02/01/2021

TO: Bonnie Harkless
PRA Analyst, Office of Strategic Operations and Regulatory Affairs , CMS

FROM: Ann Meadow, Sc.D., Project Officer, DOTPA project

SUBJECT: Requesting non-material/non-substantive change to an approved ICR

RE: OMB Control Number 0938-1096 (effective 7/12/2010) for "Data Collection for Developing Outpatient Therapy Payment Alternatives (DOTPA)"

Following issuance of the OMB control number for the above-referenced ICR, we were advised by the key stakeholders of the project to make a few changes to the OMB-approved forms. Stakeholders included therapy professional associations and providers of Medicare outpatient therapy. Aside from several clarifications or corrections to instructions, changes they recommended involved adding items from the approved version of the CARE-C instrument (used in community office settings) to the approved version of the CARE-F (used in facility settings), and adding items from the approved version of the CARE-F to the CARE-C. As a result, the CARE-F would contain a set of patient-self report items; the previous CARE-F had no patient self-report items. Also, the CARE-C would include clinician-assessed items covering patient functional performance; the previous version had no such performance assessments. These additions change the total hours in the OMB approval notice from 14,271 to 20,774. Total responses remain unchanged.

CMS agrees that the proposed changes are advisable, as they will make the two research instruments more consistent with one another. Community providers indicated a belief that it would be unfair to depend solely on patient self-report for functional assessment on the CARE-C; CMS believes clinician assessed functional performance items taken from the CARE-F will improve acceptability of the CARE-C as we recruit community-based providers for the study.

Below we describe the changes, referencing the page, section number and classification of the change (addition, clarification, or correction). Two items were deleted (noted below). Below we describe changes to the admission version of each instrument; discharge versions would have the same changes.

CARE-C and CARE-F (please refer to attached CARE-F with color highlighting) – These items were changed in both versions of the instrument.

Clarification: (CARE-C: Page 1 Section I.A.3; CARE-F Page 1 Section I.A.3). Language added to clarify the type of assistance (if any) the patient received in self-reporting, by distinguishing a proxy from a recorder and identifying which type of assistant helped.

Deletion: (CARE-C: Page 4 Section II.D.4, highlighting in RED; CARE-F: Page 17 Section IV.G.4, highlighting in RED). We dropped the body diagram locating pain because optical scanners cannot read it; this information is available elsewhere.

Clarification: (CARE-C: Page 16 Section III.G; CARE-F Pages 20-23 Section V.B-D). We clarified terms describing speech-language and cognition disorders for clinicians completing these items.

Addition: (CARE-C: Page 17 Section III.G.3; CARE-F: Page20 Section V.B.1). "Wet vocal quality and/or throat clearing" was added to the item response for assessing swallowing, because it is a strong indicator of a possible swallowing disorder.

Addition: (CARE-C: Page 17 Section III.G.4; CARE-F: Page 20 Section V.B.3). We slightly revised the scale on the "Swallowing Function" item by including a level for "moderate"; the previous version did not include this refinement, intended to improve reliability.

Correction: (CARE-C: Pages 18-22 Section II.G.6-13; CARE-F: Pages 14-15 Section IV.D.2-4 & Pages 22-23 Section V.D.2-5). The scale for these items had erroneous break points ("< 20%, between 20% and 50%, more than 50%") for the intervals; they were corrected to be the same break points that are used on the source instrument.

CARE-C (please refer to attached CARE-C with color highlighting)

Addition: (Page 5 Section II.D.6). We added a pain item from CARE-F to allow proxy respondents to identify pain in community-based populations with communication disorders.

Correction: (Pages 6-8 Section II.E.1-4). An option labeled "Don't Know" was previously omitted but is necessary in case a proxy is unable to determine a response.

Correction: (Page 6 Section II.E.1). A basic mobility item (reach overhead while standing) in a source instrument had been inadvertently omitted and is reinstated in the mobility battery.

Addition: (Pages 12-15 Sections III.C-F). A set of clinical observational items measuring self-care, mobility and IADLs were copied from CARE-F to CARE-C, to obtain a clinically trained assessment of patient functional status.

Deletion and Correction: (Page 18 Section III.G.5, highlighted in RED). The observational assessment of cognitive status has been removed from the section on "Cognitive Status, Mood and Pain." It was part of a battery we incorporated from a source instrument but we did not intend to use this item from the battery.

CARE-F (please refer to attached CARE-F with color highlighting)

Addition: (Pages II-IV Section II.A-B). A subset of patient reported items pertaining to mobility and daily activity from the CARE-C have been copied to CARE-F.

Correction: (Page 12 Section IV.B.5). An item measuring patient's change in mental status from the baseline was inadvertently omitted and was reinstated in the battery of items taken from the Brief Interview for Mental Status (BIMS).