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

Data Element Specifications for Public Comment

Prepared for
Center for Medicare & Medicaid Services
Center for Clinical Standards and Quality
Quality Measurement & Health Assessment Group
Cindy Massuda/Charlayne Van, COR
CMS Contract No. HHSM-500-2013-13014I

Prepared by
RAND Corporation

August 2016

Contents

List of Acronyms

3MS	Modified Mini-Mental State
BIMS	Brief Interview for Mental Status
BiPAP	Bilevel positive airway pressure
CAM	Confusion Assessment Method
CARE	Continuity Assessment Record and Evaluation tool
CMS	Centers for Medicare & Medicaid Services
CPAP	Continuous positive airway pressure
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
MDS	Minimum Data Set
OASIS-C2	Outcome and Assessment Information Set
PAC	Post-acute care
PAC PRD	Post-Acute Care Payment Reform Demonstration
PHQ-2	Patient Health Questionnaire–2
PHQ-9	Patient Health Questionnaire–9
SNF	Skilled nursing facility
TBI	Traumatic brain injury
TPN	Total parenteral nutrition

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

The Centers for Medicare & Medicaid Services (CMS) seeks comments from stakeholders on data elements that meet the IMPACT Act domains of: cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. In this document, we summarize each data elements including background and current usage.

In addition to general comments, CMS is specifically interested in public feedback regarding the topics 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.

Project Overview

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014)[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 the Centers for Medicare & Medicaid Services (CMS) currently requires for use by home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long-term acute 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

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

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, the four post-acute care settings leverage different 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)[ii] for Home Health Agencies (HHAs), the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for Inpatient Rehabilitation Facilities (IRFs), the Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LCDS) for Long-Term Care Hospitals (LTCHs), and the Minimum Data Set (MDS 3.0) for Skilled Nursing Facilities (SNFs). In their current form, these assessment instruments collect on different items, limiting the comparability across PAC settings.

Standardizing assessment data elements across PAC settings has important implications for patients/residents, families, providers, and policymakers. At the patient/resident level, standardized data elements may ensure the collection of high quality, reliable information that will aid in improving person-centered outcomes and goals, guide the choice of PAC providers, and improve care coordination. Standardized assessment data elements may accompany people as they traverse care settings, fostering seamless transitions, and support care transitions through meaningful, clinically relevant information that is understood by all. At the provider level, standardized assessment data elements may promote data exchangeability, thus enhancing efficiency through data sharing. Data that are reusable, informative, interoperable, and communicate the same information across care settings may support providers in making discharge placements from acute care and improve transitions to PAC settings. At the national level, standardized assessment data elements will make it possible to measure and compare quality, outcomes, patient acuity, and resource use consistently across PAC settings and longitudinally, guiding policies and PAC payment reform based on patient/resident populations. 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.

[ii] The assessment instruments presented in this document represent the most current version of the assessments, as of August 2016.

Affordable Care: Reduce the cost of quality healthcare for individuals, families, employers, and government.

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 category section includes:

- Rationale for assessing each category
- 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 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

Importance of Assessing this Domain

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.

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:

- Brief Interview for Mental Status (BIMS)
- Expression of Ideas and Wants
- Ability to Understand Others: Understanding Verbal Content
- Confusion Assessment Method (CAM)
- Behavioral Signs and Symptoms
- Patient Health Questionnaire (PHQ)

Brief Interview for Mental Status (BIMS)

The *Brief Interview for Mental Status* (*BIMS*) is a performance-based cognitive assessment that assesses repetition, recall with and without prompting, and temporal orientation. It was developed to be a brief screener to assess cognition, with a focus on learning and memory.

Data Element Specification

The *BIMS* is currently used in the MDS 3.0 and in the IRF-PAI.

The *BIMS* was tested in the PAC PRD, where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings. The lowest agreement was on the "repetition of three words" memory question, with a kappa of 0.71, which still falls within the range of substantial agreement. In addition, it was found to be predictive of cost. The *BIMS* has also been found to have excellent reliability and high correlation with the well-validated Modified Mini-Mental State (3MS) test in Nursing Home populations.[1,2]

Table: Assessment Instruments using the *BIMS*

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 0.71 ("repetition of three words") to 0.91
OASIS-C2			
IRF-PAI v 1.4	✓	3-day assessment period	
LCDS v3.0			
MDS 3.0 v1.14	✓	7-day assessment period	

CMS is soliciting comment on the BIMS data element as shown below. This version of the BIMS differs from those in current use in one response option. Based on input from stakeholders and clinical advisors, the response option 2 for B1b was changed from "Communication disorder" to "Unable to make self understood."

CMS is seeking comment on the cross setting applicability of the *BIMS*. Specifically, CMS is soliciting comment on the following topics:

- Potential for improving quality
- Validity

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

B1.	Interview Attempted		
Enter ☐ Code	B1a. Interview Attempted? 0. No 1. Yes	Enter ☐ Code	B1b. Indicate reasons that the interview was not attempted 1. Unresponsive or minimally conscious 2. Unable to make self understood 3. No interpreter available

B3.	Brief Interview for Mental Status (BIMS)		
Enter ☐ Code	B3a. Repetition of Three Words Ask patient: "I am going to say three words for you to remember. Please repeat the words after I have said all three. The words are: sock, blue, and bed. Now tell me the three words." Number of words repeated by patient after first attempt: 3. Three 2. Two 1. One 0. None		
	After the patient's first attempt say: "I will repeat each of the three words with a cue and ask you about them later: sock, something to wear; blue, a color; bed, a piece of furniture." You may repeat the words up to two more times.		
Enter ☐ Code	B3b. Year, Month, Day B3b.1. Ask patient: "Please tell me what year it is right now." Patient's answer is: 3. Correct 2. Missed by 1 year 1. Missed by 2 to 5 years 0. Missed by more than 5 years or no answer		
Enter ☐ Code	B3b.2. Ask patient: "What month are we in right now?" Patient's answer is: 2. Accurate within 5 days 1. Missed by 6 days to 1 month 0. Missed by more than 1 month or no answer		
Enter ☐ Code	B3c.1. Ask patient: "What day of the week is today?" Patient's answer is: 2. Accurate 1. Incorrect or no answer		
Enter ☐ Code	B3c. Recall Ask patient: "Let's go back to the first question. What were those three words that I asked you to repeat?" If unable to remember a word, give cue (i.e., something to wear; a color; a piece of furniture) for that word.	Enter ☐ Code	B3c.2. Recalls "blue"? 2. Yes, no cue required 1. Yes, after cueing ("a color") 0. No, could not recall
Enter ☐ Code	B3c.1. Recalls "sock"? 2. Yes, no cue required 1. Yes, after cueing ("something to wear") 0. No, could not recall	Enter ☐ Code	B3c.3. Recalls "bed"? 2. Yes, no cue required 1. Yes, after cueing ("a piece of furniture") 0. No, could not recall

How the BIMS is Collected

The *BIMS* can be administered by any clinician who has been trained to conduct this assessment, using the data element script. This data element can be collected at admission to the PAC setting.

