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:

This letter is submitted on behalf of the Sheltering Arms Rehabilitation Center, Richmond Virginia. Sheltering Arms operates two IRFs in the Richmond VA metro area.

We appreciate this opportunity to comment on the Continuity Assessment Record and Evaluation (CARE) instrument. We at Sheltering Arms 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. We have participated in the two Open Door Forums held to date and on the two Technical Expert Panels.

Sheltering Arms examined the (a) structure and content of the instrument, (b) 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;
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 view 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 providers to be involved in the project.

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

Our key concerns include: serious concerns regarding validity and reliability of the instrument and the individual items; extensive administrative burden; and the potential for the instrument, and potentially for the project therefore, to block access for patients.

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

A. *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. Reliability and biases in different settings, using items with varying legacies and with staff with different care philosophies and training, are particular and important issues.

Factors that could reduce the value for 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. Sheltering Arms is concerned about reliability between settings when what appear to be IRF PAI functional items are then to be used across settings with a new scale. See 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, as noted. 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.

Therefore in summary, one of the statutory purposes of the project is to develop a way to predict placement of patients in a post acute care provider, 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.

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.

One of the purposes of the instrument is to collect data on resource use and 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?

Sheltering Arms 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.

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).

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.

B. *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 any 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 is to 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. Sheltering Arms suggests that CMS provide a waiver from the 75% rule for all IRFs participating in the study.

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% and a Medicare margin for providers of only 2.7%. At Sheltering Arms we are now beginning to experience likewise reductions in our admissions to both of our hospitals.

In addition to the 75% Rule, another factor adversely affecting Sheltering Arms 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. Sheltering Arms has had over 200 cases denied and we have responded by further changing our 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, we are forced to divert substantial revenues to defend against inappropriate denials and recover payments. Denials are the result of reviews by the fiscal intermediary (NGS) under a local coverage determination

(LCD). Additionally, NGS has conducted aggressive probe audits and pre- and post-payment reviews denying 100% of the cases reviewed.
At Sheltering Arms we have had over 200 inpatient admissions denied by our fiscal intermediary (NGS) in the last year. These denials have resulted in a reduction of over $2 million in reimbursement leading to a significant change in our admissions and patient mix.

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 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 a complete medical review is not being conducted. We are aware of one company that has over 300 cases amounting to over $3 million in dispute the amount of payment. We are also aware of at least one California provider who states it is no longer able to make payroll because of the RAC reviews and is closing. 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 and administrative 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.)

All this turmoil imposed on inpatient rehabilitation hospitals and units results in a disruption in their normal patient population. SNFs, on the other hand, are not experiencing any restrictions on the types of patients they may treat. Choosing this moment in history to test the CARE instrument confounds the findings. During "normal" times, the CARE instrument would be gathering information to compare conditions, outcomes, and resource consumption of patients whose post-acute site of care was determined by their treating physicians. In the face of the 75% Rule and coercive pressure from various audits and retrospective reviews, however, the CARE instrument will be looking for comparisons in an unsettled, atypical environment. 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.

C. *Burden on Acute Care Providers and Post Acute Care Providers*

We at Sheltering Arms have 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 IRF PAI – which takes approximately 40 minutes. 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, additional 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 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 are 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 burden for them. Sheltering Arms is very concerned that discharge planners – or others upon whose shoulders this task might fall – will not have the resources available or take the time to complete the forms as intended. Lack of time, resources or lack of competence would lead to unreliable data. To the extent something unreliable is treated as if it is 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 rehabilitation care.

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. 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).

D. *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.

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 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.

E. *Medicare as a Precedent*

Sheltering Arms 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.

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 to 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.

Most 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 potential adverse impacts on patient care and access must be addressed as the demonstration project is conducted.

Sincerely,

James E. Sok, FACHE
President and CEO
Sheltering Arms Hospitals