's Northland Hospital – Smithville, and
Vice President, Regional Services, Saint Luke's Health System

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September 24, 2007

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

Re: Comments on Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument
Document Identifier/Form # - CMS-10243
OMB # - 0938-NEW
Federal Register – vol. 72, No. 144, pgs, 41328-41329 (July 27, 2007)

Dear Ms. Harkless:

I am writing on behalf of Family Caregiver Alliance (FCA) in response to the Centers for Medicare and Medicaid Services' request for comments on the Medicare Continuity Assessment Record and Evaluation (CARE) instrument. For over thirty years, FCA has focused on supporting and sustaining family and friends who provide long-term care at home and in the community. FCA commends CMS for this effort to standardize assessment for hospital discharge and post acute care.

The CARE instrument and its use in the Post Acute Care Payment Reform Demonstration provides a great opportunity to promote caregiver assessment and to collect valuable information to help predict resource use, not only by discharge patients, but by their family caregivers as well. In order to do this effectively, we urge CMS to include a few additional questions about family members and other informal caregivers who will be providing care to patients once they return home or to the community.

As an organization that provides direct support services to caregivers in the San Francisco Bay Area and manages a nationwide caregiver call center, FCA knows first-hand the challenges that family members and friends face when their loved one is discharged from acute and post-acute care settings. Family caregivers are often left with little or no information about how to access resources or support services for themselves or the care recipients; they are often overwhelmed by the responsibilities suddenly before them; and they are often unprepared or unable to carry out tasks such as medication management, transferring and wound care and, in many cases involving dementia patients, to provide the necessary supervision required.

Therefore, it is imperative that family and other informal caregivers are recognized and supported in the discharge process. At the very least, family caregivers should be identified and noted in patients' charts, and they should be provided with referrals to resources where they might be able to find additional services or information. We are pleased to see that the CARE instrument takes that first step in identifying a patient's caregiver.

Beyond that, it is critical that in each case where the feasibility of a patient's discharge plan depends on a family caregiver, there is an assessment of the caregiver's needs, followed up by the provision of and/or a referral to appropriate supports and services. In 2005, FCA convened a national consensus conference on caregiver assessment with over 50 experts from the field.[1] Among other consensus items, conference participants agreed that caregiver assessment should be conducted during times of care transitions, such as when a care recipient is moved from hospital to home. More specifically, they agreed that caregiver assessment should be part of Medicare's "safe and effective discharge" planning from hospitals in appropriate cases.

The CARE instrument includes many questions that could be used to identify the hospital discharge and post acute care situations in which a caregiver assessment is essential. It may also be necessary to add some new questions or to edit existing questions in the instrument. In any case, it is important to use the opportunity presented by this information gathering tool to further explore the types of cases in which a caregiver assessment is beneficial for the caregiver and essential to ensuring that the care recipient receives quality care after discharge. From this information and analysis, a protocol could be established to determine when Medicare should require a caregiver assessment and how that assessment should be conducted. One useful resource for CMS is the principles and guidelines for caregiver assessment that resulted from the FCA-sponsored consensus conference, including information and guidance about the domains that should be included in an assessment, who should perform the assessment and how it should be conducted

In addition to helping establish a protocol for caregiver assessment, the CARE instrument also provides the opportunity for CMS to determine caregivers' information and service needs and the extent to which access to resources are currently being provided – or not provided – to caregivers when a patient is discharged. The *Federal Register* states that one use for the data collected with the CARE instrument will be to "predict resource use." Knowing the education, training and support needs of family caregivers charged with providing care to a patient upon discharge is important to helping physicians, nurses, medical social workers and others understand the types of services and information they should offer to family caregivers. Asking the right questions can also help to identify the steps that are already being taken to support family caregivers.

---

[1] Family Caregiver Alliance. *Caregiver Assessment: Principles, Guidelines, and Strategies for Change: Report from a National Consensus Development Conference.* (San Francisco, CA: Family Caregiver Alliance, April 2006).

In order to accomplish that, we urge CMS to add two to three additional questions to the CARE instrument under Section IX, Discharge Status, inquiring about whether resources or referrals to resources were made available to caregivers. Examples of such questions include:

- *Will the caregiver (identified in Questions B2) need support services, education or training in order to provide the necessary care? If so, what types? (i.e. respite, counseling, skills training (transferring, toileting, behavior management, etc.), support group)*
- *Was access to services made available to the caregiver, either through direct provision or referral to outside resources?*
- *Was a caregiver assessment performed? If so, who conducted it?*

Finally, Section IX, question B2 currently asks whether the patient has a caregiver "willing and able" to provide the necessary care. Assessors should be given further information as to exactly what "willing and able" means, and they should be instructed to ask this question of the caregiver, not answer it themselves based on the patient's comments or staff observation. Family caregivers are charged with many and varied caregiving tasks, and while they may be willing and able to provide basic care, they may require training and/ or assistance. The CARE instrument should be used to help determine what additional assistance they require – or flag them for further assessment – so they can provide the best care possible and help prevent further harm or injury to both themselves and the care recipient.

The CARE instrument and the Post Acute Care Payment Reform Demonstration present a great opportunity to develop and test a protocol to identify hospital discharge and post acute care situations in which a caregiver assessment is needed and to assess the types of support currently being offered – or not offered – to caregivers. We hope CMS will act quickly to make use of this opportunity. We would be happy to work with CMS in this effort, and we offer any assistance we can.

Thank you for your consideration of our suggestions. If we can be of any further assistance, please feel free to contact Amy Friedrich-Karnik at (415) 434-3388 or afriedrich@caregiver.org.

Sincerely,

Kathleen A Kelly

Kathleen Kelly, MPA
Executive Director

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

Comments on CMS-10243
CARE Tool

Dear Ms. Harkness:

The development of an assessment tool that is standard across all post acute settings for the Post Acute Care Payment Reform Demonstration project is aligned with home health agencies interests. Home health agencies have consistently sought to obtain the most complete data from the prior care sites for purposes of appropriate discharge planning to home and care management once in the home. The information sharing, which is the keystone of this project, is meeting a need of the home health industry.

Despite our support for the concept of a standard post acute care assessment form, we need to indicate our grave concern re: the ability of the home health industry to implement a third major change in a 4-year period. In 2008 PPS Refinement will be implemented. A significant revision of the OASIS assessment will be field-tested late this year and a report is due to CMS in September 2008. National home health organizations have indicated that an implementation date in 2009 is probable. Both these changes will significantly impact the documentation and billing systems of the home health industry. Home health clinicians will need a complete re-training on the OASIS assessment based on the number of items changed and revised. The Post Acute Care Payment Reform Demonstration project report is due in Congress in 2011. Many of the items in the CARE Tool are consistent with items in the revised OASIS (OASIS-C) and the plan of care. It is unclear whether the CARE Tool items would be extracted from these exiting forms. The home health clinician is already burdened with significant documentation requirements. We would not support the imposition of yet another document.

The following comments reflect our concerns re: items on the proposed CARE Tool assessment.

1. The discussion of the assessment process continually refers to the 2-day assessment period and the form includes the possibility of multi-disciplinary contribution to the single assessment. In an in-patient setting it may be possible for various disciplines to complete their portion of a single assessment tool. However, in home health the assessment of a patient has traditionally been individual to the discipline completing it. There have not been assessment forms completed by multiple disciplines. Input from another discipline is sought as part of coordination activities. OASIS guidance has been clear that the discipline noted on the OASIS needs to complete assessment based on their assessment of the patient at the specific time-point in question. The implementation of such an assessment requirement in home health would also be extremely difficult logistically. In addition,

since the unit of service in home health has always been the visit and not the number of days of service, which 2 visits would be considered for the 2-day assessment period?

2. The scoring of the patient's functional limitations assessed in the in-patient sites may differ from the home setting due to various environmental barriers, e.g., multiple changes in ambulation surfaces, obstacles due to furniture and clutter, lighting etc. These factors are not controlled as in the inpatient site and may impact on the patient's safety in the home environment.

3. Several items would be difficult to assess in the home setting:

   a. Mobility Endurance (#11): indicates a 50-foot distance for assessment. In many homes this distance is problematic.

   b. Mode of Mobility: The distances indicated (50-150 ft) for the ambulation assessment (B5a) may not be appropriate for a home setting due to the size and layout of the home. The wheeling response (B5b) also has the same issue.

4. Many of the items in the "Current Medical Items" section "D" treatments are only occasionally seen in the home setting. The lab items in section "H" are not usually available on referral data provided to home health agencies.

5. Using the initial visit for certain assessments in the CARE Tool will affect the accuracy of the assessment. The initial visit in home health is a quite lengthy due to the regulatory requirements. In some situations it may be too taxing an experience for an accurate assessment of certain patient characteristics. This is particularly true of the cognitive, confusion and mood assessments in the CARE Tool. In addition, for certain patients many of the behavioral issues in the assessment would need to be completed by report of the caregiver. A more accurate assessment of the patient's needs is often clearer on subsequent visits.

6. Certain items may require another discipline to complete for accuracy of assessment.

   (a) The Swallowing assessment in section "V" may more appropriately be completed by a Speech Therapist on certain diagnostic groups or may require information not immediately available. On the initial visit the modifications in diet would be based on the MD order and the report of the patient and caregiver. An in-depth assessment of swallowing would only be accomplished by the Speech Therapist at a later visit.
   (b) The assessment of ROM and grip will require more clearly defined choices so assessments by nursing and therapy professionals are consistent and accurate. This issue has been prevalent in OASIS assessments.
   (c) The guidance of the Wound Ostomy and Continence Nurses Society (WOCN) and the National Pressure Ulcer Advisory Panel (NPUAP) need to be factored into the instructions for these questions. A standard manner of assessment is required so that comparisons can be made between professionals and agencies. The assessment of skin and wounds is a particular challenge for therapists. This is another example of where consistency between professional types has been an issue with OASIS.

(a) Discharge care options: Many of the options in this item relate to in-patient settings. There should be an "N/A" option to be used when no further post acute care is needed. If the item is left blank, it may appear incomplete.
(b) Discharge Delay: Many of the options in "E8" do not apply to home health.

In summary, the use of a standard tool to determine appropriate post acute care will enhance the discharge process and promote both continuity of care and patient safety. However, the home health industry will have undergone two major changes during the study period of the CARE Tool. It would be hoped that the changes under PPS Refinement and the OASIS-C revision would be considered when designing the post acute assessment tool. Multiple system changes over the next four years may foster inaccuracy in the completion of assessment items and place a burden on both home health agencies and CMS.

Sincerely,

Ingrid Jimenez
Vice President for Operations

Kindred Healthcare

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

Dear Ms. Harkless:

Kindred Healthcare, Inc. is the largest provider of Long Term Acute Hospital ("LTAC") services in the nation. We are also a major provider of skilled nursing and rehabilitative care and feel we are uniquely situated to comment on and participate in the CARE demonstration project. Kindred's Chicago Hospital was a pilot site for the CARE instrument and we are very interested in continuing our participation in this demonstration.

We agree with and incorporate by reference the comments submitted by the Federation of American Hospitals and the Acute Long Term Hospital Association. The primary purpose of this comment letter is to summarize information on the operability of the CARE instrument and related issues. These comments have been shared informally with CMS's contractor, Research Triangle Institute.

Timeframe

Given that the CARE assessment will be used in a Demonstration Project starting this January 2008, it is almost impossible for any current healthcare provider applications to be changed prior to the start of the demonstration. What follows is general guidance for creating applications that will be used by providers. It is hoped that future implementations of CARE will incorporate these comments.

Freestanding Application

The initial CARE data entry application is a freestanding application that is being supplied to participants in the Demonstration Project. This makes sense for quick implementation and for healthcare providers who do not have much information technology already in place. However, it raises issue about workflow, data exchange and data ownership for organizations that manage their own technology and that have their own uses for the data.

AHIC Use Case – Quality Reporting

Provider organizations routinely report data to a variety of third-party organizations. The data is collected, abstracted or otherwise extracted from the systems of the healthcare provider organization. These systems directly support the routine care delivery and associated administrative processes and on-going quality improvement efforts. This data is then passed along to the outside agency.

This is the model describe in the AHIC Quality Use Case:

http://www.hhs.gov/healthit/documents/UseCaseQuality.pdf

The key features of the AHIC use case are that it allows for review of the data within the provider organization, use of clearinghouses and other intermediate data aggregators and delivery to various recipient organizations. The use case also includes supplying the information request definition to the provider organization as an initial step.

Workflow and Data Integration

Many health care provider organizations have systems for documenting and planning care. These are closely coupled with the care processes with various workflow tools to ensure that activities are performed at the appropriate time. An effort is made to minimize the number of different applications that an individual user must interact with. Every application change has the potential for actions to be skipped and to require redundant data entry (including possibilities of data entry error).

Ideally, extracting or abstracting information from the providers' operational systems meets any data reporting needs. This is the case for LTACH DRG-based billing where staff review the medical record and supply the ICD-9 codes that accurately code the encounter – the user only enters the codes, all the other data is already "present" in the application. It is also the case for SNF MDS assessments and associated RUG codes, where clinicians assess the individual over the specified time interval, reporting on the components of the assessment over time until the entire assessment is completed. At various points in the assessment, data, such as a list of medications, can be pulled in from other elements in the care record. In

addition, actions resulting from the assessment, such as the RAP's, can be used for subsequent care plans. Finally, the RUG code is passed along to a resident account application for billing.

Again, the advantage of a local application to the provider is that a tight coupling of data between the assessment and other applications is possible. In particular, it allows for the assessment to be completed using queries of other data known to the organization. Arms-length applications, even those that make use of data standards, require much more design effort to function smoothly with other applications.

Assessment Technical Specification

Providers run a mix of purchased and in-house developed applications. Both vendors and the healthcare organizations require access to detailed technical specifications so that they can implement the CARE assessment. These specifications would cover the presentation and logic of the assessment as well as the formatting of the data for transmission to the recipient organization.

The specification of the assessment itself includes the questions, the coding for answering the questions, any edit or consistency checks on the answers, "skip logic" and other requirements for presenting and completing the assessment. The data specification defines how the data is to be formatted and packaged for transmittal. The data specification can build on existing standard formats, such as HL7 or X12, or can be assessment-specific, such as the MDS.

Use of HL7 Messages

There have been discussions about making CARE "interoperable" and possibly using HL7 messages for some of the data, such as current meds and most-recent lab values.

Provider organizations have been using HL7 messages for many years. In general, an organization has messages dating from when that connecting applications were first installed – a variety of HL7 v2 messages, often with locally defined vocabulary. Almost all these messages are between applications within a single organization or follow negotiated agreements between healthcare partners.

Very few organizations are using HL7 v3 messages, although some are using other HL7 XML-based technology such as the CDA (Clinical Document Architecture), to package information to send outside the organization.

If the plan is to leverage the existing HL7 messages (as opposed to an organization's ability to set up new HL7 messages), then the ways in which those messages are used should be understood.

The existing HL7 messages in and between provider organizations are almost entirely event driven – a new patient is admitted, a new order is placed, a lab test is run. The message contains the data about that event. The most straightforward approach to send messages to a new application is to "T" or split the message to go both to its original destination and to the new recipient. Very few organizations use the query/response messages that are in the HL7 specification.

The CARE assessment asks for current medications. These are accumulated over time and are the result of much activity and logic – orders start and stop based on many conditions. Simply looking at the flow of orders between the ordering application and the pharmacy application (as would be seen in the HL7 messages), does not tell you if the order is active at a point in time (consider a medication that is only given once, the order becomes inactive when the med is given).

The rules for defining the "most recent" results for physiologic data are simpler but still present a challenge to the event-driven model. You only know what is most recent at the time the CARE assessment is completed. Messages that are communicating results must be accumulated to maintain history so that at any point in time they can be queried for the most recent value of a particular parameter. Some of the physiologic values being asked for, such as temperature or blood pressure, are not interfaced and thus are not currently available as messages to be re-routed.

It would certainly be possible to create new messages that contain the relevant data as part of completing the CARE assessment. This would be new work for the provider application to identify and package the relevant data. It would also require a transport methodology to get the data into the CARE application.

Use of Standard Vocabulary

There are many overlapping standards for vocabulary. While it is highly desirable to use these standards for CARE, the broad standard itself does not automatically ensure interoperability. For example, LOINC codes can and should be assigned to specific questions and their answers. However, as these codes are newly being created to match the specific CARE questions, they will not already exist in the provider systems but will have to be mapped to existing data usage if there is going to be any sharing data outside the scope of CARE itself. SNOMED, ICD-9, RxNorm and other coding standards will be appropriate to some of the questions in CARE. The use of standards will be helpful in working with the CARE data, but this discussion needs to be at the individual item level, not just in broad statements of interoperability.

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Data Ownership and Access

The Post-Acute Care Payment Reform Demonstration has stated that one of its goals is interoperability. Under this heading, there have been discussions about making data collected from the web-based tool available to the reporting healthcare provider, with or without benchmark results.

It is important that the healthcare provider retain a copy of the data supplied to others. Not only does this provide transparency to the whole process, it also provides a basis for resolving any data quality and interpretation issues.

Assuming a web application is used where the data is stored outside the provider organization, a simple automated process is needed to transfer the data back to the provider. This should not depend on additional actions taken by the person who completes the CARE assessment but built in to the organizational profile (to transmit the data when the assessment is completed) or use a query capability (so that the provider organization can set up their own automated process to periodically request data).

Looking to the Future – IHE RFD Profile

The various use cases of one organization requesting data of another is addressed by many of the IHE (Integrating the Healthcare Enterprise, www.ihe.net) profiles. All the IHE profiles create implementation guides that build on, and further constrain, existing standards. The RFD (Retrieve Form for Data Capture) profile addresses the use case of an organization supplying an electronic form to be completed using software on another system and the data from the completed form sent to a recipient organization. RFD seems to address at least some of the CARE data collection needs.

The profile uses XForms to represent the form and XML to package the resulting answers. The forms can be presented using a browser (with/without additional software). They can also, be selectively pre-filled by an intermediate application or managed in a complex manner.

The RFD profile is approved for trial implementations and a few implementations are being organized by CDISC (Clinical Data Interchange Standards Consortium, www.cdisc.org) to start over the next few months. These initial implementations will involve Life Sciences companies, healthcare providers and their EHR vendors.

The RFD profile might be a useful model for future CARE implementations.

This is a link to the RFD profile:

http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_RFD_TI_2007_08_15.pdf

* * * * * *

We appreciate the opportunity to comment on this notice and hope that the agency carefully considers the comments in this letter. If appropriate, we would welcome the opportunity to meet, at your convenience, to discuss our views. If you have any questions, please feel free to contact me at (703) 518-9900.

Respectfully submitted,

William M. Altman

William M. Altman
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AMERICAN
SPEECH-LANGUAGE-
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ASSOCIATION

September 24, 2007

Bonnie L. Harkless
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Division of Regulations and Development – C
Room C4-26-05
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Baltimore, MD 21244-1850

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

Dear Ms. Harkless:

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association representing over 127,000 speech-language pathologists, audiologists and speech-language and hearing scientists qualified to meet the needs of the estimated 49 million (or 1 in 6) children and adults in the United States with communications disorders. We appreciate the opportunity to comment on the Centers for Medicare Services (CMS) supporting statements submitted to the Office of Management and Budget (OMB) related to the Medicare Continuity Assessment Record and Evaluation (CARE) instrument. While we support the agencies efforts in the development of such an instrument, we are concerned that the current iteration lacks the sensitivity to fulfill its intended purpose and will adversely affect the availability of services for individuals with communication and cognitive impairments.

General Concerns

According to the Supporting Statement, the CARE instrument is intended to be used to "document medical severity, functional status and other factors related to outcomes and resource utilization..." ASHA is concerned that these multiple objectives cannot be successfully achieved by a single tool; and that the time and resources spent beta testing the current tool will not yield information that can successfully predict the most appropriate post-acute placement for patients with very diverse profiles. We are concerned that a "one-size-fits-all" approach is unrealistic from a clinical, reimbursement, and data analysis perspective.

Lack of Sensitivity to Assess Communication and Cognitive Status

ASHA finds that the current tool does not appropriately measure an individual's cognitive or communication status. To illustrate how the proposed tool cannot capture the needs of

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individuals with communication disorders, nor be used to measure outcomes in any way, a patient scenario is provided in Attachment A. The shortcomings of the CARE instrument become obvious when considering how the items would be compromised by a communication disorder. Further, the omission of assessing reading and writing skills limit the information about an individual's functional status that can be obtained from this tool.

In terms of assessing cognitive status, ASHA believes that the items included provide only a limited overview of memory and attention and do not address the functional impact of cognitive disorders. For example, the instrument does not measure basic safety questions, such as an individual's ability to recognize danger or call 911, which could lead to inappropriate placement of the patient.

ASHA strongly believes only discipline-specific assessments can assess severity and measure outcomes in any functionally and statistically meaningful way. The limited item scales used in the tool for communication, swallowing, and cognition are not only insufficient to determine functional status, but they have no value as outcome measures. In other words, one of the basic purposes – outcomes measurement – of the instrument is not achieved.

ASHA's National Outcomes Measurement System (NOMS) has been recognized in CMS' Documentation Guidelines as an accepted tool for measuring outcomes. Additional information on NOMS can be found in Appendix B. Not only does NOMS use seven-point rating scales that make it comparable to other outcome tools, but the rater selects only the scales that are relevant to functional deficits displayed by an individual patient. In an online application with drop-down menus, NOMS allows for collection of data with much greater specificity and relevance without adding space on a paper tool. To see how NOMS data can be used to effectively capture functional abilities, again refer to the patient scenario in Appendix A.

Inter-Rater Reliability Concerns

ASHA also has concerns about the accuracy of the data based on who completes the CARE tool. Although the majority of the tool may be appropriate for completion by a nurse, the Functional Status section (VI) should be completed by rehabilitation professionals from the appropriate discipline for patients who are identified as having any deficits in this area. The Functional Status section should include items relevant to functional cognition, communication, and swallowing (Functional Communication Scales from ASHA's NOMS) rather than, or in addition to, assessing them in other sections of the tool. As noted above, limited item scales provide no useful information in terms of severity, resource allocation, or outcomes.

ASHA recommends the development of a glossary and training manual at a minimum to ensure some level of consistency. A number of items are ambiguous and lack objectivity (i.e., "Would you be surprised if the patient were to die in 12 months?"). Inter-rater reliability will be seriously confounded by items such as these.

Summary of Overall Concerns

- ASHA believes this tool cannot be successful in its implementation for its stated purposes.

- ASHA believes that certain patient groups—particularly individuals with communication, swallowing, or cognitive problems—will suffer a disadvantage because this tool is not adequate to assess their resource needs or be sensitive to changes in outcomes.
- ASHA recommends that functional items for communication, cognition, and swallowing be placed in section VI—Functional Status so that they can be rated on a 7 point scale. ASHA's Functional Communication Scales from NOMS can be used or modified to meet this objective.
- The tool lacks an assessment of critical safety skills that would be relevant for consideration of a home discharge, such as the patient's judgment and ability to recognize an emergency situation, call 911, communicate pain, and comprehend written directions. The World Health Organization's *International Classification of Functioning, Disability and Health,* which has been endorsed by the Institute of Medicine and widely implemented in Europe, recognizes the importance of such critical functional activities.

Response to Specific Items in CARE Instrument

II. Admission Information

A2 – CMS should consider better defining Short Stay acute hospital (#3) and Long-term care hospital (#4). In addition, #4, Long term care hospital may need to be clarified.

B3 – ASHA suggests that CMS add another option "Paid help not living in the home" to this list.

B5e Functional cognition: The examples for assessing prior cognitive functioning are too broad (i.e., taking medication and shopping). ASHA recommends rating two levels of functioning: one for basic safety awareness (taking medications, recognizing an emergency, using stove; and one for a higher level (e.g., money management, making and keeping medical appointments, developing a shopping list).

B7 – History of falls – ASHA recommends that the wording of this question be changed to "Has the patient fallen within the past year", or "Has the patient had "two or more falls in the past year or any fall with injury in the past year". This revision will add clarity to the question.

B8 – Prior Mental Status – ASHA recommends eliminating the word 'acute', because the change in mental status can be gradual or acute. The new language would read: "Is there any evidence of a change in mental status."

III. Current Medical Items

ASHA recommends that "tube feeding" be added to the list of treatment options in subsection D. Patients will present with a requirement of tube feeding.

IV. Cognitive Status

The items in this section do not provide sufficient information to rate cognitive impairment for the purpose of discharge placement, resource allocation, or measuring outcomes. This section

relies on a few objective items (e.g., ability to state the date and recall three items) to arrive at a highly subjective estimate of short term memory and long term memory impairment. The items are too rudimentary to predict functional cognitive ability that would help identify the most appropriate post-acute placement or the patient's potential to benefit from rehabilitation. At best this section may indicate the presence or absence of cognitive impairment. If cognitive impairment is identified, functional items should be added to the Functional Status section (VI) to assess safety awareness for basic and higher level tasks.

ASHA recommends assessing basic alertness and level of consciousness as a screening tool for functional cognition. Patients who can respond verbally could be asked for orientation to time, place, and reason for hospitalization. Functional memory could be screened by having the patient discuss family members, work history, or where they have lived in the past in order. ASHA suggests asking items such as "What would you do if you smelled smoke?" or "What would you do if you couldn't get out of bed?" to screen daily decision making.

V. Impairments

Items related to swallowing in section C1 describe signs and symptoms of a swallowing disorder while items in C2 indicate method of nutrition and hydration. Neither section, however, offers information about the severity of the swallowing disorder or can be used to measure outcomes. At most, information in this section can be used to trigger a referral to a speech-language pathologist for evaluation. Moreover, the tool fails to gather any other information about nutritional status that could be critical to the patient's health and post acute discharge (e.g., risk for malnutrition or dehydration).

For section D, the heading "Impairments – Hearing, Vision, & Communication Comprehension." "Communication Comprehension" is unclear and should read "Impairments – Hearing, Vision, and Communication." ASHA's concerns about the items in this section have been described in other areas of these comments and are also illustrated in the patient scenario in Appendix A.

VI. Functional Status

Communication should be included as a supplemental functional ability (VI. Section C) for patients who had a therapy consultation or who will need post-acute care or personal assistance following discharge. Communication is the foundation of most tasks and activities and has a profound impact on a person's functional abilities. The patient's ability to communicate is not adequately detailed in the Impairment Section and cannot predict needed resources or track outcomes. See ASHA's recommendation above about incorporating Functional Communication Measures from ASHA's National Outcomes Measurement System. We believe that a more sensitive measurement system is needed if the CARE tool is to meet its goals.

