Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data:

Data Element Specifications for Public Comment 2

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Contents

List of Acronyms

ADE	Adverse drug event
AM-PAC	Activity Measure for Post Acute Care
CARE	Continuity Assessment Record and Evaluation tool
CMS	Centers for Medicare & Medicaid Services
DOPTA	Developing Outpatient Therapy Payment Alternatives
FFS	Fee-for-service
HHA	Home health agency
IMPACT Act	Improving Medicare Post-Acute Care Transformation Act of 2014
IRF	Inpatient rehabilitation facility
IRF-PAI	Inpatient Rehabilitation Facility Patient Assessment Instrument
LCDS	LTCH CARE Data Set
LTCH	Long-term acute care hospital
MCI	Mild Cognitive Impairment
MDS	Minimum Data Set
MR	Medication reconciliation
OASIS-C2	Outcome and Assessment Information Set
PAC	Post-acute care
PAC PRD	Post-Acute Care Payment Reform Demonstration
PHQ-9	Patient Health Questionnaire–9
PROMIS	Patient-Reported Outcomes Measurement Information System
ROC	Resumption of care
SNF	Skilled nursing facility
SOC	Start of care
TBI	Traumatic brain injury

Project Overview

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act)[i] requires that the Secretary of the Department of Health and Human Services implement submission of standardized data from post-acute care (PAC) providers using the assessment instruments that CMS currently requires for use by Home Health Agencies (HHAs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCH), and Skilled Nursing Facilities (SNFs). It requires the submission of standardized data on specified assessment domains and specified quality measurement domains. It specifies that the "data be standardized and interoperable so as to allow for the exchange of such data among such post-acute care providers and other providers and the use by such providers of such data that has been exchanged, including by using common standards and definitions in order to provide access to longitudinal information for such providers to facilitate coordinated care and improved Medicare beneficiary outcomes…."

CMS has contracted with the RAND Corporation (HHSM-500-2013-13014I; TO #HHSM-500-T0001), to develop standardized patient/resident assessment data elements to meet the requirements as set forth under the IMPACT Act of 2014, Section 2(a).

Currently, HHAs, SNFs, IRFs, and LTCHs utilize assessment instruments for the collection and reporting of patient medical, functional, and cognitive data to CMS. These instruments are as follows: the Outcome and Assessment Information Set (OASIS-C2) for HHAs, the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs, the Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LCDS) for LTCHs, and the Minimum Data Set (MDS 3.0) for SNFs. The current assessment instruments are setting-specific and contain assessment items with varying concepts, definitions, and measurement scales. The move towards standardized assessment data elements facilitates cross-setting data collection, outcome comparison, and interoperable data exchange, while improving care coordination, fostering seamless transitions, improving person-centered outcomes and goals, and providing for reliable information that may support providers in making appropriate discharge placements. Ultimately, standardized assessment data elements across PAC settings will support the priorities of the CMS Quality Strategy, which is built from the three broad aims of the National Quality Strategy:

- **Better Care:** Improve the overall quality of care by making healthcare more patient-centered, reliable, accessible, and safe.
- **Healthy People, Healthy Communities**: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- **Affordable Care:** Reduce the cost of quality healthcare for individuals, families, employers, and government.

[i] http://www.gpo.gov/fdsys/pkg/BILLS-113hr4994enr/pdf/BILLS-113hr4994enr.pdf

Project Title: Development and Maintenance of Post-Acute Care Cross-Setting Standardized Assessment Data

The Centers for Medicare & Medicaid Services (CMS) solicits for comments on the development and use of standardized data elements developed to meet the IMPACT Act domains of: cognitive function and mental status; medical conditions and co-morbidities; impairments; medication reconciliation; and care preferences. In this document, we summarize the background and current usage of each proposed data element.

In addition to general comments, CMS is specifically interested in public feedback regarding the dimensions below. Please consider these topics during your review of the draft data element specifications:

- **Potential for improving quality**, which includes consideration of the data element's ability to improve care transitions through meaningful exchange of data between providers; improve person-centered care and care planning; be used for quality comparisons; and support clinical decision-making and care coordination;
- **Validity**, which includes consideration of the data element's proven or likely inter-rater reliability (i.e., consensus in ratings by two or more assessors) and validity (i.e., whether it captures the patient attribute being assessed);
- **Feasibility for use in PAC**, which includes consideration of the data element's potential to be standardized and made interoperable across settings; clinical appropriateness; and relevance to the work flow across settings;
- **Utility for describing case mix**, which includes whether the data element could be used with different payment models, and whether it measures differences in patient severity levels related to resource needs.

Data Elements by Category

In the following sections, data elements are being considered to standardize patient/resident assessment data by the categories delineated within the IMPACT Act. Each domain section includes:

- Rationale for assessing each domain
- Descriptions of the assessment data elements in each section, including:
    - Current use of the data elements including description of where the data element appears in the same, or similar, form across existing PAC assessment instruments
    - Performance of the data element, such as inter-rater and cross-setting reliability estimates
    - Proposed modifications to the data element, if applicable
    - Request for public comment
    - Details on how data elements are administered and coded

For data elements that were evaluated in the Post-Acute Care Payment Reform Demonstration (PAC PRD), we provide kappa statistics that indicate a measurement of reliability. The kappa

statistic is the result of a calculation measuring whether two or more people using the same assessment tool would respond to a data element in the same way. Calculated kappa values range from 0 to 1. For the purposes of this study, and following general usage, the range of agreement is defined as follows: moderate agreement, kappa > 0.40; substantial agreement, kappa > 0.60; and almost perfect agreement, kappa > 0.80. In general, data elements evaluated in the PAC PRD had substantial agreement; less than 20 percent of the data elements had kappa values lower than 0.60.

Of note, the PAC PRD, authorized by the Deficit Reduction Act of 2005, was a first step toward harmonizing data elements across PAC settings. In the PAC PRD, Congress directed CMS to address the relative costliness and outcomes of similar types of Medicare beneficiaries discharged to different PAC settings. As part of meeting this objective, the demonstration developed a uniform patient assessment instrument, called the Continuity Assessment Record and Evaluation (CARE) tool, to collect data on the medical, functional, and cognitive status of patients at admission or discharge from a PAC setting. The CARE tool was tested across PAC settings in over 200 providers in 11 geographically diverse markets, resulting in 455 patient assessments that formed the basis for robust inter-rater and cross-setting reliability estimates for most data elements in the CARE tool.

Cognitive Function and Mental Status

Patients/residents in PAC settings are at risk for cognitive impairment and depression. Cognitive impairment is associated with a number of disorders, conditions, and injuries (e.g., dementia, depression, traumatic brain injury [TBI], stroke) and can manifest in a variety of ways, such as difficulty communicating; impairments in learning, memory, or orientation; confusion; and behavioral symptoms. Conducting cognitive assessments is critically important in order to screen for cognitive impairment, assess the severity of disorder, develop a care plan, and monitor progression. There are multiple benefits to assessing cognitive status of patients/residents in PAC settings. For example, understanding an individual's needs allows for better person-directed care planning, including initiating appropriate pharmacologic or behavioral therapy, anticipating the patient's ability to understand and participate in treatments during their stay, and identifying appropriate support needs at the time of discharge. Information about cognitive status is critical to transfer across settings so that receiving providers have information about the patient upon arrival. Hence, reliable data elements assessing cognitive impairment are needed in order to initiate a management program that can optimize a patient's prognosis.

Estimated rates of clinical depression range from 9 to 28 percent in HHAs and 6 to 45 percent in SNFs, but depression generally is thought to be under-evaluated and under-detected in PAC settings. Undetected depression can lead to degraded physical and mental health and functioning, increased medical care utilization and costs, reduced quality of life, and premature death. It can also exacerbate other chronic medical conditions, compromise treatment participation and compliance, slow recovery from injuries and surgeries, and lead to rehospitalization. However, depression is treatable, and standardizing routine assessment of depression in PAC patients/residents has the potential to improve quality of care and patient/resident outcomes. There is also a high incidence of anxiety-related distress in PAC patients/residents, and therefore, this is an important area of assessment.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of cognitive function and mental status:

- DOTPA CARE
- Complex Sentence Repetition
- PASS Medication Management
- Staff assessment of mental status
- Behavioral Signs and Symptoms
- PROMIS Anxiety Items
- PHQ9-OV

DOTPA CARE

The Developing Outpatient Therapy Payment Alternatives (DOTPA) project had two main purposes: to identify, collect, and analyze therapy-related information tied to beneficiary need and the effectiveness of outpatient therapy services, and to explore payment method alternatives to the current financial caps on Medicare outpatient therapy services. The DOTPA Continuity Assessment Record and Evaluation (CARE) tool data elements assess cognitive function in all patients/residents to allow for a broad assessment over time of multiple cognitive components. The subset of CARE data elements pertaining to memory, attention, and problem solving have been recommended for inclusion. These DOTPA data elements score functional performance and record level of assistance, both of which are essential for risk adjustment and discharge planning.

Data element specifications

The DOTPA study tested the tools with Medicare beneficiaries in a variety of settings, including SNFs and IRFs, and found them to be highly reliable (Cronbach's alpha > 0.7).[1] The individual scales were tested as part of the activity measure for post acute care AM-PAC assessment and showed high test-retest reliability (0.91-0.97), high subject-proxy reliability (0.68-0.90), high setting-specific intraclass correlation coefficient (ICCs; 0.82-0.93), and high internal consistency reliability (Cronbach's alpha = 0.90-0.95).[1]

CMS is soliciting comment on the DOTPA CARE data elements as shown below.

INSTRUCTIONS:
"All items in Section A5. DOTPA CARE-C are based on staff/caregiver input or chart review. Do Not Ask Patient/Resident."

A5a. Does the patient/resident have any problems with memory, attention, problem solving, planning, organizing, or judgment?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

A5b. Please describe the patient's/resident's problems with the following: memory, attention, problem solving, planning, organizing, and judgment.

- ☐ 0 = **Mildly impaired**: Demonstrates some difficulty with one or more of these cognitive abilities
- ☐ 1 = **Moderately impaired**: Demonstrates marked difficulty with one or more of these cognitive abilities
- ☐ 2 = **Severely impaired**: Demonstrates extreme difficulty with one or more of these cognitive abilities
- ☐ 9 = Unknown or unable to assess

A5c. How often is the patient/resident able to complete simple problems without assistance?

Simple problems: Following basic schedules; requesting assistance; using a call bell; identifying basic wants/needs; preparing a simple cold meal

Without Assistance: Patient performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5d. How often is the patient/resident able to complete simple problems with assistance?

Simple problems: Following basic schedules; requesting assistance; using a call bell; identifying basic wants/needs; preparing a simple cold meal

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5e. How often is the patient/resident able to complete complex problems without assistance?

Complex problems: Working on a computer managing personal, medical, and financial affairs; preparing a complex hot meal; grocery shopping; route finding and map reading

Without Assistance: Patient/resident performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5f. How often is the patient/resident able to complete complex problems with assistance?

Complex problems: Working on a computer managing personal, medical, and financial affairs; preparing a complex hot meal; grocery shopping; route finding and map reading

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5g. How often is the patient/resident able to recall basic information without assistance?

Basic Information: Personal information (e.g., family members, biographical information, physical location); basic schedules; names of familiar staff; location of therapy area

Without Assistance: Patient/resident performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5h. How often is the patient/resident able to recall basic information with assistance?

Basic Information: Personal information (e.g., family members, biographical information, physical location); basic schedules; names of familiar staff; location of therapy area

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5i. How often is the patient/resident able to recall complex information without assistance?

Complex information: Complex and novel information (e.g., carry out multiple-step activities, follow a plan); anticipate future events (e.g., keeping appointments)

Without Assistance: Patient/resident performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5j. How often is the patient/resident able to recall complex information with assistance?

Complex information: Complex and novel information (e.g., carry out multiple-step activities, follow a plan); anticipate future events (e.g., keeping appointments)

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5k. How often is the patient/resident able to complete simple activities without assistance?

Simple activities: Following simple directions; reading environmental signs or short newspaper/magazine/ book passage; eating a meal; completing personal hygiene; dressing

Without Assistance: Patient/resident performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5l. How often is the patient/resident able to complete simple activities with assistance?

Simple activities: Following simple directions; reading environmental signs or short newspaper/magazine/ book passage; eating a meal; completing personal hygiene; dressing

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5m. How often is the patient/resident able to complete complex activities without assistance?

Complex activities: Watching a news program; reading a book; planning and preparing a meal; managing one's own medical, financial, and personal affairs

Without Assistance: Patient/resident performance without cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

A5n. How often is the patient/resident able to complete complex activities with assistance?

Complex activities: Watching a news program; reading a book; planning and preparing a meal; managing one's own medical, financial, and personal affairs

With Assistance: Patient/resident performance with cueing, assistive device, or other compensatory augmentative intervention

- ☐ 0 = Never or Rarely
- ☐ 1 = Sometimes
- ☐ 2 = Usually
- ☐ 3 = Always
- ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the DOTPA CARE data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the DOTPA CARE data elements are collected

For the data elements that comprise DOTPA CARE, a clinician with experience doing cognitive assessments will review the medical record; conduct interviews with staff; interview any others who interacted closely with the patient/resident, including family, friends, and caregivers; and observe the patient/resident in a variety of situations. The information is collected within a 2-day assessment window.

How the DOTPA CARE data elements are coded

For the gateway question A5a, a code of 0, "no," is recorded if the patient/resident has no problems with the cognitive abilities listed: memory, attention, problem solving, planning, organizing, or judgment. A code of 1, "yes" is recorded if the patient/resident has any problems with the cognitive abilities. A code of 9, "unknown or unable to assess" is recorded if information sources are not available and/or documentation in the medical record are insufficient to assess this question. The assessor only continues completing the section if given the response 1, "yes."

For the A5b data element, a code of 0, "mildly impaired" is recorded if the patient/resident demonstrates some difficulty with one or more cognitive ability. A code of 1, "moderately impaired," is recorded if the patient/resident demonstrates marked difficulty with one or more cognitive ability. A code of 2, "severely impaired," is recorded if the patient/resident demonstrates extreme difficulty with one or more cognitive ability. A code of 9 is recorded if information sources are not available and/or documentation in the medical record is insufficient to complete this question.

For the remaining data elements of Problem Solving, Memory, Attention, a code of 0, "never or rarely," is recorded if the patient/resident has never or rarely had these problems in the 2-day look back period. A code of 1, "sometimes," is recorded if the patient/resident has sometimes had these problems in the 2-day look back period. A code of 2, "usually," is recorded if the patient/resident has usually had these problems in the 2-day look back period. A code of 3, "always," is recorded if the patient/resident always has these problems in the 2-day look back period. A code of 9 is recorded if information sources are not available and/or documentation in the medical record is insufficient to complete this question.

Complex Sentence Repetition

The data elements that comprise Complex Sentence Repetition screen for cognitive impairment. These data elements test whether a patient is able to perfectly repeat back to the assessor a complex sentence that was read aloud.

Data element specifications

Complex Sentence Repetition is not in use in any of the four PAC assessment instruments and was not tested in the PAC PRD. These data elements were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

CMS is soliciting comment on the Complex Sentence Repetition data elements as shown below.

Complex Sentence Repetition	
Enter Code ☐	**F7a. Instruct patient/resident:** "I am going to read you a sentence. Repeat it after me, exactly as I say it. Remember, do not begin until I have given you the whole sentence [pause]: *After the bell rang, the man standing on the stairs quickly exited the building.*" **If the response is not exactly correct say, "Let's try that again" and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time.** 1. Sentence was exactly correct 0. Sentence was not exactly correct or no answer
Enter Code ☐	**F7b. Instruct patient/resident:** "Now I am going to read you different sentence. Repeat it after me, exactly as I say it. Remember, do not begin until I have given you the whole sentence [pause]: *Though he typically watches westerns, lately he has preferred watching comedies."* **If the response is not exactly correct say, "Let's try that again" and repeat the sentence. If the response is still not exactly correct, repeat the sentence a final time.** 1. Sentence was exactly correct 0. Sentence was not exactly correct or no answer

CMS is seeking comment on the cross setting applicability of the Complex Sentence Repetition data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC

- Utility for describing case mix

How the Complex Sentence Repetition data elements are collected

Complex Sentence Repetition can be administered by any clinician who has been trained to conduct this assessment. The assessor begins by instructing the patient/resident, "I am going to read you a sentence. Repeat it after me exactly as I say it." The assessor stresses that the patient/resident should not begin until the entire sentence has been provided. The assessor then reads the first sentence, "After the bell rang, the man standing on the stairs quickly exited the building." The patient/resident gets three chances to repeat the sentence correctly. After the first chance, if it is not exactly correct the assessor says "Let's try that again" and repeats the sentence. If it is again not correct, the assessor reads the sentence a final time. Then, the assessor scores this part of the test and moves to the second sentence, "Though he typically watches westerns, lately he has preferred watching comedies." In the event that the patient/resident does not say the phrase correctly, the assessor repeats the same process to give two more chances.

How the Complex Sentence Repetition data elements are coded

These two tests are scored a "1" if the sentence was exactly correct, or a "0" if the sentence was not exactly correct or if no answer was given.

PASS Medication Management

The data elements that comprise the PASS Medication Management Task assess the patient's/resident's ability to manage medications by asking him or her to perform tasks including finding, reading, and understanding medication directions and putting pills correctly in a pill box. This task measures cognitive skills for activities of daily living and daily decision-making. There are two versions, one for a clinic setting and one for home, which are identical except that the home version has patients use their own medications.

