Federation of
American
Hospitals™

Charles N. Kahn III
President

September 24, 2007

BY OVERNIGHT MAIL

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:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay acute, rehabilitation, cancer and long-term care hospitals in urban and rural parts of the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") notice on the Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument.

In general, the FAH believes that the CARE instrument will be too onerous for completion in the acute care setting. Hospitals are not staffed to complete this hour long tool for every Medicare patient being discharged. In addition, with respect to the suitability of the CARE instrument for long term care hospitals, FAH supports the comments of the Acute Long Term Hospital Association ("ALTHA") and would specifically reiterate that the instrument falls short of adequately capturing the unique characteristics of patients in the long term acute care hospital setting. What follows are FAH comments on the individual sections within the CARE Instrument.

Signatures of Persons who Completed a Portion of the Accompanying Assessment

The FAH agrees that all persons who complete the CARE Instrument must sign the attestation that the information entered into the document accurately reflects the patient's condition. The FAH recommends that there be one person assigned who is responsible for the oversight of the Instrument completion, similar to the Registered Nurse Assessment Coordinator (RNAC) in the Skilled Nursing Facility (SNF) or the Inpatient Rehabilitation Facility (IRF) – Patient Assessment Instrument (IRF-PAI) Coordinator in the inpatient rehab facility.

Also, the FAH has a concern about readily sharing the license number of the employees. We recommend that the license number be removed from this document.

I. Administrative Items

One limitation in reviewing this Instrument at this time is the lack of an instruction manual for the items in the Instrument. The FAH recommends that CMS provide an instruction manual to the demonstration facilities to use in completing the Instrument.

Item A1.4.: What is the purpose of the Interim item? When will this assessment be completed?

Item C5.: CMS has stated that the CARE Instrument is to be completed on Medicare Fee For Service patients only. Does this include patients where Medicare is secondary?

Item C11.: What is the purpose of checking all race/ethnicity boxes that apply? What is this item be used for? Many citizens of the United States have multiple ethnicity in their family lineage.

Item C13.: Advanced Care Directives are required as a question upon admission to the facility. Are the questions in this item based upon a physician's order in the medical record based upon the patient's wishes?

Item D.: This item should be structured to request information on primary and secondary payer only. The FAH understanding is that this tool would apply only to Medicare FFS patients. We are not sure of the purpose of checking all payers that apply or how this information will be used.

Item D8.: TRICARE is now the name for the military benefits program rather than CHAMPUS.

II. Admission Information

General Comments: Need to know the source of information for this section, i.e., patient, family, other.

Item A2.: To maintain consistency with the billing requirements, the "Admitted From" item must match the NUBC recommended admission source code definitions.

Item A4a.: CMS does not have a definition of subacute SNF in the regulations. Please provide a definition of subacute SNF. The FAH recommends that all definitions match the current definitions in CMS regulations. A SNF is defined as a Medicare certified skilled nursing facility bed.

Item B4c & d.: Need more iteration on number of stairs and handrail availability.

Item B4e.: Add more examples e.g., bedside commode, shower chair.

Item B5.: FAH appreciates the simplification of this section, however, it should include information on transfers and toileting.

Item B6.: Add more examples e.g., bedside commode, shower chair.

III. Current Medical Items

Item A.: What are the instructions for completing this section? Is it a coder's responsibility for coding the information in this section from information found in the medical record? The FAH recommends that only coders be allowed to complete this section of the Instrument as they have knowledge of coding compliance standards. The FAH also recommends that comprehensive coding guidelines accompany this Instrument for this section.

Item B.: The FAH has several comments on this section.

i. The Instrument must allow for reporting of E-Codes

ii. Since the UB-04 accepts up to 21 diagnosis codes, the CARE Instrument should also allow for 21 diagnosis codes.

iii. In the IRF-PAI there is a section to distinguish between the etiologic diagnosis, diagnosis for interruption or death or complications arising during the stay in the post acute setting. Is this guidance being discontinued in this new instrument?

Item C1.: How are the therapeutic or major procedures during admission defined?

Item D. This section needs to be divided into equipment, medications and medical devices and procedures to help simplify the completion of this section. Also, the medications need to be removed and placed into Item E of this section.

