RESPONSES TO 60-DAY PUBLIC COMMENT PERIOD

The Centers for Medicare and Medicaid Services established a research project titled "Developing Outpatient Therapy Payment Alternatives" (DOTPA) designed to identify, collect, and analyze therapy-related information tied to beneficiary need and the effectiveness of outpatient therapy services. The immediate goals are to develop and assess the feasibility of a comprehensive and uniform therapy-related data collection instrument and to determine the subset of the measures that CMS can routinely and reliably collect in support of payment alternatives. The ultimate goal is to develop payment method alternatives to the current financial cap on outpatient therapy services. Data collection instruments will be administered to Medicare beneficiaries upon admission and discharge from outpatient therapy providers.

The data collection instruments (CARE-C for patients in community settings and CARE-F for patients in institutional settings) are comprised of a set of common assessment items administered to all patients and a set of supplemental items only administered for specific conditions or at particular times (i.e., discharge only).

Analysis of and Response to Public Comments

We received 11 comments from physical therapists, occupational therapists, hospitals, professional associations, and health care associations. All comments were reviewed, analyzed and grouped into categories based on subject matter. Summaries of the public comments and our responses to those comments follow.

General Comments

CMS received several comments related to concern over burden to beneficiaries and providers related to this data collection. CMS also received comments suggesting general changes and other comments suggesting changes to and additions of specific assessment items. Additionally, several commenters requested clarification of terms and underscored the need to provide sufficient staff training. The following summarizes comments received and responses to those comments.

1. Study Purpose

Comment 1.1: One commenter felt that CMS needs to provide more clarification on the purpose of the study and research questions and that one purpose should be collecting data associated with determining appropriateness/need for outpatient therapy services.

> **Response:** The purpose of this one-time data collection is to collect data associated with patient utilization of therapy services not available in claims submitted to Medicare that are feasible for use in Medicare payment for therapy services. The data collection instruments are not intended to be the final instruments used for payment purposes. Rather, this one-time data collection is intended to provide information on what data are feasible to collect as well as what measures are valid and statistically reliable. Establishing criteria for appropriateness or coverage of services is not within the scope of this project.

Comment 1.2: One commenter felt that CMS should implement instead the study design and data collection plan based on a report by Ciolek and Hwang (2004), conducted under contract to CMS.

> **Response:** CMS refers interested parties to the Statement of Work for the Request for Task Order Proposal (RTOP CMS-07-033) for the scope of work specified by CMS for this project.

2. Respondent Burden

Comment 2.1: Several commenters felt that the proposed data collection instruments were too long (had too many items or too many response categories).

> **Response:** The purpose of this one-time data collection is to identify patient assessment items for Medicare outpatient therapy services that are: (1) best predictive of utilization of Medicare outpatient therapy services and/or reliable for use in measures of therapy outcomes; (2) minimally gamable; and (3) as minimally burdensome as possible, conditional on usefulness for case mix or outcomes measurement. CMS understands that provider and beneficiary burden is an important consideration, especially for an assessment instrument that would be used in a payment system. The data collection results, including data collection burden, will guide the development of any instrument used for payment purposes. CMS expects that the data collection instruments in this one-time data collection will contain items that will not be used in any assessment instrument used for Medicare outpatient therapy payment.

Comment 2.2: Several commenters felt that the proposed data collection instruments would take too much time for patients and clinicians to complete and would reduce treatment time.

> **Response:** It is not the intention of CMS for this data collection to interfere with patient care. The CARE Tool, on which the CARE-F instrument in this data collection was based, has been successfully used by approximately 150 providers, including skilled nursing facilities, in the Medicare Post Acute Care Payment Reform Demonstration (PAC:PRD). This data collection is testing a modified (and shortened) version of the CARE Tool. The CARE-C instrument, intended to be used with community-based providers, includes items based on or derived from those found in assessment instruments used in a number of outpatient therapy settings (e.g., the AM-PAC and the NOMS). This instrument also features a core-and-supplemental approach in which many of the items are completed only for patients with certain conditions, functional status, or impairments. However, understanding the items' burden on providers and beneficiaries is an important component of data analysis. CMS anticipates a total data collection burden (reporting plus record keeping) of 20 minutes per assessment for providers using the CARE-C instrument and 35 minutes per assessment for providers using the CARE-F instrument.