Data element specifications

The PASS Medication Management Task has been tested in older adult populations and has shown good discriminatory validity. Two studies of community-dwelling older adults found that patients with mild cognitive impairment (MCI) needed significantly more assistance ($F = 7.10$, $p = 0.009$) and had significantly lower adequacy scores ($p = 0.0095$) than individuals with normal cognition[2,3]. The PASS Medication Management task is also significantly correlated with the Global Cognitive Score ($r = -0.43$, $p < 0.0001$).[4]

CMS is soliciting comment on the PASS Medication Management data elements as shown below.

SAY TO PATIENT/RESIDENT:
The next task involves managing medications.

ASK PATIENT/RESIDENT: "Please read the prescription label and find the directions for taking this medication."

HAND PATIENT/RESIDENT FIRST BOTTLE OF MEDICATION AND WAIT UNTIL PATIENT/RESIDENT LOOKS UP

"If you were taking this medication today, when would you have to take the next pill?"

SUBTASK 1:
A4a. Reports next time first medication is to be taken correctly (based on testing time, matches direction on label)

No Assistance	☐		
Verbal Assistance (Guiding or Directing Cues)	☐	☐	☐
Visual Assistance (Gestures or Demonstration)	☐	☐	☐
Physical Assistance (Tactile Cues, Physical Help)	☐	☐	☐
88 = Not attempted (Due to environmental limitations or patient/resident safety)	☐		

ENTER SUBTASK 1; A4a SCORE ☐

ASK PATIENT/RESIDENT:

"This medication organizer is like a pillbox. It has the days of the week across the top [POINT] and the time of the day [POINT] along the side. Using the organizer, distribute the pills to be taken tomorrow and the following day according to the directions on the prescription label [PAUSE].

"Do you know what you are to do? Do you have everything that you need?"

WAIT FOR RESPONSE

SUBTASK 3

A4c. Distributes pills from first pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated)

No Assistance	☐		
Verbal Assistance (Guiding or Directing Cues)	☐	☐	☐
Visual Assistance (Gestures or Demonstration)	☐	☐	☐
Physical Assistance (Tactile Cues, Physical Help)	☐	☐	☐
88 = Not attempted (Due to environmental limitations or patient/resident safety)	☐		

ENTER SUBTASK 3; A4c SCORE ☐

ASK PATIENT/RESIDENT:

"This medication organizer is like a pillbox. It has the days of the week across the top [POINT] and the time of the day [POINT] along the side. Using the organizer, distribute the pills to be taken tomorrow and the following day according to the directions on the prescription label [PAUSE].

"Do you know what you are to do? Do you have everything that you need?"

WAIT FOR RESPONSE

SUBTASK 3

A4c. Distributes pills from first pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated)

No Assistance	☐		
Verbal Assistance (Guiding or Directing Cues)	☐	☐	☐
Visual Assistance (Gestures or Demonstration)	☐	☐	☐
Physical Assistance (Tactile Cues, Physical Help)	☐	☐	☐
88 = Not attempted (Due to environmental limitations or patient/resident safety)	☐		

ENTER SUBTASK 3; A4c SCORE ☐

ASK PATIENT/RESIDENT: "Now, please read the prescription label on this bottle and find the directions for taking this medication."

[HAND CLIENT SECOND BOTTLE OF OWN MEDICATION OR BOTTLE WITH <u>NON-CHILD-PROOF LID</u> AND WAIT UNTIL CLIENT LOOKS UP].

"If you were taking this medication today, when would you have to take the next pill?"

SUBTASK 4
A4d. Reports next time second medication is to be taken correctly (based on testing time, matches direction on label)

No Assistance	☐		
Verbal Assistance (Guiding or Directing Cues)	☐	☐	☐
Visual Assistance (Gestures or Demonstration)	☐	☐	☐
Physical Assistance (Tactile Cues, Physical Help)	☐	☐	☐
88 = Not attempted (Due to environmental limitations or patient/resident safety)	☐		

ENTER SUBTASK 4; A4d SCORE ☐

ASK PATIENT: "Again, using the organizer, distribute the pills to be taken tomorrow and the following day according to the prescription directions on the label. Do you know what you are to do?" **WAIT FOR RESPONSE**
SUBTASK 6 **A4f. Distributes pills from second pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated)** No Assistance ☐ Verbal Assistance (Guiding or Directing Cues) ☐ ☐ ☐ Visual Assistance (Gestures or Demonstration) ☐ ☐ ☐ Physical Assistance (Tactile Cues, Physical Help) ☐ ☐ ☐ 88 = Not attempted (Due to environmental limitations or patient/resident safety) ☐
ENTER SUBTASK 6; A4f SCORE ☐
INSTRUCTION: **CALCULATE AND ENTER PASS MEDICATION MANAGEMENT INDEPENDENCE MEAN SCORE**

CMS is seeking comment on the cross setting applicability of the PASS Medication Management Task data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the PASS Medication Management Task data elements are collected

The PASS Medication Management Task protocol outlines which objects the clinician needs (such as two prescription medication bottles) and how to situate the materials and the patient/resident at the table. Following the protocol and script, the clinician asks the patient/resident to perform each task and observes how well the patient/resident is able to complete each one, in terms of task independence, task safety, and task adequacy outcomes. The

clinician can help the patient/resident with tasks if necessary, but assistance must be recorded in the final score.

How the PASS Medication Management Task data elements are coded

Each data element in PASS Medication Management is rated on a four-point scale (from 0 to 3 points). This is the same for each task. This is comprised of three subtask scores on the following: task independence, task safety, and task adequacy outcomes.

For subtasks 1 through 6, a code of 3 is recorded if no assistance was given for task initiation, continuation, or completion. A code of 2 is recorded if no tactile cues or physical assistance was given, but occasional verbal or visual assistance was given. A code of 1 is recorded if no physical assistance was given, but occasional tactile cues were given or continuous verbal or visual cues were given. A code of 0 is recorded if physical assistance was given, or if continuous tactile cues were given, or if the patient/resident was unable to initiate, continue, or complete subtask or task.

Staff Assessment of Mental Status

The data elements that comprise Staff Assessment of Mental Status assess long-term memory, short-term memory, memory/recall ability, and decision-making based on staff observation. These data elements are intended for use among patients/residents in all PAC settings who were unable to complete the interview-administered Brief Interview for Mental Status (BIMS) because of refusal, nonsensical answers, or inability to make him- or herself understood at least some of the time. It is important to note that a patient who gives incorrect answers to the BIMS is still considered to have completed the BIMS.

Data element specifications

The table below shows the assessment instruments using the Staff Assessment of Mental Status data elements. Studies testing the MDS 3.0 version of staff assessment for mental status in nursing home patients have shown it to have good inter-rater reliability ($r = 0.80$)[5] and good validity based on its correlation with other assessments such as the Blessed Test ($r = 0.66$, $p < 0.05$) and the Reisberg Global Deterioration Scale ($r = 0.59$, $p < 0.05$).[6]

Table: Assessment Instruments Using the Staff Assessment of Mental Status Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the Staff Assessment of Mental Status data elements as shown below. This version is similar to that which is in use in the MDS 3.0.

A1a. Short-term Memory OK
Seems or appears to recall after 5 minutes ☐ 0 = Memory OK ☐ 1 = Memory problem ☐ 9 = Unknown or unable to assess
A1b. Long-term Memory OK
Seems or appears to recall long past ☐ 0 = Memory OK ☐ 1 = Memory problem ☐ 9 = Unknown or unable to assess
A1c. Memory/Recall Ability: IS THE PATIENT/RESIDENT NORMALLY ABLE TO RECALL:
A1ci. Current season ☐ 0 = No ☐ 1 = Yes ☐ 9 = Unknown or unable to assess
A1cii Location of own room ☐ 0 = No ☐ 1 = Yes ☐ 9 = Unknown or unable to assess
A1ciii Staff names and faces ☐ 0 = No ☐ 1 = Yes ☐ 9 = Unknown or unable to assess
A1civ That he or she is in a nursing facility/hospital bed/rehabilitation facility/home ☐ 0 = No ☐ 1 = Yes ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Staff Assessment of Mental Status data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Staff Assessment of Mental Status data elements are collected

The assessor determines the patient's or resident's short-term memory status by determining his or her performance in following through on a direction given 5 minutes earlier. The assessor observes how often the patient/resident has to be reoriented to an activity or instructions, and

observes the patient's/resident's cognitive function in various daily activities. The assessor determines patient's/resident's long-term memory status by reviewing memorabilia (photographs, memory books, keepsakes, videos, or other recordings that are meaningful to the patient/resident) with the patient/resident or observing responses to family who visit. The assessor observes if the patient/resident responds to memorabilia or family members who visit. The assessor observes if the patient/resident remembers facility or home routines. These observations should be made by staff across all shifts and departments and by others with close contact with the patient/resident. The assessor asks direct care staff across all shifts and family or significant others about the patient's/resident's short-term memory ability. The assessor also reviews the medical record for indicators of the patient's/resident's short-term memory during the 7-day look-back period.

How the Staff Assessment of Mental Status data elements are coded

The short-term and long-term memory items are coded 0, "memory ok" if the patient is able to recall information after 5 minutes; or 1, "memory problem" if the most representative level of function shows the absence of recall after 5 minutes or the absence of recall of long past information.

Behavioral Signs and Symptoms

Behavior disturbances put additional time and resource burden on providers; disrupt care; result in poorer patient outcomes; and place the patient at risk for injury, isolation, and inactivity. These symptoms may also disrupt the institutional or home environment and affect the safety and privacy of other patients/residents, caregivers, and staff. Behavioral disturbances warrant assessment and documentation to inform care planning and patient transitions.

The data elements that comprise Behavioral Signs and Symptoms assess whether the patient has exhibited any behavioral symptoms that may indicate cognitive impairment or other issues during the assessment period. Based on feedback from advisors and prior public comment, it has been noted that additional challenges related to presence and frequency of patient behaviors should be assessed, such as impact on resident, impact on others, and rejection of care.

Data element specifications

As shown in the table, supplements to the Behavioral Signs and Symptoms – Presence & Frequency are included in the Minimum Data Set (MDS) 3.0. The Impact on Resident and Impact on Others data elements give additional insight into severity of identified behavioral symptoms and potential need for treatment/intervention. In the study to develop and validate the MDS 3.0, these data elements were found to be clinically relevant assessment of the effects of behavior and were rated useful and important by nursing home staff who used them.

Table: Assessment Instruments Using the Behavioral Signs & Symptoms - Impact on Resident, Impact on Others, and Rejection of Care Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the data elements that comprise Behavioral Signs and Symptoms as shown below. The data elements being put forward for public comment are identical to those tested in the PAC PRD.

B1. BEHAVIORAL SYMPTOMS – PRESENCE & FREQUENCY

B1a. Physical behavioral symptoms directed toward others

(e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)

- ☐ 0 = Behavior not exhibited
- ☐ 1 = Behavior of this type occurred 1 to 3 days
- ☐ 2 = Behavior of this type occurred 4 to 6 days, but less than daily
- ☐ 3 = Behavior of this type occurred daily
- ☐ 9 = Unknown or unable to assess

B1b. Verbal behavioral symptoms directed toward others

(e.g., threatening others, screaming at others, cursing at others)

- ☐ 0 = Behavior not exhibited
- ☐ 1 = Behavior of this type occurred 1 to 3 days
- ☐ 2 = Behavior of this type occurred 4 to 6 days, but less than daily
- ☐ 3 = Behavior of this type occurred daily
- ☐ 9 = Unknown or unable to assess

B1c. Other behavioral symptoms not directed toward others

(e.g., physical symptoms such as hitting or scratching self, pacing, rummaging, public sexual acts, disrobing in public, throwing or smearing food or bodily wastes, or verbal/vocal symptoms like screaming, disruptive sounds)

- ☐ 0 = Behavior not exhibited
- ☐ 1 = Behavior of this type occurred 1 to 3 days
- ☐ 2 = Behavior of this type occurred 4 to 6 days, but less than daily
- ☐ 3 = Behavior of this type occurred daily
- ☐ 9 = Unknown or unable to assess

Overall Presence of Behavioral Symptoms

B1d. Were <u>any</u> behavioral symptoms in the prior 3 questions (B1a-c) exhibited by the patient/resident (coded 1, 2, or 3)?

- ☐ 0 = No -> SKIP TO B1k, Rejection of Care Section
- ☐ 1 = Yes

IMPACT ON PATIENT/RESIDENT:
Considering all the behavioral symptoms noted in B1a to B1c**, did any of the identified symptom(s):**

B1e. Put the patient/resident at significant risk for physical illness or injury?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

B1f. Significantly interfere with the patient's/resident's care?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

B1g. Significantly interfere with the patient's/resident's participation in activities or social interaction?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 8 = Not Applicable
- ☐ 9 = Unknown or unable to assess

IMPACT ON OTHERS:

Did any of the identified symptom(s):

B1h. Put others at significant risk for physical injury?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

B1i. Significantly intrude on the privacy or activity of others?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

B1j. Significantly disrupt the delivery of care or living environment of others?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess

REJECTION OF CARE – PRESENCE & FREQUENCY
B1k. Did the patient/resident reject evaluation of care (e.g., bloodwork, taking medications, ADL assistance) that is being offered by members of the care team or caregiver and necessary to achieve the patient's/resident's goals for health and well-being? Do not include behaviors that have already been addressed (e.g., by discussion or care planning with the patient/resident or family), and determined to be consistent with patient/resident values, preferences, or goals. ☐ 0 = Behavior not exhibited ☐ 1 = Behavior of this type occurred 1 to 3 days ☐ 2 = Behavior of this type occurred 4 to 6 days, but less than daily ☐ 3 = Behavior of this type occurred daily ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross-setting applicability of the data elements that comprise Behavioral Signs and Symptoms. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Behavioral Signs and Symptoms data elements are collected

If any behavioral symptoms are identified in the Behavioral Symptom – Presence & Frequency data elements, clinicians are instructed to record responses for data elements related to Impact on Resident and data elements related to Impact on Others. These data elements are skipped if no behavioral symptoms were identified in Behavioral Symptom – Presence & Frequency. These data elements follow up on the 7-day look-back period used in Behavioral Symptom – Presence & Frequency. Response is based on review of the medical record, staff interviews, and interviews with others who observed the behaviors identified. Next, assessors are instructed to record whether and how often the resident rejected evaluation of care that is necessary to achieve the resident's goal for health and well-being. The Rejection of Care data element also has a 7-day look-back period, and response is based on review of the medical record and interviews with staff and others who had close interactions with the resident.

How the Behavioral Signs and Symptoms data elements are coded

Overall Presence of Behavioral Symptoms is coded as 0 for "No" if no behavioral symptoms were identified in the Behavioral Symptom – Presence & Frequency data elements, and if behavioral symptoms were identified the assessor skips to the Rejection of Care – Presence & Frequency data element, which is coded as 1 for "Yes." If Overall Presence of Behavioral

Symptoms is coded as “Yes,” the three Impact on Resident data elements and three Impact on Others data elements are coded as 0 for “No” or 1 for “Yes.” The Rejection of Care data element is coded on a scale that ranges from 0 for “Behavior not exhibited” to 3 for “Behavior of this type occurred daily.” Coding of the Rejection of Care data element is not dependent on whether behavioral symptoms were identified in Behavioral Symptom – Presence & Frequency.

PROMIS® Anxiety Items

The Patient-Reported Outcomes Measurement Information System (PROMIS®) was developed as part of a National Institutes of Health (NIH) Roadmap initiative that set the standard for modern behavioral health measurement development. PROMIS is at the forefront of NIH efforts to fund research that advances behavioral health measurement by developing new self-reporting tools based on the principles of item response theory (IRT). PROMIS tools provide researchers and clinicians with reliable, precise assessments of patient-reported health status for physical, mental, and social well-being by asking what patients are able to do and how they feel.

PROMIS item banks have been developed for a large number of health-related quality of life (HRQOL) domains using rigorous methodology (see PROMIS website for more information about item development). Item banks consist of collections of items representing a single construct or domain (e.g., Anxiety), each of which has known psychometric properties due to the extensive testing and analysis conducted to build the bank. This allows for subsets of items from an item bank to be selected either by hand or by computer to create brief assessments of a domain. Because the properties of the items are known and they have all been calibrated to the same scale, comparable scores can be generated for subsets of items from the same bank. For example, an item bank representing physical function may have over 100 items in it.

The data elements that comprise the PROMIS Anxiety Item Bank assess self-reported fear (fearfulness, panic), anxious misery (worry, dread), hyperarousal (tension, nervousness, restlessness), and somatic symptoms related to arousal (racing heart, dizziness). The PROMIS Anxiety Item Bank has a total of 29 items, from which 11 items were selected on the basis of relevance for PAC settings. These items are intended to assess levels of anxiety across a wide range of symptom severity.

All 11 items are based on the same look-back period (past 7 days) and the same response scale (a 5-point Likert-type scale where 1=never; 2=rarely; 3=sometimes; 4=often; 5 =always) to assess the frequency of the symptoms.

Data element specifications

The full PROMIS Anxiety Item Bank contains 29 anxiety items. Details on the development and calibration of the item bank can be found in Pilkonis et al., 2011.[7] The items were calibrated and tested in the U.S. general population and clinical groups. A seven-item short-form is available with an alpha reliability coefficient of 0.93, and has a correlation of 0.96 with the total item bank. The selected 11-item anxiety item bank shows high convergent validity with the general distress scale from the Mood and Anxiety Symptom Questionnaire (r = 0.80). It correlates highly (r = 0.81) with the depression item bank[7] and with the Center for Epidemiological Studies Depression scale (r = 0.75).[8]

CMS is soliciting comment on the Anxiety data elements as shown below.