Item G1.: Define formal evaluation. Which discipline is to perform this review? What pressure ulcer scale is to be used? The FAH recommends that CMS provide the formal evaluation tool so that the evaluation is consistent in all settings.

Item G5.: FAH questions why only wounds with complications are included in this section. It would seem logical that the agency would also be interested in the resources utilized in treating wounds that are healing in a normal manner.

Item H.: How will the information in the Physiologic Factors section be used? How is this section going to drive payment? How does this section represent the management of abnormal values of the patient's stay and the utilization of resources?

IV. Cognitive Status

Item G3.: Need a separate code for patients who are unable to respond.

V. Impairments

Item B3.: In order to determine the resource utilization for this item, a secondary question should be asked that indicates the number of times assistance is required.

Item C1f.: For this item, what if the patient is NPO for reasons other than a swallowing disorder (e.g., NPO for procedure)? How is that to be reflected?

Item E.: Need to provide more standard definitions of "Within Normal Limits" and "Limited Range of Motion" and how this is measured.

Item J.: This seems to be duplicative of Current Medical Items D: Treatments. Eliminate Item J and incorporate the question into Current Medical Items D.

VI. Functional Status

Item A: The FAH recommends that CMS develop decision trees for each of the items in this section (similar to the decision trees in the IRF-PAI Training Manual).

Item C.: How will the person completing the Instrument in the acute care setting know that the patient needs post acute care or personal assistance following discharge? At what point in time will this Instrument be completed in the acute care setting? This will make a difference to how this Item is completed.

> **Items C12 – C18:** How in the acute care setting will the person completing the tool be able to observe these items?

VII. Engagement

Item A.: What is the value of this section?

VIII. Frailty/Life Expectancy

Item A.: Given the complexity of end of life decisions, is the person completing the form qualified to make the judgment about end of life? What happens if this information

has not been shared by the physician with the patient's family and is viewed by the patient's family? The FAH recommends that this item be removed from the Instrument or that a physician complete this portion of the instrument after conversation with the patient and his/her family.

IX. Discharge Status

Item A2.: The FAH strongly recommends that the discharge location match the patient status code assignments defined by the NUBC and reported on the UB-04.

Item B1e.: Remove the word "unpaid" from this section. It serves no value.

Item B4c.: Remove the word "unpaid" from this section. It serves no value.

Item D.: The FAH strongly recommends that the Discharge Care Options items match the patient status code assignments defined by the NUBC and reported on the UB-04.

Item E2.: The FAH strongly recommends that the Provider Type items match the patient status code assignments defined by the NUBC and reported on the UB-04.

Item E5.: How is the referring provider going to have the receiving provider's Medicare Provider Identification Number? What if the receiving provider does not have a Medicare Provider Identification Number? If the referring provider is able to obtain the Medicare Provider Identification number should they also not be able to provide the National Provider Identification code?

In addition, with respect to questions regarding the "appropriate" level of care, we strongly believe that the judgment of the referring or treating physician as to what level of care is reasonable and necessary is controlling.

X. Feedback

From a review standpoint, it took over 1 hour just to read through the document. There are concerns that it will take much longer to complete when assessing an actual patient.

* * * * * *

We appreciate the opportunity to comment on this notice and hope that the agency carefully considers the comments in this letter. 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 or Steve Speil, Senior Vice President, Health Finance and Policy, of my staff at (202) 624-1500.

Respectfully submitted,

MOSES CONE HEALTH SYSTEM

Rehabilitation Center

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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 on behalf of Moses Cone Health System Rehabilitation Center in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services, as mandated by Congress under Section 5008 of the Deficit Reduction Act of 2005.

My comments and concerns regarding the CARE tool for all post-acute settings are presented below.

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.

2. The CARE tool presents coding issues that will impact clarity related to Medical Necessity for services. 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. Section VI, Functional Status, contains a variety of measurement scales that have not been tested for psychometric scaling properties. In addition, there are no provisions for credentialing to assure inter-rater reliability.