Many items in Supplemental Functional Ability are too specific—they assess different levels of cognitive and physical ability but neglect other important ones. For example, is it useful to evaluate ability to "wipe down surface" if the individual cannot perform other household cleaning tasks? Placing and receiving telephone calls are a combination of communication, upper extremity, and cognitive abilities—it is not clear why these two items were selected, since the

content of the phone calls are not described. This should be replaced by a more functional item such as "Call 911 and provide name and address."

These supplemental items do not capture the individual's cognitive ability to recognize the need to perform these activities and the ability to plan when to perform them (e.g., to shop, prepare a meal, do laundry, or make a phone call). Also, these tasks do not capture the patient's cognitive ability to recognize and perform activities that are critical to the patient's safety, such as calling 911, making medical appointments, or turning off the stove.

VIII. Frailty/Life Expectancy

A. This question is poorly worded ("would you be surprised?") and may have poor reliability depending on who is performing the assessment (if not the patient's physician). If there is a reason to retain this question, reword it to "Based on this assessment, how likely is the patient to be readmitted to an acute care hospital in the next 6 months? And: How likely is it that the patient will die in the next 12 months? Responses would be: Very likely. Somewhat likely. Not likely at all. Not assessed. Unknown.

IX. Discharge Status

B. If this tool is to determine how much assistance a patient would need to be discharged into the community, then **IV Cognitive Status, item C4** should be expanded to capture the frequency of assistance needed for daily safety and decision-making needs.

Thank you for the opportunity to provide comments on the CARE instrument. Should you have any questions regarding our comments, please contact Ingrida Lusis, ASHA's Director of Health Care Regulatory Advocacy, at 301-571-0482 or via email at ilusis@asha.org.

Sincerely,

Noma B. Anderson, Ph.D.
President

Appendix A

Possible Patient Scenario

Case history

Patient is a 73 year-old female who is two weeks post-onset of a left-hemisphere stroke. As a result, she has mild to moderate weakness of her right arm and leg, a moderate receptive language deficit, moderate to severe expressive language deficit, and moderate speech deficit due to dysarthria. Deficits appear to be more pronounced for spoken than written language, although writing is problematic due to right hand weakness. Swallowing function is remarkable only for minimal food and liquid spillage from her mouth due to muscle weakness on the right side of her face. She can tolerate a regular diet. She was admitted to a rehabilitation hospital from acute care and is now being considered for discharge to another level of care.

For the purposes of this appendix, an explanation of the patient's findings is entered in parentheses.

Issues related to assessment using the CARE tool

Section IV. Cognitive Status

Item	Initial Assessment	Discharge Assessment
B1. BIMS Interview Attempted?	**0. No**	**0. No**
B1a. Indicate reason that BIMS interview was not attempted.	**2. Communication disorder** (Patient was initially unable to respond to even simple commands or produce single words)	**2. Communication disorder** (Patient now able to follow simple commands and produce a few spontaneous words but still unable to repeat words or answer simple questions due to language deficits)
C1 – 4. Short-term and long-term memory; recall; decision-making	**8. Unable to assess**	**8. Unable to assess**

Comments:

At both admission and discharge from acute care, this patient's communication disorder precluded an assessment of cognitive status. No mention is given on the CARE tool to attempt to elicit responses via written means. This patient has less impairment for written language and may be able to demonstrate some cognitive functions if presented with printed choices (particularly for items B3a, B3b, and C3), although consultation with the speech-language pathologist would be necessary to make this determination. For other aspects of cognitive status (sections D-G), some determinations could be made from behaviors observations but responses may not be reliable if elicited verbally. Discharge decisions would be made, however, with very limited information about this patient's true cognitive status, which may well be intact.

Section V.D. Impairments – Hearing, Vision, and Communication Comprehension

Item	Initial Assessment	Discharge Assessment
D1. Understanding verbal content	**2. Usually/sometimes understands** (patient will respond to some simple yes/no questions and one-step commands with cueing; may even respond verbally to questions such as "how are you?" with an appropriate response of "fine")	**2. Usually/sometimes understands** (patient now able to respond consistently to yes/no questions and follows one-step commands without cueing; continues to have difficulty following conversations or following more complex commands)
D2. Expression of ideas and wants	**2. Exhibits difficulty** (patient produces 1-2 words and is difficult to understand – approximately 50% intelligible)	**2. Exhibits difficulty** (patient now producing short phrases and intelligibility has improved to near 75% for 1-2 word phrases)

Comments:
One intended purpose of the CARE tool is for outcomes measurement. Without sensitive measures, however, true outcomes cannot be documented. The lack of sensitivity of a 3 point scale is evident in this scenario. This patient's comprehension of spoken language improved from admission to discharge but is not captured by the tool. She is now able to understand longer commands which will have a positive impact on her ability to participate in her rehabilitation program. However, this is not captured in the scale as currently designed. As mentioned before, no consideration is given to written forms of language but since her reading comprehension is stronger than her auditory comprehension, she may have even stronger functional skills in this area than can be reflected on this tool. Without appropriate sensitivity, or the ability to consider reading skills, it appears that this patient has made no gains in comprehension abilities, which is simply not the case.

Item D2 also lacks the sensitivity required to show true functional outcomes. A confounding factor is the lack of distinction between speech and language in this item. This patient clearly showed changes in both speech intelligibility and language production, however, neither was significant enough to increase her from a "2" to a "1". It is also a reality that for some patients both speech and language abilities may be impaired immediately following a stroke but one may recover more quickly than the other. In a case such as this, the person may be rated as a "1" because of dual deficits, but even if language improved to functional limits, they may remain a "1" due to severe speech deficits. On this tool, no outcome would be noted; even when significant gains were achieved.

For comparison purposes, ASHA's Functional Communication Measures (FCMs) for spoken language and motor speech are included below to demonstrate the benefit of more sensitive

scales. FCMs are 7-point scales (with 7 being the highest or most functional level and 1 being the most impaired level) that could easily be incorporated into an online application.

FCM	Initial Assessment	Discharge Assessment
Spoken Language Comprehension	**Level 3** Individual usually responds accurately to simple yes/no questions; is able to follow simple directions out of context with moderate cueing.	**Level 4** Individual consistently responds accurately to simple yes/no questions and occasionally follows simple directions without cues; moderate contextual support is needed to understand complex sentences/messages.
Spoken Language Expression	**Level 2** Individual attempts to speak, although few attempts are accurate or appropriate; occasionally produces automatic and/or imitative words and phrases.	**Level 3** With consistent and moderate cueing, the individual can produce words and phrases that are appropriate and meaningful in context.
Motor Speech	**Level 3** Communication partner must assume primary responsibility for interpreting the communication exchange; individual is able to produce short sound combinations or automatic words intelligibly; with consistent and moderate cueing, can produce simple words and phrases intelligibly.	**Level 4** In simple structured conversation with familiar conversation partners, the individual can produce simple words and phrases intelligibly.

It would be much more beneficial and useful to include communication items in the functional status section with more sensitive scales. Communication underlies most functional abilities and should not be separated from functional status determinations. In addition, determinations about the subtle differences and changes in communication abilities is best made by a speech-language pathologist rather than administrative staff who may be required to complete this form.

Appendix B

NOMS Background Information

National Outcomes Measurement System (NOMS), as developed by American Speech-Language-Hearing Association (ASHA), is a nationally aggregated data collection system, utilization, and benchmarking tool for speech-language pathology services for adults and children in both school and health care settings. Over 2000 adult health care facilities are currently using the system.

Effective SLP Functional Assessment/Outcomes Tool

NOMS is the most appropriate tool for tracking and collecting speech-language pathology outcomes for the following reasons:

- NOMS has a robust database from which to establish national risk-adjusted quality benchmarks;
- NOMS has been tested and validated;
- NOMS is widely accepted by the speech-language pathology community; and
- NOMS is designed to address the continuum of care.

Background

In 1993, ASHA formed a Task Force on Treatment Outcomes and Cost Effectiveness which was initially charged with determining the suitability and usefulness of existing nationally aggregated databases and database collection systems such as the Functional Independence Measures (FIM), OASIS, and MDS. After an exhaustive search, the Task Force concluded that none were comprehensive or sensitive enough to account for speech-language pathology services. Therefore, in 1997, the National Outcomes Measurement System (NOMS) and its performance measures, the Functional Communication Measures (FCMs), were developed. In the fall of 1998, ASHA launched the Adult Healthcare Component, the largest of three NOMS data collection systems.

Use of NOMS Data

NOMS data can be used to address a variety of areas related to speech-language pathology service provision, such as:

- how long it will it take to get from a non-functional skill level (all nutrition and hydration by non-oral means) to a functional level (nutrition and hydration by mouth) for adult patients with dysphagia;
- the average number of sessions needed to treat an adult with aphasia or dysarthria;
- the average functional gain a patient will demonstrate during a given time period within a specific treatment setting; and
- a patient's function/independence after a course of treatment by a speech-language pathologist.

NOMS Data Collection

The key to NOMS is the use of FCMs; a series of disorder-specific rating scales designed to describe the change in an individual's functional communication ability over time, from admission to discharge, in various speech-language pathology treatment settings. Each scale contains seven discrete gradations of change designed to gauge progress in the areas most commonly addressed by speech-language pathologists. Each scale ranges from a least functional (level 1) to most functional (level 7).

The full set of FCMs consists of 15 scales which are: (1) Alaryngeal Communication (2) Attention (3) Augmentative-Alternative Communication (4) Fluency (5) Memory (6) Motor Speech (7) Pragmatics (8) Reading (9) Problem Solving (10) Spoken Language Comprehension (11) Spoken Language Expression (12) Swallowing (13) Voice (14) Voice Following Tracheostomy and (15) Writing. The following are some of the speech and language diagnosis captured by the FCMs:

- **Aphasia** refers to problems with expressive and/or receptive language skills. A person with aphasia may not be able to understand or comprehend what is said. For example, follow directions and answer yes/no questions or may not be able to verbally produce words, phrases and sentences appropriately to express their thoughts, wants and needs. A person with aphasia may also have difficulty reading or writing.
- **Dysphagia** refers to the ability to chew food and swallow food and liquid without difficulty. A person with dysphagia may not be able to chew food, clear all food from the mouth into the throat, or safely get food and liquid from the mouth to the stomach without risk of choking or aspiration.
- **Apraxia** refers to motor speech problems as a result of difficulty coordinating the muscles needed for speech.
- **Dysarthria** refers to motor speech problems as a result of muscle weakness. A person with dysarthria may have difficulty using the muscles of speech and respiration appropriately to produce speech intelligibly.
- **Cognitive-Communication Impairment** refers to problems with memory, attention, and reasoning skills. A person with cognitive-communication impairments may have difficulty concentrating on a task amid distractions, paying attention for more than a few minutes at a time, or performing more than one task at once. A person may also have difficulty recalling already learned or new information and solving everyday problems.

In development of the FCMs, the scales were field tested across the continuum of health care settings and refined by committees of clinical experts. Prior to being finalized, the scales underwent extensive peer review and revision through scoring brief case studies using the FCMs.

For data collection, FCMs are chosen and scored by the speech-language pathologist on admission and again at discharge to depict the amount of change in communication and/or swallowing ability after speech and language intervention. For each case entered into NOMS, the speech-language pathologist selects specific FCM(s) based on the patient's actual cognitive, communication, and/or swallowing impairments. By scoring the FCMs that specifically relate to the patient's treatment program, clinicians can assess the amount of functional change. The FCMs are not dependent upon administration of any particular formal or informal assessment measures, but are clinical

observations provided by the speech-language pathologists of the patient's communication and/or swallowing abilities to be addressed in an individualized treatment plan.

Provider Friendly

The system is designed to minimize financial and technological barriers to provider participation. NOMS is a web-based tool that takes an average only a few minutes for the clinician to complete. Training and testing in the use of the system can be typically completed in fewer than two hours. By using a web-based application, clinicians easily access benchmarks for patients with similar characteristics in the development of their treatment plans.

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September 24, 2007

Centers for Medicare and Medicaid Services (CMS)
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Re: Comments on Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument
Document Identifier/Form # - CMS-10243
OMB # - 0938-NEW
Federal Register – vol. 72, No. 144, pgs, 41328-41329 (July 27, 2007)

Dear Ms. Harkless:

The Alzheimer's Association appreciates the opportunity to comment on the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument. The Association commends CMS for this effort to standardize assessment for hospital discharge and post acute care. We believe that use of the CARE instrument will improve hospital discharge planning and post-acute care and outcomes for Medicare beneficiaries with Alzheimer's disease and other dementias.

In our comments below, we suggest one change in Section IV on Cognitive Status and the addition of questions to assess the need for supervision to prevent unsafe behaviors. Most importantly, we urge CMS to add a caregiver assessment to the CARE instrument. Such an assessment is essential when the feasibility of a patient's discharge plan depends on a family member or other informal caregiver. A caregiver assessment is not needed, however, in all hospital discharge and post acute care situations. The Post Acute Care Payment Reform Demonstration, that will use the CARE instrument, provides a unique and immediate opportunity to determine which questions within the CARE instrument can be used to identify the hospital discharge and post acute care situations in which a caregiver assessment is essential and to develop a protocol for this purpose.

The Alzheimer's Association is the premier source of information and support for the more than 5 million Americans with Alzheimer's disease and other dementias. Through our national network of chapters, we offer a broad range of programs and services for people with these conditions, their families, and other caregivers. We also represent their interests on dementia-related issues before Federal, State, and local government and with health and long-term care providers.

In our work with people with Alzheimer's disease and other dementias, we are constantly reminded that hospital discharge is often very difficult for people with these conditions. One reason for this difficulty is that people with Alzheimer's and other dementias are usually hospitalized for treatment of serious co-existing medical conditions. When they are discharged to home, their dementia greatly complicates treatments and care they need for the medical condition that caused the hospitalization. Families and other informal caregivers must manage complex medical treatments and prescribed medications, diet, exercise, and other care for a person who may not understand or be able to comply or assist with their care. A pilot study conducted for the Alzheimer's Association shows the extreme stress and anxiety confronted by people with Alzheimer's and other dementias and their caregivers in this situation.[1]

The frequent alternative to being discharged to home is nursing home placement. Although almost all people with Alzheimer's and other dementias would rather live at home, and most families and other informal caregivers would rather have them at home, many hospital patients with these conditions who are admitted to the hospital from home are discharged to a nursing home. One study of a large sample of elderly patients discharged from two hospitals found that among patients admitted to the hospital from home, those who had cognitive impairment consistent with dementia were 2 to 4 times more likely than those who did not have cognitive impairment to be discharged directly to a nursing home and 3 to 7 times more likely to be living in a nursing home 3 months after discharge.[2]

Despite the problems associated with hospital discharge for patients with Alzheimer's disease and other dementias, these conditions are often not explicitly recognized or taken into account in hospital discharge planning. Medicare claims data indicate that, on average, about 25% of all elderly hospital patients have Alzheimer's or another dementia.[3] Yet only a small proportion of elderly patients have a diagnosis of the condition in their hospital discharge record; for example, only 4% of the 16,316 patients age 65 and older who were discharged from Johns Hopkins Hospital in 1996 and 1997.[4] It is possible that Alzheimer's disease and other dementias may be recognized and taken into account in hospital discharge planning even if the conditions are not documented in a patient's hospital record, but anecdotal reports from Alzheimer's Association chapters and other sources indicate that this frequently does not happen.

We believe the CARE instrument will effectively identify cognitive impairment due to Alzheimer's disease and other dementias. Section IV includes questions about important aspects of cognitive status, including short and long-term memory and cognitive skills for decision-making. Responses to these questions can trigger attention to important dementia-related care issues for hospital discharge planning. Use of the same instrument in post acute care, including Medicare-funded skilled nursing home care, home health care, and inpatient

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[1] Naylor MD, Stephens C, Bowles KH, Bixby MB. Cognitively impaired older adults: From hospital to home. *American Journal of Nursing.* 2005;105:52–61.

[2] Sands SP, Yaffe K, Covinsky K, Chren MM, Counsell S, Palmer R, Fortinsky R, Landefeld CS. Cognitive screening predicts magnitude of functional recovery from admission to 3 months after discharge in hospitalized elders. *Journal of Gerontology: Medical Sciences.* 2003;58A(1):37-45.

[3] Maslow K. How many hospital patients have dementia? In N. Silverstein and K. Maslow (eds.) *Improving Hospital Care for People with Dementia* (New York, NY: Springer Publishing Co., 2006).

[4] Lyketsos CG, Sheppard JE, and Rabins PV. Dementia in elderly persons in a general hospital. *American Journal of Psychiatry.* 2000;157(5):704-707

rehabilitation, will not only help to increase attention to dementia-related care issues in these settings but also improve continuity of care. Inclusion of the Brief Interview for Mental Status (BIMS), which will also be used in the revised Minimum Data Set (MDS 3.0), will further improve continuity of care for Medicare beneficiaries with Alzheimer's disease and other dementias.

Parts E, F, and G in Section IV address three issues that are important for Medicare beneficiaries with Alzheimer's and other dementias, but the same issues (behavioral symptoms, mood, and pain) are also important for other Medicare beneficiaries who do not have cognitive impairment. Including these parts in Section IV on Cognitive Status implies that assessment of behavioral symptoms, mood, and pain is only or especially relevant for beneficiaries with cognitive impairment, which is not true. We suggest that these three parts be moved from Section IV. One option is to create two new sections, one on Behavioral Symptoms and Mood and another on Pain.

Section VI on Functional Status includes questions on a wide array of activities that are important for discharge planning and post acute care for Medicare beneficiaries with Alzheimer's disease and other dementias. The wording of these questions and the reminder to assessors that assistance may be required because the "patient's performance is unsafe or of poor quality," make the questions particularly appropriate for beneficiaries with these cognitive impairment due to Alzheimer's and other dementias.

Need for supervision is an additional issue that is very important for discharge planning and post acute care for Medicare beneficiaries with Alzheimer's disease and other dementias and should be included in the CARE instrument. Many people with Alzheimer's disease and other dementias need supervision to prevent unsafe behaviors, including unsafe use of a stove or other equipment, taking too much or too little medication, wandering, and getting lost. Questions about unsafe behaviors and the need for supervision to avoid negative outcomes from these behaviors could be added to Section II, part B5, pertaining to prior functioning, or Section IX on Discharge Status.

Finally, and most importantly, the Alzheimer's Association strongly urges CMS to add a caregiver assessment to the CARE instrument and to use the Post Acute Care Payment Reform Demonstration, which will incorporate the CARE instrument, to determine which questions within the CARE instrument can be used to identify situations in which a caregiver assessment is essential.

In 2005, the Family Caregiver Alliance conducted a national consensus conference on caregiver assessment.[5] One outcome of the conference was consensus that caregiver assessment should be conducted in situations where the feasibility of a patient's discharge plan depends on a family member or other informal caregiver. Conference participants agreed that caregiver assessment should be part of hospital discharge planning for Medicare beneficiaries, but that not all hospital discharges require such an assessment. They agreed that a protocol should be

[5] Family Caregiver Alliance. *Caregiver Assessment: Principles, Guidelines, and Strategies for Change: Report from a National Consensus Development Conference.* (San Francisco, CA: Family Caregiver Alliance, April 2006).

developed to determine when Medicare should require a caregiver assessment as part of a "safe and effective discharge." The CARE instrument includes many questions that instrument could be used to identify the hospital discharge and post acute care situations in which a caregiver assessment is essential. It is possible that a few additional questions should be added and some existing questions should be adjusted to assure that caregiver assessment is conducted in the discharge and post acute care situations in which it is essential, but the total number of additional questions should be limited to avoid unnecessary burden for the person, the family, and hospital and post acute care staff members.

Section IX now includes a question about whether the patient currently has one or more caregivers who are both "willing and able to provide the necessary care." Instructions for assessors should state that this question must be asked explicitly of the caregiver(s) rather than being answered on the basis of the patient's comments or staff observation. In addition, the question might be made more specific by referencing patient care needs that are identified earlier in the CARE assessment, for example, need for assistance with medical items from Section III, functional impairments from Section V, or activities of daily living from Section VI. The caregiver could be asked, for example, whether he or she is willing and able to provide assistance with wound care, toileting, or medication management, if the assessment indicated that the patient needed such assistance.

Reports from the Family Caregiver Alliance Consensus Conference include valuable information about the domains that should be included in a caregiver assessment and how the assessment should be conducted. We would be happy to work with CMS to select an assessment instrument to be added to the CARE instrument for evaluation in the Post Acute Care Payment Reform Demonstration.

The opportunity created by the Post Acute Care Payment Reform Demonstration to develop and test a protocol to identify hospital discharge and post acute care situations in which a caregiver assessment is needed should not be wasted. We hope CMS will act quickly to make use of this opportunity.

Thank you for your consideration of our suggestions. If we can be of any further assistance, please feel free to contact Katie Maslow at (202) 638-8667 or Katie.Maslow@alz.org.

Sincerely,

Brenda Sulick

Brenda Sulick
Director, Federal Health Policy Issues

Katie Maslow

Katie Maslow
Associate Director, Quality Care Advocacy

September 24, 2007

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Attn: Bonnie L. Harkless

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

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

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

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

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

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

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

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

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

d. The CARE tool bases functional assessments on the most usual performance, not the lowest level of performance, over a 2-day assessment period upon admission to a post-acute setting, within the interim period (every 14 days), and upon discharge from a post-acute setting.
e. The different rating scales for the various items, the lack of tested psychometric scaling properties, and the inconsistency with the FIM™ instrument, which has been widely used and fully tested in several million applications for over 20 years, is likely to be confusing to providers and will not yield reliable and valid measures of burden of patient care as reflected in the various post-acute settings.
f. There is some redundancy among the items in section IV, Cognitive Status; section V, Impairments; and section VI, Functional Status.
g. Using the AlphaFIM® instrument in acute care settings, the FIM™ instrument in SNF, IRF, and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) in HHAs would be a more appropriate approach. The AlphaFIM® instrument uses 6 FIM™ items to project a patient's full FIM™ rating; the OmegaFIM™ instrument also uses 6 FIM™ items to project a full FIM™ rating for higher-functioning patients. These FIM™ instrument items, which have been fully tested and validated, can be easily supplemented with additional items, such as Instrumental Activities of Daily Living (IADLs) or other similar items.
h. A consistent rating scale, such as the 7-point scale used in the FIM™ instrument, provides the best way to measure the true burden of patient care. Burden of care is not well appreciated as a concept, but it is the most important factor in determining the long-term care needs of an individual with disability.

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

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

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

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

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

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

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

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

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

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

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

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

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

I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at **541-732-5083.**

Sincerely,

Cornelia M Byers

Cornelia M. Byers, MD
Medical Direcotor, Inpatient Rehabilitation Unit
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September 24, 2007

Centers for Medicare and Medicaid Services
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Attn: Bonnie L. Harkless

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3. Ways to enhance the quality, utility, and clarity of the information to be collected
4. The use of automated collection techniques or other forms of information technology to minimize the information collection burden

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

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

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

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

d. The CARE tool bases functional assessments on the most usual performance, not the lowest level of performance, over a 2-day assessment period upon admission to a post-acute setting, within the interim period (every 14 days), and upon discharge from a post-acute setting.
e. The different rating scales for the various items, the lack of tested psychometric scaling properties, and the inconsistency with the FIM™ instrument, which has been widely used and fully tested in several million applications for over 20 years, is likely to be confusing to providers and will not yield reliable and valid measures of burden of patient care as reflected in the various post-acute settings.
f. There is some redundancy among the items in section IV, Cognitive Status; section V, Impairments; and section VI, Functional Status.
g. Using the AlphaFIM® instrument in acute care settings, the FIM™ instrument in SNF, IRF, and LTCH settings, and the OmegaFIM™ instrument (augmented with the LIFEware℠ System) in HHAs would be a more appropriate approach. The AlphaFIM® instrument uses 6 FIM™ items to project a patient's full FIM™ rating; the OmegaFIM™ instrument also uses 6 FIM™ items to project a full FIM™ rating for higher-functioning patients. These FIM™ instrument items, which have been fully tested and validated, can be easily supplemented with additional items, such as Instrumental Activities of Daily Living (IADLs) or other similar items.
h. A consistent rating scale, such as the 7-point scale used in the FIM™ instrument, provides the best way to measure the true burden of patient care. Burden of care is not well appreciated as a concept, but it is the most important factor in determining the long-term care needs of an individual with disability.

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

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

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

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

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

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

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

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

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

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

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

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

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

I am grateful for the opportunity to provide comments on this important demonstration project. If you have any questions about these comments, or if you need further information, please contact me at **541-732-5864**

Sincerely,

George Andries, Jr., FACHE
Director, Providence Regional Rehabilitation Services
Providence Medford Medical Center

September 21, 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, MD 21244-1850

Dear Ms. Harkless:

Re: Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

AARP appreciates the opportunity to comment on data collection for the Medicare Continuity Assessment Record and Evaluation (CARE) instrument that will play an important role in the Post-Acute Care Payment Reform Demonstration. We commend CMS for its leadership role in recognizing the importance of looking across the continuum of post-acute care hat a patient may require. This tool is an important way to look at an entire episode of care in a patient-centered way. It will provide useful information on Medicare beneficiaries and their post-acute care, and will enhance opportunities to improve the quality of care in the post-acute environment.

We commend the Centers for Medicare and Medicaid Services for addressing the issue of caregivers, including family caregivers, in the discharge status portion of the assessment. The involvement of caregivers, especially family caregivers, before and after discharge from a hospital or other facility can be critical to the individual's ability to get necessary care and services. It may also prevent the need for additional care or placement in a nursing home. Discharge is a key transition point in care, and ensuring that the necessary supports and services are in place for both the patient and the family caregiver can be essential for a smooth transition without gaps in care.

We believe that the discharge section of the CARE tool could be further strengthened by including some additional elements. Along with assessing the availability of a caregiver at discharge – including the willingness to take on the role and the ability to provide care – there should also be an assessment of the needs of the caregiver. Assessing the availability of a caregiver and the caregiver's needs must include a conversation with the provider and the caregiver. In addition, talking to a caregiver prior to and at discharge can give the provider valuable information about a patient's health and functional status.