The assessor reads the script asking the patient/resident to remember three words; “SOCK, “BLUE,” and “BED.” Then, immediately after asks the patient/resident to repeat the three words by stating, “Now tell me the three words.” If the patient/residents does not recall all three words on the first attempt, the assessor re-presents the three words with the category cues for each word: “Let me say the three words again. They are SOCK, something to wear; BLUE, a color;

and BED, a piece of furniture. Now tell me the three words." The assessor may re-present the words with the category cues twice before moving on to the next question. If the patient/resident correctly states all three words on the first trial, the assessor gives the cue words before moving on to the next question (e.g., "That's right, the words are SOCK, something to wear"; etc.)

For the temporal orientation questions, each is asked separately. A patient/resident is given up to 30 seconds to respond to each. No hints or clues may be provided.

The assessment may be stopped after completing temporal orientation if all responses are either completely unrelated to the question, incomprehensible, incoherent, or not answered.

How the BIMS is Coded

Questions B3a and B3b.1 are coded as a 3 for a correct response and 2, 1, or 0 for varying degrees of incorrect responses. Question B3b.3 is coded as a 1 for a correct response and 0 for an incorrect response.

For each question of the group B3c.1 through B3c.3, a code of 2 is recorded if the patient/resident is able to recall the word without cuing, 1 for recalling the word after cuing, and 0 for not being able to recall even after cuing.

After coding patient/resident responses, a "cognitive status" composite analytic variable is created by summing codes across the response options. Codes are classified as "Intact" or "Borderline" (>12), "Moderately Impaired" (8 to 12), or "Severely Impaired" (<8). Patients/residents who are unable to complete the *BIMS* will be screened out of this assessment by the related question "Interview Attempted?" described above.

Expression of Ideas and Wants

The IMPACT Act highlights the ability to express ideas and to understand verbal content. Problems making oneself understood can be very frustrating and can contribute to social isolation and mood and behavior disorders. The data element *Expression of Ideas and Wants* asks the assessor to consider verbal and non-verbal forms of communication. Specially, the data element to collect on the expression of ideas and wants assesses whether the patient/resident is able to express or communicate requests, needs, opinions, and to conduct social conversation in his or her primary language, whether in speech, writing, sign language, gestures, or a combination of these.

Data Element Specification

The data element *Expression of Ideas and Wants* is currently used in LCDS and IRF-PAI. The MDS 3.0 includes a similar data element, *Makes Self Understood*, which differs in the phrasing and response options and the assessment period (3 days for LCDS and IRF-PAI vs. 7 days for the MDS). Note that, in the MDS 3.0, speech quality is assessed by a separate data element. OASIS-C2 uses a similar item, *Speech and Oral (Verbal) Expression of Language*, which differs in response option phrasing but uses similar tiers of difficulty. This data element offers guidelines for matching a patient's speech ability with a response option. It also differs by splitting the "Rarely/Never expresses self" item into two assessment response options, severe difficulty expressing and unable to express. The data element as collected in the LCDS and the IRF-PAI is shown below.

The data element, *Expression of Ideas and Wants* was tested in the PAC PRD. When combined with the data element, *Understanding Verbal Content* (see next section), the *Expression of Ideas and Wants* data has been shown to be reliable. The PAC PRD formed a composite *Communication* variable from these two data elements, which was shown to have substantial agreement for inter-rater reliability (kappa range of 0.74 to 0.80).

Table: Assessment Instruments Using the *Expression of Ideas and Wants* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓		Composite variable of *Communication* that included *Expression of Ideas and Wants* had substantial agreement, kappa range of 0.74 to 0.80
OASIS-C2	✓	Differences in response options	

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
IRF-PAI v 1.4	✓	Same as version tested in PAC PRD 3-day assessment period	
LCDS v 3.0	✓	Same as version tested in PAC PRD 3-day assessment period	
MDS 3.0 v 1.14	✓	Makes Self Understood B0700 7-day assessment period Differences in response options	

CMS is soliciting comment on the BIMS data element as shown below. This data element is similar to the version tested in the PAC PRD and in current use in the four PAC assessments, with two exceptions. In the version below, the first response option was changed from "Expresses complex messages without difficulty and with speech that is clear and easy to understand" to the version that is shown, which omits the criteria of speech clarity. The second response option was changed from "Exhibits some difficulty with expressing needs and ideas (e.g. some words or finishing thoughts) or speech is not clear": the version below omits the phrase "or speech is not clear." The fourth response option was also changed from "Rarely/Never expresses self or speech is very difficult to understand" to the version shown below by omitting the wording that refers to speech clarity. This change is based on feedback from stakeholders and clinical advisors who suggested disambiguating expression and speech clarity in this data element. They affirmed the importance of assessing speech clarity, but recommended that this be assessed with a separate data element

CMS is seeking comment on the cross-setting applicability of the data element, *Expression of Ideas and Wants*. Specifically, CMS is soliciting comment on the following topics:

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

Specific to this data element, CMS is soliciting comment on the proposed modification to remove references to speech clarity.