D1. SELECTED ITEMS FROM PROMIS® EMOTIONAL DISTRESS - ANXIETY V2.0 ITEM BANK [Patient/ Resident]

SAY TO PATIENT/RESIDENT:

"I am now going to ask you about your emotional distress, specifically anxiety and how you have been feeling over the past 7 days. I will also ask about some common problems that sometimes go along with feeling anxious. This is not meant to give you a diagnosis. Some of the questions might seem personal, but all patients/residents are asked to answer them. Knowing the answers to these questions will help us provide you with a more individualized care plan."

D1a. In the past 7 days, I had difficulty sleeping

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/ RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1b. In the past 7 days, I felt worried

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1c. In the past 7 days, my worries overwhelmed me

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1d. <u>In the past 7 days</u>, I had trouble paying attention

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1e. <u>In the past 7 days</u>, I felt nervous

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1f. <u>In the past 7 days</u>, I felt anxious

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1g. <u>In the past 7 days</u>, I had difficulty calming down

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1h. In the past 7 days, I had a racing or pounding heart

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1i. In the past 7 days, I found it hard to focus on anything other than my anxiety

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1j. In the past 7 days, I felt like I needed help for my anxiety

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

D1k. In the past 7 days, I had sudden feelings of panic

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = PATIENT/RESIDENT DECLINED TO RESPOND
- ☐ 9= UNKNOWN OR UNABLE TO ASSESS

CMS is seeking comment on the cross setting applicability of the Anxiety data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Anxiety data elements are collected

The Anxiety data elements are collected using a direct patient/resident interview. The assessor explains the reason for the interview before beginning. Then the assessor shows the interview response choices on a cue card and reads each question to the patient/resident. The patient/resident is asked to respond to each question by giving the closest answer, and the assessor records the responses in the boxes to the left of each data element. While reading each of the statements and showing the patient/resident the response options, the assessor does not offer any predetermined definitions. The response should be based on the patient's/resident's own interpretation of frequency response options.

How the Anxiety data elements are coded

The data elements are coded on a rating scale of 1 to 5. The assessor records a code of 1 for "Never," 2 for "Rarely," 3 for "Sometimes," 4 for "Often," and 5 for "Always."

If the patient/resident uses his or her own words to describe a symptom, this should be briefly explored. If the patient/resident has difficulty selecting between two frequency responses, the higher frequency should be recorded.

Patient Health Questionnaire-9 Observational Version (PHQ9-OV)

The data elements that comprise the Patient Health Questionnaire-9 Observational Version (PHQ9-OV) assess distressed mood in patients/residents who cannot complete a patient/resident mood interview due to an inability to communicate. Distressed mood is a common condition in PAC settings that is sometimes under-recognized and under-treated. It is particularly important to identify signs and symptoms of distressed mood among PAC patients/residents because mood disorders are often treatable.

The PHQ-9 has been validated in older adults,[9-13] home health,[14] skilled nursing facilities,[15] and rehabilitation populations.[16] The PHQ-9 has also been shown to be a reliable and valid screening tool for detecting signs and symptoms of depression in patients/residents with complex medical issues, including stroke and TBI.[16,17] However, because some question whether a patient/resident mood interview can be faithfully administered to patients with moderate to severe cognitive impairments and whether the PHQ-9 is appropriate for patients in LTCHs, there is a need for an observation-based method of assessing mood.

Data element specifications

As shown in the table, the PHQ9-OV is included in the MDS 3.0 and has been validated in the nursing home population and has demonstrated feasibility in that setting.

Table: Assessment Instruments Using the PHQ-9 Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the PHQ9-OV data elements as shown below.

C1. STAFF ASSESSMENT OF PATIENT/RESIDENT MOOD (PHQ-9-OV©)

C1a1. SYMPTOM PRESENCE: - Little interest or pleasure in doing things

- ☐ 0 = No (**SKIP TO C1B1**)
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess (**SKIP TO C1B1**)

C1a2. SYMPTOM FREQUENCY: - Little interest or pleasure in doing things

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1b1. SYMPTOM PRESENCE: - Feeling or appearing down, depressed, or hopeless

- ☐ 0 = No (**SKIP TO C1C1**)
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess (**SKIP TO C1C1**)

C1b2. SYMPTOM FREQUENCY: - Feeling or appearing down, depressed, or hopeless

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1c1. SYMPTOM PRESENCE: - Trouble falling or staying asleep, or sleeping too much

- ☐ 0 = No (Skip to C1d1)
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess (Skip to C1d1)

C1c2. SYMPTOM FREQUENCY: Trouble falling or staying asleep, or sleeping too much

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1d1. SYMPTOM PRESENCE: - Feeling tired or having little energy

- ☐ 0 = No (Skip to C1e1)
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess (Skip to C1e1)

C1d2. SYMPTOM FREQUENCY: - Feeling tired or having little energy

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1e1. SYMPTOM PRESENCE: - Poor appetite or overeating

- ☐ 0 = No (**SKIP TO C1F1**)
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess **(SKIP TO C1F1)**

C1e2. SYMPTOM FREQUENCY: - Poor appetite or overeating

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1f1. SYMPTOM PRESENCE: - Indicating that s/he feels bad about self, is a failure, or has let self or family down

- ☐ 0 = No **(SKIP TO C1G1)**
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess **(SKIP TO C1G1)**

C1f2. SYMPTOM FREQUENCY: - Indicating that s/he feels bad about self, is a failure, or has let self or family down

- ☐ 0 = Never or 1 day
- ☐ 1 = **2-6 days** (several days)
- ☐ 2 = **7-11 days** (half or more of the days)
- ☐ 3 = **12-14 days** (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1g1. SYMPTOM PRESENCE: - Trouble concentrating on things, such as reading the newspaper or watching television

- ☐ 0 = No **(SKIP TO C1H1)**
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess **(SKIP TO C1H1)**

C1g2. SYMPTOM FREQUENCY: - Trouble concentrating on things, such as reading the newspaper or watching television

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1h1. SYMPTOM PRESENCE: - Moving or speaking so slowly that other people have noticed. Or the opposite – being so fidgety or restless that s/he has been moving around a lot more than usual

- ☐ 0 = No **(SKIP TO C1I1)**
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess **(SKIP TO C1I1)**

C1h2. SYMPTOM FREQUENCY: - Moving or speaking so slowly that other people have noticed. Or the opposite – being so fidgety or restless that s/he has been moving around a lot more than usual

- ☐ 0 = Never or 1 day
- ☐ 1 = 2-6 days (several days)
- ☐ 2 = 7-11 days (half or more of the days)
- ☐ 3 = 12-14 days (nearly every day)
- ☐ 9 = Unknown or unable to assess

C1i1. SYMPTOM PRESENCE: - States that life isn't worth living, wishes for death, or attempts to harm self ☐ 0 = No **(SKIP TO C1J1)** ☐ 1 = Yes ☐ 9 = Unknown or unable to assess **(SKIP TO C1J1)**	
C1i2. SYMPTOM FREQUENCY: - States that life isn't worth living, wishes for death, or attempts to harm self ☐ 0 = Never or 1 day ☐ 1 = 2-6 days (several days) ☐ 2 = 7-11 days (half or more of the days) ☐ 3 = 12-14 days (nearly every day) ☐ 9 = Unknown or unable to assess	
C1j1. SYMPTOM PRESENCE: - Being short-tempered, easily annoyed ☐ 0 = No **(SKIP TO TOTAL SCORE)** ☐ 1 = Yes ☐ 9 = Unknown or unable to assess **(SKIP TO TOTAL SCORE)**	
C1j2. SYMPTOM FREQUENCY: - Being short-tempered, easily annoyed ☐ 0 = Never or 1 day ☐ 1 = 2-6 days (several days) ☐ 2 = 7-11 days (half or more of the days) ☐ 3 = 12-14 days (nearly every day) ☐ 9 = Unknown or unable to assess	
PHQ-9-OV TOTAL: Add values from C1a2, C1b2, C1c2, C1d2, C1e2, C1f2, C1g2, C1h2, C1i2 and C1j2 →	

CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the PHQ9-OV data elements are collected

The data elements that comprise the PHQ9-OV are collected through interviews of staff, family members, and other individuals who know the patient/resident well. The interviews are conducted in a location that protects the patient's/resident's privacy. The purpose of assessment is explained at the outset of each interview. Staff or family members are encouraged to report

symptom frequency, even if they believe that the symptom is unrelated to depression. Unclear responses are explored, focusing the discussion on the specific symptom listed on the assessment. Medical records covering the past two weeks can also be consulted to look for indications of how the patient/resident has been feeling or behaving. This medical record information is used to supplement what was learned during the interviews.

How the PHQ9-OV data elements are coded

For symptom presence, code 0 for "No," 1 for "Yes," and 9 for "Unknown/unable to assess," For symptom frequency, code 0 for "never or 1 day," 1 for "2-6 (several days)," 2 for "7-11 (half or more of the days)," 3 for "12-14 (nearly every day)," 9 for "unknown/unable to assess." The total score is calculated by adding the values for the symptom frequency data elements: C1a2, C1b2, C1c2, C1d2, C1e2, C1f2, C1g2, C1h2, C1i2, and C1j2. The sum is entered in the box for the PHQ-9-OV TOTAL.

Medical Conditions: Continence

Impaired bladder and bowel continence is common among older persons in the United States, but age-adjusted rates differ across settings. Among persons 65 years and older, the prevalence of bladder incontinence is 24 percent in the general noninstitutionalized population, 40 percent in those receiving home health care services, 37 percent in those in skilled nursing facilities, and 70 percent in those in long-term care residents.[18] The prevalence of bowel incontinence also varies across settings. Among persons 65 years and older, the prevalence of bladder incontinence is 17 percent in the general noninstitutionalized population, 13 percent in those receiving home health care services, 33 percent in those in skilled nursing facilities, and 60 percent in long-term care residents.[18] Bladder or bowel continence has been shown to be associated with adverse outcomes, including skin breakdown, falls, social isolation, poor quality of life, and depression.

A number of treatment options are available for patients who experience bladder incontinence, including noninvasive behavioral methods, lifestyle changes, bladder training, pelvic muscle exercises, toileting schedules, pharmacologic treatment, and surgical procedures. Depending on the type and underlying causes, treatment of bowel incontinence may include laxatives; enemas; establishment of toileting routines; dietary changes; antidiarrheal medications; treatment of underlying conditions, such as irritable bowel disease; biofeedback; strengthening exercises; surgery; colostomy; and improving the patient's mobility or ability to recognize or communicate needing assistance with having a bowel movement.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of Medical Conditions: Continence.

- Bladder – Device Use
- Bladder – Incontinence
- Bladder – Incontinence Interview
- Bowel – Device Use
- Bowel – Incontinence
- Bowel – Incontinence Interview

Bladder - Device Use

The data elements that comprise Bladder – Device Use document use of equipment and devices to manage bladder incontinence.

Data element specifications

The table shows the assessment instruments using the Bladder—Device Use data elements. Similar data elements that assess bladder management device use are currently collected in the MDS 3.0. The PAC PRD tested similar data elements that showed good feasibility and reliability across PAC settings. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

Table: Assessment Instruments Using the Bladder - Device Use Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the Bladder - Device Use data elements as shown below.

C1a: Does this patient/resident use an external or indwelling urinary catheter, have a urostomy, or require intermittent urinary catheterization?

Enter Code	
☐	0. No **[SKIP to C2a: Frequency of Incontinent Events]** 1. Yes

IF yes, indicate device(s): (For each device, enter 1 if Yes; enter 0 if No.)

☐ Indwelling urethral catheter

☐ Other indwelling catheter (include suprapubic catheter and nephrostomy tube)

☐ External catheter (include condom catheter)

☐ Urostomy

☐ Intermittent catheterization

☐ Other

C1b: If patient/resident has indwelling or external CATHETER, at what point was device first placed?

Enter Code	
☐	1. In current setting? 2. Prior setting? 3. Prior to hospitalization for this illness/exacerbation? 9. Unknown

C1c: If patient/resident has an indwelling or external CATHETER, what is the reason the device was put in place?

Enter Code	
☐	1. Retention 2. Skin Protection (i.e.; presence of Stage 3 or 4 pressure ulcer) 3. Comfort Care 4. Other (specify):_____ 9. Unknown

C1d: If patient/resident has a bladder device **(C1a=1; Yes):** Does the patient/resident need assistance to manage equipment or devices related to bladder care for ANY reason (e.g., cognitive impairment/mental status, physical limitation, medical issue, etc.)?

Enter Code	
☐	0. No 1. Yes

CMS is seeking comment on the cross setting applicability of the Bladder - Device Use data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bladder - Device Use data elements are collected

The Bladder – Device Use data elements can be administered by any clinician who has been trained to conduct this assessment. Devices include external catheter, indwelling urethral catheter, suprapubic catheter, nephrostomy tube, and urostomy. In men, condom catheters are commonly used intermittently or at night only and should be counted for purposes of this data element. Ostomy bags are sometimes used to collect urine in the absence of an ostomy. Such use without the presence of an ostomy should not be counted for this data element.

First, the assessor reviews the patient's/resident's medical record as well as the nurse and nursing assistant notes. The assessor then directly observes the patient/resident and documents information pertaining to bladder device use. If the patient/resident does not use a bladder device, the first data element of Bladder – Device Use (C1a above) is coded 0, and the assessor skips the remaining data elements.

If the patient/resident does use an indwelling or external catheter, the assessor moves on to the C1b and C1c data elements, which assess when and why the catheter was placed. If this information cannot be obtained through medical record review, the assessor may ask the patient/resident and/or caregiver. For example, if patient/resident is capable of communicating, the assessor may ask: "When was your catheter first placed?" and read the response options. If the patient/resident is unable to communicate or is unable to provide this information (e.g., due to severe cognitive impairment) and has a primary caregiver (e.g., spouse, significant other, family member, professional caregiver, or other relation who assisted in the patient's/resident's care outside of the current setting) who is physically present at the time the assessment is conducted, the assessor should then ask the caregiver when and why the catheter was placed and read each response option.

The final data element (C1d) asks whether the patient/resident requires any assistance to manage use of a bladder device. This data element is completed if the patient/resident has a bladder device (i.e., if C1a is coded 1 for "yes"). Information to complete this question can be found in the medical record and nursing notes, through direct patient observation by the assessor, or through communication with the patient, care team, and family/caregivers.

How the Bladder - Device Use data elements are coded

If the patient/resident does not use a bladder device, the first data element of Bladder – Device Use (C1a above) is coded 0 and the assessor then skips the remaining data elements. If the

patient does use a bladder device, C1a is coded 1. The assessor then indicates the type of bladder device or devices by entering a 1 for “yes” and a 0 for “no” for each listed device type; at what point the device was first placed in C1b; and the reason the device was put in place in C1c.

For C1d, “any reason” could be any cognitive, psychiatric, physical mobility, or medical reason that prevents the patient/resident from managing bladder device use independently. If a patient/resident does not require assistance, C1d is coded as 0; if the patient/resident does require assistance, it is coded as 1.

Bladder – Incontinence

The data elements that comprise Bladder – Incontinence assess the frequency of bladder incontinence experienced by the patient during the assessment period.

Data element specifications

The table shows the assessment instruments using the Bladder—Incontinence data elements. Similar data elements assessing the frequency of incontinent events, but which do not address whether the patient/resident experienced incontinent events immediately prior to hospitalization, are currently in use the MDS 3.0, the LCDS 3.0, and IRF-PAI, and they were tested in the PAC PRD. The draft data elements, depicted below were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

Table: Assessment Instruments Using the Bladder - Incontinence Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
OASIS-C2			
IRF-PAI v 1.4	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
LCDS v3.0	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
MDS 3.0 v1.14	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	

CMS is soliciting comment on the Bladder - Incontinence data elements as shown below. One distinction from other versions in use is that it asks whether the patient/resident experienced incontinence prior to the current hospitalization.

C2a: Indicate the frequency of incontinent events.	
Enter Code ☐	0. No incontinent events during the assessment period **[SKIP to C3a: Bowel Device Use]** 1. Incontinent events less than daily (on only one or two days during the assessment period) 2. Incontinent events daily (at least once a day during the assessment period) 3. Incontinent events more than daily (more than once a day on each day during the assessment period) 8. Not applicable (e.g., patient/resident has indwelling catheter or no urine output due to renal failure) **[Please proceed to C3a: Bowel Device Use]** 9. Unknown
C2b: If the patient/resident has incontinent events **(C2a=1, 2, or 3)**, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation?	
Enter Code ☐	0. No 1. Yes 9. Unknown

CMS is seeking comment on the cross setting applicability of the Bladder – Incontinence data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bladder - Incontinence data elements are collected

The Bladder – Incontinence data elements can be administered by any clinician who has been trained to conduct this assessment. For these data elements, "incontinent event" is defined as any amount of involuntary bladder or bowel leakage during daytime and/or nighttime.
First, the assessor reviews the patient/resident's medical record as well as the nurse and nursing assistant notes. The assessor also directly observes the patient/resident and documents information pertaining to incontinent events. If this information cannot be obtained through medical record review, the assessor asks members of the care team and the patient and presents the response options.

If the patient/resident has incontinent events (i.e., if data element C2a is coded as 1, 2, or 3), the assessor then indicates if the patient/resident had incontinent events immediately prior to the hospitalization for current illness or exacerbation in data element C2b. Information to complete

this question can be found in the medical record, data recorded in the physician's patient/resident intake report, the patient's/resident's transfer documentation, and nursing and nursing assistant notes as well as through communication with the patient and family/caregivers.

