June 8, 2010

TO: Bonnie Harkless, PRA Analyst,

CMS Office of Executive Operations and Regulatory Affairs

FROM: Ann Meadow, Sc.D.

CMS Office of Research, Development, and Information

Regarding the Paperwork Reduction Act ICR # CMS-10298, CMS program staff submits the information below. It is being submitted to fulfill OMB's request for a response to the comments OMB received last month from the American Health Care Association and the National Association for the Support of Long-term Care. CMS believes it is not necessary to revise the PRA package in response to the comments.

1. *Comment: "CMS has provided stakeholder input as it has moved forward with the DOTPA project. In order to continue this important dialogue, before finalizing the CARE-C and CARE-F tools and asking providers to use them in the field for gathering information, we urge strongly that CMS and its project contractor convene a stakeholder meeting of providers to review the project and purpose of the CARE tools. The CARE tools would add reporting burdens to facilities or entities that agree to participate in the project, and we believe that a clearer understanding of how the CARE tools would be used might promote a more active response from the providers who will be asked to participate.*

   Response: We appreciate the recognition of CMS' efforts to involve stakeholders thoughout this project. Stakeholder input has informed questionnaire development directly and indirectly through in-person discussions, an Open Door Forum, technical expert panels, advisory representation on the instrument development team, and the PRA 60-day comment period. Both stakeholders and experts have demonstrated that a therapy-related data collection instrument at the beneficiary level may have many uses, including but not limited to risk adjustment, care planning, outcomes measurement, and payment policy development. Opinions on differences in the proposed content of the instrument may reflect differences in use as well as differences in expert opinion on the best method to achieve a particular goal. CMS' goal for this data collection has been clear from the beginning. The contractor is to collect beneficiary level data related to outpatient therapy services in order to develop and assess alternative payment policies. CMS believes that the contractor, RTI International, has obtained sufficient information about the state-of-the-art for therapy-related data collection from stakeholders and experts to identify the measures that can be reasonably collected for purposes of developing payment policy. The instrument is not perfect, neither is the state-of-the-art. CMS must move forward to collect the data and assess both the collection process and the data collected.

   This data collection instrument is for research purposes. This instrument is not designed to be implemented on a permanent basis; it is designed to provide the data

necessary for CMS to evaluate the adequacy of the measures themselves, the payment alternatives possible with a given subset of the measures, and the data collection process. There will be many opportunities for stakeholders to comment upon any proposed new payment policies and any associated data collection requirements.

In the near term, before the beginning of data collection, we are planning to meet with representatives of key stakeholder provider associations to discuss the data collection and its importance, and to discuss concerns they may have with the existing instrument. We anticipate this meeting will take place later this summer. Over the longer-term, we are planning an Open Door Forum and technical expert panel to receive input on this data collection, the resulting analyses, and on implementation issues for feasible alternatives to existing Medicare payment policy for outpatient therapy.

Comment: In addition, we would like to know if and how CARE C and F relate to the CARE tool demonstration that is required under the Deficit Reduction Act and how all these tools will be integrated with MDS 3.0, which applies to all Medicare and Medicaid nursing home residents, or if these tools will replace the MDS 3.0."

Response: CMS understands why nursing facilities would seek assurances that CARE-F, which was designed for nursing home residents receiving Part B therapy services, relates to the CARE tool that was developed pursuant to Section 5008 of the Deficit Reduction Act. That is why there is a strong similarity between the CARE-F instrument and the CARE tool used in the Post-Acute Care Payment Reform Demonstration. In fact, to a large extent the CARE-F items are a subset of the full CARE tool.

The following items were excluded from the CARE Tool in creating the CARE-F instrument:

- *Administrative Items:* Patient Medicaid number, Social Security Number, and Payer information.
- *Admission Information:* Structural barriers in the home prior to current illness.
- *Current Medical Information:* Medications, Allergies and adverse drug reactions, and Physiologic factors.
- *Impairments:* Grip strength.
- *Overall Plan of Care/Advance Directives:* Entire section.
- *Discharge Status:* Attending physician, Discharge care options, and Discharge location information.
- *ICD-9 Coding:* Entire section on admission instrument, Major procedures on discharge instrument.

A small number of items were added in creating the CARE-F instrument to include analogous items from the CARE-C instrument or at the urging of respondents to the 60-day comment period:

- *Current Medical Information:* How long patient has experienced the condition for which they are receiving therapy, and Surgical status.
- *Cognitive Status, Mood, and Pain:* Difficulty remembering, organizing, or attending in daily life.
- *Impairments:* Diet modification, and Difficulty communicating in daily life.
- *Functional Status:* Participation.

All of the items in this study will be subject to review and analysis regarding their utility in developing alternatives for outpatient therapy payment. Any proposals that CMS might make for payment operations would seek to use only items that help differentiate payment levels appropriately and/or reliably measure outcomes and that impose reasonable administrative burdens.