C1b.	Expression of Ideas and Wants
Enter ☐ Code	**4. Expresses complex messages without difficulty** **3. Exhibits some difficulty with expressing needs and ideas (e.g. some words or finishing thoughts)** **2. Frequently exhibits difficulty with expressing needs and ideas** **1. Rarely/Never expresses self** **8. Unable to assess** **9. Unknown**

How Expression of Ideas and Wants is Collected

The *Expression of Ideas and Wants* data element can be administered by any clinician who has been trained to conduct this assessment. The assessor uses the coding below to record the patient's or resident's verbal and non-verbal forms of communication. This data element can be collected at admission to and at discharge from the PAC setting.

How Expression of Ideas and Wants is Coded

The assessor codes this data element as follows. A code of 4 is recorded if the patient/resident expresses complex messages without difficulty. A code of 3 is recorded if the patient/resident exhibits some difficulty with expressing needs and ideas. A code of 2 is recorded if the patient frequently exhibits difficulty with expressing needs and ideas, and a 1 is recorded if the patient/resident patient rarely or never expresses him/herself. If this data element is unable to be assessed, a code of 8 is recorded; if an assessment of the patient's or resident's abilities is unknown, a code of 9 is recorded.

Ability to Understand Others: Understanding Verbal Content

Inability to understand direct person-to-person communication can severely limit association with others and inhibit one's ability to follow instructions, thereby affecting health and safety. The data element, *Ability to Understand Others* assesses comprehension of direct person-to-person communication whether spoken, written, or in sign language or Braille.

Data Element Specification

This data element is currently collected in the MDS 3.0, IRF-PAI, LCDS, and the OASIS-C2. The MDS 3.0 data element assesses similar content as the *Understanding Verbal Content* data element in the IRF-PAI and LCDS, but differs in the assessment period (7 days), ordering of response options, and some of the description for the response labels. The OASIS-C2 data element (*Understanding of Verbal Content*) has similar wording and response options as the LCDS and IRF-PAI versions. Finally, the OASIS-C2 also includes the *Speech and Oral (Verbal) Expression of Language*, which is not included in any other PAC setting. This data element was tested in the PAC PRD. The PAC PRD version of *Understanding Verbal Content* is identical to the version tested in the LCDS v3.0, MDS 3.0 v1.14, OASIS-C2, and IRF-PAI 1.4. The only difference being that the PAC PRD is based on 2-day look-back period versus 7-days for the MDS or 3-days for the LCDS and IRF-PAI.

Used in conjunction with the data element, *Expression of Ideas and Wants* (see previous section), the *Understanding Verbal Content* data element has been shown to be reliable. The PAC PRD forms a composite *Communication* variable from the two data elements, which was shown to have substantial agreement for inter-rater reliability (kappa range of 0.74 to 0.80).

Table: Assessment Instruments Using the *Understanding Verbal Content* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	2-day assessment period	Composite variable of Communication that included Understanding Verbal Content had substantial agreement, kappa range of 0.74 to 0.080
OASIS-C2	✓ Speech and Oral (Verbal) Expression of Language	Some variation in wording	
IRF-PAI v 1.4	✓	3-day assessment period	
LCDS v 3.0	✓	3-day assessment period	

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
MDS 3.0 v 1.14		Differences in response options Some variation in wording 7-day assessment period	

CMS is soliciting comment on the data element *Ability to Understand Others* as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Ability to Understand Others*. Specifically, CMS is soliciting comment on the following topics:

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

Specific to this data element, CMS also solicits comment on whether or not it is advisable to retitle the data element that has previously been called *Understanding Verbal Content* to *Ability to Understand Others*.

C1a.	Ability to Understand Others (excluding language barriers)
Enter ☐ Code	**4.** Understands: Clear Comprehension without cues or repetitions **3.** Usually Understands: Understands most conversations, but misses some part/intent of message. Requires cues at times to understand **2.** Sometimes Understands: Understands only basic conversations or simple, direct phrases. Frequently requires cues to understand **1.** Rarely/Never Understands **8.** Unable to assess **9.** Unknown

How Ability to Understand Others is Collected

The *Ability to Understand Others* data element can be administered by any clinician who has been trained to conduct this assessment. The assessor performs the assessment in the patient's or

resident's preferred language. Patients/residents with a hearing impairment should be interviewed using their usual communication devices or techniques.

The assessor interacts with the patient/resident and observes his or her understanding of others' communication. Consults are also done with direct care staff over all shifts, the patient's family, and the speech language pathologist, if involved in care. The assessor also reviews the medical record for indications of how well the patient/resident understands others. This data element can be collected at admission to and at discharge from the PAC setting.

How Ability to Understand Others is Coded

The data element, *Ability to Understand Others,* is coded as follows: If the patient/resident clearly comprehends messages and demonstrates comprehension through use of words or actions, a code of 4 is recorded. If the patient/resident misses some part of the intent of the message but comprehends most of it, a code of 3 is recorded. (The patient may have periodic difficulties in integrating information.) A code of 2 is recorded if the patient/resident demonstrates frequent difficulties integrating information, and responds adequately only to simple and direct questions or instructions; 1 is recorded if the patient/resident demonstrates very limited ability to understand communication. If the assessment cannot be completed, a code of 8 is recorded; for unknown, 9 is recorded.

Confusion Assessment Method (CAM)

The CAM is an instrument that screens for overall cognitive impairment as well as features to distinguish delirium or reversible confusion from other types of cognitive impairments.

Data Element Specification

The CAM is currently collected in the MDS 3.0 and the LCDS, and includes staff observations of delirium. Specifically, both use versions of the four-item CAM (Short CAM), but response options differ. The LCDS v3.0 includes two response options (yes/no, indicating that the behavior is present or not present) while the MDS v3.0 offers three response options (behavior continuously present, behavior present but fluctuates in onset, behavior not present). The LCDS and MDS versions of the CAM also differ slightly in wording and criteria for the *Altered Level of Consciousness* item. The version of the Short CAM tested in the PAC PRD includes four questions, but differs from the version administered in the LCDS v3.0 and MDS 3.0 v1.14, in that a psychomotor retardation question was included in the PAC PRD. That question is not included in what is being put forward for public comment.