In addition, a number of commenters remarked that there were additional items that they would like on the data collection instruments to measure other aspects of patients' function or impairments. Design of this instrument is the result of careful attention to creating a balance between comprehensiveness, so that no potentially relevant measure is excluded, and response burden, so that the instrument will be completed by sufficient numbers of beneficiaries to produce valid and reliable information.

Comment 2.3: Some commenters questioned whether CMS would compensate providers for time spent assisting patients with completing the data collection or otherwise would provide a stipend for participation.

Response: At this time, for budgetary reasons, CMS cannot provide any stipends for data collection.

3. Data Collection Instruments' Ability to Identify Intended Factors

Comment 3.1: A number of commenters remarked that it is very important for factors associated with outpatient therapy utilization and outcomes be collected in a reliable and valid manner.

Response: CMS agrees that the reliability and validity of items is a very important consideration in developing an assessment instrument used for payment. To the extent possible, these data collection instruments have been based on existing research on and approaches to patient assessment. A multi-disciplinary team of contract staff, consultants, technical expert panel members, and nominees of therapy associations contributed to the development of the data collection instruments. In addition, CMS received extensive input from associations, and there are several items in the instruments based on joint work with the associations.

CMS is using a modified version of the CARE Tool for patients in nursing facility settings. CMS also consulted extensively with developers of existing instruments to identify or develop items for use in the CARE-C instrument for this data collection. The core of the CARE-C instrument is based on the CARE-F and the AM-PAC short form. The AM-PAC is recognized as one of the more comprehensive of existing therapy-related proprietary instruments. The AM-PAC short form item pools have been donated to the public domain. Furthermore, testing these items' reliability and validity is an important part of developing alternative assessment item sets for use in Medicare outpatient therapy payment.

Comment 3.2: Some commenters felt that other, existing, assessment instruments should be used in the data collection. Examples cited by commenters include the Focus on Therapeutic Outcomes (FOTO) Patient Inquiry tool and the American Speech-Language-Hearing Association (ASHA) NOMS instrument.

Response: For this data collection, CMS' goal is to develop a cross-setting, cross-discipline, and cross-condition set of items for assessing patients' medical,

functional, and cognitive condition that could be used for payment. This approach is consistent with the CARE initiative to develop a comprehensive set of assessment items to be used across treatment settings. These items are divided into 4 data collection instruments (admission and discharge versions of assessment instruments for patients in community versus institutional settings). This was done to: (1) reduce the number of items on each instrument; (2) provide items most relevant in each setting to avoid ceiling and floor effects; and (3) create a single data collection instrument for each setting that covers the full range of conditions among patients receiving outpatient therapy. It is CMS' understanding that existing instruments, including the FOTO and NOMS instruments, have strengths in assessing particular patient populations but not the full range of Medicare beneficiaries receiving outpatient therapy. An assessment instrument that addresses the range of medical, functional, and cognitive conditions should improve comparability across patients to better ensure consistency of case mix measurement, especially for patients receiving care from multiple disciplines. In addition, CMS intends to avoid using items not in the public domain.

Comment 3.3: A number of commenters felt that completion of certain sections/items should be discipline-specific.

Response: CMS understands that Medicare beneficiaries receive outpatient therapy services in a variety of single-discipline and multidisciplinary environments. Which specific discipline assesses and treats a particular patient would be based on disciplines' scopes of practice; local treatment patterns; and patients' specific medical, functional, and cognitive issues. CMS intends for individual providers to complete the assessments consistent with their current workflow practices. Consistent with the CARE initiative, CMS intends for case mix adjustors and outcomes items based on items that multiple disciplines can complete. Whether certain items are completed by one discipline or another should be based on disciplines' scope of practice and clinical judgment rather than CMS requirements.