How the Bladder - Incontinence data elements are coded

For data element C2a, "No incontinent events during the assessment period" is coded as 0; "Incontinent events less than daily (on only one or two days during the assessment period)" is coded as 1; "Incontinent events daily (at least once a day)" is coded as 2; and "Incontinent events more than daily (more than once a day on each day during the assessment period)" is coded as 3. If the patient has no urine output for reasons such as renal failure, the data element is coded as 8, "not applicable." In instances when the frequency of incontinent events is unknown, the data element is coded as 9.

If a patient/resident does not require assistance, data element C2b is coded as 0; if the patient/resident did not have incontinent events prior to current illness, exacerbation, or injury, it is coded as 0. If the patient did have incontinent events prior to current illness, exacerbation, or injury, C2b is coded as 1. If accurate information regarding incontinent events prior to hospitalization cannot be obtained, the data element is coded as 9, "unknown."

Bladder - Incontinence Interview

The data elements that comprise Bladder – Incontinence Interview assess the extent to which incontinent events of the bladder are perceived as a problem or burden by the patient/resident and caregiver.

Data element specifications

The Bladder – Incontinence Interview data elements are not in use in any of the four PAC assessment instruments, and were not tested in the PAC PRD. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

CMS is soliciting comment on the Bladder - Incontinence Interview data elements as shown below.

Bladder – Incontinence	
C5: Ask patient/resident: "Have you experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"	
Enter Code ☐	0. No **[SKIP to C6: Caregiver Perspective]** 1. Yes 9. Unable to assess/no response **[SKIP to C6]**
C5a: If patient/resident reports experiencing incontinent events **[If C5 = 1]**, **Ask Patient/Resident** – "How big of a problem or burden are incontinent events (or "accidents", "leaking") to you?"	
Enter Code ☐	1. No problem 2. Small problem 3. Moderate problem 4. Big problem 9. Unable to assess/no response
C6: Ask caregiver: "Has the patient/resident experienced any bladder incontinent events (or "accidents" or "leaking of urine") during the past 3 days?"	
Enter Code ☐	0. No **[SKIP to C7: Patient/Resident Perspective-Bowel Incontinent Events]** 1. Yes 8. Not applicable (i.e. caregiver not present) **[SKIP to C7]** 9. Unable to assess/no response **[SKIP to C7]**
C6a: If patient/resident experiences bladder incontinent events **[If C6=1]**, **Ask Caregiver** – "How big of a problem are the patient's/resident's bladder incontinent events in the context of their overall care?"	
Enter Code ☐	1. No problem 2. Small problem 3. Moderate problem 4. Big problem 9. Unable to assess/no response

CMS is seeking comment on the cross setting applicability of the Bladder - Incontinence Interview data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bladder - Incontinence Interview data elements are collected

The Bladder – Incontinence Interview data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements are administered through direct patient and caregiver interview. For all patients/residents who are able to communicate, the

assessor reads the question "Have you experienced any incontinent events (or 'accidents' or 'leaking of urine') during the past 3 days?" followed by each response option.

If patient/resident reports experiencing incontinent events (i.e., if data element C5 is coded as 1), then the assessor asks "How big of a problem or burden are incontinent events (or 'accidents', 'leaking') to you?" and reads each response option. No definitions for response options are given. The patient/resident should interpret response options based on his or her view of the extent to which incontinent events are problematic or burdensome.

If the patient/resident has a primary caregiver at the current facility (i.e., a member of the interdisciplinary care team such as a certified nursing assistant, registered nurse, or other caregiver who has been primarily responsible for the patient's/resident's daily care during the assessment window), the assessor asks "Has the patient/resident experienced any incontinent events (or 'accidents' or 'leaking of urine') during the past 3 days?"

If the caregiver reports that the patient/resident endorses having incontinent events within the past 3 days (i.e., the response to C6 is "Yes"), data element C6a should be administered. This item asks the caregiver "How big of a problem or burden are the patient's/resident's bladder incontinent events in the context of their overall care?"

How the Bladder - Incontinence Interview data elements are coded

For data element C5, the patient's response is coded on the form regardless of information identified via chart review (e.g., the medical records indicate the patient/resident has incontinent events, but the patient indicates otherwise). A response of "no" is coded as 0, "yes" is coded as 1; for instances in which information cannot be obtained and/or the patient does not respond, the assessor records a code of 9.

For data element C5a, "no problem (e.g., incontinent events are not viewed as burdensome or do not interfere with or restrict patient's/resident's lifestyle, activities, or behaviors)" is coded as 1; "small problem" is coded as 2; "moderate problem" is coded as 3; and "big problem" is coded as 4. If patient/resident cannot decide between two response options, the assessor records the higher code. If the patient self-reports incontinent events but does not respond to the question regarding how burdensome the events are after it is repeated three times, the data element is coded as 9.

For data element C6, "no" is coded as 0, "yes" is coded as 1, "not applicable" (e.g., caregiver is absent) is coded 8, and "unable to assess" is coded as 9.

For data element C6a, "no problem" is coded as 1, "small problem" is coded as 2, "moderate problem" is coded as 3, and "big problem" is coded as 4. For instances in which information cannot be obtained or the caregiver does not provide an answer, the data element is coded as 9. If the caregiver cannot decide between two response options, the assessor records the higher code (i.e., "big problem", if between "moderate" and "big").

Bowel - Device Use

The data elements that comprise Bowel – Device Use document use of equipment and devices to manage bowel incontinence. Devices include ileostomy, colostomy, or any other fecal diversion appliance.

Data element specifications

The table shows the assessment instruments using the Bowel—Device Use data elements. A similar data element assessing bowel device use was tested in the PAC PRD. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

Table: Assessment Instruments Using the Bowel - Device Use Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14			

CMS is soliciting comment on the Bowel - Device Use data elements as shown below.

C3a: Does this patient/resident use an indwelling or external device (ostomy or other fecal diversion appliance)?	
Enter Code ☐	0. No **[SKIP to C4a: Frequency of Incontinent Events]** 1. Yes
C3b: IF patient/resident has indwelling or external bowel device (e.g., ileostomy, colostomy), at what point was device first placed?	
Enter Code ☐	1. In current setting? 2. Prior setting? 3. Prior to hospitalization for this illness/exacerbation? 9. Unknown
C3c: If patient/resident has an indwelling or external bowel device **(C3a=1;Yes):** Does the patient/resident need assistance to manage equipment or devices related to bowel care for ANY reason (e.g., cognitive impairment/mental status, physical limitation, medical issue, etc.)?	
Enter Code ☐	0. No 1. Yes

CMS is seeking comment on the cross setting applicability of the Bowel - Device Use data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bowel - Device Use data elements are collected

The Bowel – Device Use data elements can be administered by any clinician who has been trained to conduct this assessment. Devices include ileostomy, colostomy, or any other fecal diversion appliance. First, the assessor reviews the patient/resident's medical record as well as the nurse and nursing assistant notes. The assessor then directly observes the patient/resident and documents information pertaining to bowel device use. If the patient/resident does not use a bowel device, the assessor skips the remaining data elements.

If the assessor indicates that the patient/resident has indwelling or external bowel device, he or she then moves on to data element C3b, which assesses when the device was first placed. If this information cannot be obtained through medical record review, the assessor should ask the patient/resident and/or caregiver. For example, if patient/resident is capable of communicating, the assessor may ask: "When was your colostomy first placed?" and read response options. If the patient/resident is unable to communicate or is unable to provide this information and has a primary caregiver (e.g., spouse, significant other, family member, professional caregiver, or

other relation who assisted in the patient's/resident's care outside of the current setting) who is physically present at the time the assessment is conducted, the assessor asks the caregiver when and why the device was placed and reads each response option.

The final data element (C3c) assesses whether the patient/resident needs assistance to manage equipment or devices related to bowel care for any reason. In this data element, "any reason" can be any cognitive, psychiatric, physical mobility, or medical reason that prevents the patient/resident from managing bowel device use independently. This section of the data element is completed if the patient/resident has a bowel device (i.e., if C3a is coded as 1, "yes"). Information to complete this question can be found in the medical record and nursing notes; through direct patient observation by the assessor; or through communication with the patient, care team, and family/caregivers.

How the Bowel - Device Use data elements are coded

If the patient does use a bladder device, C3a is coded 1. The assessor then indicates at what point the device was first placed in C3b; if the patient/resident does not use a bowel device, data element C3a is coded 0. If a patient/resident does not require assistance, C3c is coded as 0; if the patient/resident does require assistance, it is coded as 1.

Bowel – Incontinence

The data elements that comprise Bowel – Incontinence assess the frequency of bowel incontinence experienced by the patient during the assessment period, which may indicate a change in health status or need for additional assessment and/or alternative interventions.

Data element specifications

The table shows the assessment instruments using the Bowel—Incontinence data elements. Similar data elements assessing the frequency of incontinent events, but which do not address whether the patient/resident experienced incontinent events immediately prior to hospitalization, are currently in use the MDS 3.0, the LCDS 3.0, OASIS C2, and IRF-PAI and were tested in the PAC PRD. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

Table: Assessment Instruments Using the Bowel - Incontinence Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other Information
Assessment used in PAC PRD	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
OASIS-C2	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
IRF-PAI v1.4	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
LCDS v3.0	✓	Does not address whether the patient/resident experienced incontinence prior to hospitalization	
MDS 3.0 v1.14	✓	Does not address	

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other Information
		whether the patient/resident experienced incontinence prior to hospitalization	

CMS is soliciting comment on the Bowel - Incontinence data elements as shown below.

C4a: Indicate the frequency of incontinent events.	
Enter Code ☐	0. No incontinent events during the assessment period **[End Section]** 1. Incontinent event only once during the assessment period 2. Incontinent events more than once during the assessment period 3. No bowel output during the assessment period **[End Section]** 8. Not applicable (e.g., patient/resident has a colostomy) **[End Section]** 9. Unknown
C4b: If the patient/resident has incontinent events **(C4a=1 or 2)**, did the patient/resident have incontinent events immediately prior to the hospitalization for current illness or exacerbation?	
Enter Code ☐	0. No 1. Yes 9. Unknown

CMS is seeking comment on the cross setting applicability of the Bowel – Incontinence data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bowel - Incontinence data elements are collected

The Bowel – Incontinence data elements can be administered by any clinician who has been trained to conduct this assessment. For these data elements, "incontinent event" is defined as any amount of involuntary bowel leakage during daytime and/or nighttime.

First, the assessor reviews the patient/resident's medical record as well as the nurse and nursing assistant notes. The assessor also directly observes the patient/resident and documents information pertaining to incontinent events. If this information cannot be obtained through

medical record review, the assessor asks members of the care team and the patient and presents the response options.

If the patient/resident has incontinent events (i.e., if data element C4a is coded as 1 or 2), the assessor indicates whether the patient/resident had incontinent events immediately prior to the hospitalization for current illness or exacerbation. Information to complete this question can be found in the medical record, data recorded in the physician's patient/resident intake report, the patient's/resident's transfer documentation, and nursing and nursing assistant notes as well as through communication with the patient and family/caregivers.

How the Bowel - Incontinence data elements are coded

For data element C4a, "No incontinent events during the assessment period" is coded as 0; "Incontinent events only once during assessment period" is coded as 1; and "Incontinent events more than once during the assessment period" is coded as 2. If there is no bowel output during the assessment window, the data element is coded as 3. If the data element is not applicable to the patient (e.g., patient/resident has a colostomy), C4a is coded as 8.

If a patient/resident does not require assistance, data element C4b is coded as 0; if the patient/resident did not have incontinent events prior to current illness, exacerbation, or injury, it is coded as 0. If the patient did have incontinent events prior to current illness, exacerbation, or injury, it is coded as 1. If accurate information regarding incontinent events prior to hospitalization cannot be obtained, the data element is coded as 9, "unknown."

Bowel - Incontinence Interview

The data elements that comprise Bowel – Incontinence Interview assess the extent to which incontinent events of the bowel are perceived as a problem or burden by the patient/resident and caregiver.

Data element specifications

The Bowel – Incontinence Interview data elements are not in use in any of the four PAC assessment instruments and was not tested in the PAC PRD. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated moderate to excellent reliability.

CMS is soliciting comment on the Bowel - Incontinence Interview data elements as shown below.

Bowel - Incontinence	
C7: Ask patient/resident: "Have you experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"	
Enter Code ☐	0. No **[SKIP to C8: Caregiver Perspective]** 1. Yes 9. Unable to assess/no response **[SKIP to C8]**
C7a: If patient/resident experiences incontinent events **[If C7 = 1]**, **Ask Patient/Resident** – "How big of a problem or burden are incontinent events (or "accidents"; "leaking") to you?"	
Enter Code ☐	1. No problem 2. Small problem 3. Moderate problem 4. Big problem 9. Unable to assess/no response
C8: Ask caregiver: "Has the patient/resident experienced any bowel incontinent events (or "accidents" or "leaking of stool") during the past 3 days?"	
Enter Code ☐	0. No **[End section]** 1. Yes 8. Not applicable (i.e. caregiver not present) **[End section]** 9. Unable to assess/no response **[End section]**
C8a: If patient/resident experiences incontinent events **[If C8=1]**, **Ask Caregiver** – "How big of a problem are the patient's/resident's bowel incontinent events in the context of their overall care?"	
Enter Code ☐	1. No problem 2. Small problem 3. Moderate problem 4. Big problem 9. Unable to assess/no response

CMS is seeking comment on the cross setting applicability of the Bowel - Incontinence Interview data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Bowel - Incontinence Interview data elements are collected

The Bowel – Incontinence Interview data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements are administered through direct patient and caregiver interview. For all patients/residents who are able to communicate, the assessor reads the question "Have you experienced any bowel incontinent events (or 'accidents' or 'leaking of stool) during the past 3 days?" followed by each response option. The patient's response to this question is coded on the form, regardless of information identified via chart review (e.g., the medical records indicate the patient/resident has incontinent events, but the patient indicates that they do not).

If patient/resident reports experiencing bowel incontinent events (i.e., if data element C7 is coded as 1), the assessor asks "How big of a problem or burden are incontinent events (or 'accidents', 'leaking') to you?" and reads each response option. No definitions for response options are given. The patient/resident should interpret response options based on his or her view of the extent to which incontinent events are problematic or burdensome.

If the patient/resident has a primary caregiver at the current facility (i.e., a member of the interdisciplinary care team such as a certified nursing assistant, registered nurse, or other caregiver who has been primarily responsible for the patient's/resident's daily care during the assessment window), the assessor asks "Has the patient/resident experienced any incontinent events (or 'accidents' or 'leaking of stool) during the past 3 days?"

If the caregiver reports that the patient/resident endorses having incontinent events within the past three days (i.e., data element C8 is coded as "yes"), then data element C8a should be administered. This data element asks the caregiver "How big of a problem or burden are the patient's/resident's incontinent events in the context of their overall care?"

How the Bowel - Incontinence Interview data elements are coded

For data element C7, "no" is coded as 0, "yes" is coded as 1, and instances in which information cannot be obtained and/or the patient does not respond are coded 9.

For data element C7a, "no problem (e.g., incontinent events are not viewed as burdensome or do not interfere with or restrict patient's/resident's lifestyle, activities, or behaviors)" is coded as 1; "small problem" is coded as 2, "moderate problem" is coded as 3; and "big problem" is coded as

4. If patient/resident cannot decide between two response options, the assessor records the higher response code. If the patient self-reports incontinent events but does not respond to the question regarding how burdensome the events are after it is repeated three times, the data element is coded as 9.

For data element C7b, “no” is coded as 0, “yes” is coded as 1, “not applicable” (e.g., caregiver is absent) is coded as 8, and “unable to assess” is coded as 9.

For data element C8a, “no problem” is coded as 1, “small problem” is coded as 2, “moderate problem” is coded as 3, and “big problem” is coded as 4. In instances when this cannot be assessed or the caregiver does not provide an answer, the data element is coded as 9. If the caregiver cannot decide between two response options, the assessor records higher response code (i.e., “big problem”, if between “moderate” and “big”).

Medical Conditions: Pain

Pain is a highly prevalent medical condition that is frequently under-recognized, under-detected, and undertreated. Among PAC patients/residents pain is sometimes to be expected, but assessment and effective management of pain are nevertheless essential, both to maintain a standard of care and to support recovery. Medical recovery without pain management has been shown to lead to functional decline and complications related to immobility, such as skin breakdown and infections. Uncontrolled pain often leads to lower participation in rehabilitation and, ultimately, increased healthcare utilization and costs. Regular and systematic pain assessment enables pain management, which not only relieves symptoms but also promotes person-centered care, helps with transitions between care settings, enhances participation in rehabilitation, decreases social isolation, and improves mental health. Although pain treatments may not be uniformly effective, evidence indicates that pain assessments can be applied broadly across PAC settings. A standardized set of pain assessment data elements could therefore help PAC providers assess patients/residents' pain through the duration of their stay and across the continuum of care.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of Medical Conditions: Pain.

- Pain Frequency
- Pain Severity
- Pain Effect on Sleep
- Pain Interference – Therapy Activities
- Pain Interference – Other Activities
- Pain Relief
- Observational Assessment of Pain or Distress

Pain Frequency

The Pain Frequency data element asks patients/residents to self-report how often they have experienced pain on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. The frequency of pain is an important characteristic of the pain and pain management, and provides a basis for evaluating treatment need and response, as well as the extent to which pain may be affecting the patient's/resident's quality of life.