The Short CAM has been shown to be effective in identifying delirium in validated research studies.3 The four items selected for the Short CAM were found to best distinguish delirium from other types of cognitive impairment. When tested in the PAC PRD, the CAM had substantial inter-rater reliability agreement for the "Inattention and Disorganized Thinking" questions (kappa range of 0.70 to 0.73); and the "Altered Level of Consciousness" question showed moderate agreement (kappa of 0.58).

Table: Assessment Instruments Using the *Confusion Assessment Method (CAM)*

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	Includes 3 (yes, continuous/yes, does not fluctuate/no) response options Includes psychomotor retardation item 2-day assessment period	Substantial agreement for *Inattention* and *Disorganized Thinking* items (kappa range of 0.70 to 0.73). Moderate agreement for *Altered Level of Consciousness* (kappa of 0.58)
OASIS-C2			
IRF-PAI v1.4			
LCDS v3.0	✓	Includes two (yes/no) response options 3-day assessment period	

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
MDS 3.0 v1.14	✓	Includes three (yes, continuous/yes, does not fluctuate/no) response options	

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

CMS is seeking comment on the cross-setting applicability of the CAM. Specifically, CMS is soliciting comment on the following topics:

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

C1610. Signs and Symptoms of Delirium (from CAM©), Shortened Version Worksheet (3-day assessment period)		
	⬇ Enter Code in Boxes	
CODING: **0. No** **1. Yes**	☐ ☐	**Acute Onset and Fluctuating Course** **A.** Is there evidence of an acute change in mental status from the patient's baseline? **B.** Did the (abnormal) behavior fluctuate during the day, that is, tend to come and go or increase and decrease in severity?
	☐	**Inattention** **C.** Did the patient have difficulty focusing attention, for example, being easily distractible, or having difficulty keeping track of what was being said?
	☐	**Disorganized Thinking** **D.** Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject.
	☐ ☐	**Altered Level of Consciousness** **E.** Overall, how would you rate the patient's level of consciousness? **E1.** Alert (Normal) **E2.** Vigilant (hyperaltert), or Lethargic (drowsy, easily aroused) or Stupor (difficult to arouse) or Coma (unarousable)

How the CAM Data Element is Collected

The CAM can be administered by any clinician who has been trained to conduct this assessment. The assessor observes patient behavior for the signs and symptoms of delirium during the BIMS interview. Within the 3-day assessment period, the assessor reviews medical record documentation to determine the patient's baseline status, fluctuations in behavior, and behaviors that might have occurred during the assessment period that were not observed during the BIMS. The assessor may interview staff, family members, and others in a position to observe the patient's behavior during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How the CAM is Coded

For A, the assessor records a code of 1 if there is evidence of an acute change in mental status from the patient's or resident's baseline, and 0 if there is no change in mental status.

For B, the assessor records a code of 1 if the severity of the patient's/resident's behavior increased or decreased during the day, and 0 is assigned if the patient's/resident's behavior did not fluctuate at all during the day.

For C, the assessor records a code of 1 if the patient/resident had difficulty focusing attention, was easily distracted, or had difficulty keeping track of what was said AND the inattention did not vary during the look-back period. A code of 0 is recorded if the patient/resident remains focused during the interview and all other sources agree that the patient/resident was attentive during other activities.

For D, the assessor records a code of 1 if, during the interview and according to other sources, the patient's or resident's responses were disorganized or incoherent, conversation was rambling or irrelevant, ideas were unclear or flowed illogically, or the patient/resident unpredictably switched from subject to subject. A code of 0 is recorded if all sources agree that the patient's/resident's thinking was organized and coherent, even if the answers were inaccurate or wrong.

For E, the assessor records a code of 1 to E1, and 0 to E2, if all sources agree that the patient/resident was alert and maintained wakefulness during conversation, interview(s), and activities. The assessor records a code of 0 to E1, and 1 to E2, if, during the interview and according to other sources, the patient/resident was consistently lethargic (difficult to keep awake), stuporous (very difficult to arouse and keep aroused), vigilant (startles easily to any sound or touch), or comatose.

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 impact 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 included in the *Behavioral Signs and Symptoms* group assess whether the patient has exhibited any behavioral symptoms that may indicate cognitive impairment or other issues during the assessment period. These include physical, verbal, and other disruptive or dangerous behavioral symptoms, but exclude wandering. Such behavioral disturbances can indicate unrecognized needs and care preferences and are associated most commonly with dementia and other cognitive impairment, and less commonly with adverse drug events, mood disorders, and other conditions.

Data Element Specification

The *Behavioral Signs and Symptoms* data elements were tested in the PAC PRD with two response options per data element (yes/no to indicate that behavior is present/not present). These data elements are also currently in use in the MDS 3.0 v1.14, but each question includes four response options ranging from "behavior not exhibited" (0) to behavior "occurred daily" (3). The OASIS-C2 includes a similar data element which records the frequency of disruptive behaviors on a 5-point Likert scale ranging from "never" (0) to "at least daily" (5).

Because of the low incidence, the PAC PRD did not report inter-rater reliability for these items.

Table: Assessment Instruments Using the *Behavioral Signs & Symptoms* Data Elements

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	2 response options	
OASIS-C2	✓	Collects frequency of "disruptive behavioral symptoms on a 5-point scale ranging from never to at least daily Separate data element collects cognitive, behavioral, and psychiatric symptoms that occur once a week	

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	4 response options ranging from behavior not present to behavior occurring daily	

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

CMS is seeking comment on the cross-setting applicability of the data elements included in the group, *Behavioral Signs and Symptoms*. Specifically, CMS is soliciting comment on the following topics:

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

E. Behavioral Signs and Symptoms

Has the patient exhibited any of the following behaviors during the 3-day assessment period?

Enter ☐ Code

E1. Physical behavioral symptoms directed toward others (e.g. hitting, kicking, pushing)

0. No
1. Yes

Enter ☐ Code

E2. Verbal behavioral symptoms directed toward others (e.g. threatening, screaming at others)

0. No
1. Yes

Enter ☐ Code

E3. Other disruptive or dangerous behavioral symptoms not directed toward others , including self-injurious behaviors (e.g. hitting or scratching self, attempts to pull out IVs, pacing)

0. No
1. Yes

How Behavioral Signs and Symptoms is Collected

The *Behavioral Signs and Symptoms* data elements can be administered by any clinician who has been trained to conduct this assessment. The assessor reviews the medical record for the assessment period, interviews staff across all shifts and disciplines, talks to family and friends who visit frequently, and observes the resident in a variety of situations in the assessment period. The assessor then indicates whether or not the patient/resident has exhibited any behavioral

symptoms during the 3-day assessment period. This data element can be collected at admission to the PAC setting.