4. The Functional Status tools do not indicate need for an assistive device or aid, extra time, and do not separate setup from supervision. In addition, the Functional Status tools do not separate contact guard or touching assistance from supervision. All of these situations contribute to burden of care and discharge planning.

5. The GARE 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. This may underestimate the burden of care.

6. Many of these items are 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.

7. The demonstration project sampling method does not 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.

8. 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.

9. Each facility will need to acquire 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.

10. Computer program interfaces and mapping will be necessary to link the CARE tool software with clinical, management, financial, and hospital billing systems.

11. The rehab industry can currently run on-demand reports from IRF-PAI data and has access to a comparative database that can be used for benchmarking and performance improvement. Assuring a similar feature in the new system will be critical to effective performance improvement activities.

Thank you 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 336-832-7545.

Sincerely,

Anne Macner

Anne Macner
Executive Director, Post-Acute Rehabilitation
Moses Cone Health System

[redacted] [redacted]

The Institute for

Matching Person & Technology, Inc.

21 September 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:

I am writing on behalf of the Institute for Matching Person & Technology to comment on the proposed CARE Tool for a Uniform Post-acute Patient Assessment Instrument. I am also a member of the Board of Governors of the American Congress of Rehabilitation Medicine, who is writing to you separately and whose perspectives and recommendations I fully endorse.

I applaud CMS's commitment to develop a new post-acute patient assessment instrument to enhance post-acute placement, quality monitoring, outcome assessment, and payment. I also applaud the developers of the CARE tool for reaching out to all the current stakeholders.

The Institute for Matching Person & Technology specializes in assessing the support needs of persons with disabilities across settings, focusing primarily on the selection of appropriate assistive technology. Measures are compatible with the World Health Organization's ICF framework, which is becoming the international standard for characterizing disability. The recently released IOM report, *The Future of Disability in America*, recommends that the ICF be adopted in the U.S. across federal agencies, healthcare settings, and so on as the means to achieve a common language to characterize disability/disablement. It also recommends enhanced attention to assistive technology.

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[redacted] [redacted]

As a result of my years of research on the match of individuals with the most appropriate support for them, it is imperative that we more adequately measure the ICF domains of Activities and Participation, Environmental Factors, and Personal Factors. This means going beyond mere functioning to include subjective well-being, use of support and assistive technology, satisfaction with activity performance, mood, practitioner and program trust, the individual's self-determination and motivation. My measures include these constructs and they have consistently yielded very high predictive validity across disability types, ages, and settings. I am happy to make this data available to you if you so wish. I realize that the CARE tool will include a degree of modularity and, thus, strongly endorse the need for this.

To summarize, I am making the following recommendations:
(a) Ensure that the CARE tool is compatible with the World Health Organization's ICF framework.
(b) Include a measure of support use and needs, including assistive technology as a modular option.
(c) Address individual subjective well-being, satisfaction with activity performance, mood, practitioner and program trust, and level of self-determination and motivation.

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

Sincerely,

Marcia J. Scherer, Ph.D., MPH, FACRM
President

Associate Professor of Orthopaedics and Rehabilitation
University of Rochester Medical Center

Fellow, American Psychological Association
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(b) Evaluation, Measurement, and Statistics, and
(c) Applied Experimental and Engineering Psychology

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24 September 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, MD 21244-1850

RE: CARE Tool

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed CARE Tool. I previously served on Technical Expert Panels for the MDS, MDS-PAC, MedPAC, and Failure to Thrive initiatives , and I was also the Field Supervisor for the congressionally-mandated Rehabilitation Staff Time Measurement (STM) study for the rehabilitation prospective payment system (PPS) (1998 - 2002). In the latter position, we used the MDS-PAC in 12 sites nationwide.

First I wish to compliment the authors on the work they have done. I see many changes in the CARE tool that reflect improvements on previous measures. I am offering the following suggestions for your consideration.

1. I found no section that would documents "**Goals for Stay**" such as (a) medical stabiliization, (b) rehabilitation/functional improvement, (c) recuperation, (d) monitor to avoid complications, and (e) palliative care. There were included in the MDS-PAC and were useful. With the CARE tool proposed for use across the continuum of care, this would be important for each admission, as well as with repeat admissions.