Assessments of family caregivers' needs could show that caregivers might benefit from respite care, training, or other supports that could be provided at the local level. Documenting the needed resources and trying to connect a family caregiver to such resources, or at a minimum, providing information about these resources, could enable a discharge to an individual's home in the community and help ensure better care for the individual. In addition, documenting supports that a caregiver might need could provide crucial information to a home health agency or other provider that will be supplying services to the patient.

Noting a general amount of time that a caregiver might need to spend assisting an individual could also be helpful in assessing whether an individual is able to provide necessary care. It should also be noted whether a caregiver, if there is one who will be providing care, was provided with any necessary medical or other instructions or information that would be needed to care for the patient. This information could be critical to a smooth discharge and to prevent an unnecessary admission to a hospital or other facility. Discharge can also provide an opportunity to ask the patient and family caregiver how satisfied they were with the care.

We believe that most patients, and certainly their caregivers, would benefit from knowing the care team's assessment of the patient's overall condition. Therefore, we recommend the inclusion of a section on prognosis.

Finally, as CMS is comparing patients across post-acute settings to assist in the development of "payment groups that reflect patient severity and related cost and resource use across post acute settings," CMS may want to consider collecting data at fixed intervals to measure patient progress over time. In addition, if the form is intended to be completed mainly at admission and discharge, it could be difficult to sort out the effects of different length of treatment intervals and selection bias since it appears unlikely that patients will be randomized among various post-acute care settings. In addition, how will CMS account for patients that might die while in a post-acute setting?

We appreciate your consideration of our comments on the CARE tool. If you have any questions or need additional information, please contact Rhonda Richards of our Federal Affairs staff at (202) 434-3770.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Relations and Advocacy

September 21, 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, MD 21244-1850

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We appreciate your consideration of our comments on the CARE tool. If you have any questions or need additional information, please contact Rhonda Richards of our Federal Affairs staff at (202) 434-3770.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Relations and Advocacy

THE CONNECTICUT ASSOCIATION
for **Home Care,** *Inc.*

Incy S. Muir, RN, CNAA, MPA
Chair, Board of Directors

Brian Ellsworth
President/Chief Executive Officer

September 24, 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: CMS-R-249, CMS-10238, CMS-102, 105, CMS-10243 and CMS-10244: Agency Information Collection Activities: Proposed Collection, Comment Request

Dear Ms. Harkless:

On behalf of 82 certified home health agencies and hospice providers serving over 50,000 elderly and disabled Medicare beneficiaries annually, the Connecticut Association for Home Care, Inc. (CAHC) is pleased to submit the following comments on the "Testing of Revised OASIS Instrument for Home Health Quality Measures and Data Analysis," and "Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument" that was published for proposed collection in the *Federal Register* on July 27, 2007.

CAHC has identified several concerns with the proposed testing and implementation of these instruments. Our specific concerns include the following:

Timing of OASIS Revisions and CARE Instrument Testing

CAHC is particularly concerned about the timing of testing processes for both the OASIS revisions and the CARE instrument. It does not make sense to test both processes concurrently and then make additional changes to the OASIS instrument based on each of these findings. If the plan is to include the CARE instrument measures in the OASIS assessment in the future, CAHC strongly recommends that CMS postpone testing the OASIS Assessment revisions until the CARE instrument is finalized. These changes can then be incorporated into the revised OASIS instrument.

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Agency Burden

CAHC feels that CMS has significantly underestimated the burden and cost for agencies to implement the OASIS revisions. To expect that clinicians will voluntarily offer to complete OASIS testing outside of their normal work schedule is overly optimistic. In Connecticut, many of our member agencies have expressed reluctance to participate in this testing due to the timing of PPS Refinement Final Rule changes and concerns about the burden on agency staff and operations. This is despite the fact that CMS is planning to provide minimal payment incentives for participation in the testing process.

Regarding the actual implementation of these OASIS revisions, CAHC disagrees with CMS's assertion that the OASIS revisions pose a minimal burden for agencies because certain OASIS items do not need to be completed with each assessment. Based on review of the proposed revisions, the overall assessment increases the total OASIS assessment to 132 items. Many of the items (for example Influenza) require completion, if only to indicate that the OASIS start-of-care (SOC) falls outside of flu season.

In addition, the amount of changes is significant for agencies utilizing an electronic documentation system and those using manual data collection. Necessary operational and clinical documentation system changes and proper staff training will take a significant amount of time and resources to implement. Some of the process measures have already been implemented in agency clinical documentation and these agency-specific measures will need to be modified to reflect the new OASIS items so that agencies can avoid duplication in documentation. This will take a significant amount of time, in addition to the current burden agencies are facing with implementation of the PPS Refinement Final Rule changes.

Therefore, CAHC feels implementation of the new or revised OASIS measures will create additional burden for the agencies, despite the deletion of several OASIS items.

Specific Comments regarding OASIS Revisions

The proposed changes to the OASIS assessment reflect comments that have been provided by MedPAC and industry professionals. Ultimately, it may be worthwhile and necessary to incorporate some of these changes into our OASIS assessment, in order to improve the accuracy of OASIS data collection and to include items associated with evidence-based practice. Based on the review of the draft revisions, CAHC recommends the following specific wording change:

- Influenza/Pneumococcal Immunization-CAHC members have recommended that the timing for completion of this item be expanded to reflect the expanded time period for administration of influenza/pneumococcal vaccine recommended by the Centers for Disease Control-for example "September-April." This particular section may be revised to just include the date of the last immunization to avoid any confusion regarding reference to "this year's flu season."

Summary of Comments

In conclusion, CAHC recommends a delay in the testing for the revised OASIS assessment until after the testing of the CARE instrument has been completed and these items have been incorporated into the draft OASIS revision. Both of these processes should be delayed to provide agencies with enough time to implement the significant changes associated with the PPS Refinement Final Rule. By expanding the test period, CMS will reduce the burden on agencies to implement these changes. In addition, CAHC recommends a re-calculation of the burden estimate on agencies to implement OASIS changes and clinician completion of the OASIS assessment. The added burden of including a large number of process measure items outweighs any relief afforded by removal of the original OASIS items.

Thank you for consideration of these comments. Please contact me at 203-265-9931 or skehan@chime.org if you have any questions or concerns.

Sincerely,

Kimberly Skehan, RN, MSN
Vice President for Clinical & Regulatory Services
Connecticut Association for Home Care, Inc.
110 Barnes Road, P.O. Box 90
Wallingford, CT 06492
DL: 203-294-7348
Email: skehan@chime.org

ks

AOTA® The American Occupational Therapy Association, Inc.

Via overnight express mail

September 25, 2007

The Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development – C
Attention: Bonnie L. Harkless, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8016

Re: Agency Information Collection Activities: Proposed Collection; Comment Request: Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

Dear Ms. Harkless:

The American Occupational Therapy Association (AOTA) represents over 37,000 occupational therapy professionals, many of whom serve the Medicare populations in acute care hospitals and in post acute care settings including long-term-care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies. We appreciate the opportunity to comment on the Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument, as published in the Federal Register on July 27, 2007 at 72 Fed. Reg. 41328. AOTA presents the following comments on the CARE instrument:

Policy Considerations

AOTA respectfully requests that the Centers for Medicare and Medicaid Services (CMS) consider several different policy issues in reviewing the utility and efficiency of the CARE instrument. AOTA is highly invested in assuring that the CARE instrument will be the appropriate instrument to collect data for purposes of accomplishing the objectives it was created to achieve, including use in the inpatient setting only (outpatient settings would require entirely different considerations and items) and developing a setting neutral PAC payment model. ***AOTA requests that CMS allow adequate time to pilot and analyze the instrument data collection as part of the demonstration project.***

It will be critical for CMS and its contractor, Research Triangle Institute International (RTI) to use caution and to validate the data collected and its relationship to post acute care (PAC) placement, costs, and outcomes. For instance, with regard to the utility of the instrument, AOTA raises concerns whether the

CARE instrument will accurately predict PAC patient placement needs. Currently, it is questionable whether a number of items in the current tool will be accurate when implemented. ***AOTA requests that CMS and RTI consider the validity of each of the questions closely.***

With regard to the administrative burden placed on occupational therapy practitioners filling out the instrument, how will CMS and RTI manage multiple persons completing the instrument without encountering an inter-rater reliability problem? AOTA is concerned that an occupational therapist would not be qualified to complete every section of the CARE instrument, particularly if the therapist is required to assert clinical judgment in areas in which they are not knowledgeable. How will CMS and RTI assure that the CARE instrument is completed within the 2-day assessment period in the home health setting, for example, when the patient may only be able to see one practitioner for an hour in a given day (due to fatigue) and then not again for a series of days? Members also inform us that in the skilled nursing facility setting the therapist might see the patient one time in 2 days, but is highly unlikely to see the patient again within that two day period and one visit is not enough time to complete the entire CARE instrument. ***AOTA would like more guidance provided (either in the instrument itself or through a user manual) as to which professionals are qualified to fill out the various sections of the instrument.***

AOTA asserts that acute hospital and PAC setting personnel training on the CARE instrument must be detailed and rigorous before launching into the demonstration project. AOTA also recommends that RTI develop a user manual, including a definition of terms, for purposes of training and implementation of the demonstration project.

AOTA is also concerned about the technology needs in the acute hospital and PAC settings. It is our understanding that a computer is required to complete this form under the CMS technological scheme for the CARE instrument, but our members inform us that many PAC settings are not yet at the stage of entering data electronically, especially in rural areas. If a computer system is required for the demonstration, will it allow a therapist to look back to obtain other data from the patient's medical record to complete certain standard items on the instrument that do not require observation? In some cases, the therapist does have access to a computer, but does not have internet access, especially in the home health setting. Will the demonstration require access to internet-based data entry? ***AOTA requests clarification about the technology expectations for the facilities that volunteer to participate in the demonstration.***

Below, we provide AOTA's detailed responses to specific items in the CARE instrument. AOTA requests that specific changes be made to the CARE instrument in the following.

Response to Specific Items in CARE Instrument

II. Admission Information

- RTI should provide more detailed definitional information, e.g., what defines "some help" under Prior Functioning at B5(2) and what defines a "history of falls" under B7? Would it be one or more falls in the past year?
- Consider adding Instrumental Activities of Daily Living (IADLs) under B5a, such as money management, cooking for self, cleaning home, driving or accessing community, etc.
- If the patient is in the home health setting there may not be any stairs under B5c.
- Functional Cognition should also include consideration of basic safety awareness under B5e.
- Under B6, instead of mobility device and aids, AOTA prefers the use of the term assistive technology or the specific addition of the terms orthotics and prosthetics, which are currently left out.
- Under B8, Prior Mental Status, the use of the term acute does not account for the potential for a chronic mental health condition in a patient.

III. Current Medical Items

- Under section C, Procedures, AOTA is confused by the request for ICD-9 CM procedure codes. ICD-9 codes are diagnosis codes and CPT codes are typically procedure codes, so it this a typographical error?
- The CARE instrument is based on the ICD-9 coding scheme and moving to the ICF language now in this tool would assist in the process to prepare for ICD-10. The ICF language is already adopted by 180 countries worldwide and is being recommended by the Institute on Medicine.
- Under section D, Treatments, please clarify what time frame the occupational therapist is being asked to consider in answering the question "which of the following treatments are required?" The use of the term *required* is confusing. Is the therapist being asked to essentially transcribe what has already been provided and can be identified in the medical record or are they being asked to make a clinical judgment as to the most appropriate treatments *required* at the time they are seeing the patient and completing the instrument? In addition, AOTA requests that RTI add an "Other" category under D32. For instance, there is no option for other treatments like being tube fed.
- Under section G6, AOTA again requests addition of an "other" category since there are additional possible turning surfaces, such as elbows.

IV. Cognitive Status

- Use of the BIMS under section B makes sense to therapy practitioners, but feedback indicates that many therapists also use a second related standardized assessment tool to verify the status of the patient. Consider addition of related standardized assessment tools.
- Under section C1 and C2, the "memory OK" category is confusing and subjective, AOTA request a more descriptive word choice than "OK". Also

sensitivity to change in memory is not really measured by these three choices; we suggest breaking the options down into more descriptive degrees.

- Communication should be included as a supplemental functional ability (Section C) for patients who had a therapy consult or who will need post-acute care or personal assistance following discharge.
- Under section E, the items should ask more detailed questions about communication deficits other than the option of "unable to respond."
- Section G, Pain, does not belong under Cognitive Status, but should appear under the Impairments section V. Also, section G3's introduction of coding number 8 if patient is unable to respond seems inconsistent with the 0-10 pain severity scale suggested in the same section. What if the therapist codes an 8 out of 10 in terms of severity of pain? Won't that number be confused with the therapist stating that the patient was unable to respond?
- What is the distinction between G3 and G4 in terms of pain severity? They appear to be two different ways of asking the same question.

V. Impairments

- Should include additional topics under section A such as balance, pain mobility/gait, etc.
- Under section C, Swallowing, the listed signs and symptoms are not indicative of the severity of the problem.
- Under section E1, Range of Motion, wrist and finger joints should be added.
- This entire section does not consider weaknesses in trunk strength; instead it focuses primarily on the extremities.
- Under section J, clarify whether the occupational therapist should record a mobility device that is needed at time of assessment as observed or if the therapist should be making a clinical judgment that a device is needed going forward. In addition, again, we prefer the use of the term assistive technology or addition of orthotics and prosthetics to the categories of devices.

VI. Functional Status

- Please clarify the lack of consistency between the 6 point scale used in sections A, B, and C1-C6, and the 4 point scale used in section C7-C18. Using one consistent scale across the Functional Status items will reduce potential error.
- The section C directions refer to a therapy consult. At what stage could the patient have obtained a therapy consult? Prior to assessment with the CARE instrument? These directions are confusing.
- Under section C6, Mode of Mobility, it is possible that in the home setting, for example, that the patient's home environment will not allow the types of mobility testing indicated. Therefore, additional categories need to be added to the "if activity was not attempted code," including: Environment Does Not Permit and Other. Similarly, reason for refusal should be stipulated as there is a need for a category which would account for indicators of functioning which may not match the patient's (or caregiver's) expectations for therapy because of individual

differences in goals. For instance, the patient may not wish to exert the energy required for self care but rather to have the caregiver bathe them so that they may participate in valued IADL or social activities instead or there may be specific gender or cultural differences that lead to patient refusal.

- The directions to section C7-18 are impractical in requesting that the therapist be able to observe each of the listed activities. For instance, should the OT be present and able to observe while the patient takes their medications or completes all the tasks of laundry, etc? Also, would the therapist have to prompt the activity or expect that it will occur spontaneously within the 2-day assessment period? If you are requiring observation of these items, can a therapist rely on the caregiver's observation to answer the items? Less restrictive language such as "activities which you have observed or assessed by some other means" should be used.

VII. Engagement

AOTA is pleased to see that consideration is being given to the degree of engagement of the patient in therapy. AOTA asserts, however, the way this section is worded and the scale that is used sounds more like a compliance standard rather than an attempt to understand the patient's physical or emotional readiness to participate in treatment.

VIII. Frailty/Life Expectancy

Asking in A1 and A2 whether the occupational therapist would be "surprised" seems like a subjective and difficult to measure standard. AOTA requests a word choice change in this section and more clarification as to the objective of this item for the personnel completing it. This item may also have poor reliability depending on who is completing the instrument (if not the patient's physician).

IX. Discharge Status

The tool lacks an assessment of critical safety skills that would be relevant for consideration of a home discharge, such as the patient's judgment and ability to recognize an emergency situation, call 911, communicate pain, and comprehend written directions. The World Health Organization's *International Classification of Functioning, Disability and Health,* which has been endorsed by the Institute of Medicine and widely implemented in Europe, recognizes the importance of such critical functional activities.

X. Other Useful Information and XI. Feedback Sections

AOTA is pleased to see the opportunity to provide additional information about the patient's specific circumstances, goals, and objectives. The majority of the items in the CARE instrument are based on a normative model that does not fit each and every patient, nor does it fit with the occupational therapy philosophy of client-centeredness.

* * * * *

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the Data Collection for Administering the Medicare CARE Instrument. AOTA looks forward to a continuing dialogue with CMS and RTI on the administrative, coverage and payment policies that affect the ability of occupational therapists to provide quality care to Medicare beneficiaries.

Sincerely,

Sharmila Sandhu

Sharmila Sandhu, Esq.
Regulatory Counsel

cc: Barbara Gage, PhD, Principal Investigator, RTI, International

St. Vincent's Medical Center

September 21, 2007

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

Dear Ms. Harkless:

I have recently learned about the proposed CMS patient assessment instrument (CARE). I have spoken to our Director of Case Management who had the opportunity to participate in the recent conference call sponsored by AHA to review this proposal. As the Chief Nurse Executive of a 390 bed acute care medical center, I have grave concerns about the burden that this proposal would place on our Case Management and Nursing staff. As healthcare providers, our team is already challenged with all of the demands for detailed documentation and timely patient flow. In addition to the national nursing shortage, we are faced with regulatory requirements and escalating fiscal constraints. We are continuously striving to meet all of our quality outcomes, while ensuring that we provide the safest disposition plan. One of our corporate goals is to facilitate the flow the patients out of our overcrowded Emergency Department. The additional documentation requirements proposed in this draft will undoubtedly have a negative impact on our ability to discharge patients in an efficient manner.

I am continuously seeking opportunities to increase the time that our nurses spend at the bedside, rather than time spent in charting in the medical record or on the computer. In order to optimize our clinical outcomes for patients, we need to maximize our Nursing Care Hours per Patient Day. By shifting an additional documentation responsibility onto the staff, we will further erode that limited time spent in education, assessing and caring for our patients.

I understand that the current pilot study may recommend that the CARE instrument replace the variety of current assessment tools (MDS, OASIS and IRF PAI). While I respect the attempt to consolidate and standardize these tools, I do not believe that the burden should be placed onto acute care institutions. I appreciate your consideration.

Sincerely,

Dale Danowski

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Roger C. Lipitz Center for Integrated Health Care

September 21, 2007

To Whom It May Concern:

I am writing to express my interest in the Center for Medicare and Medicaid's proposed post-acute assessment tool, the Medicare Continuity Assessment Record and Evaluation ("CARE"), and my concern regarding the adequacy of proposed measures of patients' social and environmental characteristics. Numerous studies document the relevance of patients' family caregivers to valued health care delivery[1-5] and long-term care outcomes.[6, 7] Measures of patients' social and environmental factors are limited in the proposed CARE. Without more precise and comprehensive information regarding the abilities, competence, and preparedness of patients' lay caregivers within the CARE, I fear that a important opportunity will be missed to improve the quality of patient care and to accurately catalog ongoing and future home health care quality improvement processes.

For patients discharged home with home health care, the inclusion of comprehensive measures of patients' social situation and characteristics of the built environment must be a priority. Published studies substantiate the significant ongoing contributions of patients' unpaid family caregivers alongside formal home health care. [8] In ongoing work using a nationally representative sample of Medicare home health users, I have found *less than 2% of home health patients live alone without help from families or friends*. A greater understanding of caregivers' abilities, knowledge, and needs is a prerequisite to developing educational programs and interventions to improve caregiver competence, a potentially modifiable aspect of care. Likewise, understanding aspects of the built environment for patients with limited functioning could prove beneficial to developing targeted interventions, identifying service needs, or categorizing resource requirements for payment purposes.

Information along a number of dimensions is needed to accurately record the abilities, preparedness, and competence of patients' lay caregivers. An important overarching issue is who is responsible for completing these questions, and whether the respondent is sufficiently informed of patients' social and environmental circumstances. At a minimum, a question should be included that indicates whether the person completing the social and environmental portion of the CARE has had any contact with patients' caregivers. More preferable would be a process (particularly when discharge home is reliant upon the help of a lay caregiver) that incorporates caregivers' own reports of their willingness, abilities, and preparedness.

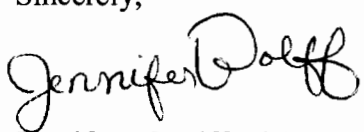
Additional items should delineate caregivers' preparedness to assist with patient-specific tasks. For example, some caregivers may be willing to provide task assistance such as lifting, but may be physically unable to do so. My understanding is that the CARE will reside on a computer-based platform, and if so, I wonder whether the opportunity exists to field questions

generated by responses elsewhere in the CARE regarding patients' functioning and clinical needs (questions regarding caregivers' preparedness would be customized to reflect only those activities that are relevant to a particular patient). A number of conceptually distinct functions could be aggregated across patient needs, such as toileting/transfers, feeding, wound care, transportation/shopping, medication management. Lastly, the tool should include some assessment of caregivers' perceived or actual preparedness – potential items might include caregivers' familiarity with patients' health needs and treatments, confidence in their ability to monitor patients' health status and respond to changes, and whether the caregiver assisted the patient prior to the episode or that they are new to their role.

The development of the CARE represents an important opportunity to collect meaningful information salient to patients' post-acute experiences. I appreciate the attention and interest being afforded to its development and am hopeful that future iterations will expand and refine measures of patients' social and environmental characteristics.

Please do not hesitate to contact me if I can be of further assistance.

Sincerely,



Jennifer L Wolff, Ph.D.
Assistant Professor

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A not-for-profit organization

September 20, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

I am writing on behalf of John Muir Medical Center-Concord Campus 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 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 (925) 674-2530.

Sincerely,

Donna Brackley

Donna Brackley, MSN, MA, RN
Senior Vice President, Patient Care Services

Kentucky Hospital Association

Representing Kentucky Health Care Organizations

September 21, 2007

Bonnie L. Harkless
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

Dear Ms. Harkless:

The Kentucky Hospital Association, on behalf of all Kentucky hospitals, appreciates the opportunity to comment on CMS's proposed new data collection for administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument.

The overall concern of Kentucky hospitals with the CARE instrument is the additional time commitment that will be required of hospital staff to complete the form and the duplicative nature of the documentation. Hospital staffs that have reviewed the form indicate that this documentation would take at least 45 minutes to complete for a non-complex case. As such, it will significantly impact hospital case management/social services departments. Further, the overall conclusion is that this form is duplicative of the transfer form, history and physical, discharge summary, medication reconciliation data and physician progress notes which are already completed and transferred with the patient. Detailed information on the time required and duplicative nature of the form are outlined below.

After review of the Supporting Statement for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument as well as the Care Tool itself Kentucky hospitals have indicated the following specific concerns:

1. The tool is extremely detailed and we believe that the time estimates to complete, 20 minutes for patients discharging to home and 45 minutes for patients discharging to post-acute settings are underestimated. For some patients, hospitals estimate the time spent collecting this information maybe upwards to 2 hours.

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2. Use of the tool may require additional staff resources. One Kentucky hospital system provided the following detailed, estimated potential associated staffing costs if their care management staff assumed responsibility for completion of the form:

Hospital	Average Monthly Medicare Discharges (based on 2007 data)	Hours needed to complete CARE tool @ 1 hour/form	Estimated cost per hospital per month to complete tool. Assumes average salary including benefits @ $40/ hour	Estimated FTEs required (based on 173 hours per work per month)
Norton Audubon	531	531	$21,240	3
Norton Hospital	478	478	$19,120	2.76
Norton Suburban	349	349	$13,960	2
System	1358	1358	$54,320	7.76

3. Section A.4 of the Supporting Statement, states that "the information cannot be obtained from any other source". Many components of this tool are already collected in sections of CareLINK and in assessments and reports in the patient's electronic medical record (EMR). Does this mean that an acute care provider would not be able to integrate this form with existing patient information sources? Integration would decrease the time spent completing the tool and ensure reliability of information collected.

4. It is not possible for one clinician to complete the tool. Because of their scope of practice some sections should be completed by a physician, wound care nurse, physical therapist and occupational therapist. ICD 9 codes would need to be added by the Coding Department. See comment 5.

5. Several sections require ICD codes. Currently, Coding Department staff assigns these codes after careful analysis of a discharged record several days post discharge. If this information is required at time of discharge, a major revamping of the inpatient coding process may be required. Alternatively, if a diagnosis were entered into the tool, would the ICD 9 codes autopopulate?

6. Section Specific comments:

    a. II. Admission Information: If the patient was unable to provide this information, it would not be available to an acute care provide: A3a (Last Primary Diagnosis), A3b (ICD-9 CM Code) and A4 (Medical services provided in the last 2 months).

    b. III. Current Medical Items, Sections A-Primary Diagnosis, B-Diagnosis and C –Procedures: Completion of this section requires medical judgment and should be completed by a physician or physician extender. As mentioned above, codes may need to be assigned by a coder or a clinical documentation specialist (CDS) nurse. If assigned by a CDS, what if a coder does not agree? How does this process correlate with the selection of the principal diagnosis and final DRG which occurs after discharge and is the exclusive responsibility of the inpatient coder? Would any discrepancy between the two processes affect hospital reimbursement?

        i. Section E: Can this be integrated with the Medication Reconciliation report?

        ii. Section G: May need to be completed by a wound care specialist.

        iii. Section H: Can this information be integrated with data in the EMR?

    c. V. Completion may require additional consults to speech, physical and occupational therapists to complete thorough assessments of related functions, adding to the cost per case.

    d. IX. Discharge Status. Acute care providers do not know a discharge provider's Medicare Provider's Identification number? Do providers want to widely share this number?

In summary, Kentucky hospitals have three major concerns about the Care Tool - time and associated costs, duplication of data that is available in other patient reports and assessments in acute care provider electronic medical

records, and the need to involve multiple disciplines to accurately complete the Care Tool.

We hope CMS will seriously consider the impact on additional costs to health care institutions and modify the CARE Tool to reconcile the issues we have outlined in these comments.

Thank you for the opportunity to comment.

Sincerely,

Nancy C. Galvagni
Senior Vice President

University of Colorado at Denver and Health Sciences Center

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September 16, 2007

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless, Room C4-26-05
75000 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS – 10243 (OMB#: 0938 – NEW)
Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

From: Eric A. Coleman, MD, MPH

Thank you for the opportunity to comment on the above noted proposed form. I direct a national program aimed at improving quality and safety at the time of care transitions or "hand-offs". The CARE tool has the potential to overcome many of the current challenges to ensuring that core information is exchanged between providers and also sets the stage for measuring quality (and eventually adjusting payment) across an entire episode of care. As you may be aware, under the leadership of Andrew Kramer, MD, my colleagues and I at UCHSC contributed the background conceptual paper that helped to lay the framework for the CARE Instrument. It is very exciting to see the subsequent progress first hand and to be given this opportunity to comment. My comments are primarily directed to item (3): ways to enhance the quality, utility, and clarity of the information to be collected.