How Behavioral Signs and Symptoms is Coded

For E1 to E3, the assessor records a code of 1 if the patient/resident has displayed the described behavior during the assessment period, and 0 if the patient/resident has not displayed the behavior. E1 pertains to physical behavioral symptoms directed towards others, such as hitting, kicking, or pushing. E2 pertains to verbal behavioral symptoms directed towards others, such as threatening or screaming at others. E3 specifies other disruptive or dangerous behavioral symptoms not directed towards others, including self-injurious behaviors, such as hitting or scratching self, attempting to pull out IVs, or pacing.

Patient Health Questionnaire (PHQ)

CMS is soliciting comment on the use of the Patient Health Questionnaire (PHQ). Specifically, CMS is soliciting comment on the advantages and limitations of the various versions of the PHQ for purposes of assessment data standardization. Two commonly used versions of the PHQ, the PHQ-9 and the PHQ-2, are described below.

The PHQ-9 and PHQ-2 are both clinically meaningful and reliable assessments, but they are very different in length and comprehensiveness. The PHQ-9 collects more information than the PHQ-2, but poses additional burden to patients/residents and assessors. On the other hand, the brevity of the PHQ-2 may be seen as a limitation, especially when trying to obtain information on people who screen positive for signs and symptoms of depression. An alternative to choosing between the two data elements, raised by stakeholders and clinical advisors, is to fashion a data element that utilizes the PHQ-2 as a gateway item for the longer PHQ-9. A "gateway" item is an item that, when scored a certain way, governs how scoring is completed for one or more additional items. This is called a "skip pattern." When a skip pattern is encountered, the assessor "skips" over the next item (or several items) and goes on to the next item active on the patient/resident assessment. Applying the PHQ-2 as a gateway item to the PHQ-9, an assessor would start out by conducting the PHQ-2 and, if patient scored beyond a threshold level indicating signs and symptoms of possible depression, the assessor would continue to administer the remaining seven items from the PHQ-9. Patients/residents who reported few or no depressive symptoms in the PHQ-2 would not be asked the additional items on the PHQ-9.

The PHQ-9

Data Element Specification

CMS currently collects on the PHQ-9 by means of the MDS 3.0 for Nursing Homes. The PHQ-9 has been validated in older adults,[4-8] home health,[9] skilled nursing facilities,[10] and rehabilitation populations.[11] 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.[11,12]

The PHQ-9 has good sensitivity and specificity in the detection of signs and symptoms of depression;[13-16] and performs similarly across sex, age, and racial/ethnic groups.[4,6,17-21] The PHQ-9 was used with 3,258 residents of SNFs in the national validation of the MDS 3.0, where it was found to be highly correlated with a physician diagnosis of depression.[10,23] In the national validation of the MDS 3.0, most facility residents (86 percent) successfully completed a PHQ-9 interview, and facility nurses were able to complete an observational version of the PHQ-9 for 92 percent of the residents who did not complete an interview. These high rates of participation have also been seen in actual implementation of the MDS 3.0. Evaluation of MDS 3.0 reports submitted during 2011-2012 show rates of resident participation in mood assessment interviews to be high (88 percent),[24] although reported rates of possible mood disorder are lower than rates obtained in some research studies.[25-29]

Table: Assessment Instruments Using the PHQ-9 Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD		PHQ-2 was tested	Substantial to almost perfect agreement, kappa range of 0.74 to 0.91
OASIS-C2		PHQ-2 is used for data collection	
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓		

The PHQ-2

The PHQ-2, which consists of the first two questions of the PHQ-9, assesses the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure). At least one of the two must be present for a determination of probable depression, which signals the need for additional clinical assessment to determine a depression diagnosis.

Data Element Specification

The PHQ-2 is currently in use in the OASIS-C2. The PHQ-2 was tested in the PAC PRD, where it was found to have almost perfect agreement for inter-rater reliability (kappa range of 0.84 to 0.91) when tested in all four PAC settings.

Table: Assessment Instruments Using PHQ-2 Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓		Substantial to almost perfect agreement, kappa range of 0.74 to 0.91
OASIS-C2	✓		
IRF-PAI v 1.4			
LCDS v 3.0			
MDS 3.0 v 1.14		Uses PHQ-9	

PHQ-2 as Gateway Data Item for PHQ-9

The PHQ-9 and PHQ-2 are both clinically meaningful and reliable assessments, but they are very different in length and comprehensiveness. The PHQ-9 collects more information than the PHQ-2, but poses additional burden to patients/residents and assessors. On the other hand, the brevity

of the PHQ-2 may be seen as a limitation, especially when trying to obtain information on people who screen positive for signs and symptoms of depression. An alternative to choosing between the two data elements, raised by stakeholders and clinical advisors, is to fashion a data element that utilizes the PHQ-2 as a gateway item for the longer PHQ-9. As described above, a "gateway" item is an item that, when scored a certain way, governs how scoring is completed for one or more additional items. Applying the PHQ-2 as a gateway item to the PHQ-9, an assessor would start out by conducting the PHQ-2 and, if patient scored beyond a threshold level indicating signs and symptoms of possible depression, the assessor would continue to administer the remaining seven questions from the PHQ-9. Patients/residents who reported few or no depressive symptoms in the PHQ-2 would not be asked the additional items on the PHQ-9.

CMS is soliciting comment on the PHQ-9 and PHQ-2 data elements, and a combined data element that would utilize the PHQ-2 as a gateway to the PHQ-9. The PHQ-9 and PHQ-2 are shown below.