Data element specifications

The table shows the assessment instruments using the Pain Frequency data element. A similar data element assessing pain frequency is currently in use in the MDS 3.0. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Pain Frequency Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	5 day lookback	

CMS is soliciting comment on the Pain Frequency data element as shown below.

H2: Pain Frequency	
Enter Code ☐	**Ask Patient/Resident** - "How often during the past 3 days have you had pain or hurting?" 1. Rarely or not at all 2. Occasionally 3. Frequently 4. Almost constantly 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Frequency data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Pain Frequency data element is collected

The Pain Frequency data element can be administered by any clinician who has been trained to conduct this assessment. The assessor reads the question and response choices to the patient/resident while showing the response options to the patient/resident on a written sheet or card. The patient/resident can respond verbally and/or by pointing to the written response choice. No pre-determined definitions are offered to the patient/resident. The response should be based on the patient's/resident's interpretation of frequency response options.

How the Pain Frequency data element is coded

"Rarely or not at all" is coded as 1; "occasionally" is coded as 2; "frequently" is coded as 3; and "almost constantly" is recorded as 4. If the patient/resident is unable to decide between two options, then the assessor should code for the option with the higher frequency to ensure that the patient's/resident's pain frequency is not under-reported. If the patient/resident is unable to answer the question (e.g., the patient does not respond or replies "I don't know," "can't say," "it comes and goes," "it depends on what I'm doing") after three repetitions, this is considered a nonresponse and is coded as 9.

Pain Severity

Consistent use of a standardized pain severity assessment improves the validity and reliability of pain assessment. Using the same scale across different PAC settings may improve continuity of care. The Pain Severity data element assesses whether the patient/resident is responding to pain medication regimens and/or non-pharmacological interventions, and consists of one numeric rating scale.

Data element specifications

The table shows the assessment instruments using the Pain Severity data element. A similar data element assessing pain severity is currently in use in the MDS 3.0 and was tested in the PAC PRD. This data element as depicted below uses a four-point scale to assess pain severity, instead of a 0 to 10 rating. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Pain Severity Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	2-day assessment period	Substantial to almost perfect agreement, kappa range of 0.79 to 0.88
OASIS-C2		Asks about any standardized pain assessment being conducted, and indication of severe pain	
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Varies in wording (P*ain Intensity*) 5-day assessment period	

CMS is seeking comment on the cross-setting applicability of the Pain Severity data element as shown below.

H5: Pain Severity	
Enter Code ☐	**Ask Patient/Resident -** "Please rate the intensity of your **worst** pain over the last 3 days." 1. Mild 2. Moderate 3. Severe 4. Very severe, horrible 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Severity data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Pain Severity data element is collected

The Pain Severity data element can be administered by any clinician who has been trained to conduct this assessment. The data element is completed for all patients/residents capable of any communication and for whom an interpreter is present or not required.

To complete the data element, the assessor reads the question and response choices as written while showing the patient/resident the response scale on a written sheet. This may help some patients/residents in accurately responding to the data element. The patient/resident may provide a verbal response, point to the written response, or both. No pre-determined definitions may be offered to the patient/resident. The response should be based on the patient's/resident's interpretation of severity response options.

How the Pain Severity data element is coded

The assessor codes the response as 1 if the patient/resident selects "Mild"; 2 if the patient/resident selects "Moderate"; 3 if the patient/resident selects "Severe"; 4 if the patient/resident selects "Very severe, horrible"; and 9 if the patient/resident is unable to respond or does not answer after three repetitions of the question.

Pain Effect on Sleep

The Pain Effect on Sleep data element asks patients/residents to self-report how often pain has limited their ability to sleep on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. This data element may inform decisions on the need to adjust the timing of pain interventions to promote better sleep, and provides a basis for evaluating treatment schedules and response to pain treatment.

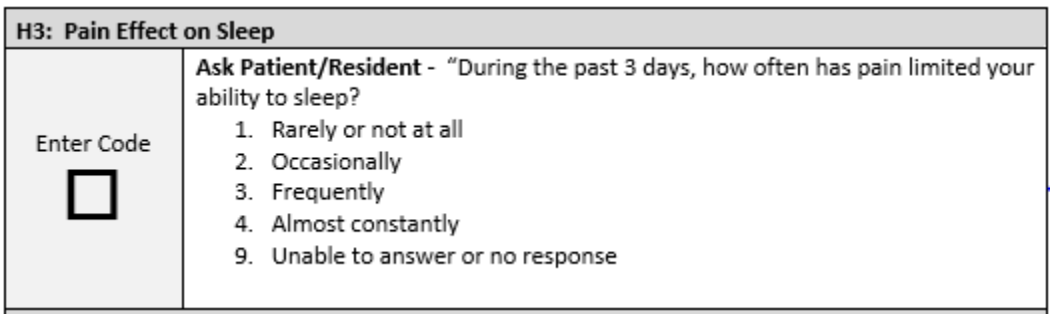
Data element specifications

The table shows the assessment instruments using the Pain Effect on Sleep data element. A similar data element is currently in use in the MDS 3.0. The PAC PRD also tested a similar data element, which showed good feasibility and reliability across PAC settings. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Pain Effect on Sleep Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the Pain Effect on Sleep data element as shown below.



H3: Pain Effect on Sleep	
Enter Code ☐	**Ask Patient/Resident** - "During the past 3 days, how often has pain limited your ability to sleep? 1. Rarely or not at all 2. Occasionally 3. Frequently 4. Almost constantly 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Effect on Sleep data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC

- Utility for describing case mix

How the Pain Effect on Sleep data element is collected

The Pain Effect on Sleep data element can be administered by any clinician who has been trained to conduct this assessment. The assessor reads the question and response choices to the patient/resident while showing the response options to the patient/resident on a written sheet or card. The patient/resident can respond verbally and/or by pointing to the written response choice. No pre-determined definitions are offered to the patient/resident. The response should be based on the patient's/resident's interpretation of frequency response options.

How the Pain Effect on Sleep data element is coded

"Rarely or not at all" is coded as 1, "occasionally" is coded as 2, "frequently" is coded as 3, and "almost constantly" is recorded as 4. If the patient/resident is unable to decide between two options, then the assessor should record the code for the option with the higher frequency. If the patient/resident is unable to answer the question (e.g., no response or patient/resident becomes frustrated and states "I don't know") after three repetitions, this is considered a nonresponse and is coded as 9.

Pain Interference - Therapy Activities

The data elements that comprise Pain Interference – Therapy Activities asks patients/residents to self-report how often pain has limited their ability to participate in rehabilitation therapy activities on a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. Assessing frequency of pain interference with therapy-related activities can help to gauge the impact of pain on quality of life during PAC and has implications for care planning.

Data element specifications

The table shows the assessment instruments using the Pain Interference—Therapy Activities data elements. The PAC PRD tested a data element that assesses the effect of pain on participation in therapy activities, which showed good feasibility and reliability across PAC settings. The draft data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Pain Interference - Therapy Activities Data Elements

Instrument	Has Same or Similar Data Elements	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14			

CMS is soliciting comment on the Pain Interference – Therapy Activities data elements as shown below.

H4: Pain Interference - Therapy Activities	
Enter Code ☐	**Ask Patient/Resident -** "During the past 3 days, have you been offered any physical, occupational, or speech therapies by your care providers?" 0. No **[SKIP to H4b: Pain Interference-Other Activities]** 1. Yes **[Proceed to H4a: Pain Interference-Therapy Activities]** 9. Unable to answer or no response **[SKIP to H4b: Pain Interference-Other Activities]**
H4a: Pain Interference - Therapy Activities	
Enter Code ☐	**If yes: Ask Patient/Resident –** "During the past 3 days, how often have you limited your participation in physical, occupational, and/or speech therapy sessions due to pain?" 1. Rarely or not at all 2. Occasionally 3. Frequently 4. Almost constantly 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Interference – Therapy Activities data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Pain Interference – Therapy Activities data elements are collected

The Pain Interference – Therapy Activities data elements can be administered by any clinician who has been trained to conduct this assessment. First, the assessor reads the first data element (H4), which asks if the patient/resident has been offered rehabilitation therapies by care providers in the past 3 days. The assessor also reads a list of activities meeting the definition of rehabilitation therapies.

The second data element (H4a) is read only if the patient/resident responds "yes" to the first question. The assessor reads the second question and response choices to the patient/resident while showing the response options to the patient/resident on a written sheet or card. The patient/resident can respond verbally and/or by pointing to the written response choice. No pre-determined definitions are offered to the patient/resident. The response should be based on the patient's/resident's interpretation of frequency response options.

How the Pain Interference - Therapy Activities data elements are coded

For H4, ‘no” is coded as 0, and “Yes” is coded as 1. If the patient is unable to answer the question (e.g., patient/resident becomes frustrated and states “I don’t know”) after three repetitions of the question, this is considered a nonresponse and is coded as 9.

For H4a, “rarely or not at all” is coded as 1, “occasionally” is coded as 2, “frequently” is coded as 3, and “almost constantly” is coded as 4. If the patient/resident is unable to decide between two options, then the assessor should code for the option with the higher frequency. If the patient/resident is unable to answer the question (e.g., no response or patient/resident becomes frustrated and states “I don’t know”) after three repetitions, this is considered a nonresponse and is coded as 9.

Pain Interference - Other Activities

The Pain Interference – Other Activities data element asks patients/residents to rate how often pain has limited their ability to participate in other activities a scale from rarely (1) to almost constantly (4) within a 3-day assessment period. Assessing frequency of pain interference with daily activities can help to gauge impact of pain on quality of life and ability/motivation to participate in activities that the patient/resident values and has implications for care planning.

Data element specifications

The table shows the assessment instruments using the Pain Interference – Other Activities data element. A similar data element assessing the effect of pain on participation in activities is currently in use in the MDS 3.0. It was also tested in the PAC PRD and showed good feasibility and reliability across PAC settings. The OASIS C2 also has a similar item that assesses the frequency with which pain interferes with activity or movement. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Pain Interference - Other Activities Data Element

Instrument	**Has Same or Similar Data Elements**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓		
OASIS-C2	✓	Assesses frequency with which pain interferes with activity or movement	
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

CMS is soliciting comment on the Pain Interference – Other Activities data element as shown below.

H4b: Pain Interference - Other Activities	
Enter Code ☐	**Ask Patient/Resident -** "During the past 3 days, how often have you limited your participation in other activities (**excluding** physical, occupational, and/or speech therapy sessions) due to pain?" 1. Rarely or not at all 2. Occasionally 3. Frequently 4. Almost constantly 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Interference - Other Activities data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Pain Interference - Other Activities data element is collected

The Pain Interference – Other Activities data element can be administered by any clinician who has been trained to conduct this assessment. The assessor reads the question and response choices to the patient/resident while showing the response options to the patient/resident on a written sheet or card. The patient/resident can respond verbally and/or by pointing to the written response choice. No pre-determined definitions are offered to the patient/resident. The response should be based on the patient's/resident's interpretation of frequency response options.

How the Pain Interference - Other Activities data element is coded

"Rarely or not at all" is coded as 1, "occasionally" is coded as 2, "frequently" is coded as 3, and "almost constantly" is recorded at 4. If the patient/resident is unable to decide between two options, then the assessor should code for the option with the higher frequency. If the patient/resident is unable to answer the question (e.g., no response or patient/resident becomes frustrated and states "I don't know") after three repetitions, this is considered a nonresponse and is coded as 9.

Pain Relief

The Pain Relief data element asks patients/residents to rate how much relief they have felt from pain due to pain treatments or medications on a scale from no relief (1) to very much relief (4) within a 3-day assessment period. Asking about relief from pain is important in determining the extent to which pain management regimen could improve the patient's/resident's quality of life.

Data element specifications

The Pain Relief data element was derived from the Brief Pain inventory, a widely used measure which has shown good reliability and validity in PAC settings. Pain Relief is not in use in any of the four PAC assessment instruments, and it was not tested in the PAC PRD. This data element underwent cognitive testing and revisions were made based on PAC patient feedback. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

CMS is soliciting comment on the Pain Relief data element as shown below.

H6: Pain Relief	
Enter Code ☐	**Ask Patient/Resident –** " During the past 3 days how much relief have you felt from pain due to pain treatments and/or medications?" 1. No relief 2. Some relief 3. Quite a bit of relief 4. Very much relief 8. Not applicable- patient/resident has not received pain treatments or medications in the past 3 days 9. Unable to answer or no response

CMS is seeking comment on the cross setting applicability of the Pain Relief data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Pain Relief data element is collected

The Pain Relief data element can be administered by any clinician who has been trained to conduct this assessment. The assessor reads the question and response choices to the patient/resident while showing the response options to the patient/resident on a written sheet or card. The patient/resident can respond verbally and/or by pointing to the written response choice.

No pre-determined definitions are offered to the patient/resident. The response should be based on the patient's/resident's interpretation of relief response options.

How the Pain Relief data element is coded

"No relief" is coded as 1, "some relief" is coded as 2, "quite a bit of relief" is coded as 3, and "very much relief" is recorded as 4. If the patient/resident is unable to answer the question (e.g., "sometimes it helps but other times it doesn't. I can't say") after three repetitions, this is considered a nonresponse and is coded as 9.

Observational Assessment of Pain or Distress

The data elements that comprise Observational Assessment of Pain or Distress collect staff observations of patients'/residents' expressed behavioral indicators of potential pain or distress and should be administered to all patients/residents who are unable to communicate (i.e., cannot reliably make self-understood via verbal communication, written communication, communication board, eye blinks, etc.).

Data element specifications

The Observational Assessment of Pain or Distress data elements were derived from the Indicators of Possible Pain or Distress item used in the MDS 3.0 and tested in the PAC PRD, the Frequency of Pain or Distress item used in the MDS, and from the advice of technical experts.

Table: Assessment Instruments Using the Observational Assessment of Pain or Distress Data Elements

Instrument	**Has Same or Similar Data Elements**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	Does not include frequency or evidence that indicators diminished/resolved	
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Does not include evidence that indicators diminished/resolved	

CMS is soliciting comment on the Observational Assessment of Pain or Distress data elements as shown below.

E1a. OBSERVATIONAL ASSESSMENT OF PAIN OR DISTRESS.

For all patients/residents who are unable to participate in the pain interview, please note whether any of the following behaviors were observed.

Patients/residents should be observed twice daily (morning AND evening) during care activities

(i.e., during transfer procedures, repositioning, bathing, toileting, wound care/dressing changes, range of motion, ambulating, or other exercises, etc.), when behavioral signs of potential pain or distress are most likely to be expressed, over the course of 3 consecutive days.

CHECK ALL THAT APPLY

☐ **a=**Non-verbal sounds (e.g., crying, whining, gasping, moaning, or groaning)

☐ **b=**Vocal complaints of pain (e.g., "that hurts, ouch, stop")

☐ **c**=Facial expressions (e.g., grimaces, winces, wrinkled forehead, furrowed brow, clenched teeth or jaw, rapid eye blinking; tightly closed eyes)

☐ **d=**Body movements or postures (e.g., bracing, guarding, rubbing or massaging a body part/area, clutching or holding a body part during movement, rigid, tense body posture; withdrawing an extremity to an external stimulus; fidgeting; increased pacing, rocking; restricted movement; gait or mobility changes)

☐ **z=**None of these signs observed or documented.

E1b. For patients/residents who demonstrated any indicators of potential pain or distress listed in E1a (*Observational Assessment of Pain or Distress*), identify the frequency with which patient complains or shows evidence of potential pain or distress over the past 3 days.

☐ 1 = Indicators of potential pain or distress observed less than daily

☐ 2 = Indicators of potential pain or distress observed daily (at least once per day on each day of the assessment window)

☐ 3 = Indicators of potential pain or distress observed more than daily (multiple times per day on each day of the assessment window)

☐ 9 = Unknown or unable to assess

E1c. For patients/residents who demonstrated any indicators of potential pain or distress listed in E1a (*Observational Assessment of Pain or Distress*), is there any evidence that these indicators resolved or diminished in response to pain medications or treatments over the past 3 days?

- ☐ 0 = No
- ☐ 1 = Yes
- ☐ 8 = Not applicable – patient/resident has not received pain medications or treatments within the past 3 days
- ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Observational Assessment of Pain or Distress data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Observational Assessment of Pain or Distress data elements are collected

Data sources for this item includes the patient's/resident's medical record, direct observation of the patient/resident, and communication from members of the interdisciplinary care team (e.g., nurses, certified nursing assistants, physical and occupational therapists, physicians) and non-staff caregiver(s) (e.g., family members) who have observed the patient/resident during care activities.

First, the assessor carefully reviews the patient's/resident's medical record for any mention of pain or distress-related behaviors over the past 3 days. Data recorded in the nursing and nursing assistant notes are critical for this section, as are data from therapist notes (e.g., physical and occupational therapy) when applicable. Next, the assessor interviews the direct care provider(s) on the interdisciplinary care team who worked most closely with the patient/resident during the past 3 days, such as nursing/nursing assistant staff. Last, the assessor directly observes the patient/resident if possible during care activities, when indicators of pain or distress are most likely to be demonstrated.

How the Observational Assessment of Pain or Distress data elements are coded

For each indicator 1 through 9, the assessor checks 1 if non-verbal sounds were observed, including but not limited to crying, whining, gasping, moaning, or groaning, or reported during the look-back period. A code of 2 is checked if vocal complaints of pain are observed, including but not limited to "that hurts," "ouch," or "stop." A code of 3 is checked if facial expressions indicating pain are observed, including but not limited to grimaces, winces, wrinkled forehead, furrowed brow, clenched teeth or jaw, rapid eye blinking, or tightly closed eyes. A code of 4 is

checked for indications of pain through body movements or posture, including but not limited to bracing, guarding, rubbing or massaging a body part/area; clutching or holding a body part during movement; rigid, tense body posture; withdrawing an extremity to an external stimulus; fidgeting; increased pacing, rocking; restricted movement; gait or mobility changes. A code of 9 is checked if medical record review, direct care provider interview(s), and direct observation of the patient/resident provide no evidence of pain or distress indicators.