1. Time Spent on Assessment: I would imagine that you will receive a fair amount of comment on this point. Two months ago, I testified before the Institute of Medicine Committee on preparing the workforce for an aging population. One of my primary points is that we need to constructively look at the proportion of time health care professionals spend conducting assessment versus executing the care plan. I offered the phrase "all assessed up and nowhere to go". Thus I am somewhat concerned about the potential for unintentional consequences from the CARE tool. Specifically could completing the tool adversely affect quality and safety if already limited attention and resources are diverted away from preparing patients for self-care to ensure that all of the boxes on the form have been ticked?
2. Episodes of Care: I am the primary care physician for a panel of frail Medicare beneficiaries. As a scientist, I have also explored episodes of care for this population (Coleman EA, Min S, Chomiak A, Kramer AM. Post-Hospital Care Transitions: Patterns, Complications, and Risk Identification. Health Services Research. 2004;37(5):1423-1440.) Both of these experiences have shed insight into how frequently care episodes overlap. It will be important to clarify the time points at which the CARE

tool will be completed and what happens when a patient is re-hospitalized at the same or different hospital.

3. Family Caregiver: There is certainly a wealth of evidence that attests to the importance of family caregivers in assuring effective care transitions and adherence to the care plan. The questions included on the CARE tool do not seem to capture the roles and potential contributions of these "silent care coordinators". The VA GEC Tool has questions regarding family caregivers that might help inform this effort. The Family Caregiver Advocacy Groups (Family Caregiver Alliance, United Hospital Fund, National Family Caregivers Association) may be able to provide more concrete input.
4. Prognosis: I would strongly endorse keeping this question: ***Would you be surprised if the patient were to die in the next 12 months?*** Prognosis is critical for care planning, honoring patient preferences, and matching both care intensity and care setting to patients' goals. In general, patients want to know their prognosis and have open discussions with their health care professionals. Including this question is an important step to facilitate these discussions.
5. Indication for Medications: I believe that OBRA requires that in nursing homes, every medication must also include an indication. This is an important patient safety step and should be promulgated across all settings via the CARE tool.
6. The Short Term Memory Question: The short term memory question is not adequate to accomplish its apparent objective—if ANY portion of the CARE Instrument were to be allowed to expand, I would definitely vote for this question to be the one.
7. Time Period for Falls: This question would be strengthened by providing a time frame (i.e., in the past 6 months).
8. How Long Did It Take: Just a logistical suggestion—it might be useful to add a prompt at the beginning of the CARE tool to note start time on watch or clock rather than rely on the impression of the (generally stressed and overworked, and likely to exaggerate) evaluator?

Again, thank you for the opportunity to comment. If you have any questions, please let me know.

Sincerely,

E. Cole

Eric A. Coleman, MD, MPH
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September 19, 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 American College of Certified Wound Specialists (ACCWS) appreciates having the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the draft Medicare Continuity Assessment Record and Evaluation (CARE) instrument. ACCWS is a professional membership association for Certified Wound Specialists®. *Only individuals certified as a CWS® may become Fellows of The College and use the designation "FACCWS" after their names.* The purposes of The College are to stimulate and support patient care, education, research and knowledge in the interdisciplinary field of wound management; and more specifically to elevate the standards of prevention, care and treatment of acute and chronic wounds and, thereby, improve the public health.

Section II. Admission Information

- **Section A2: Admitted From.**

  The ACCWS suggests the addition of:
  - "Short stay (less than 24 hours)"
  - "Emergency Department with admission to the hospital"
  - "Emergency Department visit without admission to the hospital".

Section III, Current Medical Items

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

  ACCWS strongly recommends adding Enteral Tube Feeding to this section. Enteral Feeding Tubes are medical devices and, as such, must be monitored for complications that could impact wound healing.

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

  ACCWS recommends use of the NPUAP pressure redistribution nomenclature as is found at www.npuap.org which differentiates between "reactive" and "active" surfaces.

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

  ACCWS recommends that "Complex Dressing Changes" be changed to "Complex Wound Management". Examples include, but are not limited to, wounds that require advanced wound interventions/modalities (growth factors, bioengineered skin substitutes, advanced wound dressings, negative pressure wound therapy, etc.) or wounds requiring significant clinical caregiver time/resources.

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

  ACCWS strongly recommends that "compression therapies" be added to the list of treatments.

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

  ACCWS recommends that "Complex Dressing Changes" be changed to 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 valid and reliable risk assessment tool. Specifying a score with this tool would help serve as a reference point for other assessment tools that may be used.

Additionally, 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 are at high risk for the development of a pressure ulcer. ACCWS recommends that "Complex Dressing Changes" be changed to recommends that clinicians be directed to consider patients with non removable medical devices as high risk and be coded a "2" on Item G1.

The phrase "healed scar" is not clear, ACCWS recommends that "Complex Dressing Changes" be changed to suggests using the phrase "A scar over a bony prominence (for example, from a healed pressure ulcer or surgical repair of an ulcer)".

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

  ACCWS recommends that "Complex Dressing Changes" be changed to suggests that all the stages of pressure ulcers be included as 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.

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

  Deep tissue injury is a new label of pressure ulcers defined as a "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).

- **Section G2a. Stage 2**

  ACCWS recommends that "Complex Dressing Changes" be changed to believes it is important to distinguish in the description of Stage 2 pressure ulcers that are true pressure ulcers and those that are a result of a skin tear, tape stripping, or incontinence associated dermatitis. ACCWS recommends that "Complex Dressing Changes" be changed to recommends the description of a Stage 2 pressure ulcer include wording to ensure true Stage 2 ulcers only are recorded in this section.

- **Section G2c. Stage 4**

  ACCWS recommends that "Complex Dressing Changes" be changed to recommends modifying the definition of a Stage 4 pressure ulcer to "Full

thickness tissue with exposed bone, tendon, or joint capsule. Necrotic tissue may be present on some parts of the wound bed. Often includes undermining and tunneling." (NPUAP, 2007)

- **Section G2d. Unstageable**

  Devices that prevent skin assessment should be included. ACCWS recommends that "Complex Dressing Changes" be changed to suggests the phrase read "dressing, *device* or cast".

- **Section G3.**

  ACCWS recommends that "Complex Dressing Changes" be changed to 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.**

  ACCWS recommends that "Complex Dressing Changes" be changed to recommends adding "undermining" in this data element. Our suggested wording would be "Indicate if any unhealed stage 3 or stage 4 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. In addition, venous leg ulcers are the result of chronic underlying etiologies related to chronic venous insufficiency. ACCWS recommends that "Complex Dressing Changes" be changed to also suggests 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**

  ACCWS recommends that "Complex Dressing Changes" be changed to recommends removing Item E "None of the above apply".

The American College of Certified Wound Specialists 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.

Sincerely,

Donald E. Mrdjenovich, DPM, CWS, FACCWS
Chair

Sutter Maternity & Surgery Center

A Sutter Health Affiliate

Community Based, Not For Profit

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September 17, 2007

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

September 17, 2007

Dear Ms. Harkless:

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

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

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

Sincerely,

JoAnna Goodman, RN
Case Manager
Discharge Planner/Utilization Review
Sutter Maternity and Surgery Center
Santa Cruz, CA 95065

St.Vincent's Medical Center

Received - 9/20/07
Opened - 9/24/07

September 20, 2007

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

Dear Ms. Harkless:

Both I and members of my staff appreciated the opportunity to participate in the conference call sponsored by AHA to discuss the proposed CARE instrument. The information presented raises a number of concerns as follows:

- The time constraints of approximately ten to twenty minutes for a low-complexity patient versus approximately forty-five minutes for a high-complexity patient to complete the CARE instrument are unrealistic expectations in the current acute care setting. The turn-over on acute units is such that it is not unusual for a unit to have a range of seven to fifteen new patients on any given day (substantially different and more fast-paced when compared to nursing homes). Some units also have large numbers of high-complexity patients. It is my understanding from the conference call that the CARE tool does not have to be completed on the day of admission. However, the daily influx of new admissions secondary to the turn-over would continue to compound the issue of time constraints. What is the differentiating criteria for a low-complexity patient versus a high-complexity? Would not all patients hospitalized in an acute care setting qualify as high-complexity? Also, in the pilot study, what percentage of nurses at the bedside are contributing to the completion of the instrument?

- Case managers are generally held responsible to facilitate the safe discharge of patients and to facilitate them through the continuum of care. The ratio of Case Managers to patients on average is approximately 1:30 and they are responsible for the discharge planning, utilization review with the insurance providers, and most recently the added responsibility for issuing the "Important Message From Medicare" prior to discharge. The addition of the CARE tool will adversely impact the time and workload of an already over-burdened staff. Off-loading to the nursing unit staff and coordinating the completion of the tool by the other disciplines (i.e. – physical therapy, social work, etc…) would be equally difficult since they are also over-burdened and stressed. In light of the fact that there is a critical shortage of nurses and physical therapists I firmly believe that the implementation of this tool would have deleterious effects by further increasing the migration of licensed staff from the acute care setting.

- It was mentioned during the conference call that the CARE tool would reduce the workload of the Case Managers because there would be a reduction in the number of callbacks from post-acute providers and improve continuity of care. How would the

quality outcomes and proposed cost-savings be measured? I foresee this impact being minimal since the number of callbacks is quite low. Face-to-face communication with nursing home and home care agency liaisons on a regular basis probably contributes to the minimal number of callbacks. Also, the MAR and therapy evaluations and notes are routinely shared with nursing homes. Perhaps the liaisons from the post-acute accepting providers in completing the tool should be given due consideration. This also brings into question the CARE instrument's return on investment for the acute provider since the number of staff and the time required to complete the instrument would substantially have to increase.

- The addition of the CARE instrument to the acute care discharge process results in a cost-shifting from post-acute providers to the acute providers. Both nursing and ancillary providers' (i.e. therapists, social workers, etc...) salaries are generally lower in the post-acute setting. The shifting from post-acute to acute will most likely require the procurement of additional staff.

- Acute care providers are already struggling with improving throughput by facilitating discharges to reduce back-ups in the emergency room. The time and increased workload associated with the CARE tool would negate these on-going efforts. The emergency rooms are currently over-stressed by a patient population who utilizes the services in lieu of a primary care physician.

- Currently at our hospital the chart is half paper and half electronic. What allowances are being considered for hospitals under these circumstances? The implementation of the ECIN discharge planning software is being considered. I am interested in understanding how the CARE tool would interface with the ECIN software and our current information technology and being made privy to additional costs which may be incurred with the implementation.

In closing, I have over twenty-seven years of nursing experience with an extensive background in acute care, home care, and nursing home settings and am well-versed in the OASIS and MDS - at one point working in all three settings simultaneously. As such, and as delineated above, I have grave concerns in regard to the implementation of this tool in the acute care setting. I again wish to thank you for considering our input in regard to the CARE instrument and the impact on acute care hospitals. In the event you wish to contact me, I can be reached at (203) 576-5163.

Sincerely,

Christine M. Babina, RN/BSN
Director of Case Mgt. / Social Work

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September 18, 2007

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

Re: Post Acute Care (PAC) Payment Reform Demonstration Program Comment Request posted in the Federal Register/Vol 72, No. 144, July 27, 2007

Dear Ms. Harkless:

The American Health Care Association (AHCA), a federation of state long term care associations representing nearly 11,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, subacute centers, assisted living residences, and homes for persons with mental retardation and developmental disabilities. We are pleased to have the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the Post Acute Care Payment Reform Demonstration (PAC-PRD); specifically the draft Medicare Continuity Assessment Record and Evaluation (CARE) Instrument.

AHCA believes the current draft of the PAC-PRD offers a good start to developing a payment system that may become more accurate and responsive to rapidly changing care service environments. We commend the Department of Health and Human Services (HHS) and CMS for their efforts in developing a discharge and treatment instrument that contains assessment elements that can be shared across several care settings, that aims to improve care transitions, and that may even allow stakeholders to evaluate beneficiary care outcomes and cost comparisons. It is extremely important that payment systems are seamless and are based on diagnostic-specific conditions rather than the site-specific method currently used.

We are concerned, however, that personnel completing the CARE assessment are required to certify accuracy and truthfulness of responses, thus putting clinicians and their organizations at greater risk for substantial criminal, civil and/or administrative penalties for submitting false information. Experience with a similar attestation requirement on the Minimum Data Set (MDS), has shown that numerous factors influence coding and are

extrinsic to the clinician's coding decisions. For example, tool complexity, facility caregiver staff turnover, lack of MDS training for clinicians and state regulatory staff, difference in coding interpretation between providers, state agencies and the States' Resident Assessment Instrument (RAI) Coordinators, and the inability to effectively and timely communicate and integrate coding updates and clarifications - all these are factors impacting the coding accuracy and the perception of truthfulness. We are also concerned that the request to note the professional's license number for all individuals completing the assessment exceeds medical record standards and prematurely communicates an assumption of provider guilt before coding irregularities are adequately researched.

AHCA is looking forward to assisting CMS with the demonstration and in providing our assistance in finding volunteers to participate in the demonstration. If fact, we have already connected nursing facility volunteers with the PAC-PRD project team and have arranged for Barbara Gage, RTI to address our members at our annual convention in October 2007.

We appreciate the opportunity to comment on the specific needs and concerns of long term care providers. Attached are general and specific comments related to each CARE instrument section

Sincerely,

Bruce Yarwood
President and CEO

Cc. Kerry Weems
Herb Kuhn
Jeffrey Kelman, MD

ahca®

American Health Care Association

General Comments

Before the demonstration is implemented, the CARE instrument needs further refinement. Throughout the PAC-PRD tool, there are several data elements that without clearer definition will be open to various interpretations by the clinicians using the tool. Long term care providers have learned from the Minimum Data Set (MDS) that inter-rater reliability is good only for those individuals receiving adequate training. However, as staff turnover, tool and definition refinements occur, and time and resources spent on employee training dwindles, assessment accuracy suffers. Thus, AHCA recommends that clear standards and definitions be established to help improve the accuracy and reliability of the assessment data and that the electronic tool be developed with pull-down boxes or electronic tutorials containing the definitions rather than having clinicians rely on a hard-copy manual (that may or may not contain all the recent updates) for coding clarification and direction.

Definitions like "directly from the community, skilled nursing facility, long term care facility, and community based residence," need more attention and should to be applied consistently throughout the assessment. For example, the instrument defines "directly from the community" as a private home, assisted living, group home, adult foster care and long term nursing facility. In another instance, assisted living, group home and adult foster care is defined as a "community based residents" and the nursing facility is defined as an example of "permanently in a long term care facility." Skilled nursing facility (SNF) is grouped with subacute SNF and transitional care unit. Since most nursing facilities care for both skilled and non-skilled patients and dually eligible, who are generally considered skilled patients, AHCA recommends that the instrument make the distinction between patients considered to be skilled and non-skilled. We also recommend that "direct from the community" and "community based residents" include private home, group home, assisted living, retirement housing, adult day care, free-standing in-patient hospice facility and adult foster care. We recommend eliminating the element "permanent in a nursing home" and using non-skilled nursing home designation.

AHCA recommends that the draft CARE Instrument clearly establish coding directions at the beginning of each section. Each section direction should include the assessment timeframe like "code for the most usual performance for the 2-day assessment period" and should not repeat the direction in the section unless the assessment timeframe differs for a specific element. Some data element show their own assessment time frame that is a repeat of the 2-day assessment period and this is confusing and leads one to wonder about the significance of the repeat. In other tool sections, the coding assessment period

instructions are missing and it is not clear under what time periods should the assessment finding be noted.

Once the demonstration markets have been determined and nursing facilities selected for participation, AHCA recommends that affected state Quality Improvement Organizations (QIOs) and survey teams receive training on the demonstration purpose and CARE tool so that both entities working with or surveying participating facilities are aware of the effort and can look for indications of potential instrument impact on care transition and planning.

We also recommend that the 2-day assessment period be carefully evaluated with regard to application to all elements in the CARE instrument. Conditions like risk for falls and bowel incontinence cannot be fully assessed using a short evaluation period. Discharge assessment having a standardized shortened evaluation will limit the amount of information that can be used by the receiving facility; particularly when patients are admitted on Fridays or over the weekend when interdisciplinary staff members are not available to provide input on the assessment sections relevant to their service. In nursing facilities, this situation is particularly problematic in rural areas where physical/occupational/speech therapists, dieticians, and social workers may not be at the facility on a regular daily basis.

Signature of Persons who Complete a Portion of the Accompanying Assessment

The proposed CARE instrument calls for signatures of all persons who complete any portion of the assessment. By signing, individuals certify "that I may be personally subject to or may subject my organization to substantial criminal, civil and/or administrative penalties for submitting false information." AHCA recommends that this phrase, be stricken from the statement since the CARE instrument contains numerous elements starting with Section IV Cognitive Status through Section IX Discharge Status that require a judgment response. A judgment is an opinion that is influenced by numerous factors and often varies from individual to individual. The CARE instrument even calls for some responses that cannot be accurately or truthfully answered. For example, Section IX, CI asks "Will the patient be able to pay for their medications after discharge?" Section VI, C18 asks about the patient's "Ability to use public transportation – includes boarding, riding, and alighting from transportation." In these examples, clinicians are asked to accurately and truthfully respond to questions beyond their sphere of professional practice and control.

Often clinical opinions are based on patient reports or reports from others. Other judgment opinions may come from family members or reports from other staff. In Section IV, G5b the assessor is to ask the patient "During the last two days, have you limited your activities because of pain?" In this type of question, the patient or individual responding for the patient offers the response. It is unclear how the clinician can certify the accuracy and truthfulness of a surrogate response. Even more concerning is whether the clinician, based on clinical observation, codes differently from the patient response and by doing so, has breached any claim to accuracy and truthfulness.

Long term care has dealt with a similar attestation requirement in the MDS. CMS programs like the Data Assessment and Verification (DAVE and DAVE II) has looked at MDS accuracy and has identified areas of that instrument that are consistently miscoded and misinterpreted. Known factors impacting coding accuracy relate to MDS complexity and ambiguous coding instruction.

When coding irregularities are identified by the state regulatory agency, providers are asked to correct the coding. While some coding irregularities involve true errors, others do not. In the case where there is a dispute over the coding, providers are essentially asked to change coding by the state regulatory agent who had no involvement in completing the assessment at the time the patient was assessed. Many providers make the requested changes not because they agree with them, but because they fear reprisal or other consequences if they refuse. AHCA believes, therefore, that the error identification system sometimes forces clinicians to code an element(s) inaccurately and accept coding recommendations from other individuals that have had no involvement in patient care over the time period being assessed.

Government MDS studies have also looked at MDS accuracy and have cited issues with the lack of medical record documentation to support MDS assessment coding. Lack of medical record documentation is a separate issue and should not be used as the only source for determining accurate and truthful MDS assessment coding. Various individuals provide objective and subjective information contained in the medical record. Entries in the medical record also do not necessarily conform to the required MDS assessment look-back periods. In addition, other information sources, like nurse assistant recordings or medications prescribed under facility "standing orders" policy are separate from the information kept in the medical record. Most importantly, coding and medical record difference occur when two different disciplines, like nursing and rehabilitation, code findings. Professional disciplines note services and outcomes in a manner common to their standard of practice. For example, the physical therapist may account for rehabilitation minutes differently from the increments required on the assessment instrument. In many instances, a non-rehabilitation staff person is responsible for completing the entire assessment and as a result, the risk of error in interpreting and coding minutes of services increases. Again, this situation is more problematic in nursing facilities where all disciplines may not be full-time staff of the facility.

AHCA questions the need for requiring the license number of the individuals completing the assessment. We are not familiar with any other medical document that requires a license number and question the rationale for the inclusion in the certification statement. We are also concerned that this requirement unfairly singles out a clinician when a coding dispute occurs. As discussed above, there are many considerations impacting coding practices and many of them come from entities not directly involved with patient assessment.

AHCA is also concerned with the draft PAC-PRD tool directing the assessor to list those sections she/he completed. Some providers use a care team approach in assessing

patients, discuss findings and then reach consensus on what to code. In this instance, assessment coding becomes a product of the care team rather than an individual's product. Making providers identify each area they completed is burdensome. Deciding who gets to sign and certify when the coding decision came from care team consensus is problematic.

AHCA strongly recommends that the certifying statement be revised to eliminate the criminal, civil and penalty statement and only request signatures of those clinicians involved in the assessment.

Section I: Administrative Items

Assessment Type

- C9 – Social Security Number: AHCA does not understand the rationale for making the social security number optional. Social Security numbers are nationally recognized and protected along with any information derived from the CARE assessment.
- C12a – Interpreter: The question asks if an interpreter is available but it is not clear whether the presence of an interpreter pertains to the time the question is being asked.
- C13b – Documentation of individuals having authority to make decisions: The question needs to distinguish between individuals having the authority to make financial and medical care decisions for the patient. Having legal decision-making authority in financial matters does not grant authority in medical decision-making. If the patient does not appoint a proxy decision maker (persons with durable power of attorney for health care and includes guardians), many states designate a priority order of default decision makers. State law varies on how default decision makers are designated. The data element needs to be revised to read "Does the medical record document the person having legal authority to make medical care decisions if the patient is unable?"

Section II: Admission Information

A. Pre-Admission Service Use

- A1 and A2: See general comment on definitions of long term care, community based care and permanently in a long term care facility.
- A3b: Asks for ICD-9 CM Code and asks for the code again in Section III, Current Medical Items, A. The latter section instruction, however, asks for the code "if it is available." Should "not available" also apply to A3b or eliminated from Section II, A?

B. Patient History Prior To This Current Illness, Exacerbation, or Injury

- B1 (2) and (3): See general comment on definitions of long term care, community based care and permanently in a long term care facility.

- B3f: Paid help living in the home (other than home care) does not include privately paid help not living in the home. Consider adding a bullet for privately paid help.
- B4: Structural barriers at home cannot be accurately assessed unless home visits are completed. Home visits are a component of case management (required in some states under worker injury laws) and life care applications. See discussion on certifying accuracy and truthfulness.
- B5: The questions in this section solicit information about the patient's ability with everyday activities prior to the current illness. Eating and toileting are omitted from this section. Since one's ability to eat and toilet are late-loss activities of daily living (ADLs), we recommend they be included in this section on prior function.
- B5: Having an assessment period over the last 2-days does not allow for assessment of usual activity prior to the illness.
- B7: An accurate history of falls cannot be obtained when looking at the last 2-days. A lengthier look-back period is needed for this element.

Section III: Current Medical Items

B. Other Diagnoses, Comorbidities, and Complications:

- Please explain what is meant by "under-reported" diagnoses.
- B16: After 15 opportunities to list additional comorbid conditions, it is questionable whether respondent will identify that the list is **Not** complete. Has the prevalence of 15 or more comorbid conditions been found to be an issue needing monitoring? If not, consider omitting B16.

C. Procedures (Diagnostic and Therapeutic Interventions)

- Do the 15 interventions pertain to those administered over the last 2-days? The data element does not specify the time period.

D. Treatments

- Is an emergency room stay before hospitalization considered part of the hospital stay? If the patient is treated in the emergency room and then discharged to another setting, is the CARE tool completed by the emergency room staff?
- Do the 15 treatments pertain to those administered over the last 2-days? The data element does not specify the time period.
- Column 1 – Admission/Discharge With: The column does not distinguish those treatments noted on admission compared to those on discharge. The note "Use at any time during stay is only necessary at discharge" is confusing. We recommend having 3 columns – admission, discharge and any time during stay.
- D4: Define what is considered for Central Line Management.
- D9 and D9c: Is Continuous Cardiac Monitoring considered uninterrupted monitoring? Does continuous monitoring (with breaks) apply to these two elements?
- D12c: If suctioning is prescribed on an as needed basis, is it coding at D12c and if so, how?

- D13 and D15: Is Continuous Positive Airway Pressure (CPAP) and Bilevel Airway Pressure (BiPAP) considered under ventilator? If not, we recommend including elements for CPAP and BiPAP coding.
- The treatment list excludes Enteral and Parenteral Feedings. Their inclusion needs to be considered.
- We recommend reorganizing this section to group either alphabetically or having similar treatment together, like IV lines, to make it easier for clinicians to code items.

E. Medications

- Medication needs to be defined as to whether gases (oxygen), inhalers, creams and topicals and patches are included.
- Planned Stop Date needs clarification. If the medication is discontinued in the 2 day assessment period, is this considered a planned stop date? Are stat medications (one or 2 doses) considered in the coding for planned stop date? Are PRN medications to be noted under frequency as "PRN" or the number of times the medication was given?
- E31: Having more than 30 medications given over a 2 day assessment period most likely would not indicate the patient is a candidate for discharge. We are not clear as to why the instrument is asking if the list is complete.

F. Allergies & Adverse Drug Reactions

- Do drug reactions include side effects as well as drug/drug and drug/food reactions? Definition is needed.
- F9: Consider restating the element perhaps consistent with other similar elements – "Is this list complete?"

G. Skin Integrity

- If staging is based on the National Pressure Ulcer Advisory Panel (NPUAP) definition and stages, we recommend the inclusion of "deep tissue injury."
- G4: Undermining of adjacent tissue in stage 3 and 4 pressure ulcers is different from tunneling (sinus tract). Undermining involves a bigger area than tunneling. We recommend adding "undermining" to the element description.
- G6e: Data element is confusing. Is it designed to acknowledge the existence of pressure ulcers not found on hips, back and buttocks? If so, recommend changing (e) to other (non turning surface) ulcer/wound found.

H. Physiologic Factors

- Does the 2 day assessment time apply to these questions? If so, please add to instruction at top of section.
- H21: Add Pro Time to International Normalized Ratio (INR). Not all clinicians use or may recognize the INR designation.

Section IV: Cognitive Status

C. Observational Assessment of Cognitive Status

- C1: Data elements repeat B2 and B4. Consider eliminating element.

E. Behavioral Signs & Symptoms
- It is not clear if the 2 day assessment period applies to all elements except F2a to F3. Section direction needs clarifying.

G. Pain
- G3 Pain Severity and G4 Pain Severity appear to be similar. Needs explanation. Consider using or including a standardized pain scale like Wong-Baker FACES Pain Rating Scale.
- G5: Eliminate "at night" from the data directions. "At night" does not account for difference in circadian sleep cycles.