2. Under **Section II, Admission Information, B5., Prior Functioning**. The items here are very basic activities of daily living (1 self-care item addressing bodily-oriented activities, 3 mobility items, and 1 functional cognition item). The preface addresses "everyday activities prior to this current illness." For the CARE tool to be useful for measuring recovery (compared to prior functioning), it would be useful to include all items in **VI.C.** These reflect the array of "everyday activities" that will allow for a better reflections of ***recovery*** and will match the items

used to measure ***progress*** (difference between VI C at admission 2 day assessment and VI C at discharge 2 day look back).

3. **IV. Cognitive Status, C. Observational Assessment of Cognitive Status....** One item on the MDS-PAC that was useful for rehabilitation practitioners on the PPS Study was Procedural Memory. Please consider the addition of this item.

4. **V. D. Impairments – Hearing & Communication Comprehension.** Please consider an item that addresses "Method" of communication. For example, (a) hearing aid, (b) lip reading, (c) signs/gestures, (d) writes messages. From MDS-PAC.

5. **V. Impairments – Sensation (missing).** Analysis of MDS data for stroke survivors indicated that intact sensation made a difference in functional status, and there is no item that addresses sensation. I would suggest that you refer to R Upper Extremity/ Left Upper Extremity/ Right Lower Extremity/ Left Lower Extremity, and code it with:

1. Within Normal Limits. Sensation is within normal limits
0 Partial or absent sensation: Sensation is altered or absent

6. **V. Impairments – Motor Control (missing).** Functional range of motion does not mean that an individual has motor control, and both are important. I would suggest that you refer to R Upper Extremity/ Left Upper Extremity/ Right Lower Extremity/ Left Lower Extremity, and code it with:

1. Within Normal Limits. Coordination is within normal limits
0 Incoordination. Coordination is inconsistent or absent

7. **V. J. Mobility Devices and Aides (sic) Needed (N.B. should be Aids-Aide is a person)** This section focuses solely on mobility, but there are many other assistive devices that are relevant across the continuum of care. At minimum, there should be listed (a) adaptive eating utensils, (b) orthotics/splints, (c) prosthetics.

8. **VI. Functional Status C Mode of Mobility.** In our nursing home study, we found that Mode of Mobility in Wheelchair was very important information, namely (a) propels using handrim, (b) propels using feet, (c) power chair with joystick, (d) power chair with _____ .

Thank you again for the opportunity to comment.

Sincerely,

Margo B. Holm

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September 21, 2007

Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attn. Bonnie L. Harkless
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7500 Security Boulevard
Baltimore MD, 21244-1850

Dear Ms. Harkless:

In the **Federal Register** of July 27, 2007 (Vol. 72, No. 144, pp. 41328-29) The Centers for Medicare and Medicaid Services (CMS) identified, and requested public comment on, several data collection tools. Fundamental Clinical Consulting LLC, a consultant to Post Acute Care (PAC) facilities nationwide, is pleased to offer comments on one of these: the Continuity Assessment Record and Evaluation (**CARE**) instrument.

The **Federal Register** described the **CARE** tool as *"...a uniform patient assessment instrument designed to measure differences in patient severity, resource utilization, and outcomes for patients in acute and post-acute care settings."* In its upcoming PAC Payment Demonstration, *"CMS will use the data from the **CARE** instrument to examine the degree to which the items on the instrument can be used to predict beneficiary resource use and outcomes."*

Fundamental recognizes that much time and effort has gone into the design of the **CARE** instrument. Contributors included CMS staff, Technical Expert Panels, and various discussion groups among others. We also recognize that a main purpose of the Congressionally-mandated PAC Demonstration is to assess the usefulness of the instrument in the context of a revised Medicare reimbursement process. We hope that the following comments will help CMS and its contractors as they go about the tasks of testing, evaluating and refining the **CARE** instrument.

1) CARE Tool User's Manual. The **CARE** tool is similar in concept to the Minimum Data Set (**MDS**) that is the foundation of Medicare payment for care in Skilled Nursing Facilities (SNFs). A key companion document to the **MDS** is the **Resident Assessment Instrument (RAI) User's Manual**. The latter is a voluminous document offering detailed definitions and instructions that go a long way toward assuring the accuracy and consistency of MDS data.