CMS is seeking comment on the cross-setting applicability of a version of the PHQ (i.e. PHQ-9, PHQ-2, or using PHQ-2 as a gateway for PHQ-9). Specifically, CMS is soliciting comment on the following topics:

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

In particular, CMS seeks comment on:

- Tradeoffs between the reduced burden of using the shorter PHQ-2 versus the slightly higher positive predictive value of the PHQ-9.
- Whether the use of the PHQ-2 as a gateway data element to the full PHQ-9 would be feasible as a way to reduce burden while collecting more complete depression screening information on patients/residents whose responses to the PHQ-2 indicate signs and symptoms of possible depression.

D0200. Resident Mood Interview (PHQ-9 ©)

Ask patient: "During the last two weeks, have you been bothered by any of the following problems?"

If symptom is present, enter 1. (yes) in Column 1, Symptom Presence.
If yes in column 1, then ask the patient: "About how often have you been bothered by this?"
Read and show the patient a card with the symptom frequency choices. Indicate response in column 2, Symptom Frequency.

	1. Symptom Presence	2. Symptom Frequency	1. Symptom Presence	2. Symptom Frequency
	0. **No** (enter 0 in columns 1 and 2)	0. **Never or 1 day**		
	1. **Yes** (also enter 0-3 in column 2)	1. **2-6 days** (several days)		
	9. **No response** (leave column 2 blank)	2. **7-11 days** (half or more of the days)	**Enter Scores in Boxes**	
		3. **12-14 days** (nearly every day)		
A.	**Little interest or pleasure in doing things**		☐	☐
B.	**Feeling down, depressed, or hopeless**		☐	☐
C.	**Trouble falling or staying asleep, or sleeping too much**		☐	☐
D.	**Feeling tired or having little energy**		☐	☐
E.	**Poor appetite or overeating**		☐	☐
F.	**Feeling bad about yourself - or that you are a failure or have let yourself or your family down**		☐	☐
G.	**Trouble concentrating on things, such as reading the newspaper or watching television**		☐	☐
H.	**Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual**		☐	☐
I.	**Thoughts that you would be better off dead, or of hurting yourself in some way**		☐	☐

D0300. Total Severity Score

Enter Score	
☐☐	Add scores for all frequency responses in Column 2, Symptom Frequency. Total score must be between 00 and 27. Enter 99 if unable to complete review (i.e., Symptom Frequency is blank for 3 or more items).

How the PHQ-9 is Collected

The PHQ-9 can be administered by any clinician who has been trained to conduct this assessment. The assessor reads the questions to the patient/resident in in the following format: "I am going to ask you how often you have been bothered by a particular problem over the past two weeks. I will give you the choices that you see on this card." The assessor will point to the cue card and read aloud: "0-1 days—never or 1 day, 2-6 days—several days, 7-11 days—half or more of the days, or 12-14 days—nearly every day." The assessor does not provide definitions, as the meaning of the response must be based on the patient's/resident's interpretation (e.g., the patient/resident must define for him or herself what "tired" means). The assessor asks each question in sequence to assess the presence (column 1) and frequency (column 2) of a symptom before proceeding to the next question. This data element can be collected at admission to and at discharge from the PAC setting.

How the PHQ-9 is Coded

Responses of "No" for Symptom Presence questions are coded as 0 in column 1 and column 2. Responses of "Yes" for Symptom Presence questions are coded as 1 in column 1 and 0, 1, 2, or 3

in column 2, where 0 is used for Symptom Frequency of never or 1 day, 1 is used for 2 to 6 days, 2 is used for 7 to 11 days, and 3 is used for 12 to 14 days. If the patient/resident gives no response to the Symptom Presence questions, column 1 is coded as 9 and column 2 is left blank. If the patient/resident is unable or unwilling to respond, or for any response that is incomprehensible or incoherent, the assessor records a code of 9 in column 1 and leaves column 2 blank.

F2. Patient Health Questionnaire 2 (PHQ-2 ©)	
Ask patient: "During the last two weeks, have you been bothered by any of the following problems?"	
Enter ☐ Code	**F2a. Little interest or pleasure in doing things?** **0.** No (If No, skip to question F2c.) **1.** Yes **8.** Unable to respond (If Unable, skip to question F2c.)
Enter ☐ Code	**F2b. If Yes, how many days in the last 2 weeks?** **0.** Not at all (0 to 1 days) **1.** Several days (2 to 6 days) **2.** More than half of the days (7 to 11 days) **3.** Nearly every day (12 to 14 days)
Enter ☐ Code	**F2c. Feeling down, depressed, or hopeless?** **0.** No (If No, skip to question F3) **1.** Yes **8.** Unable to respond (If No, skip to question F3)
Enter ☐ Code	**F2d. If Yes, how many days in the last 2 weeks?** **0.** Not at all (0 to 1 days) **1.** Several days (2 to 6 days) **2.** More than half of the days (7 to 11 days) **3.** Nearly every day (12 to 14 days)

How the PHQ-2 is Collected

The PHQ-2 can be administered by any clinician who has been trained to conduct this assessment. The assessor first asks the patient/resident: “During the last two weeks, have you been bothered by any of the following problems: Little interest or pleasure in doing things?” If the patient/resident replies “yes,” the assessor then moves on to question F2b. If the patient/resident replies “no” or is unable to respond, the assessor moves on to question F2c. This process is repeated for question F2c. If the patient/resident replies “yes,” the assessor then

moves on to question F2d. If the patient/resident replies “no” or is unable to respond, the assessor moves on to question F3. This data element can be collected at admission to and at discharge from the PAC setting.

How the PHQ-2 is Coded

For question F2a, the assessor records a code of 1 if the patient/resident replies “yes,” and the assessor then moves on to question F2b. If the patient/resident replies “no” or is unable to respond, the assessor moves on to question F2c. Question F2b is coded 0 to 3 depending on the frequency of the patient’s/resident’s feeling little interest in doing things in the past 2 weeks. A code of 0 is used for 0 to 1 days; 1 is used for 2 to 6 days; 2 is used for 7 to 11 days; 3 is used for 12 to 14 days.

Question F2c is coded like F2a: 1 if the patient/resident replies “yes,” and the assessor then moves on to question F2d. If the patient/resident replies “no” or is unable to respond, the assessor moves on to question F3. Question F2d is coded 0 to 3 depending on the frequency of the patient’s/resident’s feeling depressed, down, or hopeless in the past 2 weeks, as described for F2b.