Section V: Impairments

B. Bladder and Bowel Management: Use of Device(s) and Incontinence
- B2 (1): Stress incontinence needs defining to distinguish it from other types of bladder incontinence.
- B2 (1-4): It is not clear if these elements refer to bowel incontinence as well as bladder incontinence. If so, bowel incontinence/impairment cannot be determined over a 2 day assessment period.
- B2 (5) No bowel output over a 2 day period can occur independently of renal failure. It is not clear if the element is seeking lack of bowel or bladder output or both.
- The section does not include ostomies. Consider adding.

D. Hearing, Vision & Communication Comprehension
- It is not clear if the 2 day assessment period applies to section D.
- D2: Add element – If the patient speaks another language, is this coded under "Unable to assess?"
- D3: Add, "Has and uses glasses or contacts."
- D4: Add, "Has and uses hearing aide(s)."

F. Weight-bearing
- Range of motion for lower extremities is not included. Why?

G. Grip Strength
- To help make the tool more user-friendly, we recommend that this section immediately follow upper extremity functional range.

H. Respiratory Status
- Add element "Uses Oxygen (includes during the day and night or only at night)."

I. Endurance
- 11: Consider adding standing balance.

- 12: Consider adding sitting balance.

Section VI: Functional Status

A. Core Self Care

- 2-day assessment period is repeated. Omit second statement.
- A6: Clarify if ability to dress and undress below the waist includes slippers, shoes and socks.

B. Core Functional Mobility

- 2-day assessment period is repeated. Omit second statement.
- B5: Wheelchair use is asked at J (C and D), B5D, B6(c and d), and V1 C6. Redundant.

C. Supplemental Functional Ability

- Relocate 2 day assessment period to instruction area above elements.
- C3: Add "Unaided or with side rail/mobility bar."
- C6e and f: Do the elements assume a standard ramp pitch? If so, please note. Is it assumed that ability to go up is equal to ability to go down?
- For elements C7 through C18, relocate 2 day assessment period to instruction area above elements.
- C11: An element is needed on ability to self test for blood glucose and medication management.
- C13: Consider changing word "bench" to "seat/chair."
- C12, C14, C15, C16, C17 and C18: Detail of assessments may not be common to all Occupational therapy programs and assessments. Detail of assessments raises concern over clinician's ability to certify accuracy of responses. Example - C17: most therapy programs do not assess the patient's ability to drive a car in local community.

Section VII: Engagement

- Does the 2 day assessment apply to this section? Direction not offered.

Section VIII: Frailty/Life Expectancy

- Does the 2 day assessment apply to this section? Direction not offered.
- Cultural and religious beliefs impact how the caregiver responds to questions related to life expectancy. The questions require subjective and speculative responses and it is questionable if the information obtained can be considered with any level of confidence.

Section IX: Discharge Status

C. Other Discharge Needs

- C1: Clinicians are not in a position to accurately determine if the patient can pay for medications once discharged. A clinician cannot not answer this question then certify to accuracy and truthfulness.
- C2: Clinicians cannot accurately answer question as required by the certification statement. To properly assess patient ability to manage medications while at home, home visits are required. Consider rephrasing question to "Has the patient demonstrated on discharge that he/she is able to manage their medications?" In addition, consider adding "Has the patient stated he/she has a way to obtain needed medications." See earlier comments on certification statement.
- C3 (2): Clinicians are unable to certify if the patient will be able to drive themselves to physician and medical appointments.
- D(i): Does LTC Nursing Facility refer to a non-skilled bed? See general comments regarding definitions of post acute care settings.
- E6: One of the purposes of the CARE instrument is to capture information at discharged and to share the information with the receiving provider so that care needs are met. It would be helpful to know why sharing the information would not be done. In addition, "authorized representative" needs further definition. AHCA recommends changing to "representative authorized under state law to make health care decisions."

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September 16, 2007

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless, Room C4-26-05
75000 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS – 10243 (OMB#: 0938 – NEW)
Medicare Continuity Assessment Record and Evaluation (CARE) Instrument

From: Margaret I. Wallhagen, PhD, APRN, BC, AGSF

Thank you for the opportunity to comment on the above noted proposed form. The purpose for which these data are being collected is extremely important because the types of resources available to support individuals in post acute settings can be a critical determinant of long-term outcomes. Comments are especially targeted to item (3): ways to enhance the quality, utility, and clarity of the information to be collected.

First, overall the data collected are extensive and do include a range of variables that will assist in determining resource need and potential utilization. It also does appear that the form could be computerized in a way that might facilitate data collection, dissemination, and analysis. Given this, there are several substantive areas that I believe need to be added or expanded to make the data as meaningful and useful as they should be, and several areas where I believe the data collection could be made clearer or more comprehensive and useful. I will address the more substantive points first and then note areas for consideration related to the form itself.

1. **Caregiver/care provider data**. There is an extensive body of literature on the importance of a caregiver in relation to maintaining dependent individuals in the community and the actual cost of the provision of such services to the caregivers and their families (monetarily, physically and psychosocially). Although the data collection tool includes identification of whether the person being assessed lives with someone (I.B3), and whether there is a caregiver available at discharge who is "willing and able" to provide the care and the type of relationship this person has to the person being assessed (IX.B2/B3), there is no formal assessment of the caregiver and how this determination was made.

Informal caregivers often have minimal concept of what taking on the caregiving role entails if this is a new role that they are assuming – for example, after an individual experiences a stroke or some other permanent disability that will require on-going care provision. To make the transition safe and effective and to enhance outcomes, it would be helpful to incorporate a more formal assessment of the caregiver's actual ability to take on the care needs of the person being assessed and to make sure that these individuals have the necessary information regarding resources that they may be able to draw on to support their caregiving activities.

In addition, if the caregiver has been caring for the person being assessed for some time before the current episode, it becomes a time when a re-assessment of the caregiver's abilities and own health status would be important because the caregiver's health, which data support can be affected, is also a critical element in the long term status of the person being assessed. This specific time may be an important one in making decisions about the most appropriate subsequent placement. Either a specific targeted assessment of the caregiver (his/her health, resources, support systems) needs to be included to support the assessment that this individual is "able" as well as willing, or a supplemental assessment that can be used if a caregiver is necessary should be available. This would contribute significantly to the collection of data that are needed to identify resource allocations post acute episode.

There have been on-going efforts to incorporate some such consistent assessments in out patient facilities that work with care receivers and such efforts may contribute to the identification of specific and targeted areas of assessment.

2. **Decision-making capacity**. IV.C4 asks for the assessment of the individual's cognitive skills for daily decision-making but no specific criteria for how to make this assessment are included. Assessment of decision-making capacity is not straight forward and yet is critical to how individuals are able to manage at home and whether there are subsequent admissions/re-admissions. A more formal assessment of decision-making capacity should be included or at least a strategy for the inclusion of a more standardized approach included for situations where there is some uncertainty about these skills. At least any approach should be standardized across assessments.

3. **Sensory impairment**. V.D1 requires notation of whether the individual is able to understand verbal content with a hearing aid or device if used. My research as well as that of others document that individuals often do not admit to difficulties hearing, are often unaware of the extent of their hearing impairment, and will fill-in or fake that they hear what has been said. This can have a significant impact on an individual's understanding of

post-discharge activities and requirements and yet this area has been significantly understudied and under-appreciated. At the very least, it should be clear whether the individual is using a device (hearing aid, pocket talker, etc) vs. not using a device, and, preferably, some specific assessment of hearing should be included so that the data collected are more standardized and would further our ability to assess the impact of hearing loss on subsequent outcomes.

Other areas to consider for clarification:

1. **I.C12, Language**: it would be beneficial to assure that the "interpreter" available is a non-family member. It is also not totally clear, with only two code boxes, how the "string" variable will be captured in the data.

2. **I.B3, Living arrangement**: Include number in household

3. **II.B4, Residential setting**: Indications of potential safety problems in the home, such as lack of safety bars or the presence of throw rugs, may need a more formal assessment.

4. **II.B8, Prior mental status**: The question asks about "acute changes" vs. what the individual's actual cognitive functioning was prior to this episode. An acute change can still occur in someone who is severely cognitively impaired to start.

5. **III.G1-2, Presence of pressure ulcers**: G1 focuses on the evaluatin for "risk" of pressure ulcers as opposed to the presence (which is addressed in G2) yet G1, 2 includes "or active pressure ulcers" are present. This would seem to confound the data collected.

6. **III.G4, Unhealed pressure ulcers**: Tunneling and sinus tracts are slightly different and undermining is not included.

7. **III.H, Medical items:** Creatinine clearance is critical to medication dosing and subsequent potential ADRs. Creatinine clearance, even if calculated, would be useful data to include.

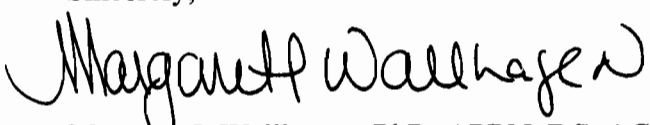
8. **V.B2, Impairments – incontinence**: Urgency, which becomes increasingly common in older individuals, is not included. It's not clear why only stress incontinence is specifically pulled out.

9. **V.G, Grip Strength**: Grip strength has been shown to be important to outcomes and to assessment of physiological status and function but what is noted here is the ability to squeeze an individual's hand which will not get a true understanding or documentation of grip "strength". It would be extremely subjective and, few individuals would actually (nor should they)

squeeze someone's hand with enough force to get a good indication of strength.

Again, thank you for the opportunity to comment. If you have any questions, please let me know.

Sincerely,



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American Medical Rehabilitation Providers Association

Kathleen C. Yosko, MS, MBA
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Marianjoy Rehabilitation Hospital
AMRPA Chairman of the Board

September 21, 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

Delivered by Courier

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

Dear Ms. Harkless:

This letter is submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA). AMRPA is the national trade association representing over 550 freestanding rehabilitation hospitals, rehabilitation units of general hospitals and numerous outpatient rehabilitation providers. Many of our members also include, in their health care networks, skilled nursing facilities and long term care hospitals which deliver varying levels of medical rehabilitation services.

We appreciate this opportunity to comment on the Continuity Assessment Record and Evaluation (CARE) instrument. AMRPA members have been very interested in the Post Acute Care Deficit Reduction Demonstration Program as authorized by Section 5008 of the Deficit Reduction Act of 2005. Several of our members participated in the two Open Door Forums held to date and on the two Technical Expert Panels. In addition, AMRPA sent the project directors and CMS staff two letters expressing our concerns about the creation of the patient assessment instrument mandated by the statute. Copies of those letters are attached as Attachments 2 and 3.

To review the CARE instrument, AMRPA created work groups to examine: (a) the structure and content of the instrument, (b) the issues of interoperability and day to day implementation, and (c) overarching study issues.

The *Federal Register* announcement states that the instrument 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 relationships between severity of illness, functional status, social support factors, and resource utilization.

   It will be used in the Post Acute Care Payment Reform Demonstration (PAC PRD) program to develop payment groups that reflect patient severity and related cost and resource use across post acute settings.

We hope CMS and OMB receive these comments as an effort to be constructive from the perspective of inpatient rehabilitation facilities and the patients we serve. Throughout the review, we found ourselves constantly trying to balance the need for an economical instrument in terms of time and administrative burden with the needs of the project to capture necessary information about patients across the varied post-acute providers.

I. OVERARCHING ISSUES REGARDING THE CARE INSTRUMENT AND RELATED STUDY CONCERNS

Our key issues are centered on serious concerns regarding validity and reliability of the instrument and its individual items; the extensive administrative burden it will impose; and the risk that the instrument, and the project will result in blocking access for patients to needed services and programs in the most appropriate setting as determined by responsible physicians.

A. Reliability and Validity of the Instrument and the Items; Methodology

1. Reliability and Validity

Two key aspects of any study and any data collection tool are whether or not they are reliable and valid. Our work groups raised numerous questions on these two issues. The reliability of observations may not be taken for granted since there is subjective variability in making such observations. To earn confidence as a basis for decision-making, observations must be both accurate and precise.

In studies where the results depend on observation and the reporting of observed values (specifically analogous to CARE instrument assessments), the value of the study can be better assessed if the two measures of variability are evaluated and reported as a quantity. Statistics such as the kappa (for dichotomous items), intra-class correlation coefficients (ICCs), standard error of measurement (SEM), limits of agreement (LOA), and item-separation reliability (for equal-interval scales in a Rasch framework) are used to evaluate reliability and reproducibility. Reliability of the CARE instrument needs to be quantified using appropriate statistical methods and research designs.

Also, for research data to be valid, reliable, and representative, the data collection personnel must be consistent, accurate, and objective in the data collection/acquisition process. Otherwise, intra- and inter-rater reliability become key potential points of

vulnerability when data acquisition occurs across multiple PAC settings, personnel types (clinical vs. administrative), and modalities (in person vs. telephonic).

Factors that could reduce the value and reliability of the CARE instrument include (1) events occurring in different settings, (2) different observers being influenced by their varying experiences with legacy definitions of items from previous assessment instruments and (3) staff with different care philosophies, levels of expertise, and training recording their personal observations. For example, AMRPA is concerned about reliability between settings when what appear to be IRF-PAI functional items are used in different settings with a new scale. See the item "Toileting" under Functional Status. Furthermore, some of the more typical functional items are now under Impairments with different scales and definitions. Many items in the instrument are taken from other CMS measurement instruments such as the IRF-PAI, MDS, and OASIS. The IRF-PAI functional independence measure items were tested for reliability and validity within the context of that measure, but if moved to another instrument with different scales as noted, they must be retested and re-confirmed before conclusions can be made about the findings they will generate.

One of the statutory purposes of the project is to develop a way to predict placement of patients to a post acute care setting, based on certain patient characteristics captured by the instrument at the time of acute care discharge. However, the key issues to be addressed are the validation of the CARE instrument against optimal/appropriate placement and whether the CARE items necessary to decide on, or at least screen for, optimal rehabilitative placement are isolated. This critical factor is not discussed or, at minimum, underemphasized. These factors must be addressed, including the physician's role in placement decisions. If not adequately addressed, then patients will be sorely disserved, underserved, and penalized. Patient advocates and providers naturally worry that the assessment might be inappropriately used in a way that decreases the odds of individual patients accessing the right care setting for their medical and functional needs. Additionally, providers will be potentially adversely affected by receiving patients they are not prepared to serve and/or receiving inappropriate payments.

Another purpose of the instrument is to collect data on resource use, but there is no evidence that this instrument can do that accurately. Would the CARE instrument be measured against the predictive power of existing tools regarding resource use? Is collection of resource use more the function of the CRU logs and protocols, plus analysis of cost reports and claims?

AMRPA is also concerned that the instrument does not give CMS a complete picture of each patient. For example, there is little on the medical management of diabetes and hence the assessment would understate the medical fragility of that patient. There is no evidence that the instrument has validity in distinguishing between patients who need, and would achieve, large functional improvement from a short, intense program as opposed to those who would benefit from a longer, less intense program with less functional improvement. These questions become exceedingly serious as CMS moves to develop a post acute care payment system.

At the Open Door Forum on July 27 the RTI Project Investigator mentioned that the instrument would be tested for reliability and validity during the course of the demonstration project, but there was no description of which we are aware as to how this will be done.

We recommend that CMS publish a description of the studies it will use to determine the reliability of the data collected for the completion of the CARE instrument. AMRPA further recommends that CMS provide information clarifying what tests of validity were applied in selecting the various data elements of the CARE instrument and what tests of validity will be used in assessing the instrument at the end of the demonstration project.

2. *Sample Size – Representativeness/Selection Bias*

We note that the study expects to recruit 21 rehabilitation units and 7 freestanding rehabilitation hospitals as well as have 44 rehabilitation hospitals and units participate voluntarily. The total number of IRF patients recruited for the study is expected to be 7,623 patients and result in 16,286 assessments which reflect admission, discharge, and interim assessments.

Selection of a representative sample of providers is crucial, since the results may not be generalizable if the study compares a limited number of post-acute providers that differ greatly in their characteristics (e.g., affiliation, profit status, billing practices, quality, and proximity to alternative care settings) from the whole universe of post-acute care providers.

We are also concerned that the proposed volume of cases and number of providers may neglect segments of the market that are small and/or rural. These providers may not have the resources to participate in the study and hence would not seek to be recruited nor be able to volunteer. It is our understanding that participating providers will not receive compensation to participate, despite the fact that double record keeping will be necessary during the demonstration (i.e. MDS and CARE, OASIS and CARE, IRF PAI and CARE). Hence, since there is a certain burden and cost involved in participating, we are concerned that these factors may skew those providers that will volunteer and may agree to be recruited. Volunteers are likely to be those sites most engaged in outcomes measurement and staff training. Their ability to cope with the demands of a new instrument may not reflect the extent of the training and resource challenge that would occur during a national roll-out of the next generation CARE instrument.

We are further concerned that the current IRF environment now, and at the time the project will be conducted, is not truly representative of the field of medical rehabilitation providers and services. The 75% Rule and medical necessity reviews continue to decrease patient choice. Facilities are closing beds; staff is being laid off, and many more patients are being channeled to SNFs. The net result is that as the study progresses – if the 75% rule continues to be implemented – the patients usually treated by IRFs prior to the 75% rule will not be present, and hence, the natural clinical laboratory of IRFs will

present a skewed picture. AMRPA previously suggested to RTI that CMS provide a waiver from the 75% rule for all IRFs participating in the study, and we reiterate that recommendation here.

There has been a significant decline – now exceeding 100,000 patients – in the number of people treated in rehabilitation hospitals and units since the implementation of the 75% rule. Furthermore, there has been a decline of more than 11% of the nation's rehabilitation beds and 10% of facilities from 2004 to May 2007, based on data from CMS's OSCAR database. MedPAC's analyses show a drop in admissions from 2004 to 2005 of 10%. In March, MedPAC predicted an additional 20% reduction in cases as a result of the phase in of the 75% rule to 65%.

In addition to the 75% Rule, another factor adversely affecting IRFs' ability to operate and provide needed care to all patients requiring inpatient rehabilitative treatment is the increasing number of medical necessity reviews. These reviews take many forms but have the same net effect on facility operations. They are a factor in driving down volume and in affecting facilities' cost structure and cash flow. Numerous cases are being denied and some facilities are responding by further changing their admission practices, thereby creating more barriers to access for patients. Even though a great percentage of denials are overturned and paid upon final appeal to an ALJ, rehabilitation hospitals and units are forced to divert substantial revenues to defend against inappropriate denials and recover payments. Denials may be the result of reviews by the fiscal intermediary under a local coverage determination (LCD)or the new Recovery Audit Contractors (RACs).
Most of the cases denied appear to be orthopedic cases, particularly single joint replacements. All this turmoil imposed on inpatient rehabilitation hospitals and units is resulting in a substantial disruption of the operating characteristics of facilities that will likely continue to change over the course of the study. Choosing this moment in history to test the CARE instrument will make it more difficult to rely on any conclusions that could be reached from the data, because the field is not in a steady state. Most research attempts to control variables and evaluate a specific hypothesis that starts with an assumption we can paraphrase as: "All else being equal…" Analyzing any research conducted in the rehabilitation community at this time will be complicated by the multiplicity of uncontrolled variables just described.

3. Burden on Acute Care Providers and Post Acute Care Providers

Each work group expressed extensive concern about the burden the instrument will exact from all post acute care providers. IRFs are used to completing a data assessment tool – the IRFPAI – which takes approximately 40 minutes according to our members. However, the CARE instrument is a new, much more extensive instrument as opposed to the parsimonious IRF-PAI. The supporting statements show a completion time of 75 minutes for IRFs. Hence, even after training is completed it will be an additional burden for the IRFs based not only on the sheer number of items, but also on the potential number of times it is to be recorded.

In addition to admission and discharge, which is done now, assessments are to be done on an interim basis. We did not find an explanation of what events would trigger an interim assessment.

Anticipated Additional Administrative Burden for IRFs for Admission and Discharge Assessments Only

35 min = excess time for one-time completion of CARE vs IRF PAI	7,623 = number of IRF patients in the demo	2 = minimum number of times assessment will be performed on each patient	=8,893.5 hours above what would have been expended on IRF PAI (assuming CARE as replacement for IRF-PAI, not an additional requirement)	4.28 FTEs over and above staffing necessary for IRF PAI --- just during demonstration.

Anticipated Additional Administrative Burden for IRFs for Additional Interim Assessments

35 min = excess time for one-time completion of CARE vs. IRF PAI	1,040 = additional # of times assessment will be performed	=606.7 hours above what would have been expended on IRF PAI (assuming CARE as replacement for IRF PAI, not an additional requirement)	0.29 FTEs over and above staffing necessary for IRF PAI --- just during demonstration.

As seen in the above chart, the time for IRFs in this project is an additional 9,500.2 hours and 4.57 FTEs. If rolled out nationally, how will this burden and additional resource requirement be addressed?

While the extent of the CARE instrument would create a burden for inpatient rehabilitation hospitals and units, at least staff in these hospitals is experienced in assessing the general categories included in the CARE instrument. Other providers involved with the demonstration do not have experience in collecting this information. For example, long term care hospitals (LTCHs) do not have experience with standardized assessment tools at all. Acute care hospital discharge planners do not have significant experience with documenting the type of medical and functional information that the CARE instrument requires. Hence, this instrument will be a huge new burden for them.

Our work groups were very concerned that discharge planners – or others upon whose shoulders this task might fall – will not take the time to complete the forms accurately as intended. Lack of time or lack of competence would lead to unreliable data. To the extent something unreliable is treated as if it were reliable, we will see faulty conclusions leading to faulty policy. Patients could be harmed one by one if erroneous observations recorded in the CARE instrument have the effect of misdirecting their care. Patients could be harmed on a population-wide basis if faulty data led us to faulty public policy that inhibits access to needed inpatient rehabilitation care.

Acute care case managers generally have 30-35 cases they are juggling. Asking them to complete another piece of paper may lead to hurried, inaccurate assessments. We are also concerned that at times patients are sent to the site that has the most aggressive marketing staff as opposed to the one that, after a close review of the patient's needs, is the most clinically appropriate location. It may be appropriate to have part of the assessment being done by the acute care hospital staff with a finer medical and functional assessment being done by external reviewers (such as IRF and/or LTCH personnel).

We recommend that as the demonstration project moves forward that CMS and RTI use that time to eliminate excess, redundant, and inconsistent elements in the instrument and seek a completion time that equals the average time to complete the existing instruments (OASIS, MDS, and IRF PAI).

B. Prediction of Optimal or Appropriate Placement

A primary use of the CARE Instrument will be to inform decisions about post-acute placement, both at the policy and individual level. Because this is a primary use, the CARE instrument needs to be validated against appropriate or optimal placement. Attention, therefore, needs to be paid to the criterion by which appropriate placement is determined.

There needs to be recognition that for many patients, there is no single "correct" or "perfect" post acute setting. Many patients can potentially "fit" into multiple settings, depending on the goals that are established, the time frame that will be tolerated, the cost to be incurred, and the risk of adverse events to which the patient will be exposed. Hence, for policy makers it can be confusing that patients with the same clinical label, i.e. stroke, may be treated in all post acute settings. Ideally, as this project goes forward, some of the factors that are involved in current decision making will become clear and others will be introduced into the mix. Social and economic factors are taken into account now by acute care facilities and PAC settings but are not captured by existing instruments, nor their effects studied. AMRPA funded the initial development of a Rehabilitation Placement Factor. That instrument and explanation of its status to date are attached. See Attachment 4. We recommend that CMS review it for purposes of this project as well.

Therefore, we are concerned about the above aspects of the study and how they will contribute, or not, to optimal placement, and therefore, the potential for inappropriately denied access. Two additional critical factors play into this concern. First is the aforementioned issue of whether the discharge planners and/or other personnel in the acute

care hospitals have the expertise and time (much less desire and inclination) to complete, or coordinate the completion, of such an extensive instrument.

Second is that throughout the OMB documents there is no mention of physicians' judgment in placement decisions from acute care to any post-acute care setting and at discharge from post-acute care settings, be it to another setting or home. Physician judgment is a central factor in such placements. Additionally, decisions must be made on what is available in the local health care arena, not upon the discharge planner or other's opinions of what setting is appropriate, for placement. To that end, we recommend that IX. Discharge Planning D. Discharge Options be redrafted to clearly reflect the physicians' (acute care and post-acute care) judgment regarding placement and the availability of types of care, as opposed to what was considered, which, from the draft, appears subjective.

C. Medicare as a Precedent

AMRPA is concerned this instrument will become (whether intended or not) the standard referral form for all transfers, including Medicare patients and non-Medicare patients. Hence, this outcome needs to be kept in mind. For example in New York, the Patient Review Instrument, required by Medicaid is the *de facto* standard instrument for communication among hospitals and post-acute providers of care. If the concerns above are not addressed, then there is the potential that the adverse aspects of the instrument and all that may flow from it will affect the larger universe of patients.

There are substantially different clinical populations in the non-Medicare segment (traumatic spinal cord injury, for example) that will not be sampled in this study. There is a great risk of a distortion in the findings that do not reflect the full nature of the factors that drive hospital operating costs and infrastructure as well as patient specific resource utilization. AMRPA recommends that data be collected on the entire universe of patients seen in the post acute setting, not just Medicare beneficiaries for this reason. While this idea is alluded to in the documents, we suggest it be made clearer.

II. ISSUES REGARDING INTEROPERABILITY AND PROVIDER IMPLEMENTATION

Rehabilitation providers currently submit IRF PAI data to CMS in a variety of ways, and many analyze these data, either with internal systems, or through other data services (such as eRehabData®). These analyses serve important goals of financial review, compliance verification, clinical program evaluation, and quality improvement. We believe that it will be extremely important for providers to be able to continue to submit, retrieve, and analyze their data and to compare to themselves and various peer groups over time. The data collection methodology provided by CMS should permit all of these functions to occur in a cost effective and efficient manner. Given the intent to try to "connect" all the different post acute settings, it will be even more important to be able to study patients and facilities in all of these settings, not just within a single type. We suspect that only third party agents will be able to provide this type of service, and it should be anticipated and encouraged by the way the CARE data system operates.

Larger providers currently use a variety of IT systems to operate and will be interested in streamlining and automating the entry of their data and submission to CMS through their own systems. Creating interfaces between IT systems is always more challenging, expensive, and time-consuming than expected. To the extent that the data entry and retrieval services provided by CMS can be built with an eye towards eventual interfacing with other systems (either at the provider or an intermediary level), there will be better quality data submissions and less costs incurred by the providers.

SUMMARY

Again, we appreciate the opportunity to review and comment on the proposed CARE instrument. We believe that the points we have raised regarding reliability and validity, burden, and potentially adverse impacts on patient care and access must be addressed as the demonstration project is conducted. We would be pleased to discuss the issues raised herein with CMS and RTI.