Comment 3.5: Two commenters were concerned that patients' self-assessments of conditions and outcomes may disagree, at least in some cases, with clinicians' assessments of those patients.

Response: There has been extensive research understanding sources of 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. However, since the purpose of this data collection is to investigate assessment items useful for case mix and/or outcomes measurement for payment, CMS intends to investigate differences between patient self-assessment, non-clinician proxy-reported assessment, and clinician-reported assessment in this data collection, review the literature to understand reasons for differences, and consider implications for their use in a payment system.

Comment 3.6: Some commenters were concerned that the data collection instrument does not include items to measure patients' ability to participate in life situations, including home and the community.

> **Response:** The data collection instrument for community-based patients features a patient-reported function section that uses items from the AM-PAC item pool (the item pool has been placed in the public domain). The American Occupational Therapy Association (AOTA) has endorsed the AM-PAC for use by its members for measuring daily activities outcomes because it most closely conforms to occupational therapy scope of practice.
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> In addition, CMS is adding a small set of items based on the Participation Measure for Post-Acute Care (PM-PAC), which attempts to measure participation in a manner consistent with the International Classification of Function (ICF) definition of participation.

Comment 3.7: Some commenters suggested that additional objective measures of patient impairment and function (e.g., gait analysis, functional movement analysis, etc.) be included in the data collection instrument, possibly as supplemental sections specific to physical therapy.

> **Response:** CMS weighed the value of items versus burden in developing these data collection instruments based on input from a technical expert panel and other experts. These experts felt that the items in the data collection instruments address these impairment issues. However, an important component of the analyses of the data collected will be to understand if additional items need to be included in an instrument used for payment purposes.

4. Ability of Providers to Administer the Data Collection Instrument

Comment 4.1: Several commenters were concerned that completing the discharge assessment for the CARE-C instrument will be difficult for providers. These commenters remarked that patients "often" do not return for their last scheduled outpatient therapy visit and that completing a discharge assessment would often not be possible.

> **Response:** CMS understands that providers in community-based settings may have difficulty administering an assessment upon discharge since, in these settings, patients may not attend their final visit. In fact, one purpose of this data collection is to understand the feasibility of collecting a discharge assessment in community-based settings and use of those data in a payment system. However, to make collecting these data more likely, CMS will ask that a discharge assessment be completed on the last or second-to-last planned visit.

Comment 4.2: Some commenters felt that collection of data on admission will be incomplete or misleading because the therapist may not have a complete understanding of the patient's medical history and therapy needs/plan of care by the first visit.

Response: CMS understands that a therapist may not have a complete understanding of a patient's condition at the first visit. CMS will therefore ask that the admission assessment be completed within the first two visits.

5. Data Collection Methods

Comment 5.1: Two commenters were concerned that data collection should include the full range of conditions for which patients receive outpatient therapy, not on a subset of diagnoses/conditions.

Response: CMS agrees that it is important to include as much of the full range of medical, functional, and cognitive issues found among the Medicare outpatient therapy population as possible. The sampling plan for this data collection specifically stratifies by setting (nursing facility, hospital outpatient, CORF/ORF, and private practices). Furthermore, in provider recruitment, CMS will attempt to identify the type of patient population the provider treats (e.g., orthopedic, post-stroke, etc.) in order to include as much of the range of patients as possible.

Comment 5.2: Two commenters remarked on the sample design plan. One commenter felt that provider types and disciplines should be sampled proportionally to their Medicare volume. One commenter felt that equal numbers of cases from the three therapy disciplines (physical therapy, occupational therapy, and speech/language pathology) should be included in the sample.