Information obtained from different sources (e.g., direct observation, direct care staff, medical record, lay care providers) may conflict. For instances in which one source of information suggests that an indicator was observed and another source of information suggests that the indicator was not observed during the assessment window, and the assessor cannot definitively resolve this discrepancy, the assessor should code that the indicator was observed on the assessment form (i.e., check the corresponding box for this indicator) in order to avoid underreporting indicators of potential pain or distress.

Impairments of Hearing and Vision

Hearing and vision impairments are common conditions among older adults that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Specifically, hearing impairments can hinder exchange of information and instructions between providers and patients/residents, and visual impairments can increase risk of falls. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess and treat these conditions increases the likelihood that patients/residents will require more intensive and prolonged treatment. Onset of these conditions can be subtle, so accurate screening tools and follow-up evaluations are essential to determining which patients/residents need hearing- or vision-specific medical attention or assistive devices and ensuring that person-directed care plans are developed to accommodate a patient's needs. Accurate diagnosis and management of a hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of Impairments of Hearing and Vision:

- Glasses / Corrective Lenses
- Hearing Aid

Glasses/Corrective Lenses

The Glasses/Corrective Lenses data element assesses the patient/resident's dependence on any device for vision impairment. Once vision impairment has been identified, use of corrective lenses (glasses, contact lenses, magnifying glass, etc.) may help mitigate a patient's potential problems reading and understanding forms, instructions, and medication labels. Specifically, corrective devices may enable patients/residents to better understand activities relevant to their care. Many patients/residents who do not have corrective lenses could benefit from them. Others may have corrective lenses that are not sufficient, or may not be carrying them upon arrival at the PAC setting.

Data element specifications

The table shows the assessment instruments using the Glasses/Corrective Lenses data element. A similar data element assessing a resident's use of corrective lenses is currently in use in the MDS 3.0; however, this data element records whether corrective lenses are used during the assessment, not if the resident uses corrective lenses regularly in everyday life. The draft data element, depicted below, performed well in the Alpha 1 pilot test.

Table: Assessment instruments Using the Glasses/Corrective Lenses Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Asks whether glasses are used during assessment, not if used regularly	

CMS is soliciting comment on the Glasses/Corrective Lenses data element as shown below.

D1. Does the patient/resident use glasses (or other corrective lenses) regularly?	
Enter Code ☐	0. No 1. Yes

CMS is seeking comment on the cross setting applicability of the Glasses/Corrective Lenses data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Glasses/Corrective Lenses data element is collected

The data element Glasses/Corrective Lenses can be administered by any clinician who has been trained to conduct this assessment. Prior to beginning, the assessor is instructed to ask the patient/resident whether he or she uses eyeglasses or other vision aids and whether the eyeglasses or vision aids are with them in the PAC setting. (Note: visual aids do not include surgical lens implants.) If the patient/resident cannot respond, the assessor then checks with family and care staff regarding the patient's/resident's use of vision aids during the 3-day assessment period. The assessor also observes whether the patient/resident uses corrective lenses (or other vision aid) during the assessment and may refer to patient/resident documentation (e.g., medical record) and other staff observations. "Regularly" is defined as use for certain specific activities (e.g., reading) on a daily or almost daily basis or for more than 25 percent of the day each day, regardless of activities.

How the Glasses/Corrective Lenses data element is coded

Regular use of glasses or corrective lenses is coded as 1; no regular use of corrective lenses is coded as 0.

Hearing Aid

The Hearing Aid data element assesses the patient/resident's dependence on any device for hearing impairment. Once a hearing impairment has been identified, use of a hearing aid may help mitigate many potential communication problems with staff and caregivers. Specifically, hearing devices may enable patients/residents to better communicate their wishes regarding their care plans and other services. Use of hearing aids—or other non-technical methods of adapting to hearing loss (speaking loudly, increasing the volume on televisions or telephone speakers)—may improve a patient's/resident's ability to engage in activities of daily living and become more sociable. Moreover, increases in ability to hear and communicate may decrease the risk of depression, falls, or injury, and improve a patient's/resident's overall quality of life. Many persons who benefit from and own hearing aids do not have them upon arrival at the nursing home, or arrive with hearing aids that are not functional.

Data element specifications

The table shows the assessment instruments using the Hearing Aid data element. A similar data element assessing a resident's use of a hearing aid is currently in use in the MDS 3.0; however, this data element records whether a hearing aid is used during the assessment, not if the resident uses hearing aids regularly in everyday life. The draft data element, depicted below, performed well in the Alpha 1 pilot.

Table: Assessment Instruments Using the Hearing Aid Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Asks whether hearing aid is used during assessment, not if used regularly	

CMS is soliciting comment on the Hearing Aid data element as shown below.

E1. Does the patient/resident use a hearing aid (or other hearing appliance) regularly?	
Enter Code ☐	0. No, the patient/resident does **NOT** use a hearing aid/appliance regularly. 1. Yes, the patient/resident uses a hearing aid/appliance regularly.

CMS is seeking comment on the cross setting applicability of the Hearing Aid data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Hearing Aid data element is collected

The data element Hearing Aid can be administered by any clinician who has been trained to conduct this assessment. Prior to beginning the assessment, the assessor is instructed to ask the patient/resident whether he or she owns a hearing aid or other hearing appliance and, if so, whether it is in the PAC setting. If the patient is unable to respond to a verbal question, the question is written down and read by the patient/resident. If the patient/resident cannot respond to the verbal or written question, the assessor then checks with family and care staff regarding the patient's/resident's regular use of hearing aids. The assessor also observes whether the patient/resident uses hearing aids during the assessment and may refer to patient/resident documentation (e.g., medical record) and other staff observations.

How the Hearing Aid data element is coded

"Regularly" is defined as for either certain specific activities (e.g., reading) on a daily or almost daily basis or for more than 25 percent of the day each day, regardless of activities. Regular use of a hearing aid is coded as 1; no regular use of a hearing aid is coded as 0.

Medication Reconciliation

Almost one-tenth of Medicare beneficiaries experienced an adverse drug event (ADE), such as delirium, bleeding, fall or injury, or constipation, during their stay in a SNF in 2011. Of these, two-thirds were classified as preventable.[19] Approximately one-half of all hospital-related medication errors and one-fifth of ADEs occur during transitions between settings, including admission to, or discharge from a hospital to home or a PAC setting, or transfer between hospitals.[20-22]

Medication reconciliation (MR) is a process of reviewing an individual's complete and current medication list. Standardized MR is important because of the large numbers of ADEs in PAC settings and the potential to promote person-centered, high-quality care by, for example, facilitating better care continuity and coordination, data exchange and interoperability between settings, payment analysis, and longitudinal outcome analysis. Using results from a previous study of SNFs,[19] we estimated the number of Medicare Fee-for-Service (FFS) patients in the four PAC settings with at least one ADE: 522,554 in HHAs, 206,236 in SNFs, 31,659 in IRFs, and 5,502 in LTCHs. MR interventions have been shown to be a cost-effective way to avoid ADEs by reducing errors, especially when medications are reviewed by a pharmacist and when MR is done in conjunction with the use of electronic medical records.[23-27] Medication discrepancies identified during MR can be resolved by changing the prescribed dose, discontinuing or restarting medications, and providing patients with better information about their prescriptions.

The data elements in this section address the process of MR at care transition points, such as any transition between acute care hospital stays and a PAC setting, or between PAC settings. The proposed MR data elements address the five steps of MR outlined by the Joint Commission: (1) develop a list of current medications; (2) develop a list of medications to be prescribed; (3) compare medications on the lists; (4) make clinical decisions based on the comparisons; and (5) communicate the new list to the patient/resident and appropriate caregivers.

The respondent for data elements below is the provider, not the patient/resident. The provider (chosen by each PAC facility/agency) will need to search for information in the patient's/resident's chart and other information sources in order to document whether certain steps of the medication reconciliation process occurred. This respondent may not necessarily be the same provider who completed medication reconciliation. Thus, clear documentation and time stamping will be key to accurately reflecting what happened in the MR process via these assessment data elements.

The sources of information to inform the MR process should include but not be limited to:

- Inspection of all medications, including the container label as well as the pills inside the container
- Patient/resident assessment, which involves asking the patient/resident to ask what drugs the patient/resident may have
- Family caregiver assessment, which involves asking as a proxy informant what drugs the patient/resident may have
- Electronic and paper medical records

- Clinical records
- Plan of care
- Medication administration records (MARs) or electronic MAR (eMARs)
- Risk management system
- Pharmacies
- Prescribers
- Discharge summary
- Discharge orders
- Transfer orders (sometimes called "discharge [or transfer] physician orders")
- Discussions with other staff responsible for completing MR.

Specific places in the patient/resident chart in which information could be found include "miscellaneous notes" or "nurse's notes" sections.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of Medication Reconciliation.

- Medication Reconciliation – Completion
- Medication Reconciliation – Use of Medications in Specific Classes
- Medication Reconciliation – Indication
- Medication Reconciliation – Discrepancies
- Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement
- Medication Reconciliation – Discrepancies Communicated to Physician
- Medication Reconciliation – Recommended Actions Taken
- Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy

Medication Reconciliation – Completion

The Medication Reconciliation – Completion data element asks the assessor whether this process took place during the allotted time frame. If not, remaining questions may not be relevant. The assessor should base his or her answer on documentation. Subsequent MR, to improve patient safety if not previously done, is desirable; however MR currently underway should not be used to answer questions in this assessment.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The Completion draft data element, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Completion as shown below.

F1b. Is there documentation that medication reconciliation was done?
☐ 0 = No ☐ 1 = Yes

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Completion data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Completion data element is collected

The assessor reviews the record for documentation of reconciliation. The definition of medication reconciliation should follow the Joint Commission's five-step process: 1) develop a list of current medications; 2) develop a list of medications to be prescribed; 3) compare medications on the lists; 4) make clinical decisions based on the comparisons; and 5) communicate the new list to the patient/resident and appropriate caregivers. All five steps should have occurred within the 3-day look-back period for medication reconciliation to be considered complete.

How the Medication Reconciliation – Completion data element is coded

A code of 0 is recorded if the assessor does not find evidence of reconciliation in the record. A code of 1 is recorded if a check box or a reconciled list or other indicator of complete MR is found in the record.

Medication Reconciliation – Use of Medications in Specific Classes

The data elements that comprise Medication Reconciliation – Use of Medications in Specific Classes assess whether and for how long a patient/resident is taking any drugs in a number of classes, most of which are most likely to cause adverse events noted by the HHS National Action Plan for Adverse Drug Event Prevention, Office of Inspector General Report on Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, and the CDC Report on The Core Elements of Antibiotic Stewardship for Nursing Homes.

Data Element Specification

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The Use of Medications in Specific Classes draft data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Use of Medications in Specific Classes data elements as shown below.

F1c. Indicate the **number of <u>DAYS</u>** the patient/resident received the following medications during the last 7 days or since admission/discharge/SOC/ROC if less than 7 days. If the patient/resident is taking more than one medication in the same class, the highest number of days should be used.	
Enter Days ☐	**F1c1**: Anti-coagulants
Enter Days ☐	**F1c2:** Anti-platelets (excluding 81 mg aspirin)
Enter Days ☐	**F1c3:** Hypoglycemics (for example, insulin)
Enter Days ☐	**F1c4:** Opioids
Enter Days ☐	**F1c5:** Anti-psychotics
Enter Days ☐	**F1c6:** Anti-microbials (excluding topicals)
Enter Days ☐	**F1c7:** Antidepressants
Enter Days ☐	**F1c8:** Diuretics
Enter Days ☐	**F1c9:** Antianxiety
Enter Days ☐	**F1c10:** Hypnotics

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Use of Medications in Specific Classes data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Use of Medications in Specific Classes data elements are collected

The assessor checks the patient's/resident's medication list for medications in the specified drug classes and notes the number of days the patient/resident took medications in this class in the past 7 days or since admission/start of care (SOC)/resumption of care(ROC) if less than 7 days.

How the Medication Reconciliation – Use of Medications in Specific Classes data elements are coded

The assessor records a number representing the number of days the patient took medications in this class in the past 7 days or since admission/SOC/ROC. If a patient/resident is taking more than one medication in the same class, the longest period should be used.

Medication Reconciliation – Indication

The data elements that comprise Medication Reconciliation – Indication assess whether the prescriber included an indication for each medication in the patient's/resident's list or lists of medications.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. In Alpha 1 testing, assessors reported indications in about 25 percent of patients assessed, with the rate varying by setting. Patients in SNFs had the highest rates, between 42 percent (facility nurses) and 56 percent (research nurses); while fewer than 10 percent of patients receiving home health care were assessed as having indications in their medication list(s). The draft Indication data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Indication data elements as shown below.

F1d. Was there an indication noted for all medications in these medication classes?

CHECK ONE BOX FOR EACH OF THE MEDICATION CLASSES THE PATIENT/RESIDENT IS TAKING

	NO (0)	YES (1)
F1d1: Anti-coagulants		
F1d2: Anti-platelets (excluding 81 mg aspirin)		
F1d3: Hypoglycemics (for example, insulin)		
F1d4: Opioids		
F1d5: Anti-psychotics		
F1d6: Anti-microbials (excluding topicals)		
F1d7: Antidepressants		
F1d8: Diuretics		
F1d9: Antianxiety		
F1d10: Hypnotics		

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Indication data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Indication data elements are collected

The Medication Reconciliation – Indication (F1d) data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements ask if the prescriber included an indication for each medication on the list or multiple lists obtained from the information sources.

How the Medication Reconciliation – Indication data elements are coded

For data elements F1d1-F1d10, the assessor marks 0 for "No" and 1 for "Yes."

Medication Reconciliation - Discrepancies

The data elements that comprise Medication Reconciliation – Discrepancies assess whether the review of medication lists identified any medication discrepancies. This is an important step for preventing mistakes in prescription of medicine to patients/residents.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation - Discrepancies data elements as shown below.

F1e. Were there discrepancies involving medications in these medication classes?

CHECK ONE BOX FOR EACH OF THE MEDICATION CLASSES THE PATIENT/RESIDENT IS TAKING

IF NO DISCREPANCIES ARE IDENTIFIED IN THE LIST OF MEDICATION CLASS NOTED BELOW SKIP TO F1i.

	NO (0)	**YES (1)**	**Missing information on sources OR lack of documentation (9)**
F1e1: Anti-coagulants			
F1e2: Anti-platelets (excluding 81 mg aspirin)			
F1e3: Hypoglycemics (for example, insulin)			
F1e4: Opioids			
F1e5: Anti-psychotics			
F1e6: Anti-microbials (excluding topicals)			
F1e7: Anti-depressants			
F1e8: Diuretics			
F1e9: Antianxiety			
F1e10: Hypnotics			

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Discrepancies data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Discrepancies data elements are collected

The Medication Reconciliation – Discrepancies (F1e) data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements ask if the review identified any medication discrepancies.

How the Medication Reconciliation – Discrepancies data elements are coded

For F1e, the assessor marks 0 for "No," 1 for "Yes" and 9 for "Unknown; missing information sources or lack of documentation."

Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement

The data elements that comprise Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement ask about the patient's/resident's involvement and the patient's/resident's family/formal caregiver's involvement in addressing high-risk discrepancies or potential adverse drug events.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements as shown below.

F1f. Were the patient's/resident's discrepancies regarding these medication classes addressed by involving the patient/resident or patient's/resident's family/formal caregiver?

CHECK ONE BOX FOR EACH OF THE MEDICATION CLASSES THE PATIENT/RESIDENT IS TAKING

	NO (0)	**YES (1)**	**Missing information on sources OR lack of documentation (9)**
F1f1: Anti-coagulants			
F1f2: Anti-platelets (excluding 81 mg aspirin)			
F1f3: Hypoglycemics (for example, insulin)			
F1f4: Opioids			
F1f5: Anti-psychotics			
F1f6: Anti-microbials (excluding topicals)			
F1f7: Anti-depressants			
F1f8: Diuretics			
F1f9: Antianxiety			
F1f10: Hypnotics			

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements are collected

The Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement (F1f) data elements can be administered by any clinician who has been trained to conduct this assessment. The data elements ask whether the PAC provider involved the

patient/resident or their family/formal caregiver in addressing high-risk discrepancies or potential adverse drug events.

How the Medication Reconciliation – Discrepancies Addressed with Patient/Resident/Caregiver Involvement data elements are coded

For F1f, the assessor marks 0 for “No,” 1 for “Yes” and 9 for “missing information sources or lack of documentation.”

Medication Reconciliation – Discrepancies Communicated to Physician

The data elements that comprise Medication Reconciliation – Discrepancies Communicated to Physician assess whether the PAC provider contacted a physician regarding the all high-risk discrepancies and potential adverse drug events within a 24-hour timeframe. It also asks about the timeline for contacting the physician.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Discrepancies Communicated to Physician data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Discrepancies Communicated to Physician data elements as shown below.

F1g. Were discrepancies regarding these medication classes communicated to the physician (or physician-designee) within 24 hours of admission/discharge/SOC/ROC?