We have seen no reference to a similar **CARE** tool User's Manual. We trust that at least a preliminary or draft User's Manual will accompany the **CARE** tool in the Demonstration sites. In fact, answers and responses to many of our immediate questions and concerns likely would be found in a well-constructed User's Manual.

2) Information Sharing Across Sites of Service. Fundamental staff noted with interest the overlap between data to be reported at a patient's discharge from an acute care hospital and data to be reported at the patient's / resident's subsequent admission to a SNF. In many cases, these events will occur within days (if not hours) of each other. This suggests a couple of questions.

First, will SNF staff have access to a discharging hospital's **CARE** instrument and, if so, will they be permitted to populate fields in the SNF Admission instrument with corresponding data from the hospital discharge version? One model of **CARE** tool administration would allow each provider in a sequence to simply update fields that have already been completed by an immediately preceding provider. The potential reduction in respondent burden would seem great.

Second, the hospital-dischargc **CARE** instrument has all the earmarks of a hospital-to-SNF transfer form that could help the receiving facility set up and prepare for the arrival of an incoming resident. Will CMS be testing and evaluating the potential of **CARE** to support and facilitate inter-facility patient transfers as part of the Demonstration?

3) Much Is Expected From One Data Collection Instrument As reported in the **Federal Register**, CMS will use data from the **CARE** tool *"...to characterize patient severity of illness and level of function in order to predict resource use, post-acute care discharge placement, and beneficiary outcomes."* This is asking much from a single data collection instrument. The set of variables required for predicting resource use might well be different from the set needed to establish appropriate placement and both might be different from the set needed to measure and compare beneficiary outcomes across providers.

4) The Potential of CARE Data to Support Outcomes Assessment and Analysis. We are willing to give the **CARE** tool the benefit of the doubt regarding the degree to which it includes items that theoretically and empirically are significant predictors of resource use. But we are less sanguine that the measures collected by the instrument are sufficiently refined to assess appropriateness of treatment setting or changes in condition – another name for clinical outcomes.

We are especially concerned that the response options for many **CARE** tool items are so subjective and vague as to render measurement and comparison of outcomes across alternative settings suspect. Consider, for example, Section *V Impairments*. Items therein likely would be among those used to compare and contrast care of patients receiving rehabilitation services in SNFs and Inpatient Rehabilitation Facilities (IRFs). Our concern is that clinicians' interpretations of item responses might differ depending on their training and experience. One example is sub-section *E Range of Motion*. How is a clinician to assess whether or not range of motion is "*Within Normal Limits*"? Would the assessment of an RN be different from an assessment of a Physical Therapist? Similarly in sub-section F, how is a clinician to assess a resident's *Weight-Bearing* level ("*fully weight-bearing*" or "*not fully weight-bearing*")? The same can be asked for *Grip Strength* in sub-section G where the tool simply asks a clinician to assess if *"the patient's ability to squeeze your hand"* is "*normal*", "*reduced/ limited*" or "*absent.*"

In principle, Skilled Nursing Facility staff are not uncomfortable assessing residents on well-grounded, subjective items – mood and behavior patterns, psychosocial well-being and physical functioning among them. Our concern is with the degree of subjectivity characterizing many of the items in the **CARE** instrument. This is all the more unfortunate in the case of *Impairments* where concepts such as range-of-motion and grip strength can be measured objectively.

5) Additional Concerns with Item Subjectivity. We also are uncomfortable with *Sections VII Engagement* and are puzzled as to why a single, highly subjective item – "*Indicate the patient's cognitive and emotional resources to comprehend current services, tolerate typical frustrations of care, and participate actively in the treatments.*" – is given such prominence. Several staff members found the associated six-point response scale (ranging from "*No Problem*" through "*Severe Problem*") to be vague. How, for example, is a clinician to distinguish a resident who "*infrequently questions value of activities*" from one who "*occasionally questions values of activities*" (criteria for classification as having "*Minimal Problem*" or "*Mild Problem*")?