Sincerely,

Bruce M. Gans, M.D.
Chairman, AMRPA Consumer and Clinical Affairs/LCDs Task Force

Mark J. Tarr
Chairman, AMRPA PPS Task Force

ATTACHMENTS

1. AMRPA Comments On Specific Subject Areas and Items of the CARE Instrument
2. AMRPA Letter of January 4, 2007 to Barbara Gage at RTI, Inc.
3. AMRPA Letter of February 26, 2007 to Barbara Gage at RTI, Inc.
4. AMRPA Rehabilitation Placement Factors
5. AMRPA Recommendations Regarding Data Interoperability

American Medical Rehabilitation Providers Association

ATTACHMENT 1

AMRPA COMMENTS ON SPECIFIC SUBJECT AREAS AND ITEMS OF THE CARE INSTRUMENT

AMRPA reviewed the areas and items in detail. However, it was very difficult to determine how several of the items were intended to be answered, or were being defined without a draft training manual or glossary. We recommend that a training manual designed to accompany the draft CARE instrument be made available for comment prior to initiation of the demonstration project.

I. Administrative Items

A. A. Assessment Type

1. A1 Reason for Assessment

We are assuming that the CARE instrument will be required to be filled out by both the acute care discharge planners, and then again, likely the same day, by a post acute care provider upon admission. This is a duplicative burden and will add administrative costs for both providers, but will be especially difficult for acute care planners, who currently have no such responsibility for filling out lengthy patient information while trying to facilitate multiple daily discharges in high volume hospitals. We noted this point above.

To what does "Interim" refer? What would trigger a requirement for an interim assessment? Does the term PAC encompass LTACH, IRF, SNF, and HHA care?

B. C. Patient Information

1. C12a If not, is an interpreter available?

It is not clear whether a family member was available to interpret or if a paid or volunteer interpreter was required. We recommend this concern be resolved by shrinking three (3) questions into one (1) by asking: "Is the accuracy of the information provided in this document jeopardized because of an unresolved language barrier?"

C. Overall Comment on Admission, Patient Information, and Discharge Information

Most if not all of this information is, we presume, being collected at the time of acute care admission. Is there a way by which the information can readily be transferred electronically to this form for the acute care hospitals? It would help ease the burden of completing the form for the acute care hospital.

II. Admission Information

A. A. Pre-admission Service Use

This section needs clarification on how to record a patient who is admitted to an acute care hospital by way of the emergency department.

1. *A2 Admitted From and Item A4 In the last 2 months*
We strongly object to using the term "Subacute" and listing it in the SNF section and anywhere in the CARE instrument. The term "Subacute" is not a licensed bed status in any state nor a recognized provider certification under Medicare. It is solely a health care industry marketing term.

2. *A3 If admitted from a medical setting, what was the primary diagnosis in the previous setting?*
This statement may be confusing if the primary diagnosis in the acute care setting differs from the "admitting" diagnoses or reason for post acute care admission. At a minimum, accompanying documents and training materials should clarify that there is no expectation that the admitting diagnosis to post-acute care would be directly related to their previous admitting diagnosis. For example, pneumonia might have been the original acute care diagnosis for a patient who had a complicated acute course and was ultimately admitted to post-acute care due to critical illness myopathy.

B. B. Patient History Prior to This Current Illness Exacerbation, or Injury
As above, if this section is to be filled out by the acute care provider, it will require a thorough nursing and therapy assessment to complete this section.

1. *B7 History of Falls*
This item could be open to inconsistent interpretation, illustrating the danger of collecting information from an unvalidated tool and treating the resulting data as if it were reliable. If a patient had experienced 2 falls in the last six months, one of them resulting in the injuries leading to this admission, there could be legitimate variation in how a conscientious person would answer the question. One person might ignore the present situation and focus on the history, deciding that one fall in 6 months doesn't constitute a "history". Another person could feel quite certain that 2 falls (including one causing injury) is definitely a "history of falls."

We recommend that the question be rephrased to be as objective as possible (e.g. Has this patient had at least ___#falls in the last ___time period?) Ideally, the language of the question would correspond with some previously validated measure that related fall experience with health risk or status.

2. *B8 Prior Mental Status*
How will this be determined? Who will be asked to determine this?. Particularly with geriatric patients, a serious infection (pneumonia or bladder infection, for example) can cause dramatic but reversible changes in mental status. How would one answer this question for a patient who was admitted on Sunday with severe mental status changes caused by an infection if the mental status had improved significantly but not cleared completely when the discharge evaluation was being completed on Wednesday? In the same case, suppose the patient was back to baseline on Tuesday and the discharge was being filled out on Wednesday. Does one answer based on mental status at that moment, or at any time during their admission?

III. Current Medical Items

The name of this section, "Current Medical Items" would be more easily understood if it were "Current Medical Status" or "Current Medical Information". While instrument developers refer to individual elements of their questionnaire as "items", in more general usage the term "items" brings to mind equipment or physical property.

Overall, this section is highly burdensome, and it is difficult expect any one person such as a nurse to be able to complete all sections because they require clinical expertise, the ability to interpret chart information, and coding expertise.

A. A. Primary Diagnosis

1. A1 Primary Diagnosis of Assessment

The instructions should emphasize that the primary diagnosis be the reason or need for the current admission. Again please note the expectation that primary diagnoses will most often change significantly between the acute and post-acute setting.

2. A2 ICD-9-CM Code

This item requires the people completing this section have knowledge of ICD-9 codes that are not likely to be coded in the acute care hospital until post discharge.

B. B. Other Diagnoses, Comorbidities, and Complications

It seems likely that this section will greatly impact resources and it is likely to be critical to reimbursement rates as well as to any measurement of outcomes. To that end, how will an answer of "yes" to number B16 be considered? Additionally, there is a fine balance here between capturing information that depicts a patient's medical status (burden) and accuracy in potential payment and placement. Also, we caution CMS/RTI that the chance for transposition of digits or other errors in entering so many ICD-9 CM codes is also significant.

C. C. Procedures (Diagnostic and Therapeutic Interventions)

This section requires coding knowledge, and would likely not be completed in the acute care hospital until after discharge. Would there be any potential negative impact on the ultimate reimbursement to the acute care hospital if it failed to complete this section? This section also needs to define the terms "therapeutic" and "major procedures." In addition, there is an apparent inconsistency in the instructions. C1 asks for "therapeutic or major procedures" while C1a – C15a ask for "diagnostic and therapeutic interventions." Yet, the question is set up in a way to imply that a "yes" answer for C1 would be required before listing interventions in C1a et seq. Consider this example: if a barium swallow study were done during an inpatient rehabilitation stay, how would this item be scored? Most clinicians would not consider it a "therapeutic or major procedure" but would consider it a "diagnostic or therapeutic intervention" (it is diagnostic).

D. D. Treatments

This section may impact reimbursement so it needs to include the following items:

i. Oral immunotherapy
ii. Oral chemotherapy

iii. Category II narcotics
iv. Sliding Scale Insulin
v. Respiratory Therapy
vi. Feeding tubes
vii. CPM
viii. Ongoing IV therapy

An explanation might be required for consistent responses to some questions. For example, item D25 asks about "multiple antibiotic administration". While the question probably is getting at simultaneous administration of multiple antibiotics (for resistant organisms, for example), a check could be placed in that box under the "Used at any time during stay" if a person had two separate and unrelated IV antibiotics. For example, a patient might receive prophylactic IV antibiotics for a 12-24 hour peri-operative period, then several days later receive a brief course of IV antibiotics for a bladder infection. Would this qualify?

E. E. Medications

The medication list will require a person with knowledge to read and cross reference physician's orders, it is duplicative of a required medication list for "medication reconciliation" for JCAHO, may increase transcription errors if it is used to generate medication orders in the next level of care, and will be very time-consuming. We suggest attaching a current medication list from the pharmacy system rather than transcribing the list on this form. We would recommend specific time-testing of this section of the instrument to quantify the staff burden of this section.6.

F. F. Allergies and Adverse Drug Reactions

This subsection seems unnecessary for estimating reimbursement or the placement of the patient in the appropriate level of post-acute care.

G. G. Skin Integrity

1. G1-2 Presence of Pressure Ulcers

This item is useful in estimating cost of care and reimbursement, and may make the acute care hospital more accountable for pressure ulcers. The data should include the date of the data collection and/or instruction on when it is to be collected.

2. G6 Turning Surfaces Not Intact

The information in G2 - G5 is sufficient to gauge the medical burden related to skin issues and hence this item may be deleted.

H. H. Physiologic Factors

The volume of data collection on this form is excessive and has questionable usefulness in either resource consumption or patient placement decisions. The vital sign sections would be more useful if it reported on a range of vital signs in the last 24 hours rather than a single value. The glucose value has limited value unless it includes 'highs' and 'lows' to indicate the stability of the patient. BUN, HbA1C, and INR should be removed. They have little to no value reported in this format.

Requesting the latest value for arterial blood gases is of little value for this type of data collection effort. The majority of hospitalized patients will not have had an ABG drawn at any time. For patients who were sick enough to require this test, if the original findings were significantly abnormal, the test would likely be repeated to monitor therapy until the ABG values normalized. Therefore, the most recent value of the ABG for those patients would be normal. So that leaves only 2 other possible circumstances: (1) a patient who is being transferred from an acute hospital into a long term acute care hospital which is perfectly capable of handling a patient with deranged ABGs, and (2) a patient whose last ABG was significantly abnormal but is about to be transferred to post acute care. Situation #1 is fine and Situation #2 is either fine (other clinical parameters have indicated patient's recovery) or malpractice if the patient is genuinely unstable and is being transferred. The inpatient rehabilitation sector is unaware of any evidence to indicate that any problem exists related to situation #2. For this reason, we believe the item related to ABGs should be deleted. Using 1.5 vertical inches of 8.5" wide paper to ask this question thousands of times a day (or equivalent memory space in computers) is disproportionate to any value it could provide.

I. General Comments

This section does not capture the patient's medical complexity including pain management, dysphagia management, unstable hypertension, unstable diabetes, IV therapy for hydration, and management for autonomic dysreflexia. We recommend it be reconsidered, the items deleted as noted, and items or instructions that capture these factors be addressed.

IV. Cognitive Items

Evaluating cognitive status is a medically and emotionally sensitive task. Because the CARE instrument process does not stipulate who will perform the assessment (or parts of the assessment), non-clinicians will frequently be required to fill this role in all likelihood. Section IV at first appears to give such specific directions that anyone could conduct the Brief Interview for Mental Status (BIMS). However, looking at item B2 reveals some pitfalls. Generally, one wants assessors to follow a script exactly to increase consistency across administrations of the instrument. Doing so in this case has the test-giver making no response to the patient's first answer before moving on to "I will repeat ...". Not only is this socially awkward, but it is very confusing for a patient to answer a question and get no feedback whatsoever. At a minimum, the tester should be instructed to say "Fine" or "thank you" after any response in B2 before launching into the second part of the instructions. In addition, you'll note the instruction to the tester: "You may repeat the words up to two more times." Since this says "may", presumably there will be a whole range of persons who do not repeat it at all, those who repeat it once more, and those who repeat it twice more. The result is that one ends up treating data as if it's a comparable test of patients' recall when, in fact, there's a 300% range in the intensity of the stimulus to which patients were exposed.

Because the CARE instrument could be used with the same patient twice in the same day (at discharge from acute and admission to post-acute) or several times within a week, it's possible the patient's second and later performances would benefit from the rehearsal effect. Most neurologists, psychiatrists and other medical specialists vary the items they use in the three word memory test, so it is highly unlikely a patient would develop a learned response that would confound findings designed to test recall in normal clinical practice. But with use of the CARE

instrument in the frail senior population, it would not be uncommon for a patient to be exposed to the sock/blue/bed prompt and questions multiple times. Before long, AARP Magazine will be running jokes for which the answer is always sock/blue/bed. While this may seem trivial, it demonstrates the complexity of evaluating cognitive status in such an ad hoc manner.

A more objective approach would be to replace the BIMS with this question: "Is there any chart entry to indicate that cognitive status is so seriously impaired that it would interfere with the patient's ability to achieve gains through rehabilitation interventions?" and these possible answers: "Yes/No/Cannot Determine."

Certain problems in cognitive testing also occur based on the site and circumstances of the questioning. For example, question F2a asks: "During the last 2 weeks have you been bothered by little interest or pleasure in doing things?" How would we expect a patient who experienced multiple trauma 15 days ago that has let to an amputation and a T8 spinal cord injury to answer that question?

A. F3. Feeling Sad

This item should be reworded. As is, even a patient who was profoundly and consistently sad might answer the question "no" if he/she never actually said the phrase "I feel sad" at any time during the last two weeks.

B. G3. Pain Severity and G4. Pain Severity

These questions are repetitive. If the purpose of asking both questions is to validate the instrument, that should have been accomplished before questions were included. It will be awkward for a caregiver who has just been told that the answer to question G3 is "10, the worst pain you can imagine" to have to follow that by asking, "Please rate the intensity of your worst pain ... as mild, moderate, severe, very severe/horrible."

On a technical note, Question G3 asks for a rating from 1-10, which presumably would be entered in the box. However, the scorer is asked to enter an "8" if the patient does not answer or is unable to respond and then skip to G6. Presumably the presence of absence of answers in G4 and G5a&b will indicate whether the "8" in G3 means the pain has been rated by the patient as level 8 or the patient was unable to respond so the scorer entered an 8. While computers can score this way, people answering the questions will likely be confused, annoyed, or both.

V. Impairments

A. A. Impairments

1. A1 Does the patient have any impairments in bladder or bowel management, hearing, vision, communication, range of motion, weight-bearing, grip strength, respiratory status, or endurance?

There are too many categories lumped together. All of the issues listed are addressed elsewhere in the assessment in further detail if the answer is yes. We assume this is part of the skip logic in the instrument. Hence, if the answer is "yes," there should be a drop down menu to indicate which one. Then each of the areas where there is a "yes" should

indicate "go to section ___ for further information to be completed." Also, does this question refer to these issues as being a new onset or an ongoing issue? This difference needs to be clarified.

B. B. Bladder and Bowel Management

1. B2a and B2b Indicate the frequency of incontinence during the 2-day assessment period.
Two (2) days is not enough time to properly observe this potential impairment. Is it for both bowel and bladder? Also, we question designating some of these areas as impairments when in IRFs they are considered part of the patient's overall functional ability. Does use of a Foley catheter/ostomy device constitute incontinence?

2. B3a and B3b Does the patient need assistance to manage equipment or devices related to bladder or bowel care?
The term "need assistance" needs to be clarified. The definition and type of "assistance" provided in an acute care setting is different from a rehabilitation setting.

3. B4 If the patient is incontinent or has an indwelling catheter, does the patient have a history of incontinence (excluding stress incontinence) prior to the current illness, exacerbation, or injury?
This item asks about the patient's history. Again, "history of" has wide variations in interpretation. Would a period of incontinence that responded to medication count? What about prolonged incontinence that was surgically corrected in the past? Answers would be more reliable if the question were very specific, such as: "Was the patient known to be incontinent immediately prior to the current illness, exacerbation, or injury?" Even at that, one could argue about the definition of "known to be", but it gets more closely at the point of determining whether the problem of incontinence is new or pre-existing.

C. C. Swallowing

1. C1, Swallowing Disorder – Signs and symptoms of possible swallowing disorder
Again, the time frame is inadequate to assess swallowing. We recommend at least three (3) days be included. What might those signs and symptoms be, especially for settings other than rehabilitation?

D. D. Impairments – Hearing, Vision & Communication Comprehension

1. D1 Understanding verbal content (with hearing aid or device if used)
How will this be assessed (i.e. language impairments)? It is very subjective. The item needs more objective tools and measurements. The descriptors indicate a more severe impairment than the bolded typed classifications. For example, it would be hard to rank a person who can participate effectively in complex conversations but periodically must ask for a word to be repeated due to a hearing loss. While the person doesn't qualify for a 3 rating because of the need for some repetition, it seems unduly harsh to rate this

person a 2 which says "comprehends only basic conversations or simple, direct phrases or requires cues to understand." While this point may seem petty, this "straw person" case describes a significant percentage of Medicare beneficiaries, so caregivers will be repeatedly frustrated by the forced choices in item D1.

2. *D2 Expression of ideas and wants*
This question only addresses individuals who communicate through speech. Communication occurs through many methods (i.e. sign language) and should be included.

3. *D3 Ability to see in adequate light (with glasses or other visual appliances)*
There is no universal tool to assess this question. Clarification or definition is needed for "adequate," "mildly to moderately impaired," "severely impaired," etc. The scale makes a big jump from 3. Adequate, which requires seeing in fine detail including newsprint, to category 2, Mildly to Moderately Impaired which is described as "can identify objects; may see large print". For rehabilitation purposes, vision at both level 1 and level 2 would be considered adequate for standard rehabilitation approaches, and of course a person with low or no vision would still be an excellent rehabilitation candidate in a comprehensive, multidisciplinary setting.

E. E. Upper Extremity Range of Motion
What is the distinction between "functional range of motion" and "within normal limits?" We recommend that CMS/RTI clarify the term "functional range of motion" or normal textbook range of motion, as well as passive range of motion, active range of motion, or active assist range of motion. Item E1a should also include wrists and hands.

F. F. Weight-bearing
"Indicate all the patient's weight-bearing restrictions in the 2-day assessment period."

This item needs to include more options (i.e. 50%, toe touch, etc.)

The question should be rephrased or the scoring scale should be reversed, because it is counter-intuitive when asked if a patient has weight-bearing restrictions to put a 0 to mean yes.

G. G. Grip Strength
"Indicate the patient's ability to squeeze your hand in the 2-day assessment period."

This is subjective and doesn't provide useful information. Who would rate this section? How are the terms "normal," "reduced/limited," and "absent" defined and assessed?

H. H. Respiratory Status
"Was the patient dyspenic or noticeably short of breath in the 2-day assessment period?"

This item would lead to very subjective results. Numerous tools already exist to assess this impairment. They include:

- Rate of perceived exertion
- Dyspeana
- Pulsox [Spell out as pulse oximetry]

This item won't work in a comprehensive rehabilitation setting. AMRPA suggests using such measures as RPE and/or oxygen saturation measures.

I. I. Endurance

Endurance is an important indicator or screen for whether a person is a candidate for rehabilitation of minimal intensity, moderate intensity, or high intensity (traditionally defined as 3 hours or more of active physical and/or occupational therapy per day, which currently is most frequently provided in an inpatient rehabilitation hospital facility or IRF. A key cut point for consideration of active therapy, found in rehabilitative placement guidelines such as those of the AHCPR for stroke patients, is whether the patient has the "endurance to sit supported for 1 hour and to participate actively in rehabilitation", that is, to attend to and engage in activity for an hour. Such abilities or behaviors over time are observable in the acute hospital if the patient is referred to a therapist, sits for patient education, eats out of bed, or waits in a chair for a test. The validity of endurance items would be improved if endurance for longer periods were recorded for patients who might possibly need rehabilitative therapies.

More detailed comments follow:

1. Mobility Endurance: Did the patient have to stop and rest two or more times when walking or wheeling 50 feet (15 meters) in the 2-day assessment period?
What are the purposes of questions I11 and I12? Are there any time limitations in assessing this?

2. 2.12 Sitting Endurance: Was the patient able to tolerate sitting at the edge of the bed for 3 minutes in the 2-day assessment period?
It is not clear how the information is expected to be helpful. This item needs to be clarified so that the clinician is assessing if the patient is supported or unsupported in this task. This assessment could be affected by the mattress firmness, tubes or other mechanics involved. The word "unsupported" needs to be inserted after the word "bed." This change would help indicate midline orientation and trunk control.

J. J. Mobility devices and aides needed

Based on the spelling, it is not clear if "Aides" or "Aids" are intended. The item should include an assessment of the amount of assistance needed. What is the definition of "full-time" and "part-time"?

VI. Functional Status

A. A. Core Self Care

The core self care items should be completed on ALL patients.

Regarding the scoring code, the definition for Dependent is so strict in saying the patient does NONE of the effort that essentially only complete quadriplegia would qualify. Any person with any motor strength would contribute some (perhaps tiny percentage) of the effort personally. In general terms a person is usually considered dependent by virtue of being able to provide less than 25% of the required effort. [This comment applies to all functional scales for the "dependent" level.]

1. *A2 Tube Feeding*
Regarding A2, the element to be scored is written in a way to make a score of 6 impossible because it specifies "once [the supplies] are presented to the patient". By definition, this establishes a person as at least using set-up and possibly being more dependent than that.

2. *A3 Oral hygiene The ability to use suitable items to clean teeth. Dentures: The ability to remove and replace dentures from and to mouth, and manage equipment for soaking and rinsing*
Management of teeth and management of dentures are two different issues and should be assessed separately. A response to the item as it is now would not be clear which was assessed without referring back to the record to see if the patient has dentures.

B. B. Core Functional Mobility
We agree that the core functional mobility items should be completed on ALL patients. Coding. We also recommend that the term "most usual" be delted and the phrase say "Code the patient's most usual performance for the 2-day assessment period using the 6- point scale below. **Code the patient at the time of the greatest burden."**

1. *B4, Toilet transfer: The ability to get on and off a toilet or commode.*
Toilets and commodes are different things, require different skills, and need to be assessed separately. The item should be broken apart.

2. *B5, does this patient primarily use a wheelchair for mobility?*
Please clarify if this is to be assessed at time of discharge or at the time the evaluation is being completed. There appear to be errors in answers 2 and 3, which begin with the caveat "once standing", which is unlikely for a person being tested in a wheelchair.

3. *B5a, Code for the longest distance the patient can walk (observe their performance).*
Add to the instructions regarding "observe their performance" "using what assistance? walker, cane, none, etc." The 6 point scale for measurement needs to be included with each distance category, so that there would be 5b and 5b(i) for level of assistance.

C. C. Supplemental Functional Ability: Complete only for patients who had therapy consult or who will need post-acute care or personal assistance following discharge.
Are we to presume all the core items above here are filled in by somebody other than a therapist? It is very unlikely that nurses in acute care will be measuring feet walked etc.

1. *C3 Roll left or right; C4 Sit to lying; C5 Picking up object*

The item on picking up object needs clarification of whether it requires adding the words "...and regain standing or seated balance."

These items should be in a different section. We suggest moving these to section B1, Lying to sitting on side of bed.

2. *C6d Four steps-exterior*
It is difficult to test this item in all settings (i.e. acute care). The question should specify "without rail" if that's what we're trying to find out rather than giving the option of "with or without rail". The latter choice makes the answers far less specific and less comparable.

3. *C7 Telephone answering*
This question highlights the sophistication required to do functional assessments of persons who have adapted to an impairment. The phrase "pick up call in patient's customary manner" could imply a modified speaker phone operated through sip and puff technology. On the other hand, some persons filling out the CARE instrument would rate a person down for not being able to literally "pick up" a hand receiver. Detailed instructions to users and obsessive training will be essential to maximize the consistency of answers and therefore the value of the data.

4. *C13 Wipe down surface*
As another example of the importance of instructions, the instrument or User's Guide should clarify whether throwing out a paper towel after wiping a surface qualifies as "Includes ability to clean cloth of debris in patient's customary manner."

5. *C16 Get in/out of car*
Rating the ability to get in and out of a car becomes less meaningful when it is modified by "Does not include open/close door or fasten seatbelt." Those caveats automatically move the task to no better than "minimal assistance."

6. *C17 Drive a car and C18, Use public transportation*
Why did the scale change to a 4-point scale? How will these sections affect resource use and payment?

D. General Comments
In the acute hospital setting, caregivers will naturally be forced to guess answers to most questions in this section unless they are strictly trained to enter "N" to indicate "cannot be observed in patient's current environment." Many deficits in higher-functioning patients are only uncovered when a patient attempts a task that he/she was expected to be able to do, so it is important for a patient not to be documented as able to do something that has not been tested.

Also the following items – C14 Light shopping, C15 Laundry, C16 Get in/out of car, C17 Drive a car, C18 Use public transportation – do not apply to a home health level of care. Would there be "skip" logic if they were home health patients?

VII. Engagement

A. A1 Engagement: Indicate the patient's cognitive and emotional resources to comprehend current services, tolerate typical frustrations of care, and participate actively in the treatments.

Is it fair to judge someone who has depression? Please clarify the differences/definitions in the scale, number 2-Moderate to Severe problem, and 3-Moderate Problem.

VIII. Frailty/Life Expectancy

This section is entirely subjective with no objective measurements.

A. A1 Would you be surprised if the patient was readmitted to an acute care hospital in the next 6 months.

Given the age range of most Medicare patients and the relationship of hospital utilization to age, few experienced providers would be very surprised to see even the most healthy beneficiary hospitalized for something within the next six months. Knowing this, it is hard to understand the value of this question.

B. A2 Would you be surprised if the patient were to die in the next 12 months?

1. What is the rational for asking these questions?
2. What impact do these questions have on placement and payment? The mere existence of the question is likely to raise public fear regarding the possibility of "rationing."
3. Most clinicians and almost all non-clinicians would feel uncomfortable in making this speculation. When people are faced with discomfort, they often develop protective mechanisms to minimize their own distress. Because it is stressful (as well as highly unreliable) to assess an individual's life expectancy, raters are likely to develop a strategy for answering this question that minimizes their stress. A simple approach would be for any given caregiver to adopt their own answer and always use it, independent of the patient's condition. By adopting an attitude that "I'm never surprised by death" or, conversely, "I'm always surprised by death" one can answer the question in a way that feels conscientious without being stressed. Unfortunately, however, having any significant number of people use these strategies completely undermines any confidence one would have in the individual or aggregated data.

IX. Discharge Status

A. A. Discharge Information

1. A2.4, Discharge Location

As noted above, we recommend that the term "Subacute" be removed.

2. A3, Frequency of Assistance at Discharge

It was not clear to us how this information would correlate with A 2. This information will be helpful for discharge from the acute hospital and with PAC placement. When a patient is discharged home from a PAC setting, how is it intended to be used? As a case mix adjuster?

B. C. Other Discharge Needs

1. C1 Will the patient be able to pay for their medications after discharge?
First we recommend deleting the term "their." Second, it will be difficult for anyone to accurately answer. Many patients are discharged on new prescriptions and will not know their new prescription costs until they have filled them. Calculations by patients about their current status with respect to Medicare drug deductibles will also complicate this determination. Most likely this section will be answered Unable to assess or Unknown to patient.