Medical Conditions: Pain

Pain is a highly prevalent medical condition that is frequently under-recognized, under-detected, and undertreated. In the context of PAC patients/residents, although pain is sometimes to be expected, 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 Presence
- Pain Severity

Pain Presence

Pain assessment provides a basis for evaluation, treatment need, and response to treatment. The *Pain Presence* data element consists of one question to assess the presence of pain.

Data Element Specification

Pain Presence is collected in the MDS 3.0, the IRF-PAI, LCDS, and the OASIS-C2. The *Pain Presence* data element is currently used in the MDS 3.0, but has a longer look-back period of 5 days. The IRF-PAI and LCDS do not include an interview-based pain assessment. The OASIS-C2 includes reference to a standardized pain assessment which may be interview-based, but a formal assessment data element is not part of the OASIS itself.

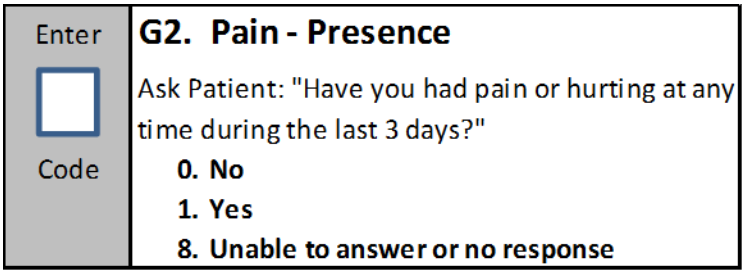
An identical version of the *Pain Presence* data element (look-back of 2 days) was tested in the PAC PRD. It demonstrated substantial to almost perfect agreement for inter-rater reliability in all four PAC settings (kappa range of 0.79 to 0.88).

Table: Assessment Instruments Using the *Pain Presence* 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	✓	5-day assessment period	

CMS is seeking comment on the cross-setting applicability of the data element, *Pain Presence*, as shown below. 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 Pain Presence is Collected

The data element, *Pain Presence* can be administered by any clinician who has been trained to conduct this assessment. Questions G2 is completed for all patients/residents capable of any communication and for whom an interpreter is present or not required. The assessor explains the purpose of the question to the patient/resident (e.g., "I'd like to ask you some questions about pain. The reason I am asking these questions is to understand how often you have pain and how severe it is.")

The assessor reads the data element, *Pain Presence* as it is written. The assessor may use other terms for pain (e.g. hurting) or follow-up discussion if the patient/resident seems unsure or hesitant. If the patient/resident is unsure whether the pain occurred in the specified time interval, the patient/resident is prompted to think about the most recent episode of pain and try to determine if it occurred during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Pain Presence is Coded

If the patient/resident replies "no," the data element is coded as 0. If the patient/resident replies "yes," it is coded as 1. If the patient/resident is unable to answer, the assessor codes the data element as 8.

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 data element, *Pain Severity*, 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 Specification

Pain Severity is currently collected in the MDS 3.0, the IRF-PAI, LCDS, and the OASIS-C2. The *Pain Severity* data element is currently used in the MDS 3.0 (*Pain Intensity*), but has a longer look-back period of 5 days. The IRF-PAI v1.4 and LCDS v3.0 do not include an interview-based pain assessment. The OASIS-C2 includes reference to a standardized pain assessment which may be interview-based, but a formal assessment data element is not part of the OASIS-C2 itself.

The *Pain Severity* data element (look-back of 2 days) was tested in the PAC PRD. It demonstrated substantial to almost perfect agreement for inter-rater reliability in all four settings (kappa range of 0.79 to 0.88).

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 data element, *Pain Severity*. Specifically, CMS is soliciting comment on the following topics:

- Potential for improving quality

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

Enter ☐ Code	**G3. Pain Severity**
	Ask Patient: "Please rate your worst pain during the last 3 days on a zero to 10 scale, with zero being no pain and 10 as the worst pain you can imagine."
	Enter 88 if patient does not answer or is unable to respond.

How Pain Severity is Collected

The *Pain Severity* data element can be administered by any clinician who has been trained to conduct this assessment. Question G3 is completed for all patients/residents capable of any communication and for whom an interpreter is present or not required. The assessor explains the purpose of the question to the patient/resident (e.g., "I'd like to ask you some questions about pain. The reason I am asking these questions is to understand how often you have pain and how severe it is.")

The assessor reads the *Pain Severity* question as it is written. The assessor may use other terms for pain or follow-up discussion if the patient/resident seems unsure or hesitant. If the patient/resident is unsure whether the pain occurred within the 3-day time interval, the patient/resident is prompted to think about the most recent episode of pain and try to determine if it occurred during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

For question G3, the assessor reads the question and response choices as written while showing the patient/resident the response scale on a written sheet. 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 the zero to 10 scale.

How Pain Severity is Coded

Question G3 is coded from 0 to 10 according the patient's/resident's response. If the patient/resident does not answer or is unable to respond, G3 is coded as 88.

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 sensory impairments:

- Ability to Hear
- Ability to See in Adequate Light

Ability to Hear

There is strong evidence that screening tools can reliably and accurately identify adults with objective hearing loss. For many persons with hearing impairment, hearing aids or assistive listening devices can reduce the effects of hearing loss.[32] The data element, *Ability to Hear* assesses level of hearing impairment, consists of one question.

Data Element Specification

Ability to Hear is currently collected in the OASIS-C2 and the MDS 3.0. The OASIS-C2 assesses patients/residents' hearing abilities via interviews, observations, physical assessment, and referral information (medical history). The data element is nearly identical to that which is featured here but uses slightly different numerical codes. The MDS 3.0 contains the data element, *Ability to Hear*, which codes the extent of hearing loss and has a look-back period of 7 days, consistent with most of the data elements in that assessment, but longer than other PAC assessments. This data element also has more response categories than OASIS-C2 (four total options ranging from "adequate" to "highly impaired" with no options for "unable to assess" or "unknown"). This data element was tested in the PAC PRD. It showed substantial agreement for inter-rater reliability across PAC settings (kappa of 0.78).