Section VIII Frailty/ Life Expectancy also is troubling. This section contains only two items. "*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***?" We are unsure who in a facility the Demonstration expects will make such determinations. We also wonder who will voluntarily risk making them on a legally binding document.

6) Potential Specialty Specific Reporting Differences. We want to expand on one issue that we raised previously. This is the possibility of systematic differences in responses to **CARE** tool items by clinicians trained in different disciplines (or providing care in different settings). Absent a User's Manual, we do not know if Demonstration protocols will require that particular items on the **CARE** instrument be completed only by staff credentialed in particular clinical disciplines. If not, then specialty-specific differences in responses are a concern. Presumably, this is one of the research areas that CMS and its contractor will explore.

7) Unreported Items. What are the consequences to the provider if certain items are left unanswered? As noted above, we would not be surprised if clinical staff were reluctant to complete the *Frailty/ Life Expectancy* items. Beyond that, what will the consequences be for providers who are unable or reluctant to complete certain items? Will CMS consider splitting the items into "required" (core) and "optional" (as feasible) groups?

8) Additional Items for Consideration. Several conditions and treatments important in the context of Long Term Care are not included in the **CARE** instrument. While not an exhaustive list, we suggest the following:

Expand *Section II Admission Information* to include immunization, X-rays, TB testing.
Expand *Section II Admission Information* to include social history – smoking, alcohol, drug use.
Expand *Section II Admission Information* to include use of hearing, vision and dental aides.
Expand *Section III D Treatments* to include splint/ brace use, pain management program, and behavioral management program.
Expand *Section III G2 Skin Integrity* to include a count of the number of Stage 1 wounds
Expand *Section III Current Medical Items* to include a section on use of CMS-defined restraints.
Expand *Section III Current Medical Items* to include an assessment of urinary or bowel incontinence and treatment plan.
Expand *Section III Current Medical Items* to include assessment of sleep patterns and problems.
Expand *Section IVG Pain* to include treatment plan implemented for pain assessed

9) Whither the MDS? The MDS in its current incarnation plays a central role in SNF reimbursement and quality of care monitoring systems. Long Term Care providers have made considerable investments in physical and human capital and devote considerable staff time to developing and reporting MDS data. Will the **CARE** tool replace most or all of the MDS or will it become an additional, complementary instrument? If the former, will replacement occur in phases (over several quarters or longer) or immediately?

Fundamental staff appreciate the opportunity to offer comments on the **CARE** instrument prior to its deployment in the PAC Payment Demonstration. We look forward to an opportunity to review and comment on Demonstration findings and the Post Acute Care payment methodology derived from them when they become available.

Sincerely,

Karen McDonald

Karen McDonald RN, BSN
Senior Vice President
Fundamental Clinical Consulting, LLC

September 25, 2007

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Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
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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 Meridian Health in response to the Post Acute Care Payment Reform Demonstration project (PAC-PRD) and the proposed Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument released July 17, 2007, by the Centers for Medicare and Medicaid Services, 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

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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 732-450-2609.

Sincerely,

Debbie Schuhardt
Corporate Director, Orthopedics, Neurosciences, Rehabilitation
Meridian Health

Cc: R. Molloy
D. Siegel, MD

September 19, 2007

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

Re: CMS CARE tool and PAC-PRD Demonstration

Dear Ms. Harkless:

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

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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.
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    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.
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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.

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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 [illegible]	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**

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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 **623-974-7169.**

Sincerely,

Patricia A. Heimann, R.N, MS, CRRN

Patricia A Heimann, RN, MS, CRRN
Acute Rehabilitation Clinical Nurse Educator
Sun Health Boswell Acute Rehabilitation Center
1601 W. Santa Fe Ave.
Sun City, AZ 85351]

Marin General Hospital
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(415) 925-7000

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

September 17, 2007

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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, Rosita Nieves R.N.

Case Manager

Association for
Home & Hospice Care
of North Carolina

3101 Industrial Drive
Suite 204
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27609

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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 Mrs. Harkless,

The Association for Home & Hospice Care of North Carolina would like to comment on the new *CARE* tool. *Form Number:* CMS–10243 (OMB#: 0938–NEW);

Especially in light of the fact that CMS states that the "three purposes of the PAC Assessment Instrument are: 1) **placement decision-making**; 2) enhancement of safety and quality of care transitions through transmission of core information to a receiving provider; and 3) provision of baseline information for longitudinal follow-up of health and function.

