September 25, 2007

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

HealthSouth is a national provider of inpatient rehabilitation services and the full spectrum of post-acute care, demonstrated by our 94 inpatient rehabilitation hospitals (also referred to as Inpatient Rehabilitation Facilities or IRFs), 6 Long-Term Acute Care Hospitals (LTCHs), 7 Skilled Nursing Facility (SNF) units, and 24 Home Health Agencies (HHAs), located in many key health care markets. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) demonstration project on the Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument ("Instrument"), released July 17, 2007, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005.

HealthSouth supports the concept of an integrated post-acute care system that will permit healthcare providers, using patient-specific criteria and measurements, to provide site-neutral post-acute care and services at various levels within a single facility and home health environment. We have expressed our desire to participate in the current pilot demonstration project.

These comments are intended to collaboratively share with CMS and other parties involved with this demonstration project some specific recommendations to improve the Instrument, and they have been developed through the input of various of our senior medical and clinical staff. We also support the comments submitted by the American Medical Rehabilitation Providers Association and the Federation of American Hospitals.

I. ROLE OF PHYSICIANS IN DISCHARGE PLANNING DECISIONS AND PROCESS

We are concerned that the Instrument as currently drafted would undermine the critically important role that physicians hold in the post-acute care continuum. It is vitally important to preserve the basic premise that medical care, in any setting, requires the oversight and direction of a physician. In fact, the Instrument would potentially diminish the role that physicians hold as primary caregivers to their patients, by asking others to answer questions that require a physician's involvement. For example:

Discharge Care Options

Section IX. (D) (Discharge Care Options) creates significant concerns about the apparent lack of physician direction, involvement, and oversight regarding patient discharge destination decisions within the CARE Instrument framework. The physician is the only member of the care team who initiates a discharge order from an acute care setting and should play a leading role in determining the patient's post-acute care placement. However, as it is currently drafted this section of the Instrument does not sufficiently clarify that a physician has adequately participated in the discharge destination decision-making process in determining the "appropriateness" of a potential post-acute care setting. We recommend that the section be simplified and reformatted to incorporate the following changes in order to maintain the clinical integrity of a physician-directed health care delivery system.

1. "Deemed Appropriate by the Provider." This column needs to be re-labeled. As currently formatted, a discharge planner could check multiple boxes with no accountability regarding medical criteria used to determine appropriateness. This column requires greater specificity about who should determine a patient's post-acute care discharge destination, as well as the standard by which such a decision is made. The word "Provider" is too ambiguous and suggests that someone (or organization, including the potential receiving post-acute facility) other than a physician can make such a determination. This language should be clarified by substituting "Deemed Reasonable and Necessary by the Attending Physician." This column heading is consistent with terms already established by CMS and best reflects the rationale for determining an appropriate post-acute setting.

2. The Instructions for Section IX, subsection D. should be changed to read, "Please check the boxes that apply to the type of service." The directions should also clarify that columns 2 and 3 should not be completed unless the box in column D1 is checked. Column D4 should be deleted for reasons specified in section II of our comments.

II. POTENTIAL BARRIERS TO CARE

A. Therapy Referral Requirement

As the instrument is currently designed, Section VI. Functional Status (C) can be skipped unless a therapy consultation has been ordered or post-acute care will be required. We are concerned because this design may subtly discourage people from ordering therapy evaluations, and could even discourage orders for brief, but important, home health services. While we do not foresee the intentional withholding of such services, it is possible, since clinicians would realize that merely ordering a therapy evaluation or a home health visit for a patient automatically triggers an extra 20- 40 minutes of paperwork for a colleague. Caregivers with excellent intentions could -- even subconsciously -- become hesitant to order therapy consultations, ignoring subtle but potentially significant functional deficits. It would be an unfortunate irony if the tool designed, in part, to assess a patient's requirement for post-acute services, had the unintended consequence of limiting assessment of post-acute needs through avoidance of therapy consultations during his or her acute care stay.