C. D. Discharge Care Options
We are very concerned about this section, how it is drafted, and how it is intended to be used in each setting. Essentially the latter two issues are unclear. By instructing the discharge planner to "Check All That Apply," the perception is that they should check any post acute type of care that seems available, instead of only those settings that are deemed appropriate, and actually being recommended for the patient, and are available. In addition, this item does not capture the physician's judgment regarding discharge recommendations which we believe is critical.

The section should be re-worded to state: "Please Indicate Which of the Following Services Is Considered Most Appropriate at Discharge. If more than one setting is attempted, indicate which ones were contacted for placement and what the placement outcome was."

There should also be a section that indicates: No further care is needed; follow up with Primary Care Physician appointment.

D. E. Discharge Location Information

a.E7, Discharge Delay
If this is answered in the affirmative, then the length of the delay needs to be mentioned.

American Medical Rehabilitation Providers Association

Kathleen C. Yosko
President and C.E.O.
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ATTACHMENT 2

January 4, 2007

Barbara A. Gage, Ph.D.
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Dear Dr. Gage:

Thank you for the opportunity to provide comments on the development of a Post Acute Care Patient Assessment Instrument (PAC-PAI). This instrument is being developed by RTI pursuant to a contract with CMS as it moves to implement section 5008 of the Deficit Reduction Act. This letter is submitted on behalf of the American Medical Rehabilitation Providers Association (AMRPA). AMRPA is the national organization that represents freestanding rehabilitation hospitals, rehabilitation units of general hospitals, and outpatient rehabilitation service providers. Most, if not all, of our members are Medicare providers.

Our comments are made pursuant to the description of the study given at the CMS Special Open Door Forum held on December 21 in Baltimore. In addition, we have examined the report titled "Uniform Assessment for Post-Acute Care" regarding the recommended thirty one (31) domains for the PAC-PAI and note in Chapter 2, which you coauthored, that they have been revised into four (4) larger domains. The four areas are: functional, medical, social, and administrative. This letter addresses some larger issues with respect to the study and then makes some initial comments regarding the domains to be considered for the instrument.

Additionally, we wanted CMS and you to be aware that AMRPA is convening a technical work group to comment upon the issues surrounding creation of such an instrument. In January, it will be reviewing the existing Medicare post-acute care instruments, as well as non-Medicare tools and make several recommendations regarding what items we believe need to be included in such a tool. We further understand that CMS will issue a separate contract to collect patient data using the PAC-PAI, collect cost data, analyze the data, and make recommendations regarding payment system revisions.

I. **General Comments About Addressing the Post Acute Care Arena**
In this project CMS seeks to design a data collection tool, collect data, collect cost information and seeks to make changes in the existing payment systems (if we heard the collective comments correctly at the Open Door Forum). We suggest that in approaching this study with such a broad scope that CMS and RTI consider the following points.

A. The Perfect Placement

There needs to be recognition that for many patients, there is no single "correct" or "perfect" post acute setting. Many patients can potentially "fit" into multiple settings, depending on the goals that are established, the time frame that will be tolerated, the cost to be incurred and the risk of adverse events to which the patient will be exposed. Hence for policy makers it can be confusing that patients with the same clinical label, i.e. stroke, may be treated in all post acute settings. Ideally, as this project goes forward, some of the factors that are involved in current decision making will become clear and others will be introduced into the mix. As we discuss in more detail below, social and economic factors are taken into account now by acute care facilities and PAC settings but are not captured by existing instruments, nor their effect studied.

B. Medicare as a Precedent

This instrument will become (whether intended or not) the standard referral form for all transfers, be they for Medicare patients or non-Medicare patients. Hence this outcome needs to be kept in mind. For example in New York, the Patient Review Instrument, required by Medicaid is the *de facto* standard instrument for communication among hospitals and post-acute providers of care.

C. Current Payment Systems, Rules and Perspectives

In listening to the discussion and reading some of the literature released to date, it appears that one of the underlying premises of the study is that the current prospective payment systems for each post acute care setting are inherently flawed and do not work. In reality each of the payment systems are generally well designed for the specific characteristics of the provider settings they are intended to serve. It is true that each is unique to its own setting. The LTCH and IRF PPS are more classic prospective payment systems than is that used for the SNFs. The true problem across the systems is that there is a lack of precision and agreement as to which patient belongs in which setting. The problem is how to deal with ambiguous patients who could be cared for in more than one setting, and how to create a fair and equitable payment representing patient characteristics, their costs, overall costs and specific type-of-facility attributes across settings (e.g. wage indices, teaching adjustments, etc.). This study has the possibility of taking the first steps to developing such a system.

D. *75% Rule, Medical Necessity Denials in IRFs and Impact on This Study*

1. 75% Rule Impact

The current problems with the 75% Rule and medical necessity denials are decreasing patient choice, not improving it. Facilities are closing beds; staff is being laid off and many more patients are being channeled to SNFs. The net result is that as the study progresses – and as the 75% rule continues to be implemented – the patients usually treated by IRFs prior to the 75% rule will not be present and hence the natural clinical laboratory of IRFs will present a skewed picture. Earlier, Bruce Gans, M.D and AMRPA staff have suggested that RTI and therefore CMS provide a waiver from the 75% rule for all IRFs participating in the study.

Effective participation by IRFs in the beta data collecting phase will be strongly enhanced if CMS will waive compliance with the 75% Rule and hold the facility harmless for medical necessity denials on patients for those hospitals that participate in the study. This will allow a stronger representation of the patient category overlap in the various settings to be obtained. The issue of overlap of patients is mentioned above and was discussed at the Open Forum and is one of the continuing issues in studying the post acute care arena.

AMRPA is quite concerned about the 75% rule, and the impact of recent medical necessity denials on IRFs. Both of these will have the aforementioned effect on the number and types of patients in IRFs when this demonstration project is conducted. There has been a significant decline in the number of people treated in rehabilitation hospitals and units since the implementation of the 75% rule. Furthermore, there has been a decline of more than 8% of the nation's rehabilitation beds over the last year. MedPAC's analyses show a drop in admissions from 2004 to 2005 of 9.5%. At its December meeting, the staff noted that for 2007 it is predicting a 20% reduction in cases as a result of the phase in of the 75% rule to 65% and a Medicare margin for providers of only 2.7%.

AMRPA has tracked the impact of the rule through our database and through the Moran Company reports. The Moran Company report for the second quarter of 2006 showed a drop of admissions of 18.4%[1] by the second quarter of 2006 relative to the program year 2004. It estimates a drop in cases of over 88,000 for the first two program years.

2. *Medical Necessity Denials Impact*

Another factor adversely affecting IRFs' ability to operate and provide needed care to all patients requiring inpatient rehabilitative treatment is the increasing number of medical necessity denials. These denials take many forms but have the same net effect on facility operations. They are a factor in driving down volume and in affecting facilities' cost structure and cash flow. Numerous cases are being denied and facilities are responding by further changing their admission practices. Additionally the denials reduce operating cash immediately and unpredictably. Denials may be the result of reviews by the fiscal intermediary under a local coverage determination (LCD). Currently at least seven (7) states have final inpatient rehabilitation services LCDs. Additionally, a number of fiscal intermediaries are conducting aggressive pre- and post-payment audits.

The third type of denial is coming from the activities of the Recovery Audit Contractors (RACs). The RACs were authorized under Section 306 of the Medicare Modernization Act and were authorized to seek over and underpayments under Medicare. Each RAC is paid an incentive payment as soon as it tells the fiscal intermediary for the provider in question that a case is denied. Of great concern, however, is that frequently it appears that the denial letters are

[1] Utilization Trends in Inpatient Rehabilitation: Update Through Q II 2006, The Moran Company. See Appendix A

being issued within a few days after the medical records are received, raising the question as to whether or not a true medical review is being conducted. We are aware of one company that has over 300 cases in dispute the amount of payment for which exceeds $3 million. In California, the RAC has been so aggressive that it is denying between 95-100% of cases. The majority of the denied cases are being appealed (for the most part successfully). However this process is placing an unnecessary economic burden on the facilities.

Most of the cases denied appear to be orthopedic cases, particularly single joint replacements. The net result of their actions is to make the 75% rule a 100% rule given various actions by FIs that deny even those cases that qualify for the 75% rule and which are in addition medically complex (e.g. over 85 year old single joint replacement with medical complexity.)

E. Additional General Thoughts for the Study

1. *Plan of Care*

   The tool should determine the need for an orchestrated plan of care as opposed to isolated therapy activities.

2. *Care, Cost and Time Value of Progress*

   Care effectiveness is not the same as cost efficiency. The overall system needs to be responsive to purchasing "value" not just the lowest cost. Value can easily be defined by the clinical outcomes as well as discharge destination and increase in quality of life, among other factors. Increase in functional abilities must be viewed carefully as a determinate of value. In some instances, a patient's quality of life will increase but not be reflected in a functional measure. For example a quadriplegic patient who learns to use a head stick or his or her family is further educated on caring for the patient may mean a tremendous amount to that patient but not be reflected in the functional scores.

   Additionally, the time value of rate of progress needs to be recognized. For example, if a payer spends the same amount of funds but the patient is in pain twice as long in order to achieve a functional benefit, then there is much value in assuring the patient is pain-free sooner. However the current payment systems do not recognize this.

   As a result of this study there needs to be a clearer articulation of the differences among the PAC settings, and standardization of the various settings, especially when they provide similar services such as rehabilitation services. This is particularly true of the institutional PAC settings, especially SNF and LTACH when it comes to providing rehabilitation services. Currently IRFs are held to a number of standards and requirements not required of these other providers.

II. Initial Comments Regarding the PAC PAI

At a minimum, we believe any data tool – and any subsequent change in any payment system – should have the following characteristics (in no particular order):

A. Maximize patient/ family outcomes.
B. Maximize access.
C. Maximize efficiency.
D. Use measurement items that meet accepted measurement standards.
E. Maximize continuity of care.
F. Maximize consumer responsiveness and satisfaction.
G. Maximize the rationality of the system.
H. Minimize gaming.
I. Minimize administrative complexity.
J. Minimize cost.
K. Adjust for patient "cost" factors.
L. Maximize provider equity.
M. Maximize innovation and investment in staff infrastructure.
N. Adjust adequately for environmental factors.
O. Encourage an economically rational organization of rehabilitation and medical capacity.
P. Minimize financial risk.
Q. Distinguish between activity the patient is capable of from that which the patient typically demonstrates.
R. Preserve its utility as a management tool for facilities, for individual patient progress assessment, and aggregation for program evaluation purposes.
S. Promote patient safety objectives.

III. Comments Regarding Specific Domains for the PAC PAI

Chapter 6 of the January 2005 report recommends that any PAC PAI address thirty one (31) domains. Upon an initial review we would concur that these domains need to be addressed at some level in such an instrument. We note that they can be grouped into the four larger domains referenced above.

However initially we note that for the instrument to be useful to help sort patients into the appropriate post acute setting, elements will need to be included that predict potential to benefit from services, which will require the participation of a knowledgeable physiatrist or other clinician in the data collecting process. Additionally referral patterns need to be examined closely. Some patents are referred to a post acute setting from hospital emergency rooms, physician offices, and other non-institutional settings.

Our initial comments on the domains follow.

A. Medical

Any PAC-PAI needs to include items which state the medical event that precipitated the admission to the acute care hospital. In addition, there need to be medical items that state and describe the patient's medical status at the time of admission and at discharge from the acute hospital either to home <u>without</u> home health services or to one of the post-acute care (PAC) settings to be included in the demonstration project (LTCH, IRF, SNF, HHA).

1. *Acute Care*
   A patient's medical status changes during the course of care in the acute setting (you hope!) and hence the medical issues to be addressed at the time of acute discharge maybe different in type, scope, and severity than those that present on acute admission. More specifically, we recommend that these items address the following:
   - Medical reason for admission, (ICD-9 codes) e.g. diagnoses, comorbidities
   - Medical status at discharge, (ICD-9 codes) e.g. diagnoses, comorbidities
   - Measures of medical severity and complexity at discharge. There are several tools that measure medical complexity. These include Comprehensive Severity Index, various nursing severity Indices, APR DRGs and numerous others.

   It is critical for PAC providers to know as much premorbid information as possible about patients in all domains in order to help develop further treatment and discharge planning.

2. *In the PAC Setting*
   Similar medical data items need to be collected at the time of admission, discharge, and possibly at a mid point in treatment in all the PAC settings. Currently, some medical information is collected in each PAC setting but varies widely. For example, SNFs collect information on whether the patient is comatose, delirious, or dehydrated but not in an IRF or LTCH, and these items in their current design may not be appropriate for cases in those settings. We recommend these items plus measures for swallowing and pain be considered.

B. Functional

The goal of the field of medical rehabilitation is to improve patients' total functional ability as well as manage patients' medical care. There are several tools which are well recognized for measuring function. They include the Barthel, Katz, and Functional Independence Measure, to mention a few. These are discussed in Chapters 2 and 3 of the above study. Some functional items are included in the Medicare tools currently used in the home health setting (OASIS), skilled nursing facility (MDS), and inpatient rehabilitation facilities (IRF-PAI). The most extensive tool is the IRF-PAI in which is embedded the Functional Independence Measure and which has been used on a national basis since January 2002.

We have found that the Functional Independence Measure bears further examination, due to missing items, weak items, and floor and ceiling effects. All the patients scoring a "7" are not homogenous nor are all patients scoring a "1." For example, a quadriplegic may score a "1" (maximal assistance) on admission and discharge but will have experienced a qualitative (but unmeasured) increase in quality of life.

We recommend that the PAC-PAI include the motor domains of self care, sphincter control, transfers, and locomotion at as a point of departure. We also recommend that the PAC-PAI include items such as:

- Cognition, including orientation
- Respiratory status such as clearing airways and shortness of breath
- Measures of executive cognition
- Depression

All measures of function must be sensitive enough to reflect the range of patients in the four (4) PAC settings. It is critical that patients' functional status be measured at the time of discharge from acute care, admission to each post-acute care setting, and discharge at a minimum.

C. Social Supports

A patient's social status and support system are critical factors in placement decisions. We recommend the PAC-PAI include extensive information about the patient's premorbid social supports and networks at the time of acute admissions and discharge and again at the time of admission and discharge from the PAC setting. At a minimum, these would include:

- Pre-admission living setting and living with whom
- Presence of family willing to assist the patient
- Presence of other social resources in terms of type, amount, quality, including friends, financial support, long term care insurance with coverage of at home custodial care
- At acute discharge, what resources are available in the PAC setting

We understand CARF and OASIS include some items that bear examination.

D. Other Items

There are other items that are extremely helpful in assessing proper care, including site of care for post acute care patients. These include:

- Respiratory status
- Depression/ mood
- Presence and degree of pressure sores
- Pain
- Safety measures including hospital acquired injuries
- Falls (which are treated differently in SNFs and IRFs)
- Other instrumental activities of daily living (shopping, housekeeping, laundry, etc).

E. Administrative/ Other

In addition to the above, information on the following factors needs to be collected:

1. Acute care hospital name, location and provider number
2. Referral Source – referring hospital, city, physician, etc.
3. Acute care physicians- surgeons, internists, etc.
4. Acute length of stay
5. Days from onset/ surgery to acute discharge/ days from onset or surgery to admission to PAC (these two points may differ)
6. Previous PAC setting (for subsequent referrals)
7. Patient characteristics such as age, height, weight, gender, educational level

8. Payers/insurance

F. Rehabilitation Placement Factors

AMRPA is developing a tool that examines factors that may influence post acute care placement for patients in need of rehabilitation services, primarily SNF and IRFs. The initial tool is focused on honing these factors for joint replacement placement patients. A copy of the tool is included for reference in this effort and we would be pleased to discuss it with you further.

G. International Classification of Function

We suggest that CMS and RTI acknowledge the International Clarification of Function (ICF) as it develops the PAC PAI. It takes a new conceptual approach to patients' functional abilities. We suggest that you examine the hierarchy within the ICF as a framework for the PAC PAI.

We appreciate the opportunity to make these initial comments. As mentioned our work group will be looking at existing tools this month and we will have further recommendations upon receiving their recommendations. In the interim if you have any questions, please feel free to contact me or Carolyn Zollar, J.D., Vice President for Governmental Relations and Policy Development at AMRPA.

Sincerely,

Bruce M. Gans, M.D.
Chair
AMRPA Consumer and Clinical Affairs Task Force

American Medical Rehabilitation Providers Association

Kathleen C. Yosko
President and C.E.O.
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ATTACHMENT 3

February 26, 2007

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Dear Barbara,

It was a pleasure to see you again at the State of the Science Symposium. We deeply appreciate the time you and your team took to be there and your suggestion of a separate presentation on the development of the post acute care assessment instrument. We hope you get some helpful suggestions. I understand from Carolyn that you have accepted our invitation to speak at the Spring Meeting on Wednesday, March 22. Our members will be most anxious to learn more about the tool and its content.

At various times we mentioned that we formed a work group to look at issues surrounding the development of the Post Acute Care Patient Assessment Instrument (PAC-PAI), as I believe it is being called. On January 26 the work group met by conference call to discuss the tool. It focused on which domains and items should be included in the instrument as it proceeds, as well as the process of accomplishing the multiple assessments envisioned.

The work group made the recommendations described below. Carolyn Zollar or I would be pleased to discuss them with you further.

A. Acceptance of Domains/ General Concerns

The group reviewed the January 2006 report from the University of Colorado, "Uniform Patient Assessment for Post Acute Care", Chapter 2, Tables 2.2, "Overview of Selected Domains and Items in the MDS, IRF PAI, and Oasis Tools," and 2.3, "Functional Measures Used in the IRF PAI, MDS, and Oasis Tools," to examine the four domains that were proposed.

1. Four Domains
   The work group supported the four (4) broad domains of Administrative Information, Medical Condition, Social Support/ Residency and Functional as identified in the report.

2. International Classification of Functioning, Disability and Health (ICF)
   The group then discussed the various coding conventions being used in other parts of the world, such as the ICD-10 now being used in Europe. Of greater interest to rehabilitation

practitioners is the International Classification of Functioning, Disability and Health (ICF). The group recommended that RTI select domains and items that are consistent with the ICF structure and that any items and domains selected for the PAC-PAI be related to the ICF structure.

3. Multiple Assessments, Placement, and One Tool
   General concerns were expressed that use of the same tool at acute discharge, and admission and discharge in all PAC setup is a difficult fit. Patients' needs vary across time and setting and the tool will need some flexibility to be applied in these varied circumstances. For example, the acute care discharge assessment may rely more heavily on an assessment of the patient's medical condition than functional and social support factors. Some additional points along these lines are discussed below under "Completion of the Document."

4. Minimizing Data Collected/IRT
   The group urged that the instrument take advantage of the knowledge of Item Response Theory to avoid collecting unnecessary elements that are not unique.

5. "Large Buckets"
   There is a concern that the tool might result in large heterogeneous groupings that are not sensitive to changes in either medical or functional status. For example, improvements in quality of life for a patient with tetraplegia who learns to use a mouth stick will not show up in current instruments.

6. Recidivism
   There must be a way of tracking rehospitalization, and the status of active complications and co-morbidities, including whether they occurred or were present at the acute level and therefore present when the patient was sent to a post acute care setting, and which ones occurred or presented at any of the PAC sites.

7. Initial Triage Factor: Medical Status:
   The group believed that the driving factor for placement choice is the patient's medical status, and argued that it should be evaluated initially and carefully. The amount, type, intensity, and diversity of physician care and nursing care is a strong influence in the choice among a SNF, LTACH, IRF, or HHA. Ideally, these decision points regarding referral decisions will be based on clinical evidence. Once that initial decision is made then the next driving factor is functional status, what the need for rehabilitation is, and at what level of intensity, frequency, and complexity it is required.

8. Completion of Document: Acute Care Hospital and Other Settings
   The work group also expressed concern about the process by which the PAC-PAI will be completed. This included concern about its completion in the acute care hospital as well as in various PAC sites. Acute care case managers generally have 30-35 cases they are juggling and asking them to complete another piece of paper may lead to hurried, inaccurate assessments. There was also concern that at times patients are sent to the site that has the most aggressive marketing staff as opposed to the one that, after a close review of the patient's needs, is the most clinically appropriate. Additionally if the

assessment says "send this patient to a SNF" and there isn't an appropriate one in the area, there could be a problem for the acute care hospital. The group also discussed the idea of having a gross assessment being done by the acute care hospital staff with a finer medical assessment and functional assessment being done by external reviewers (such as IRF and/ or LTCH personnel).

To be more specific, the screening could be broken into to two areas or steps.

a. **Acute Hospital Screening** – Case management and discharge planning in the acute care. Some case managers work on units that have a lot of post acute needs while others do not. This results in highly variable expertise in facility selection by the staff.

Case management does not need to be encumbered by a burdensome form but rather a simple tool to capture demographic and medical data as a first step.

The basic information to be collected at this point would include some we have already referenced:

i) Administrative
This would include the basic patient identifier information mentioned in the University of Colorado report. We recommend adding the patient's insurance information for Medicare and commercial insurance. At times it can be a determinant in post acute care placement.

Furthermore, case managers should not be encumbered with duplication of demographic information. The key patient identifier number is the billing number for that hospitalization. From that number all other hospital records particular to the patient can be found. If this is part of a larger database, then the hospital provider number could be pre-printed on the form.

ii) Social Support – what was the patient's living situation prior to the hospitalization? Is it likely to stay the same when discharge to home is ready to occur?

iii) Initial Medical Information – As noted above this information (both pre-hospitalization and at time of discharge) is the initial basis for making a determination regarding the patient's post acute needs. It requires a clinical perspective. The severity of the medical condition for frequency of intervention and level of healthcare professional intervention both need to be assessed. This information can determine:

(a) the need for home care versus institutional care and
(b) what level of institutional care is required[2].

[2] There are two sub-issues in the application of the form. One is the availability of a service. For example, if a patient would benefit from restorative nursing care, a service that is required at SNF level, but the SNF does not have that position filled, what leeway in discharge planning is there in not using the service because the SNF is not meeting its regulatory responsibilities? Second is the quasi-requirement for a service. For example, if there is a joint replacement patient and the orthopedic surgeon wants seven day a week therapy for the patient. Yet the local

iv) Level of Physician and Nursing Involvement
The medical information on the tool should have fields of information that document required physician involvement. These would include:

- Physician involvement – cite active medical conditions and comorbidities with ICD-9 codes. Will the patient need:
  - Daily physician involvement
  - Consulting specialists
  - Multiple days per week involvement
  - No more than once weekly
  - Plan of care / initial orders only
- On-going professional level ancillary care. Will the patient need:
  - Daily (or more often)
  - Multiple days per week
  - Less than weekly
  - None anticipated.
- Registered Nurse care. What levels of nursing care does the patient need at acute discharge:
  - Skilled nursing care
  - Restorative nursing care
  - Rehabilitation nursing care

v) Initial Information on Physical Function – These areas should be kept to a minimum as the case manager will not have time to assess them in detail and the work group expressed concern that a rushed assessment would do more harm to the patient. While we suggest a minimum collection at this point in the process, we also suggest the concept of a second review by those with expertise in measuring function, including assessments by professionals outside of the acute hospital.

Such data may either be gleaned from the chart, from discussions with hospital personnel, interviewing the patient and the family, or by an actual assessment using trained professionals as suggested above. The areas to assess are:

- Endurance and tolerance of being out of bed
- Ambulation
  - Pre-hospitalization and current status
- Bed – Chair Transfers
  - Pre-hospitalization and current status
- Toileting
  - Pre-hospitalization and current status
- Bladder function
  - Pre-hospitalization and current status
- Cognitive (Mini-mental status exam) plus family input on chronicity and severity.

SNF does not have it but the local rehabilitation hospital does. Does the requirement by the treating physician hold sway?

- Chronic
- Chronic with acute exacerbation
- Acute exacerbation only
- Transient (delirium associated with the acute illness)

b. Post Acute Care Assessment (or Intake)[3] – Upon admission to the chosen post acute care site, there should be a reassessment of the above plus a more detailed assessment of the patient's physical and cognitive functioning.

i) Physical function – These areas should be broadened so the patient's severity of functional loss can be measured in detail. We offer more specific recommendations on some of these items below under "B. Examination of Items in Domains." As mentioned in my prior letter, we recommend in the motor area the items in the Inpatient Rehabilitation Facilities Patient Assessment Instrument. For cognition, mood and communication we would recommend alternative tools be examined some of which are referenced in this letter.
   - Motor Areas both pre hospitalization and current status
     - Ambulation/Locomotion
       - ☐ Pre-hospitalization and current status
     - Bed – Chair Transfers
       - ☐ Pre-hospitalization and current status
     - Toilet transfers
       - ☐ Current status
     - Fall Risk /Fall History
     - Self Care from IRF PAI
   - Swallowing function
   - Bladder function
     - Pre-hospitalization and current status
   - Bowel function
     - Pre-hospitalization and current status
   - Emotional/Cognitive[4]
     - (Mini-mental status exam) plus family input on chronicity and severity.
       - ☐ Chronic
       - ☐ Chronic with acute exacerbation
       - ☐ Acute exacerbation only
       - ☐ Transient (delirium as noted above)
     - Depression
     - Behavior management measurement
   - Pain Assessment

[3] Only references to the physical function category are provided in this section. If there is need to have comments in the other three areas (administrative, social support or medical) we can do that at a later time.

[4] FIM measures of problem solving, memory and social interaction should be avoided. They have neither specificity nor general application across all four post acute settings.

B. Examination of Items in Domains

The work group then turned to looking at the various items included by title in the domains (not the specific items from each existing tool).

1. Bladder

   It appears under both the medical and functional domains. We agree with it being present in both however there must be some narrative clarifying that in the medical domain the measure is a physiological descriptor and in the functional domain the measure is a functional descriptor.

2. Cognitive (cognitive impairment, social cognition)

   This item also appears under both domains and a similar explanation or note is needed. Cognitive measures need to be included in the instrument. The cognitive items overall do not measure sensitively most cognitive function. In addition to looking at additional communication tools mentioned below the work group recommended that other cognitive tools such as the Mini Mental Status Examination instrument be considered.