Concerns about integration of the CARE Tool and the CARE-F instrument items with the MDS instrument are premature. CMS does not yet have results of the post-acute care studies that were mandated by the DRA and that led to CARE tool development. Under Section 5008 of the DRA, the Secretary must submit a report to the Congress on the results of the mandated studies following their completion. No doubt, experiences and lessons learned will inform subsequent congressional and executive proposals regarding the adoption of any new instruments. CMS has always recognized the need to carefully prepare providers for transitions and changes in payment systems and data collection.

2. *Comment: "We recognize that STATS and DOTPA were designed as separate projects, but, as they have developed, we have seen a growing number of areas where they could be incorporated into a joint project. Since both projects are intended to further the agency's plans to develop an alternative payment plan for therapy services, CMS might want to consider integrating the payment changes that are emerging from the STATS project with the patient classification information it hopes to obtain through the DOTPA project. Such integration could strengthen DOTPA and bring CMS and stakeholders closer to a viable alternative to the current system."*

   Response: CMS will strive to adopt the best ideas that emerge from all its research activities. When the DOTPA project ends, alternative payment methods and/or measurement methods it may produce will be analyzed to determine their applicability to the payment recommendations produced by the STATS project. It would be our goal, not only to assure that we retain important innovations, but also to assure smooth transitions to new payment methodologies. It should be noted that both projects will define multiple alternatives for improving payment for outpatient therapy. Some alternatives may be very minor modifications to the current payment methodology and some may feature more significant changes. While considering the proposed alternatives, CMS will take into consideration many factors, including the practicality of systems changes, flexibility for future upgrades, impact on clinical practice, quality and outcomes and the burden to providers.

3. *Comment: "AHCA and NASL support the development of an evidence-based therapy data collection instrument that could be used across all outpatient therapy settings. Therefore we are concerned because we see a major flaw in the CARE-C and CARE-F tools because they do not require a clinician to do the admission assessment at a point where it is essential to gather the most accurate information regarding diagnosis and conditions. Without the involvement of a clinician at admission, the reliability of the information gathered regarding clinical complexity could be compromised."*

   Response: We assume this comment addresses the CARE-C instrument, which does feature a set of patient-reported items, particularly regarding function. There has been extensive research understanding differences between patient-reported function and clinician-reported function, and this research indicates broad agreement between patient self-reported function and clinician-reported function of the patient. In community-based settings, we anticipate that patient-reported items, where appropriate, will reduce provider burden. However, there are numerous clinician-reported items on CARE-C as well, including an ICF-based primary reason for therapy section, clinician-reported diagnosis section, and several supplemental impairment and function items.

   The CARE-F instrument is an entirely clinician-reported instrument (with some performance items and some interview items).

   We believe the time frames for data collection using CARE-F and CARE-C meet our goals of allowing for timely and accurate assessment information consistent with the realities of data availability in the respective community and facility settings. The CARE-F instrument must be completed within two days of admission (three days if admission is after noon), consistent with the CARE Tool. Providers are instructed to complete the CARE-C instrument within the first two visits (this timing was established in response to comments received during the 60-day comment period).

4. *Comment: "A pressing concern that must be addressed is how a patient's needs will be assessed during the episode of care because the CARE Tools are intended only for completion within 48 hours of admission and discharge. However, the current MDS allows for reassessment five times during 100 days to account for a beneficiary's changing resource needs, while the home health care Outcome and Assessment Information Set (OASIS) allows for reassessment every 60 days.*

   "Periodic reassessment is an essential ingredient in measuring resources and outcomes. In issuing Transmittals 52 and 88 regarding the therapy cap exceptions process, CMS outlined requirements for documenting medical necessity and a plan of care. In those transmittals, CMS went into considerable detail on the need to document evaluations, subsequent re-evaluations and progress reports. Again, it is imperative that we know how the CARE C and F tools will be integrated with MDS 3.0 since additional rehabilitation assessments will be required under MDS 3.0 as of October 1, 2010."

Response: The purpose of the data collection in the DOTPA project is specifically to identify patient characteristics primarily for measuring case mix and secondarily for measuring outcomes; the instruments are not intended to support medical necessity or care planning and coordination. Nor do they satisfy the requirements for documentation. Information collected on the CARE-F and CARE-C instruments amounts to an extraction of selected pieces of information expected to be part of routine documentation. The extract must be defined uniformly or else it cannot serve the two purposes of case mix and outcome measurement. Documentation requirements for practitioners encompass broader content, because the information may be needed to justify medical necessity, coverage, and payment. CMS does not dictate uniform formats or presentations for documentation.

We do understand that nursing facilities are required to complete an MDS on their residents on a scheduled basis. This requirement is entirely separate from the DOTPA data collection. Requirements for as many as five MDS assessments per 100 days apply to Part A skilled nursing stays and are not relevant to the non-Part A stay patients who may need Part B rehabilitation services as nursing home residents. For these non-Part A patients, a facility is required to complete an MDS every 92 days, or when there is a significant change in the patient's condition.