We congratulate CMS on recognizing that discharge planning is vitally important and crucial to patient safety.

However, there are some items on the proposed tool that could negatively impact patient placement in home health which would be contrary to the Administration's and CMS' goal of eliminating institutional bias.

The tool asks:

Does the patient currently have one or more caregiver(s) both *willing and able* to provide the necessary care?

0. No ***(If No, skip to C1. Other Discharge Needs.)***

1.Yes

What happens if the discharge planner says yes - does arrangement of post acute care stop at that point as it is assumed the caregiver will provide the care? If so, the *CARE* tool would fail to adequately plan for the discharge needs of the patient.

The Medicare Home Health Benefit says:

"Where the Medicare criteria for coverage of home health services are met, patients are entitled by law to coverage of reasonable and necessary home health services. Therefore, a patient is entitled to have the costs of reasonable and necessary services reimbursed by Medicare without regard to whether there is someone available to furnish the services. However, where a family member or other person is or will be providing services that **adequately meet** the patient's needs, it would not be reasonable and necessary for HHA personnel to furnish such services. Ordinarily it can be presumed that there is no able and willing person in the home to provide the services being rendered by the HHA unless the patient or family indicates otherwise and objects to the provision of the services by the HHA, or unless the HHA has first hand knowledge to the contrary."

Families often do not fully understand all the care needs of a patient or whether or not they can cope with the long hours of caregiving or complex technical procedures until the patient is home. We also know that caregivers might be willing to provide **some** care but maybe not **all** the care. For example, a daughter might be willing to learn how to change a dressing but not be willing or competent in administering an infusion. Or, the family may be at work and not available when all dressing changes are due. As a nurse with thirty years of experience, I can assure you that a family learning how to administer insulin with a nurse by their side in a hospital room is very different once the family gets home and is trying to remember what to do the next morning. Often times, the adequacy of a caregiver cannot be safely assessed just in a hospital room. **To not consider this carefully paves a path for continued re-hospitalizations and emergent care use. Adequacy and safety of care giving is far more complex than a simple yes or no question on a discharge planning tool.**

The researchers need to also consider that if the D/C planner marks on the form that there is no willing and able caregiver, does that mean that home health would seem inappropriate as there is no one in the home to teach.

We also want to point out that the homebound question on the form should not eliminate the need for home health. Federal Medicaid law and other payers do not require that patients be homebound. State Medicaid agencies vary in their homebound policies. Even though CMS may be developing the tool for Medicare beneficiaries, it is impractical to think that the tool may not be completed for other payers. It would be inefficient for discharge planners to have to use multiple tools.

In closing, we strongly suggest that CMS needs to coordinate tool development with the State Medicaid programs as many of them are developing their own post acute care tools. Requiring multiple tools would be duplicative and costly.

Thank you for your consideration,

Sherry Thomas

Sherry Thomas, BSN, MPH
Senior Vice President

MEMORIAL HOSPITAL

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TOWANDA, PA 18848

570-265-2191

FAX: 570-265-5763

09-21-07

Bonnie Harkless
CMS, Office of Strategic Operations and Regulatory Affairs
Baltimore Maryland 21244-1850

Dear Ms. Harkless,

Please consider the following comments regarding CARE tool for use in the acute care general hospital;

The information required for the tool is extensive and will take 90 minutes for higher- complex cases and 20 minutes in the low-complex cases to gather. Memorial Hospital Inc. average length of stay for Medicare patients is 2.5 days. We have a one person Case Manager with one relief person. The areas requiring completion are inappropriate for short-term hospital. Documentation of medications and coding diagnosis will present a problem.

I see no value of the CARE tool to be used in acute care hospital for patient's being discharged.

The need for gathering such extensive data, which is what it, appears, is expensive and labor intense.