3. Mood/Depression

   An item measuring depression, mood or affect needs to be added. The MDS measures were mentioned but there did not seem to be universal support for these items. The group recommended that the NOMS items be examined. Existing items both on the MDS and IRF PAI were felt to be inadequate. Mood is increasingly recognized as affecting patients' desire and sometimes ability to recover *in toto*, participate in therapies, outcomes as well as affect the total cost of care. At the State of the Science Symposium Michael Munin, M.D. examined some of these issues in his paper.

4. Communication

   This domain is considered to be very important for discharge planning both from the acute hospital and from any PAC sites. The neuropsychological and speech fields were deemed to have better measures, such as the NOMS instrument developed by the American Speech Hearing and Language Association. RTI is encouraged to examine those. The group noted that MDS does give some more information to a discharge planner than does the IRF PAI or the OASIS.

C. MDS Items

1. Complications, Co morbidities and Diagnoses

   The group felt that no matter how it is done, all the complications and comorbidities affecting a patient at each level of care (acute admissions, acute discharge, PAC admission, PAC discharge), including both those that developed or were resolved during a stay need to be captured. Essentially, none of the existing tools capture the complete diagnoses of the patient. Of probable greater importance is the severity level of the co-morbidities and complications, not just their existence.

2. Nutrition

   The group supported including a nutrition item on the PAC-PAI since it is an important indicator of the patients' future ability to improve.

D. Other Instruments

Other instruments were discussed but none stood out as being particularly helpful nor did specific items in them stand out.

We appreciate this opportunity to provide these recommendations and hope they prove helpful. I look forward to seeing you at the Technical Expert Panel meeting on March 6-7 if we don't talk before.

Sincerely,

Bruce M. Gans, M. D.
Chair AMRPA DRA PAC PAI Work Group

ATTACHMENT 4

Rehabilitation Placement Factors Data Collection Instrument

Changes in the Medicare payment system over the past few years have resulted in an increased focus on the selection of patients appropriate to inpatient rehabilitation. In particular, CMS has placed increased scrutiny on post-acute rehabilitation services for patients with lower extremity joint replacements. One of the issues raised by CMS is the need to identify the factors that differentiate the most clinically effective and cost efficient post-acute rehabilitation placement of joint replacement patients.

Currently, the post-acute placement decision is based on a professional assessment of unique combinations of a variety of factors. Physical, functional, psychosocial status and needs, and most importantly the potential to overcome disabilities in these areas, are all factors that contribute to the rehabilitation placement decision.

Many patients who have undergone joint replacement surgery present with very similar functional deficits upon admission, regardless of their potential for recovery. Decisions regarding the most appropriate choice of post-acute discharge options for this patient population have been questioned for lack of consistent evidence-based support. Because of the nature of disability in this patient population and limitations of post-acute care measures of patient assessment, 'rehabilitation potential' is difficult to quantify. Retrospective assessments of rehabilitation potential based on pre-surgical functional abilities are limited with regard to differentiating patient potential for recovery, as the information is difficult to collect and patients are not consistently reliable sources of evaluating past performance. The instruments currently used in post-acute care settings (i.e. IRF-PAI, MDS) are designed to examine the state of the patient as a result of treatment intervention, and serve the dual function as the basis for Medicare payment. Instruments such as the IRF-PAI also have a ceiling effect in that the scale and item set is not as sensitive to distinguishing functional deficits for patients with higher overall functioning.

Fleming-AOD has developed the following draft proposal to design and construct a data collection instrument on the factors that may impact post-acute rehabilitation placement. Although this instrument is targeted toward those factors related to joint replacement patients, it may be expanded later as deemed appropriate. The patients for whom this tool would be applicable are those that have already been deemed to gain benefit from an inpatient post-acute rehabilitation stay, either in a skilled nursing facility (SNF) or inpatient rehabilitation facility (IRF). Fleming-AOD will design and deploy the instrument into both the eRehabData and the eSNFdata systems. The data collected in the instrument would then be analyzed for both SNF and IRF settings in an attempt to define differences in the patient populations and also compare the instrument's scores with the final clinical and functional outcomes for the two different systems.

One of the principles of this proposal is the differentiation between rehabilitation *potential* versus *placement.* For purposes of this proposal, rehabilitation potential may be described as the capacity or likelihood that the patient will demonstrate improvement in function, as compared to the maximum possible improvement. The rehabilitation placement decision is the consideration given to the discharge of patients to the post acute setting where the patient has the greatest opportunity (or potential) to regain the maximum return of function.

To fully assess rehabilitation potential, data should be collected on patients that are discharged to an inpatient post acute rehabilitation setting as compared to those that are not. This tool will collect data on the factors that lead to the rehabilitation placement decision of SNF or IRF, and as data is collected over time, rehabilitation *potential* can be discerned from an analysis of the factors affecting the rehabilitation placement decision, in conjunction with the outcome of treatment.

Dataset Overview

The proposed dataset consists of 30 total items. Items for inclusion in the dataset were selected based on the following criteria:

1. Relationship to potential determinants of rehabilitation placement for patients following a total hip or total knee replacement
2. Measures selected are based on review of the literature and experience of experts
3. The data set can be used by an SNF or IRF
4. Data collection efforts must not be overly burdensome to the SNF or IRF
5. Reliance on patient self report and recall of previous level of function is minimized
6. Item selection is based on using the dataset in conjunction with the items on the IRF-PAI and MDS

The following items were considered for inclusion, but are already collected on the IRF-PAI and through similar items on the MDS. Based on a review of the literature, these items may affect the post-acute placement and should be included in analysis of factors affecting placement and rehabilitation potential.

- Age
- Gender
- Race
- Marital Status
- Insurance
- Patient zip code
- Pre-hospital living setting and living with
- Comorbidities
- Diagnosis
- Current functional status (ADLs)

The dataset for the factors affecting rehabilitation placement and potential has two parts. The first part consists of 22 questions related to the referral source, surgical information, patient

demographics, and pre-surgical functioning (30 days prior to surgery, Table 1). The second part (Table 2) is based on the Medical Outcomes Study (MOS) Short Form-8 (SF-8 ^{TM}). The questions on the SF-8 ^{TM} were slightly modified to reflect the 30-day time frame.

Table 1: Basic Dataset for Rehabilitation Placement

#	ITEM	CATEGORY	SOURCE	DESCRIPTION	RESPONSE KEY
1	Referring Hospital Name	Referral Source	Chart or Referral Relations/Case Management	The name of the referring acute care hospital	Text field; can be user defined
2	Referring Hospital City	Referral Source	Referral Relations/Case Management	The city/town of the referring acute care hospital	Text field; can be user defined
3	Referring Hospital PAC Options	Referral Source	Referral Relations/Case Management	Post-acute in-patient settings owned or managed by referring hospital	In-patient rehab; SNF; Swing beds; More than one of the above
4	Referring Hospital Ownership	Referral Source	Referral Relations/Case Management	Ownership type	For Profit; Not-for-Profit; Military; Government
5	Surgeon Name	Referral Source	Chart or Referral Relations/Case Management	Name of the surgeon	Text field; can be user defined
6	Patient Height	Patient Demographics	Chart	Used for calculation of Body Mass Index	Enter Standard (English) or Metric, consistent with entry of patient weight
7	Patient Weight	Patient Demographics	Chart	Used for calculation of Body Mass Index	Enter Standard (English) or Metric, consistent with entry of patient height
8	Highest Education Level	Patient Demographics	Chart or Patient Self-Report	Highest educational degree obtained	Did not complete High School; High school graduate or equivalent; College, no degree; Associate's Degree; Bachelor's Degree; Graduate Degree
9	Previous Post-Acute Rehabilitation Setting	Patient Demographics	Chart or Patient Self-Report	Setting of rehabilitation services received within the past 5 years	Select all that apply: IRF Inpatient; SNF Inpatient; LTCH; Home Care; Outpatient; None
10	Implant Fixation Type	Patient Surgical History	Chart	Type of surgical implant fixation	Cementless; Hybrid; Cemented; Other
11	Acute Hospital Length of Stay	Patient Surgical History	Chart or Referral Relations/Case Management	Length of stay in the acute hospital bed	Enter number of days
12	# Days from Surgery to Admit to PAC	Patient Surgical History	Chart or Referral Relations/Case Management	# days from surgery to admission to the post acute setting	Enter number of days

#	ITEM	CATEGORY	SOURCE	DESCRIPTION	RESPONSE KEY
13	Stairs: Into the Home	Patient Living Environment	Chart or Patient Self-Report	Greatest number of consecutive steps that must be negotiated by the patient to go into the home	Enter the number of consecutive steps (one flight = 12 steps)
14	Stairs: Inside the Home	Patient Living Environment	Chart or Patient Self-Report	Greatest number of consecutive steps inside the home that must be negotiated by the patient	Enter the number of consecutive steps (one flight = 12 steps)
15	Preoperative Walking Distance	Premorbid/Pre-surgical Functional Status	Chart or Patient Self-Report	Usual walking distance tolerated (30 days prior to surgery)	Unlimited, greater than one mile; 6-10 blocks (up to one mile); 1-5 Blocks; Less Than One Block; Indoors only; Not Ambulatory
16	Preoperative Walking Device	Premorbid/Pre-surgical Functional Status	Chart or Patient Self-Report	Primary device used when walking (30 days prior to surgery)	No device/no assistance; No device/needs assistance of 1 or more persons; Cane(s); Crutch(es); Walker; Rolling Walker; Not Ambulatory
17	Transfers Between Sitting and Standing	Premorbid/Pre-surgical Functional Status	Chart or Patient Self-Report	Sit to stand and stand to sit transfer ability (30 days prior to surgery)	Use a modified version of FIM scale: Complete Independence; Modified Independence; Assistance Required; Unable to transfer
18	Data Source: Functional Status*	Premorbid/Pre-surgical Functional Status	Chart or Patient Self-Report	Primary source for the majority of the premorbid/pre-surgical functional status items	Patient; Patient's spouse; Family member other than spouse; Friend or guardian; Inferred from chart*; Other
19	Simple Meal Preparation	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Obtains food, opens/closes containers, prepares food, assembles meals using customary utensils (30 days prior to surgery)	Complete Independence (performs all meal preparation tasks safely, without specialized equipment; in a reasonable amount of time); Modified Independence (requires assistive devices, more than a reasonable amount of time, or there are safety considerations); Assistance (requires assistance of another person); Unable to perform/does not prepare meals

#	ITEM	CATEGORY	SOURCE	DESCRIPTION	RESPONSE KEY
20	Housekeeping	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Heavy housekeeping tasks (i.e. vacuuming, garbage disposal, cleaning floors) and light housekeeping tasks (i.e. dusting, wash/dry dishes, make bed) (30 days prior to surgery)	Complete Independence (performs all housekeeping tasks safely, without specialized equipment; in a reasonable amount of time); Modified Independence (requires assistive devices, more than a reasonable amount of time, or there are safety considerations); Assistance (requires assistance of another person); Unable to perform/does not participate in housekeeping tasks
21	Laundry	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Washing, drying, folding, and placing clothes in appropriate closet or drawer (30 days prior to surgery)	Complete Independence (performs all laundry tasks safely, without specialized equipment; in a reasonable amount of time); Modified Independence (requires assistive devices, more than a reasonable amount of time, or there are safety considerations); Assistance (requires assistance of another person for one or more laundry tasks); Unable to perform laundry tasks
22	Shopping	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Shopping for groceries or personal items; does not include transportation to and from store (30 days prior to surgery)	Complete Independence (shops safely, without specialized equipment; in a reasonable amount of time); Modified Independence (requires assistive devices, more than a reasonable amount of time, or there are safety considerations); Assistance (requires assistance of another person); Unable to shop
23	Travel	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Access to transportation to travel from one location to another, including day to day travel (30 days prior to surgery)	Complete Independence (travels from one location to another safely, without specialized equipment; uses car or public transportation); Modified Independence (requires assistive devices, more than a reasonable amount of time, or there are safety considerations); Assistance (requires assistance of another person); Unable to travel

#	ITEM	CATEGORY	SOURCE	DESCRIPTION	RESPONSE KEY
24	Data Source: IADLs*	Instrumental Activities of Daily Living (IADL)	Chart or Patient Self-Report	Primary source for the majority of the IADL items	Patient; Patient's spouse; Family member other than spouse; Friend or guardian; Inferred from chart*; Other

*Note: Definitions for the 'Data Source' responses are as follows:

Patient: the patient verbally reports or completes a written questionnaire about functional status or IADLs.

Patient's spouse: the patient's spouse verbally reports or completes a written questionnaire about functional status or IADLs.

Family member other than spouse: a relative of the patient verbally reports or completes a written questionnaire about functional status or IADLs.

Friend or guardian: a friend or guardian of the patient verbally reports or completes a written questionnaire about functional status or IADLs.

Inferred from chart: select this response when any of the two following conditions exist as the primary source for the data:

1. Information is documented in the chart, but must be interpreted. The exact wording of the response options for functional status or IADLs was not used in the chart.
2. Information is documented in the acute care or post-acute chart, but the original source of the information is unknown

Patient questionnaires, if used, should include a field to identify the primary source of the information. If this questionnaire is placed in the patient's chart, do not select the response 'inferred from chart' but instead select from the other response options listed above.

Other: select this response when none of the other response options apply

Table 2: Patient Health Perceptions (Modified SF-8™)

#	ITEM	CATEGORY	SOURCE	RESPONSE KEY
1	Overall, how would you rate your health during the month before your surgery?	General Health Perception	Patient Interview or Questionnaire	1 =Excellent; 2=Very Good; 3=Good; 4=Fair; 5=Poor; 6=Very Poor
2	During the month before your surgery, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?	Physical Functioning	Patient Interview or Questionnaire	1 =Not at all; 2=Very little; 3=Somewhat; 4=Quite a lot; 5=Could not do physical activities
3	During the month before your surgery, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?	Role-Physical	Patient Interview or Questionnaire	1 =None at all; 2= A little bit; 3=Some; 4=Quite a lot; 5=Could not do daily work
4	How much bodily pain have you had in the month before your surgery?	Bodily Pain	Patient Interview or Questionnaire	1=None; 2=Very mild; 3=Mild; 4=Moderate; 5=Severe; 6=Very severe
5	In the month before your surgery, how much energy did you have?	Vitality	Patient Interview or Questionnaire	1 =Very much; 2=Quite a lot; 3=Some; 4=A little; 5=None

#	ITEM	CATEGORY	SOURCE	RESPONSE KEY
6	In the month before your surgery, how much did your physical health or emotional problems limit your usual social activities with family or friends?	Social Functioning	Patient Interview or Questionnaire	1 =Not at all; 2=Very little; 3=Somewhat; 4=Quite a lot; 5=Could not participate in social activities
7	In the month before your surgery, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?	Mental Health	Patient Interview or Questionnaire	1 =Not at all; 2=Slightly; 3=Moderately; 4=Quite a lot; 5=Extremely
8	In the month before your surgery, how much did personal or emotional problems keep you from doing your usual work or other daily activities?	Role-Emotional	Patient Interview or Questionnaire	1 =Not at all; 2=Very little; 3=Somewhat; 4=Quite a lot; 5=Could not do daily activities

Rationale for Item Inclusion

The inclusion of patient health perception measures (Table 2) is recommended for their relationship to the outcome of healthcare. Many post-acute assessment tools reference the need to include these types of measures; the MOS Short Form is one of the most widely accepted tools.

The SF-8™ model is used in this dataset for purposes of brevity. Patient perceptions of health status before surgery are identified throughout the literature as determinants of rehabilitation potential. In particular, the pre-surgical measures of mental health and physical functioning have been shown to correlate with post-surgical functional outcome. Other options to maintain instrument brevity yet improve the research value of the instrument are to substitute the SF-8 ™ form with the SF-1 2v2 ™ form, or include only the mental health and physical functioning items from the SF-3 6v2 ™ form.

The IADL's (items 1 8-22, Table 1) are recommended for inclusion in the dataset for the following reasons:

1. IADL disability has been linked to post-acute resource utilization, especially in combination with ADL measures.
2. ADL measures, such as those included in the Functional Independence Measure, have exhibited a ceiling effect when used with higher functioning patients with fewer comorbidities.
3. Of the 8 IADL items originally described by Lawton and Brody, five items were included in the dataset. These items were selected as indicators most affected by physical functioning; only medication administration, telephone use, and money management were not included.
4. For consistency and ease of data collection, the response set (4-point) was also modified to resemble that of the IRF-PAI and MDS. Because the IADL data is dependent on patient self-report, the response set was simplified to improve accuracy in data collection and discrimination between response options for patient self-report.

The use of the modified SF-8 [TM] and the IADL scales as part of the dataset will allow for composite scores to be calculated for each of these domains. While some of the other items included in the dataset are more qualitative in nature, the SF-8 [TM] and the IADL add a quantitative component that will be useful for future analyses.

Research conducted outside of the rehabilitation industry supports the notion that there are factors, including those not directly related to the patient, that affect post-acute placement. These factors (Table 1) are included in the Referral Source (items 1-5), Patient Demographics (items 6-9), Patient Surgical History (items 10-12), Patient Living Environment (items 13-14), and Preoperative Functional Status (items 15-17). To create as comprehensive dataset as possible, consideration must be given to these items that may impact the post-acute inpatient placement decision, yet are not entirely related to patient functional status.

Activities of Daily Living items, such as those in the Functional Independence Measure, were omitted from inclusion in this proposed dataset. The rationale for exclusion is as follows:

1. ADL information is already collected on the IRF-PAI and MDS, and is based on post-surgical function.
2. Patients may have difficulty accurately recalling their functional status for time periods prior to surgery, and with the level of detail required to rate the patient on the 7-point Functional Independence Measure scale.
3. Because research indicates that the Functional Independence Measure scale has a 'ceiling' for higher functioning patients, a true indication of pre-surgical functional deficit may not be fully assessed by using the Functional Independence Measure.

Application and Implementation

This tool would not be intended for adoption by CMS but would inform research efforts on the factors affecting post-acute rehabilitation discharge. The tool would be finalized in May and incorporated into both eRehabData and eSNFdata for appropriate patients by the end of June 2006. This would allow for six months of data collection in 2006 and two months for data analysis. Data collected can be used to address the CMS restrictions on joint replacement admissions to inpatient rehabilitation. Data collection could continue on an ongoing basis for further studies.

Because items in this tool are in addition to what is collected on the IRF-PAI and MDS, and because data collection is voluntary and not overtly linked to reimbursement, there may be difficulties in getting facilities to collect and accurately record data. For this reason, computer interfaces will need to be very user-friendly. This may be accomplished through the use of user-defined drop-downs and pre-populating data sets. A pre-populating data set may be used with the referral source items so that the user could select a set of information, previously defined by the user, which would populate all referral source items.

In addition to ease in data entry, motivation to enter data may be increased through the development of reports that incorporate this data in a useful format for the facility. The reports

should allow any eRehabData customer to view aggregated information for IRFs and SNFs, and this information should be integrated with the reports currently available in eRehabData.

Should the SF-12v2 ™ or SF-8 ™ form be adopted as part of the tool, licensing obligations may need to be addressed.

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Preliminary Results of Rehabilitation Placement Factors Development

1. The instrument requires twenty (20) minutes to gather the data.

2. Discharge outcomes for the patients were virtually identical for these joint replacement patients. They were discharged home and with a high level of function. The uniform discharge outcomes do not allow the ability to link RPF indicators to outcomes because all the outcomes were the same.

3. Compared to their age group (national norms, not just joint replacement patients) the IRF-RPF patients were more cognitively active than the norm. The patients were, on average, in good health with good vitality. The standard deviations (SDs) for the data were perfectly inline with SDs for national normal data suggesting the data itself can be collected in a valid manner.

4. All patients were within a couple of ICD-9s and this data shows conclusively that the understanding of the patients can be easily expanded by simple data collection using vetted data items.

5. Data was collected only from patients in IRFs because they were the only facilities to which there was access. This limits the distribution of the patients within the data items we collected. We would hypothesize that the typical SNF patient would be lower than this IRF population on general health and vitality and the typical home health patient would be higher than the IRF on general health and vitality.

6. These data suggest that it is possible to quantify patients' rehabilitation potential but more data from more sites of care and additional conditions would be necessary to fully test that hypothesis.

American Medical Rehabilitation Providers Association

ATTACHMENT 5

AMRPA RECOMMENDATIONS REGARDING DATA INTEROPERABILITY

I. GOALS

The web-based system to support the CARE Instrument needs to meet the following goals:

A. All access to system is secure.
B. Access to the system can be made via the Internet
C. System will provide full upload and download capability for all data items captured by the CARE instrument.
D. System will provide full upload and download capability for all data calculated by the CARE instrument, especially as it relates to patient classification, reimbursement values, etc.
E. System functionality may be accessed through automated remote processes.
F. It is easy to develop code which integrates to CARE, and the code will be made publicly available.

II. GENERAL CONSIDERATIONS

AMRPA also has some general concerns which we recommend CMS consider in drafting the software for the CARE Instrument:

A. Architecture

The CARE Instrument should employ a service-oriented architecture. Such architecture will facilitate extension of existing hospital systems (e.g. billing systems, electronic medical records, etc.) to inter-operate with the CARE Instrument via server-to-server communication. This will avoid double data entry, reduce mistypes and missed updates when patient information is altered in one system. The service-oriented architecture should be based on APIs (application programming interface) which are readily available for download in a public area of the CARE Instrument site.

The CARE Instrument should send responses to API calls as HL7, XML or plain text, depending on user choice. Additionally, responses should be available in CSV format or PDF when the API calls for a report.

XML responses should follow DTD (document type definitions) which are readily available for download in a public area of the CARE site. To help providers avoid performance bottlenecks, the CARE Instrument should respond to all API calls in no more then 3 seconds.

B. Reliability

The CARE Instrument should be available 24-7 over a high-bandwidth Internet connection. It should run on a very robust server platform, utilizing redundant hot spares.

C. Development

A test system should be maintained alongside the production system, to allow developers of hospital systems test their integration code without corrupting production data. This system should also be available on a 24-7 basis.

III. SECURITY

The security of the CARE Instrument patient data is critical. AMRPA recommends CMS include the following in the software development:

A. Encryption

All access to the CARE system should be over HTTPS (possibly utilizing SOAP), SSL, or other highly secure, standards-based protocol. This approach will not only reduce the cost to developers of interfacing multiple systems, but provide the most secure method of communication.

B. Authentication

Users should be able to download certificates or keys which can be used as means of authentication for remote access. In addition users must be individually identified within the system, with each instance of a hospital system interface having its own ID (i.e. also being treated as a distinct "user." This will allow fine-grained tracking of data that moves into and out of the system.

C. Authorization

The CARE Instrument should have a role-based privilege management system to control the functionality that is available to users. For example, hospital administrator Alice may want Bob to upload data, and Charlie to view reports. Alice wants to be able to perform either function if she needs to, but she doesn't want Bob to view reports or Charlie to upload data. Alice should be able to assign the tasks of data-uploading and report-viewing to separate roles which she may confer upon users. And, she should be able to define her own roles and assign tasks to them as she sees fit. Additionally, sensible defaults should be provided.

IV. UPLOADS

AMRPA recommends the following be included in the software and systems CMS is developing:

A. Upload Types

It should be possible to upload all data required by the CARE system:

1. CARE Instrument Assessments
2. Individual Facility data, such as the wage index used in calculating payments.

B. Assessment Data

1. Supported Formats

a. CMS transmissions formats. This would allow developers of other systems to re-use an existing export to CMS as an import to CARE. The CMS transmission format for the new, integrated instrument should be supported.
b. Delimited (Tab, comma)
c. HL7 protocol
d. XML (based on a publicly available DTD)

2. For HL7 and either of the delimited formats, it should be possible to upload any combination of fields in the assessment record. This will allow upload and download of incomplete patient data.

C. Non-Assessment Data – Supported Formats

1. HL7
2. Delimited (Tab, comma)
3. XML (based on a publicly available DTD)

D. Service-Oriented Approach

Different kinds of uploads should be made available through an upload service via different API calls, which developers of other systems may use to integrate with CARE. This approach will promote remote automated access.

E. Asynchronous Imports

CARE should respond to API calls for uploads immediately, with a transaction identifier which may be used after the upload is complete to retrieve import results in a separate API call. Import of uploaded data into the CARE database should be done asynchronously. If import into the CARE database does not occur simultaneously during the upload (i.e. uploads are staged and imported after error-checking at a later time) then the API should support a query that allows hospital systems to determine if acceptance has occurred. Import results should be available as XML or a well-defined plain text protocol (so that a hospital system can easily determine the result), and contain all data validation errors.

F. Availability of Requirements

Links to file upload formats, protocols and data validation requirements should be readily available in a centralized location on the CARE website.

V. DOWNLOADS

AMRPA recommends the following be included in the final system:

A. Download Types

It should be possible for providers to download all data collected and calculated by the CARE system. These include:

1. Assessments
2. Facility data, such as the wage index used in calculating payments.
3. Calculated assessment data (CMGs, RUGs, DRGs, LTCH-DRGs, HARGs, Expected Reimbursements, etc.)
4. Usage data (logins, record time-stamps, etc.)

B. Assessment Data

1. *Supported Formats*
   a. CMS transmissions formats (while primarily inteded for uploading data to CMS, the same format should be available for downloads as well).
   b. Delimited (Tab, comma)

c. HL7 protocol
d. XML (based on a publicly available DTD)

C. Non-Assessment Data

1. *Supported Formats*
   a. HL7
   b. Delimited (Tab, comma)
   c. XML (based on a publicly available DTD)

D. Service-Oriented Approach

Different kinds of downloads should be made available through a service via different API calls, which developers of other systems may use to integrate with the CARE system. This approach will promote remote automated access.

E. Availability of Requirements

Links to file download format, protocol and data validation requirements should be readily available to providers in a centralized location on the CARE website.

VI. REPORTS

AMRPA recommends the following be considered in the final CARE Instrument system:

A. Performance

In order to avoid client performance bottlenecks and maintain the 3-second response-time goal, some reports should be pre-computed and stored in a reports database.

B. Service-Oriented Approach

Different kinds of reports should be made available through a report service as different API calls, which developers of other systems may use to integrate with CARE. This will promote remote automated access, and reduce errors and duplication as hospital systems will not have to calculate report data that the CARE system produces.

C. Remote Listing of Report Parameters

API calls should be provided to allow an external system to retrieve meta-data about the reports themselves. Specifically this requirement would include the list of available reports, run-times, download sizes, etc.

VII. TRANSPARENCY

All code and databases related to calculations of payment, compliance, groupers, or other software implementations of laws and regulations should be published to allow providers to ensure their internal systems match federal requirements.