CHECK ONE BOX FOR EACH OF THE MEDICATION CLASSES THE PATIENT/RESIDENT IS TAKING

	NO (0)	**YES (1)**	**Missing information on sources OR lack of documentation (9)**
F1g1: Anti-coagulants			
F1g2: Anti-platelets (excluding 81 mg aspirin)			
F1g3: Hypoglycemics (for example, insulin)			
F1g4: Opioids			
F1g5: Anti-psychotics			
F1g6: Anti-microbials (excluding topicals)			
F1g7: Anti-depressants			
F1g8: Diuretics			
F1g9: Antianxiety			
F1g10: Hypnotics			

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Discrepancies Communicated to Physician data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Discrepancies Communicated to Physician data elements are collected

The Medication Reconciliation – Contact Physician (F1g) data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements ask if the

PAC provider contacted a physician (or physician-designee) about all high-risk discrepancies and potential adverse drug events within 24 hours of admission/discharge/SOC/ROC.

How the Medication Reconciliation – Discrepancies Communicated to Physician data elements are coded

For F1g, the assessor selects 0 for "No, the physician was not contacted," or 1 for "Yes." The assessor also can select 9 for "Unknown; missing information sources or lack of documentation.

Medication Reconciliation – Recommended Actions Taken

The data elements that comprise Medication Reconciliation – Recommended Actions Taken are a follow up to Medication Reconciliation – Discrepancies Communicated to Physician. These data elements assess whether the PAC provider completed the physician prescribed/recommended actions within 24 hours of the physician's response.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft Recommended Actions Taken data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – Recommended Actions Taken data elements as shown below.

F1h. Were recommended physician (or physician-designee) actions regarding discrepancies for these medication classes carried out within 24 hours after the physician responded?
CHECK ONE BOX FOR EACH OF THE MEDICATION CLASSES THE PATIENT/RESIDENT IS TAKING

	NO (0)	YES (1)	Physician has not responded (8)	Missing information on sources OR lack of documentation (9)
F1h1: Anti-coagulants				
F1h2: Anti-platelets (excluding 81 mg aspirin)				
F1h3: Hypoglycemics (for example, insulin)				
F1h4: Opioids				
F1h5: Anti-psychotics				
F1h6: Anti-microbials (excluding topicals)				
F1h7: Anti-depressants				
F1h8: Diuretics				
F1h9: Antianxiety				
F1h10: Hypnotics				

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – Recommended Actions Taken data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – Recommended Actions Taken data elements are collected

The Medication Reconciliation – Recommended Actions Taken (F1h) data elements can be administered by any clinician who has been trained to conduct this assessment. These data elements ask about the outcomes from the physician (or physician-designee) response. The assessor answers whether the PAC provider completed the physician (or physician-designee) prescribed/recommended actions within 24 hours in response to discrepancies for relevant medication classes.

How the Medication Reconciliation – Recommended Actions Taken data elements are coded

The assessor selects 0 for "No, the actions were not completed" or 1 for "Yes." The assessor selects 8 for "Physician has not responded and 9 for "Unknown; missing information sources or lack of documentation."

Medication Reconciliation – List Communicated to Patient/Resident/Caregiver/Care Team/Pharmacy

The Medication Reconciliation – List Communicated to Patient/Resident Caregiver data element asks about the PAC provider's communication of the reconciled medication list with the patient/resident or patient's/resident's formal caregiver, the prescribers and the care team responsible for the patient's/resident's care, and the patient's/resident's primary pharmacy.

Data element specifications

Medication Reconciliation data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The draft List Communicated to Patient/Resident Caregiver/Care Team/Pharmacy data element, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

CMS is soliciting comment on the Medication Reconciliation – List Communicated to Patient/Resident Caregiver/Care Team/Pharmacy data element as shown below.

F1i. Was the reconciled medication list communicated to any of the following?

CHECK ALL THAT APPLY

- ☐ 1 = Patient/resident or patient's/resident's family/formal caregiver
- ☐ 2 = Prescribers and the care team responsible for the patient's/resident's care following admission/discharge/SOC/ROC
- ☐ 3 = Patient's/resident's pharmacy that will be filling most of the medications following admission/discharge/SOC/ROC
- ☐ 9 = Missing information sources or lack of documentation

CMS is seeking comment on the cross setting applicability of the Medication Reconciliation – List Communicated to Patient/Resident Caregiver/Care Team/Pharmacy data element. Specifically, CMS is soliciting comment on the following topics:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Medication Reconciliation – List Communicated to Patient/Resident Caregiver/Care Team/Pharmacy data element is collected

The Medication Reconciliation – List Communicated to Patient/Resident Caregiver (F1i) data element can be administered by any clinician who has been trained to conduct this assessment. This data element asks "Was the reconciled medication list communicated to any of the following: the patient/resident or patient's/resident's family/formal caregiver, the prescribers and care team responsible for the patient's/resident's care, the patient's/resident's pharmacy?"

How the Medication Reconciliation – List Communicated to Patient/Resident Caregiver data element is coded

The assessor selects 1 if information has been communicated to the patient/resident or patient's/resident's family/formal caregiver, 2 if information has been communicated to the prescribers and care team responsible for the patient's/resident's care, and 3 if information has been communicated to the patient's/resident's pharmacy. The assessor also can select 9 for "Missing information sources or lack of documentation."

Care Preferences

The assessment and understanding of patient care preferences and goals for care is critical to ensuring patient-centered and preference-concordant care through the course of a PAC episode/stay and beyond. In addition to clinical guidelines, information about patient preferences provides important direction for developing a care plan, selecting treatment options, and tailoring interventions.[28] Eliciting, documenting, communicating, and transferring information about a patient's preferences for care and their goals for care is critical to informing the plan of care, evaluating progress, and assuring patient-centered care in PAC settings.[29] In PAC settings, preferences are likely to encompass both preferences for health care as well as preferences for daily routine and lifestyle. Undergirding all these preferences is an implicit expression of values such as privacy, autonomy, and agency.

Use of standardized patient assessment data promotes transfer of a patient's/resident's health information and care preferences to the individual, family caregivers, and providers of services that furnish data elements and services to the patient/resident as he or she transitions from acute care to another setting and from a PAC provider to another setting or back to the home. Knowing care preferences is essential for smooth care transitions that are acceptable to the patient and family. Smooth transitions between settings are especially important for patients in PAC settings because of the negative impact of disruption on the patient's/resident's physical health and mental well-being. Accurate information may be particularly important for patients who have expectations of returning home. For example, a patient might express a preference for returning to home but also express a preference for minimal physical rehabilitation, making a return to home more difficult or impossible to achieve. Such a situation would require additional time on the part of the provider team to reset the patient's expectations, while still assessing and acknowledging the patient's stated preferences.

The following data elements are described further in the sections below. CMS is seeking comment on these data elements for use in a standardized clinical assessment of Care Preferences.

- Advanced Care Directive – Healthcare Agent (Chart Review)
- Physician Orders (Chart Review)
- Goals of Care (Chart Review)
- Preference for Involvement of Family/Friends in Care Decisions (Patient Interview)
- Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview)

Advanced Care Directive - Healthcare Agent (Chart Review)

The Advanced Care Directive – Healthcare Agent data element assesses whether the medical record contains appropriate and necessary documentation regarding a patient's/resident's surrogate health care decision maker.

Data element specifications

The table shows the assessment instruments using the Advanced Care Directive – Healthcare Agent data element. A similar data element was tested in the PAC PRD and was shown to be feasible across PAC settings. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments using the Advanced Care Directive - Healthcare Agent

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14			

CMS is soliciting comment on the Advanced Care Directive – Healthcare Agent data element as shown below.

G1a. Does the patient/resident have a designated Health Care Agent as authorized under state law to make healthcare decisions in the event that he/she is unable to make his or her own decisions **AND** there is legal documentation in the medical record?

☐ 0 = No
☐ 1 = Yes

CMS is seeking comment on the cross setting applicability of the Advanced Care Directive – Healthcare Agent data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Advanced Care Directive – Healthcare Agent data element is collected

The Advanced Care Directive – Healthcare Agent (G1a) data element can be administered by any clinician who has been trained to complete this assessment. The information to complete this data element can be found only in the patient/resident's medical record. The assessor must review the medical record and identify any evidence of a patient/resident-designated health care decision maker. This includes all legal documentation such as a state advance directive form, a Physician Orders for Life Sustaining Treatment (POLST) or Medical Orders for Life Sustaining Treatment (MOLST) form, a conservatorship form, or any other legal document conferring durable power of attorney for health care or surrogate role to an individual other than the patient/resident.

How the Advanced Care Directive – Healthcare Agent data element is coded

If there is no legal documentation found in the medical record pertaining to a surrogate health care decision maker (answer is "no"), the data element is coded as 0. If there is legal documentation found in the medical record pertaining to a surrogate (answer is "yes") the data element is coded as 1. If the documentation in the medical record is unclear as to the decision-making status of the identified individual, i.e., if it is unclear whether the identified individual is authorized by law to make health care decisions for the patient/resident, the data element is coded as 0.

Physician Orders (Chart Review)

The Physician Orders data element assesses whether the medical record contains active physician orders for specific treatment choices.

Data element specifications

The draft Physician Orders data element, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017 and was informed by a data element in the MDS 2.0.

Table: Assessment Instruments using the Physician Orders

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD			
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Similar to MDS (Version 2.0, Section A, Q10 "Advanced Directives")	

CMS is soliciting comment on the Physician Orders data element as shown below.

G1b. Does the patient/resident have any of the following physician orders documented and active in the medical record?

CHECK ALL THAT APPLY:

- ☐ a = Do not resuscitate (DNR)
- ☐ b = Do not intubate (DNI)
- ☐ c = Do not hospitalize (DNH)
- ☐ d = Antibiotic restrictions
- ☐ e = Comfort care preference(s)
- ☐ z = None of the above

CMS is seeking comment on the cross setting applicability of the Physician Orders data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity

- Feasibility for use in PAC
- Utility for describing case mix

How the Physician Orders data element is collected

The Physicians Orders data element can be administered by any clinician who has been trained to complete this assessment. The information to complete this data element can be found only in the patient/resident's medical record. The assessor reviews the patient's/resident's medical record and identifies any evidence of documented physician orders for treatment preferences, such as "do not intubate" or "do not administer antibiotics." The wording may be variable, but the intent should be clear and it should be an active physician order. Physician notes that are not orders do not apply. Standardized forms such as a POLST/MOLST form are acceptable documentation of physician orders.

How the Physician Orders data element is coded

The assessor lists as many categories as apply for physician orders (i.e., select all that apply). The codes are described as follows: a for "do not resuscitate (DNR)," b for "do not intubate (DNI)," c for "do not hospitalize (DNH)," d for "antibiotic restrictions," and e for "comfort measures only. If no applicable physician orders appear in the medical record, the assessor selects the z code, "none of the above." If "none of the above" applies, no other categories should be selected.

Goals of Care (Chart Review)

The data elements that comprise Goals of Care (Chart Review) assess whether the medical record includes documentation of key conversations the care team may have had with the patient/resident about overall goals.

Data element specifications

The Goals of Care (Chart Review) data elements are not in use in any of the four PAC assessment instruments; however, the LCDS v3.0 contains functional discharge goals (Section GG). The first data element presented here is modified from a data element tested in the PAC PRD. The draft data elements, depicted below, will be evaluated in a feasibility test in the spring and summer of 2017.

Table: Assessment Instruments using the Goals of Care

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	Modified from PAC-PRD	
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0	✓	Section GG contains functional discharge goals	
MDS 3.0 v1.14			

CMS is soliciting comment on the Goals of Care (Chart Review) data elements as shown below.

G1c. Is there documentation in the medical record indicating that a conversation between the patient/resident (or representative) and the care team (or physician) took place about the patient's/resident's goals for care?

- ☐ 0 = No **[IF NO, SKIP TO G1-END TIME]**
- ☐ 1 = Yes
- ☐ 9 = Unknown or unable to assess **[IF NO, SKIP TO G1-END TIME]**

G1d. Did the documented conversation about goals of care indicate any of the following types of goals?

CHECK ALL THAT APPLY

- ☐ 1 = Physical Goals
- ☐ 2 = Emotional Goals
- ☐ 3 = Social Goals
- ☐ 4 = Intellectual/Mental Goals
- ☐ 5 = Other: _____

CMS is seeking comment on the cross setting applicability of the Goals of Care (Chart Review) data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Goals of Care (Chart Review) data elements are collected

The Goals of Care (Chart Review) data elements can be administered by any clinician who has been trained to complete this assessment. The information to complete these data elements can be found only in the patient/resident's medical record. The assessor reviews the patient's/resident's medical records and identifies any evidence of documented discussions of goals of care. These may exist in a number of sources within the patient's/resident's medical documentation, including notes from any of the providers and the care plan. Discussions may be formal or informal, but the intent should be clear. Discussions must have taken place within arrival to this facility, or 365 days, whichever is shortest. Documentation prepared specifically for transferring to this facility may qualify, as applicable. The assessor completes data elements G1d-G1g only if item G1c has a response of "Yes."

How the Goals of Care (Chart Review) data elements are coded

A code of 0, "no," is recorded if documentation of a conversation between a provider and the patient/resident (or their proxy) did not take place, and the section is ended. If it is unclear then 9 is coded, and the section is ended. A code of 1, "yes," is recorded if there is documentation of a conversation between a provider and the patient/resident (or their proxy) discussing a patient's/resident's goals. If G1c is coded as 1, the assessor moves to G1d. The assessor checks 1 if the documented conversation included a discussion of physical goals, 2 if it included a discussion of emotional goals, 3 if it included a discussion of social goals, 4 if it included a discussion of intellectual/mental goals, and 5 if it included a discussion of other types of goals. If it is coded as 5, additional specification is necessary.

Preference for Involvement of Family/Friends in Care Decisions (Patient Interview)

The Preference for Involvement of Family/Friends in Care Decisions data element elicits the patient's/resident's preferences regarding how much information about status and treatment should be provided to the patient's/resident's family and friends, and how decisions regarding the patient's/resident's care should be made.

Data element specifications

The table shows the assessment instruments using the Preference for Involvement of Family/Friends in Care Decisions data element. A related data element is currently in use in the MDS 3.0. This data element was also tested in the PAC PRD and found to be feasible and reliable across PAC settings. The draft data element, depicted below, was evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

Table: Assessment Instruments Using the Preference for Involvement of Family/Friends in Care Decisions Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	Preferences for family or significant other involvement in care discussions (yes/no)	
OASIS-C2			
IRF-PAI v 1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	Preferences for family or significant other involvement in care discussions (yes/no)	

CMS is soliciting comment on the Preference for Involvement of Family/Friends in Care Decisions data element as shown below.

Involvement of Family/friends in Care Decisions	
A2. Ask Patient/Resident – "It is important for us to understand how you'd like your family, friends, or significant others involved in your care. How important is it to you to have your family or a close friend or significant other involved in discussions about your care?"	
Enter Code ☐	1. Very important 2. Somewhat important 3. Not very important 4. Not important at all 5. Important, but can't do or no choice 9. No response or non-responsive

CMS is seeking comment on the cross setting applicability of the Preference for Involvement of Family/Friends in Care Decisions data element. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Preference for Involvement of Family/Friends in Care Decisions data element is collected

The Preference for Involvement of Family/Friends in Care Decisions data element can be administered by any clinician who has been trained to complete this assessment. First, the assessor reads aloud the introduction: "It is important for us to understand how you'd like your family, friends, or significant others involved in your care." Then the assessor asks the question: "How important is it to you to have your family or a close friend or significant other involved in discussions about your care?" Then, he or she reads aloud each of the responses "very important, somewhat important, not very important, or not important at all" and marks that response in box next to the question.

How the Preference for Involvement of Family/Friends in Care Decisions data element is coded

The responses are coded as follows: 1 for "very important," 2 for "somewhat important," 3 for "not very important," 4 for "not important at all," 5 for "important, but can't do or no choice," and 9 for "no response or non-responsive."

Preferences for Involvement in Decision Making (Information Preferences) (Patient Interview)

The data elements that comprise Preferences for Involvement in Decision Making (Information Preferences) elicit the patient's/resident's preferences regarding the amount of information they wish to receive regarding their condition.
Data element specifications

These data elements are not in use in any of the four PAC assessment instruments and were not tested in the PAC PRD. The data elements underwent cognitive testing and revisions were made based on PAC patient feedback. The draft Preferences for Involvement in Decision Making (Information Preferences) data elements, depicted below, were evaluated in the Alpha 1 pilot test and demonstrated excellent reliability.

CMS is soliciting comment on the Preference for Involvement in Decision Making (Information Preferences) data elements as shown below.

Preferences for Involvement in Decision Making Questionnaire	
A4a. Ask Patient/Resident: "I'd like to talk to you about how you prefer to be involved in your care. Everyone copes with their condition differently. Do you prefer to know as much as you can about the details of your condition and treatment, prefer some information, or prefer not to know or to know very little?"	
Enter Code ☐	1. To know as much as you can 2. Some information 3. Not to know or to know very little 9. Unable to answer or non-responsive

CMS is seeking comment on the cross setting applicability of the Preference for Involvement in Decision Making (Information Preferences) data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Preference for Involvement in Decision Making (Information Preferences) data elements are collected

The Preferences for Involvement in Decision Making (Information Preferences) data elements can be administered by any clinician who has been trained to complete this assessment. First, the assessor reads the question: "I'd like to talk to you about how you prefer to be involved in your care. Everyone copes with their condition differently. Do you prefer to know as much as you can

about the details of your condition and treatment, prefer some information, or prefer not to know or to know very little?" The question contains the answer choices but they can be repeated, as needed. The response option "unable to answer or non-responsive" is never read aloud. The patient's/resident's response is recorded.