Sincerely,

Patricia Bergmaier RN/CPHQ

Patricia Bergmaier RN, CPHQ

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—C
Attention: Bonnie L. Harkless
Room C4–26–05,
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September 17, 2007

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

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

Sincerely,

Bruce D, Deas MD
Chief of Staff
Director of Emergency Medicine
Sutter Lakeside Hospital
5176 Hill Rd. East
Lakeport, CA 95448

Marin General Hospital
A Sutter Health Affiliate

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Sincerely,

Case Manager

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

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Sincerely,

Gary Macs MD

Gary Macs MD
Chairman
Hospital Performance Committee
Sutter Lakeside Hospital
Lakeport CA 95453

cc: Diane Pege MD

Novato Community Hospital
A Sutter Health Affiliate
With You. For Life.

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
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Sincerely,

Tina Hazelton
RN Case Management Coordinator
Novato Community Hospital
180 Rowland Way
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415.209.1474

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Sincerely,

Case Manager

Marin General
Hospital
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Sincerely,

Anna [signature] RN, CM

Case Manager

Marin General Hospital
A Sutter Health Affiliate

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Sincerely,

Susan B. Lenton RN

Case Manager

Marin General Hospital
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Sincerely,

Mary Kruger-Gomez RN

Case Manager

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
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Box 8010
San Rafael, CA 94912-8010
(415) 925-7000

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Office of Strategic Operations and Regulatory Affairs
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Sincerely,

Mary McCarthy, R.N.

Case Manager

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

Judith L Dawson RN

RNC

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
Greenbrae
Box 8010
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(415) 925-7000

9/12/07

To Whom It May Concern:

I have just become aware of the CMS plan for CARE. This will place acute care facilities under increased administrative burden which will significantly affect my Case Managers. They function under heavy workloads as it is, and the time and resources required to collect the required information for the CARE tool will undoubtedly substantially impact our ability to efficiently discharge patients.

The estimate is that the form will take 20-45 minutes per patient to complete. I am sure that this is a modest estimate after looking at the tool. This would be an undue burden for my department to accommodate. I already have a difficult time recruiting and keeping Case Mangers due to the workload, and this unfortunately will cause many to leave.

I implore you to reconsider this mandate. It will drive many very dedicated persons out of the healthcare profession due to the unrealistic amount of paperwork required.

Sincerely,

Jane Ritchie

Jane Ritchie
Manager of Case Management

Sutter Delta
Medical Center

Sutter Health

3901 Lone Tree Way
Antioch, CA 94509
(925) 779-7224

September 18, 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

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,

Susan Craig Bumatay, R.N., M.S.N.
Assistant Administrator

Novato Community Hospital
A Sutter Health Affiliate

With You. For Life.

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Sincerely,

Trudy Keller
RN Case Manager
Novato Community Hospital
180 Rowland Way
Novato, CA 94945
415.209.1474

Novato Community Hospital
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Sincerely,

Bernadette Brown, BSN
RN Case Manager
Novato Community Hospital
180 Rowland Way
Novato, CA 94945
415.209.1474

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
Greenbrae
Box 8010
San Rafael, CA 94912-8010
(415) 925-7000

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Sincerely,

Case Manager

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
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Sincerely,

JBarnes RN Case Manager

Case Manager (Joanna Barnes)

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
Greenbrae
Box 8010
San Rafael, CA 94912-8010
(415) 925-7000

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

Sincerely,

Barbara Russell, RN, MS

Case Manager

Marin General Hospital
A Sutter Health Affiliate

250 Bon Air Road,
Greenbrae
Box 8010
San Rafael, CA 94912-8010
(415) 925-7000

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Sincerely,

Lora J Burns, RN

Case Manager

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

Sincerely,

Peter Stanley M.D.
Chair, Medical Staff Performance Committee
Sutter Lakeside Hospital
Lakeport, CA 95453

Eden Medical Center
San Leandro Hospital Campus
A Sutter Health Affiliate

13855 East 14th Street
San Leandro, CA 94578
(510) 357-6500

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Sincerely,

Lisa King

Lisa King
Director, Case Management
Eden Medical Center
San Leandro Hospital Campus
13855 E. 14 St
San Leandro, Ca. 94578