Response: CMS is very sensitive to design issues; the data collection design attempts to balance having sufficient representation of patients treated among all outpatient therapy settings while not deviating excessively from proportional representation. It is important that as much of the variation in patient clinical condition be represented in the sample in sufficient number, especially those patients with less common conditions. Sampling proportionate to Medicare volume may result in some small subpopulations being insufficiently represented (e.g., those with uncommon language disorders), and sampling disciplines in strictly equal number may result in inefficient statistical estimates and reduced ability to make inferences about the Medicare outpatient therapy population as a whole.

Comment 5.4: Two commenters remarked that it is very important for there to be standardized training procedures for providers participating in the data collection.

Response: CMS agrees with this comment and is developing training manuals and procedures for data collection. In addition, CMS will hold several regional training sessions around the country at the beginning of data collection.

Comment 5.5: Two commenters suggested that CMS develop electronic versions of the data collection instruments to incorporate skip patterns and reduce the burden of paper-based data collection.

Response: 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 may not have the ability to conduct electronic data collection, especially with patient self-report. 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 site of care. As a result, this data collection is paper-based. However, providers are free to make an electronic version of the form and transmit the data to CMS if there is a data format and transmission process acceptable to CMS and its contractor that meets all CMS requirements for transmission of private health information.

6. Data Analysis Methods

Comment 6.1: A few commenters had suggestions for the analysis of the data in this one-time data collection. These include creating discipline- or setting-specific case mix models as well as developing a plan to analyze missing data (item and section non-response).

Response: CMS agrees that the analysis design is important with many important issues to consider. However, the purpose of this PRA comment period is to address the need for and reasonableness of the proposed one-time data collection and to assess respondent burden concerns. Data analysis will be addressed at a later date through additional stakeholder involvement. CMS has anticipated this need and has planned a future "CMS Open Door Forum" to address data analysis.

7. Stakeholder Involvement

Comment 7.1: One commenter felt that the speech/language pathology community has not been sufficiently represented in the study design and data collection methodology development. Another commenter felt that the speech/language pathology community had disproportionate influence on the collection methodology development, particularly for swallowing, cognition, and communication function items.

Response: CMS believes that the speech/language pathology community was given extensive involvement in the data collection instrument development process through inclusion of ASHA outcomes measurement experts in the technical expert panel and in an advisory group convened to modify the data collection instruments after the expert panel met. These experts from ASHA were involved extensively in the development of items related to conditions treated by speech/language pathologists.

8. Specific Comments on the Data Collection Instrument Items

Comment 8.1: One commenter suggested that an item be included to identify where the patient is receiving therapy.

> **Response:** RTI will distribute paper data collection instruments to all participating providers. Each instrument will have a code indicating the provider to which the data collection instrument was sent. RTI will maintain a database of participating providers indicating, among other data, the provider's type of setting and address of the particular provider location(s) participating.

Comment 8.2: One commenter suggested that CMS include the function items from the CARE-F instrument on the CARE-C instrument to better measure function and changes in function for lower-functioning community-based patients.

> **Response:** CMS is changing the data collection plan for patients in day rehabilitation programs, intended for lower-functioning community-based patients to use the CARE-F instrument in those settings rather than the CARE-C instrument. Clinicians in these programs will observe the patient for longer periods of time during each visit and may be able to respond to those items better than clinicians in clinic settings. In addition, CMS is concerned that adding function items to the instrument will be too burdensome for providers.

Comment 8.3: A few commenters suggested changing the patient-reported function items in the CARE-C instruments. Two providers were concerned that the mobility and daily activities items did not have sufficient range to measure function in the highest- and lowest functioning patients. One commenter suggested that the items be more specifically be identified with specific ADLs.

> **Response:** CMS is replacing some specific items in these sections to address the concern about the range of function in which the items, taken together, are sensitive. However, CMS feels that the three sets of function items cover the full range of ADLs.

Comment 8.4: Two commenters suggested changes to the Primary Reason for Therapy and Medical Condition items on both the CARE-C and CARE-F instruments to increase the specificity of several response categories.

> **Response:** CMS is refining several of the response categories based on the comments received.