To avoid the potential for this outcome, we offer 2 suggested approaches to modify the Instrument: 1) revise the instructions in a manner clarifying that Section VI (C) must be filled out for all patients, regardless of whether therapy consultations are made during the acute hospital stay or whether the patient will receive post-acute care or personal assistance following discharge from the acute hospital; or, 2) revise the instructions in a manner clarifying that Section VI (C) must be filled out in those circumstances where the patient needs post-acute care or personal assistance following discharge (I.E., "C. Supplemental Functional Ability: Complete only for patients who [DELETE THE FOLLOWING LANGUAGE: had therapy consult or who] will need post-acute care or personal assistance following discharge").

B. "Not Covered By Insurance"

We urge that the column labeled "*Not Covered By Insurance*" (Sec. IX, D) be deleted from the Instrument because of its potential to serve as a barrier to proper post-acute care planning and access. Given that the Instrument would be applicable to all Medicare patients, and that each type of service listed has coverage under Medicare guidelines, this column may cause confusion for staff completing the Instrument and inappropriately limit thinking regarding post-acute options. It also may confuse Medicare beneficiaries and their families, by potentially misrepresenting coverage of Medicare benefits and services. Decisions related to medical necessity and appropriateness of medical services should be made independent of a patient's insurance status. Including a phrase like "not covered by insurance" on a form that appears to evaluate post-acute care options for Medicare beneficiaries raises significant concerns.

C. Potential for Obscuring Needs Through Error Replication

Instructions released to date are not clear on whether the Instrument completed at the acute care provider will be available/accessible to the post-acute care provider. We recommend that it not be made available because it could unduly affect subsequent assessments. For example, if the assessment conducted in the acute setting failed to identify a functional deficit that requires rehabilitation, that error in the CARE report could actually increase the odds of the functional deficit also being missed in the post-acute setting. The result of such an omission would be an inadequate rehabilitation care plan. While we recognize that forwarding the assessment might appear to streamline the process or contribute to continuity, until some certainty has been achieved regarding the reliability of the assessment information, we believe the potential harm outweighs the benefits of sharing the CARE assessments across provider sites. In this vein, it would also be helpful to have more clarity regarding the relationship of the CARE tool to the patient's medical record since this will affect how the CARE instrument should be filed and what rights patients have to access the completed document.

D. Frailty/Life Expectancy

Section VIII's questions seeking opinions on whether one would be "surprised" if a particular patient were readmitted to an acute hospital or would die within a year are delicate and emotionally charged matters. We are convinced that these opinions would lack inter-rater reliability for a number of reasons, including:

- Absence of expertise in clinical prognostication within the disciplines of persons likely to be completing this CARE tool section
- Lack of reliable clinical benchmarks for predicting life expectancy
- Variations in individuals' confidence in their predictive capabilities
- Concern that certain answers might negatively affect a patient's chances of obtaining needed post-acute care.

Utilization of such responses in decision-making could inhibit opportunity for accurate care decisions based on patient need. Accordingly, we recommend that these questions be removed from the Instrument.

III. UTILITY OF INFORMATION COLLECTED

There are at least two elements related to the reliability and usefulness of any assessment instrument: (1) the question design, and (2) the expertise of the users.

A. DATA RELIABILITY

Because of the stringent timeline established by Congress, RTI has not had the opportunity to develop and test the questions as thoroughly as their analysts and the post-acute care community would have preferred. Recognizing this, it will be important to remember that during the early years of this project, we will not even know how reliable the information is that is being collected. For this reason, we encourage the project team to carefully evaluate the data, cross-checking it against existing sources and submitting it to academic and industry scrutiny, before recommending uses to which it might be put.

Even assuming that a question -- or a whole instrument -- is perfectly designed, the expertise of the users represents an important factor in its usefulness. Ninety-four of our sites are inpatient rehabilitation hospitals where we have experience using the IRF-PAI instrument. It is estimated that the CARE tool will take approximately 45 minutes to complete, compared to approximately 20 minutes to complete the IRF-PAI. In our experience, it takes about 6 hours to train a clinician to score the IRF-PAI. One can extrapolate to get an idea of the requirements involved in training people of multiple disciplines to complete the more extensive and complex CARE instrument.