How the Preference for Involvement in Decision Making (Information Preferences) data elements are coded

For the first question, if the patient/resident indicates that he or she wants to know as much as possible about his or her illness and treatment, this is coded as 1. If the patient/resident indicates that he or she wants limited information about his or her illness and treatment or that he or she doesn't want to know much, these responses are coded as 2 and 3, respectively. If a patient/resident is not responsive to the question, the nonresponse is coded as 9, without comment.

PROMIS®

The Patient-Reported Outcomes Measurement Information System (PROMIS®) was developed and is held by the National Institutes of Health (NIH) as part of the NIH Roadmap initiative that set the standard for modern behavioral health measurement development. CMS is soliciting comment on the following data elements.

- Sleep disturbance
- Fatigue
- Ability to participate in social roles and activities
- Global health

Sleep Disturbance

The data elements that comprise the PROMIS Sleep Disturbance Item Bank assess self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. This includes perceived difficulties and concerns with getting to sleep or staying asleep, as well as perceptions of the adequacy of and satisfaction with sleep. Sleep disturbance does not focus on symptoms of specific sleep disorders, nor does it provide subjective estimates of sleep quantities (total amount of sleep, time to fall asleep, amount of wakefulness during sleep). Selected items were incorporated on the basis of relevance for PAC settings.

All 12 items are based on the same look back period (past 7 days) and 5-point Likert-type rating scales (e.g.1= not at all; 2=a little bit; 3=somewhat; 4=quite a bit; 5=very much; or 1=never; 2=rarely; 3=sometimes; 4=often; 5=always; or 1= always; 2= often; 3=sometimes; 4= rarely; 5= never). Some of the positive worded items (i.e. items b, f, h and k) are in reverse order so that higher score means more sleep disturbance.).

Data element specifications

The full PROMIS Sleep Disturbance Item Bank contains 27 items. In initial testing, the Sleep Disturbance data elements showed strong correlation with the Pittsburgh Sleep Quality Index (0.85).[8] The sleep disturbance short form highly correlates with the full bank (r=0.96.) The Sleep Disturbance data elements also showed good sensitivity in patients with sleep disorders; those who were untreated had significantly higher scores than those who received treatment.[30]

It was necessary to identify items within each item bank that may be most suitable for PAC use. To assist in selecting the most appropriate items for consideration in PAC standardized assessment, feedback was solicited from project team advisors, members of a Technical Expert Panel (TEP), as well as from a large group of stakeholders. The items chosen for inclusion were generally considered more specific than other items and more useful for encouraging further discussion regarding care planning. Items that were not included were judged as being vague, too open for interpretation, possibly redundant with other assessment items in other domains, and were not applicable across PAC settings. Some items used terms that are not well understood, so questions were chosen that used more common vernacular. Some items used highly subjective phrases; such as “deep sleep” or that “sleep was refreshing.” Other items employed idioms that may not be understood universally. These items were not included in lieu of items that were less subjective. For sleep disturbance items specifically, many of the omitted items were listed as possibly pointing to depression or anxiety symptoms, which is not the purpose of this assessment. Some items were overly complex and would be difficult to interpret. These items were not included in lieu of simpler items. CMS is soliciting comment on the following PROMIS Sleep Disturbance data elements.

SAY TO PATIENT/RESIDENT: "I am now going to ask you about your sleep over the past 7 days, including your perceived difficulties and concerns with getting to sleep or staying asleep. I will also ask you what you think about the adequacy of your sleep and how satisfied you are with your sleep. All patients/residents are asked to answer these questions. Knowing the answers to these questions will help us provide you with a more individualized care plan."

X1a. In the past 7 days, I had difficulty falling asleep

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1b. In the past 7 days, it was easy for me to fall asleep

- ☐ 1 = Always
- ☐ 2 = Often
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1c. In the past 7 days, I worried about not being able to fall asleep

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1d. In the past 7 days, I had trouble staying asleep

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1e. In the past 7 days, I woke up and had trouble falling back to sleep

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1f. In the past 7 days, I was satisfied with my sleep.

- ☐ 1 = Always
- ☐ 2 = Often
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1g. In the past 7 days, I had trouble stopping my thoughts at bedtime

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1h. In the past 7 days, my sleep was restful

- ☐ 1 = Always
- ☐ 2 = Often
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1i. In the past 7 days, I had trouble sleeping

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1j. In the past 7 days, my sleep was restless

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1k. In the past 7 days, I got enough sleep

- ☐ 1 = Always
- ☐ 2 = Often
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1l. In the past 7 days, I had trouble getting into a comfortable position to sleep

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Sleep Disturbance data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Sleep Disturbance data elements are collected

The PROMIS Sleep Disturbance data elements are collected using a direct patient/resident interview. The assessor explains the reason for the interview before beginning. Then the assessor shows the interview response choices on a cue card and reads each question to the

patient/resident. The patient/resident is asked to respond to each question by giving the closest answer, and the assessor records the responses in the boxes to the left of each data element. While reading each of the statements and showing the patient/resident the response options, the assessor does not offer any predetermined definitions. The response should be based on the patient's/resident's own interpretation of frequency response options.

How the Sleep Disturbance data elements are coded

Response scales are on a five-point Likert scale, where 1= not at all; 2=a little bit; 3=somewhat; 4=quite a bit; 5=very much; or 1=never; 2=rarely; 3=sometimes; 4=often; 5=always). Some of the positive worded items (e.g. my sleep was restful) are in reverse order so that higher score means more sleep disturbance.

Fatigue

The data elements that comprise the PROMIS Fatigue Item Bank evaluate a range of self-reported symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one's ability to execute daily activities and function normally in family or social roles. Fatigue is divided into the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities. Selected items were incorporated on the basis of relevance for PAC settings.

All 10 items are based on the same look back period (past 7 days) and the same response scale (a 5-point Likert-type rating scale where 1=never; 2=rarely; 3=sometimes; 4=often; 5 =always) except item f (where 1= very much; 2=quite a bit; 3=somewhat; 4=a little bit; 5=not at all) and item g (where 1= not at all; 2= a little bit; 3=somewhat; 4= quite a bit; 5= very much). Higher score means more fatigue except for item f (I have energy), so that a higher score means more fatigue except.

Data element specifications

The full PROMIS Fatigue Item Bank contains 95 items. In initial testing, the Fatigue data elements were highly correlated with the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scale (r =0.95).[8] The calibrated fatigue bank also correlated highly (*r*=0.89) with the SF-36 Vitality Scale. [8] The Fatigue data elements also showed significant responsiveness to change in patients with various chronic conditions enrolled in treatment.[8]

It was necessary to identify items within each item bank that may be most suitable for PAC use. To assist in selecting the most appropriate items for consideration in PAC standardized assessment, feedback was solicited from project team advisors, members of a Technical Expert Panel (TEP), as well as from a large group of stakeholders. Items that were included were more specific than those not included. Items that were not included were judged as being vague, too open for interpretation, possibly redundant with other assessment items in other domains, and were not applicable across PAC settings. Some items used terms that are not well understood, so questions were chosen that used more common vernacular. For fatigue items specifically, many of the omitted items were listed as possibly pointing to depression symptoms, which is not what we are trying to assess with these questions. Many items in this question bank were double barreled or asked for the assessment or multiple activities simultaneously. Those items were not included in lieu of more targeted items. Similarly, items that were thought to be too complex were not included in lieu of items with simpler interpretations. Unique to fatigue questions are questions that ask patients if they must be forced to take part in activities. In some settings, patients are asked to take part in physical therapy or other activities that may be taxing and require the patient to exert themselves or force themselves to participate. These items were not included due to their confounding nature. CMS is soliciting comment on the following PROMIS Fatigue data elements.

SAY TO PATIENT/RESIDENT: "I am now going to ask you about fatigue, from mild tiredness to exhaustion that likely decreases your ability to function normally over the past 7 days. All patients/residents are asked to answer them. Knowing the answers to these questions will help us provide you with a more individualized care plan."

X1a. In the past 7 days, how often did you feel tired?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1b. In the past 7 days, how often did you find yourself getting tired easily?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1c. In the past 7 days, how often were you too tired to think clearly?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1d. In the past 7 days, how often did your fatigue make it difficult to make decisions?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1e. In the past 7 days, how often did you have enough energy to enjoy the things you do for fun?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1f. In the past 7 days, I have energy

- ☐ 1 = Very much
- ☐ 2 = Quite a bit
- ☐ 3 = Somewhat
- ☐ 4 = A little bit
- ☐ 5 = Not at all
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1g. In the past 7 days, I am frustrated by being too tired to do the things I want to do

- ☐ 1 = Not at all
- ☐ 2 = A little bit
- ☐ 3 = Somewhat
- ☐ 4 = Quite a bit
- ☐ 5 = Very much
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1h. In the past 7 days, how often did you have to push yourself to get things done because of your fatigue?

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1i. In the past 7 days, how often were you too tired to take a bath or shower

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1j. In the past 7 days, I am too tired to eat

- ☐ 1 = Never
- ☐ 2 = Rarely
- ☐ 3 = Sometimes
- ☐ 4 = Often
- ☐ 5 = Always
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Fatigue data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Fatigue data elements are collected

The PROMIS Fatigue data elements are collected using a direct patient/resident interview. The assessor explains the reason for the interview before beginning. Then the assessor shows the interview response choices on a cue card and reads each question to the patient/resident. The patient/resident is asked to respond to each question by giving the closest answer, and the assessor records the responses in the boxes to the left of each data element. While reading each of the statements and showing the patient/resident the response options, the assessor does not offer any predetermined definitions. The response should be based on the patient's/resident's own interpretation of frequency response options.

How the Fatigue data elements are coded

Response scales are on a five-point Likert scale, where 1=never; 2=rarely; 3=sometimes; 4=often; 5 =always), except for items f and g, so that a higher score means more fatigue.

Ability to Participate in Social Roles and Activities

The data elements that comprise PROMIS Ability to Participate in Social Roles and Activities assess self-reported perceived ability to perform one's usual social roles and activities. The activities range from professional obligations to social activities with friends and family. Selected items were incorporated on the basis of relevance for PAC settings.

All 10 items are based on the same response scale (a 5-point Likert-type rating scale where 1=always; 2=usually; 3=sometimes; 4 = rarely; 5= never). A higher score means better ability to participate in social roles.

Data element specifications

The full PROMIS Social Roles and Activities Item Bank contains 35 items. When tested in a diverse group of patients, the Ability to Participate in Social Roles and Activities data elements demonstrated good criterion validity when compared with the SF-36 (Pearson correlation = 0.549, $p < 0.01$) and construct validity; respondents without comorbidities had higher scores than those without (effect size = 0.94, $p < 0.001$).[31]

It was necessary to identify items within each item bank that may be most suitable for PAC use. To assist in selecting the most appropriate items for consideration in PAC standardized assessment, feedback was solicited from project team advisors, members of a Technical Expert Panel (TEP), as well as from a large group of stakeholders. The items selected were generally considered more specific than other items and the items were considered more useful for encouraging further discussion regarding care planning. Items that were not included were judged as being vague, too open for interpretation, possibly redundant with other assessment items in other domains, and were not applicable across PAC settings. Many items specifically flagged the need for regular interaction with friends that may not have been applicable to all patients or in all settings, but one question related to having friends was kept as it was highly rated. More so than other item banks, items in the social roles bank implied a home setting. Those items were not kept in lieu of more general items. Some items used terms that are not well understood, so questions were chosen that used more common vernacular. CMS is soliciting comment on the following PROMIS Social Roles and Activities data elements.

SAY TO PATIENT/RESIDENT: "I am now going to ask you about your ability to perform your usual social roles and activities. All patients/residents are asked to answer these questions. Knowing the answers to these questions will help us provide you with a more individualized care plan."

X1a. I have trouble participating in recreational activities with others

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1b. I have trouble doing all of my regular leisure activities with others

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1c. I have to limit the things I do for fun with others

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1d. I have trouble doing all of the family activities that are really important to me

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1e. I have trouble doing all of the family activities that I want to do

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1f. I have to limit my regular family activities

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1g. I have trouble doing all of the activities with friends that are really important to me

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1h. I have trouble taking care of my regular personal responsibilities

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1i. I have to limit social activities with groups of people

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1j. I have trouble keeping in touch with others

- ☐ 1 = Always
- ☐ 2 = Usually
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Ability to Participate in Social Roles and Activities data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Ability to Participate in Social Roles and Activities data elements are collected

The PROMIS Ability to Participate in Social Roles and Activities data elements are collected using a direct patient/resident interview. The assessor explains the reason for the interview before beginning. Then the assessor shows the interview response choices on a cue card and reads each question to the patient/resident. The patient/resident is asked to respond to each question by giving the closest answer, and the assessor records the responses in the boxes to the left of each data element. While reading each of the statements and showing the patient/resident the response options, the assessor does not offer any predetermined definitions. The response should be based on the patient's/resident's own interpretation of frequency response options.

How the Ability to Participate in Social Roles and Activities data elements are coded

Response scales are on a five-point Likert scale, 1=always; 2=usually; 3=sometimes; 4 = rarely; 5= never). A higher score means better ability to participate in social roles.

Global Health

The PROMIS was developed as part of a NIH Roadmap initiative that set the standard for modern behavioral health measurement development. The data elements that comprise PROMIS Global Health scale[32] include 10 items that assess self-reported evaluations of health in general (i.e. health related quality of life) rather than specific elements of health. These items ask overall status of respondent's physical health, pain, fatigue, mental health, social health, and overall health. They are predictive of important future events such as health care utilization and mortality.[33]

All 10 items are based on the 5-point Likert-type rating scales (e.g. the first six items have responses of 1=poor; 2=fair; 3=good; 4=very good; 5=excellent). Higher score means better global health.

Data element specifications

We present the full PROMIS Global Health Item Bank which contains 10 items. PROMIS Global Health items show strong correlations with the EQ-5D[32], VR-12[34] and the Health Utility Index Mark 3.[35] In a study to monitor population health,[36] researchers compared the PROMIS Global Health with CDC Healthy Days. The PROMIS items were found to capture a broad range of functioning across the entire continuum of physical and mental health.

CMS is soliciting comment on the following PROMIS Global Health data elements.

SAY TO PATIENT/RESIDENT: "I am now going to ask you a few questions about your overall health status. All patients/residents are asked to answer these questions. Knowing the answers to these questions will help us provide you with a more individualized care plan."
X1a. In general, would you say your health is ☐ 1 = Poor ☐ 2 = Fair ☐ 3 = Good ☐ 4 = Very good ☐ 5 = Excellent ☐ 7 = Patient/resident declined to respond ☐ 9 = Unknown or unable to assess

X1b. In general, would you say your quality of life is

- ☐ 1 = Poor
- ☐ 2 = Fair
- ☐ 3 = Good
- ☐ 4 = Very good
- ☐ 5 = Excellent
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1c. In general, how would you rate your physical health?

- ☐ 1 = Poor
- ☐ 2 = Fair
- ☐ 3 = Good
- ☐ 4 = Very good
- ☐ 5 = Excellent
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1d. In general, how would you rate your mental health, including your mood and your ability to think?

- ☐ 1 = Poor
- ☐ 2 = Fair
- ☐ 3 = Good
- ☐ 4 = Very good
- ☐ 5 = Excellent
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1e. In general, how would you rate your satisfaction with your social activities and relationships?

- ☐ 1 = Poor
- ☐ 2 = Fair
- ☐ 3 = Good
- ☐ 4 = Very good
- ☐ 5 = Excellent
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1f. In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)

- ☐ 1 = Poor
- ☐ 2 = Fair
- ☐ 3 = Good
- ☐ 4 = Very good
- ☐ 5 = Excellent
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1g. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

- ☐ 1 = Not at all
- ☐ 2 = A little
- ☐ 3 = Moderately
- ☐ 4 = Mostly
- ☐ 5 = Completely
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1h. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?

- ☐ 1 = Always
- ☐ 2 = Often
- ☐ 3 = Sometimes
- ☐ 4 = Rarely
- ☐ 5 = Never
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1i. How would you rate your fatigue on average?

- ☐ 1 = Very severe
- ☐ 2 = Severe
- ☐ 3 = Moderate
- ☐ 4 = Mild
- ☐ 5 = None
- ☐ 7 = Patient/resident declined to respond
- ☐ 9 = Unknown or unable to assess

X1j. How would you rate your pain on average?

- ☐ 0 = No pain
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 = Worst pain imaginable

- ☐ 11 = Patient/resident declined to respond
- ☐ 12 = Unknown or unable to assess

CMS is seeking comment on the cross setting applicability of the Global Health data elements. Specifically, CMS is soliciting comment on the following dimensions:

- Potential for improving quality
- Validity
- Feasibility for use in PAC
- Utility for describing case mix

How the Global Health data elements are collected

The PROMIS Global Health data elements are collected using a direct patient/resident interview. The assessor explains the reason for the interview before beginning. Then the assessor shows the interview response choices on a cue card and reads each question to the patient/resident. The patient/resident is asked to respond to each question by giving the closest answer, and the assessor records the responses in the boxes to the left of each data element. While reading each of the statements and showing the patient/resident the response options, the assessor does not

offer any predetermined definitions. The response should be based on the patient's/resident's own interpretation of frequency response options.

How the Global Health data elements are coded

Response scales are on five-point Likert scales (e.g. 1=poor; 2=fair; 3=good; 4=very good; 5=excellent for the first six items) except for the last item where 0 to 10 represents different pain levels from no pain to worst pain imaginable. A higher score means better global health status.

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