For purposes of DOTPA data collection, we feel that collecting an assessment on admission and discharge from Part B therapy (not for residence in the facility overall) is sufficient for developing likely payment alternatives. This schedule minimizes data collection burden since the mean Part B therapy episode length for patients in nursing facilities is approximately 15 days, generally much less than the length of residence in the facility. In addition, it is our understanding that an MDS assessment is not necessarily completed when the facility determines that therapy services are medically necessary.

As we stated in our response to Comment 2 above, at this time it is not possible to forecast the manner of integration of MDS and the CARE tools or whether such integration will be possible or desirable.

5. *Comment: "Perhaps the most significant problem relating to all four of the CARE Tools is that the collection activity requires the completion of "hard copy" multi-page paper forms. We see this as a critical weakness in gathering accurate and meaningful information regarding patient conditions and progress. We recognize that participants in the data collection effort will be volunteers, but a cumbersome reporting process is bound to result in the collection of flawed data. Flawed data will lead to flawed conclusions, and flawed conclusions will lead to flawed policies. A research project of this magnitude and importance deserves to have the technology necessary to collect the most accurate and reliable information possible. AHCA has already submitted comments on the enormous burden of all the required additional MDS 3.0 assessments. These multiple burdens spanning MDS 3.0 and therapy assessments need to be scrutinized and mitigated where possible."*

Response: As noted in the responses to the 60-day comment period, CMS understands that electronic data collection may be more efficient for some providers, especially those already collecting patient assessments (including patient self-assessment) electronically. In addition, skip patterns in the assessment would be easier with electronic data collection since these would skip automatically. However, many potential sample providers do not have the ability to conduct electronic data collection, especially with patient self-report (as in CARE-C). In CMS' experience, even where electronic data collection is preferred for patient assessment and self-report, many of the respondents collect the data via paper and then enter the results at a centralized computer. Very few providers have the space or resources to enter data electronically at the immediate point of care.

Furthermore, some providers have encountered significant delays or experienced a steep learning curve in using secure electronic systems CMS has made available for other data collection efforts. To keep the DOTPA project on track, without the complications that are liable to come from instituting new electronic technologies, we decided to keep the data collection paper-based. We believe this decision will reduce setup time for all providers and potentially avoid problems with using an electronic system new to staff. In addition, the paper forms have been designed to reduce data entry/scanning errors when using computerized character recognition. (Participants will send batches of assessments to the DOTPA contractor for scanning at a centralized site.)

Another consideration in our decision is the budget available for the DOTPA project. The cost of creating and implementing an electronic system for collecting and transmitting these data, including advanced features such as computerized adaptive testing (CAT), is prohibitive. It should be understood that, according to our sample size projections, in some settings a relatively small number of patients would be involved in DOTPA at each provider site. This situation makes questionable a project expenditure for training and installation of high-tech data collection infrastructure at each site.

However, we will try to provide for simplified electronic transmission of data for those providers who wish to use electronic means. If any recruited providers wish to send data in this manner, CMS will issue an ASCII format for an assessment record. Providers are free to make an electronic version of the form and transmit the data in the format meeting the CMS ASCII record specifications. This assumes a transmission process that meets data security requirements is defined and adhered to by participants. Engaging in such an activity is entirely voluntary on the part of participating providers, and CMS would not provide financial resources to develop the necessary software modifications to create the data files. However, we are willing to conduct special conference calls with interested providers and their health information system developers to assist them as they develop the data extraction and transmission systems.

6. *Last but not least, our organizations have observed with some concern that the information regarding this collection activity has not been posted to the CMS Paperwork Reduction Act (PRA) website, nor has it been posted to the project's contractor website. We believe that our comments address the updated collection documents, but we are concerned by the uncoordinated release of information regarding this collection activity. Improper posting and collection processes allow for potential inaccuracies in data collection and/or unannounced changes in the overall pilot/demonstration project. Neither of these serve or support beneficiaries.*

   Response: To provide for the greatest amount of participation, in announcing the comment period in the Federal Register, CMS makes available multiple avenues for commenters to request and review the materials, and we rely primarily on the Federal Register-listed phone and email contacts. The agency's standard for achieving public dissemination is not based primarily on disclosure through the PRA Website. Nonetheless, we, too, are distressed about our inability to post the revisions in a timely manner to the CMS PRA website. The posting is coordinated through multiple CMS components. We believe that what happened in this case is that the requirement that all posted materials comply with Section 508 of the Rehabilitation Act of 1973 created some complications in our posting process. Prior to the initial, 60-day comment period last year, multiple CMS components had reached an agreement about the format of the DOTPA instruments that would achieve compliance, but in the passage of time, the agreement may not have been recognized by all involved. We sincerely regret the delay that resulted, and we will do our utmost to avoid such delays in the future, but we also note that the program staff responsible for the DOTPA project emailed the revised materials directly to industry stakeholders who have been monitoring the project.