For the reasons mentioned here related to question design and training, we urge caution and deliberation as we go forward to develop a common appropriate post-acute assessment tool. Systematic validation of questions and comprehensive training will need to be built into the demonstration and implementation processes at every step.

a. The training will have to be particularly rigorous during the early phases of demonstration. This is because training will need to focus on all elements of the new tool, as well as clearly delineating the differences between the CARE Instrument and current tool in place (e.g. MDS, IRF-PAI, OASIS), as two systems of assessment and data collection will be in place simultaneously. A monitoring system will need to be developed and implemented to ensure the accuracy of scoring and the reliability of two different systems of reporting being used. The monitoring system also will need to identify timing of education due to staff turnovers, and trends of questionable or inaccurate data reporting habits that may be identified.

b. There are no published guidelines about any specific requirements that will be expected of those completing the CARE Instrument. It is our recommendation that the Instrument's items should be "assessed" and completed by a licensed, trained c professional (PT, OT, RN, or SLP). The Clearance Package Supporting Statement (page 4) states that the data collection does not require a signature from the respondent, which may be interpreted to mean that the persons completing the document need not sign it. There is risk of variability in the technical skills of those scoring the items

("assessment" activities require a license to ensure consistency), and may result in major discrepancies with reliability and validity of the data pulled from the Instrument.

B. Signature / Certification

It is not clear whether the Instrument has a signature requirement, and clearly the extent of personal engagement on the part of assessors will affect the reliability of the data collected. To the extent a signature requirement is intended, which we support, the cautionary statements preceding the signature should be modified in a manner that reasonably conveys the importance for accurate information without taking space and paper to restate legal penalties for errors. Clinicians and health professionals responsible for completing this Instrument should certainly be educated about the need for accurate data and information and also about the potential penalties that may be imposed for knowingly falsifying such data and information. However, that education should be achieved during the Instrument's training and implementation process and not incorporated into the Instrument itself.

C. Administrative Burden

It is likely that many parties will comment on the administrative burden associated with the new CARE tool. While we share these concerns as they relate to time and resources, we have a somewhat different concern that relates to the reliability of the content. We believe that if a tool is too bulky, people filling it out can lose focus or commitment to its importance. As people's attention fades, they become less conscientious in answering precisely and more focused on "getting through."

To protect the integrity of the entire tool and the data it generates, we recommend that considerable effort be expended at each step of the comment/demonstration/re-evaluation process to trim the Instrument to achieve optimum size. In each analysis, we urge designers to seek an elegant instrument design that includes the absolute minimum number of data elements. We strongly recommend setting a goal that the final CARE Instrument that emerges after experience during the demonstration project take no longer to complete than the average time currently required for the existing assessment tools.

IV. APPLES AND ORANGES: LIMITS ON CONSISTENCY

HealthSouth recognizes the merits of a common assessment instrument to be used in various settings. Within that framework, however, it is important to realize that observations (1) made in different settings (2) by professionals with different levels of training and experience (3) on patients at different points in their clinical course, will reflect some inherent differences. For example, Medicare guidelines recognize the special role of rehabilitation nurses and respect their unique expertise. One should not be surprised, therefore, that a functional assessment done by a specially trained rehabilitation nurse in a rehabilitation setting might differ from an assessment done a few hours earlier by a surgical nurse in a community acute care hospital. Similarly, there is a

vast difference in the purpose of a physical therapist's evaluation in the acute setting -- namely to recommend whether post-acute care is required --- and the evaluation of a therapist in an inpatient rehabilitation hospital, which involves a detailed assessment and care plan. We urge data analysts and policy-makers who will use the data resulting from CARE, and its successive versions as it is tested and refined, to remember that these differences are to be expected and do not represent contradictions or inaccuracies. While consistency of assessment is important for our ability to measure and promote the best outcomes, we must recognize certain important differences in clinical observations will exist.

HealthSouth appreciates the opportunity to provide constructive feedback on this important demonstration project and the current tool proposed to meet its objectives. Our thoughts and recommendations are shared in order to support the stated goals of the project, while ensuring the successful components and the clinical integrity of our health care delivery system are maintained. We look forward to the next phase of the project, and the potential opportunity to be involved as participating Providers at all levels of the post-acute care settings included in the demonstration.

Sincerely yours,

Justin R. Hunter
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