Table: Assessment Instruments the Using *Ability to Hear* Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	2-day assessment period	Substantial agreement, kappa of 0.78
OASIS-C2	✓		
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	7-day assessment period 4 response categories: adequate, minimal, moderate, highly impaired	

CMS is soliciting comment on the *Ability to Hear* data element as shown below. The data element for which CMS seeks comment on is identical to that which was tested in the PAC PRD, except that first response option was changed from "Hears normal conversation or TV without difficulty" to remove the reference to TV. The references to TV was removed based on feedback from stakeholders and clinical advisors who suggested that TV volume could vary and therefore was not a standard anchor for a question on hearing ability.

CMS is seeking comment on the cross-setting applicability of the data element, *Ability to Hear*. Specifically, CMS is soliciting comment on the following topics:

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

C1d.	Ability to Hear (With hearing aid or hearing appliance, if normally used)
Enter ☐ Code	**3.** Adequate: Hears normal conversation without difficulty **2.** Mildly to Moderately Impaired: Difficulty hearing in some environments or speaker may need to increase volume or speak distinctly **1.** Severely Impaired: Absence of useful hearing **8.** Unable to assess **9.** Unknown

How Ability to Hear is Collected

The data element, *Ability to Hear* can be administered by any clinician who has been trained to conduct this assessment. If applicable, the assessor makes sure the patient/resident has his/her hearing appliance in place and operational before beginning the evaluation. The assessor also requests an interpreter for patients/residents not proficient in English. The assessor then observes the patient/resident and asks about hearing function in different situations (e.g., hearing staff members, using telephone). The assessor starts by speaking in a normal tone and notes whether they need to raise their voice, speak more slowly, or speak while facing the patient/resident in order for the patient/resident to understand the assessor properly. The assessor should also speak by looking away to ensure the patient/resident is not lip-reading. If the patient/resident does not appear to be impaired, the assessor speaks in a whisper. Finally, the assessor reviews the medical record and consults the patient's/resident's family, direct care staff, and speech or hearing specialists. This data element can be collected at admission to the PAC setting.

How Ability to Hear is Coded

Question C1d is coded as 3, *Adequate*, if the patient/resident hears all normal conversation and TV without difficulty. This question is coded as 2 if the patient/resident hears speech at conversational levels but has difficulty hearing when not in quiet listening conditions, one-on-one situations, or when the speaker adjusts tonal quality, speaks distinctly, and is facing the patient/resident. A code of 1 is assessed is the patient/resident fails to comprehend conversational speech, even when the speaker makes maximum adjustments. This question is coded 8 for *Unable to Assess* and 9 for "*Unknown*."

Ability to See in Adequate Light

Visual impairment is associated with many poor outcomes. Functional disability and higher levels of depressive symptoms are among the most commonly cited co-morbidities with vision loss in both community and long-term care populations.[33,34] Furthermore, vision impairment may increase the risk of delirium[35,36] in hospitals and other institutional settings and complicate rehabilitation care for patients/residents, placing individuals at a greater risk for falls and injuries.[37] An accurate diagnosis of visual impairments may lead to improvements in multiple domains of a patient's life.

Data Element Specification

The data element, *Ability to See in Adequate Light* is currently collected in the MDS 3.0 and OASIS-C2. The data element in the MDS 3.0 contains 5 response options ranging from 0 (*adequate*) to 4 (*severely impaired*). The OASIS-C2 assesses patients/residents' visual abilities through interviews, observations, physical assessment, and referral information (medical history). The OASIS-C2 evaluates the extent to which patients/residents can see in various contexts (with the assistance of corrective lenses, if necessary). The impairment scale ranges from 0 (normal) to 2 (*severely impaired*). IRF-PAI and LCDS do not include visual or hearing impairment, outside of free entry of ICD codes. This data element was also tested in the PAC PRD.

The *Ability to See in Adequate Light* data element was tested in the PAC PRD assessment. The PAC PRD found substantial agreement for inter-rater reliability across settings for this data element (kappa of 0.74).

Table: Assessment Instruments Using the *Ability to See in Adequate Light* Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	2-day assessment period	Substantial agreement, kappa of 0.74
OASIS-C2	✓	Assesses vision status on 3-point scale ranging from *normal* to *severe*	
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	7-day assessment period 5 response options	

CMS is soliciting comment on the *Ability to See in Adequate Light* data element as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Ability to See in Adequate Light*. Specifically, CMS is soliciting comment on the following topics:

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

C1c.	Ability to See in Adequate Light (with glasses or other visual appliances)
Enter ☐ Code	3. Adequate: Sees fine detail, including regular print in newspapers/books
	2. Mildly to Moderately Impaired: Can identify objects; may see large print
	1. Severely Impaired: No vision, or object identification questionable
	8. Unable to assess
	9. Unknown

How Ability to See in Adequate Light is Collected

The data element, *Ability to See in Adequate Light* can be administered by any clinician who has been trained to conduct this assessment. The assessor first asks the patient/resident about his or her visual abilities (e.g., *Do you have any difficulty reading the newspaper? Can you read the labels on your medication bottles?*). The assessor tests the accuracy of these findings by asking the patient/resident to look at a newspaper and read aloud, starting with larger headlines and ending with the smallest print. If the patient/resident is illiterate or does not speak English, photos of objects of different sizes may be used. These tests are done using the patient's/resident's customary visual appliance for close vision (e.g., eyeglasses, magnifying glass) and in adequate lighting. If results are inconclusive, the assessor asks direct care staff about the patient's/resident's usual visual patterns over the assessment period. If the patient/resident is unable to communicate or follow directions, the assessor observes the patient's/resident's eye movements to see if his or her eyes seem to follow movement and objects. This data element can be collected at admission to the PAC setting.

How Ability to See in Adequate Light is Coded

Question C1c is coded as 3, *Adequate*, if the patient/resident sees fine detail, including regular print in newspapers/books. This question is coded as 2 if the patient/resident patient sees large print, but not regular print in newspapers/books OR the patient/resident is not able to see newspaper headlines, but can identify objects in his or her environment. A code of 1 is recorded if the patient's/resident's ability to identify objects in his or her environment is in question, but the patient's/resident's eye movements appear to be following objects (especially people walking by), or if the patient/resident has no vision, sees only light, colors or shapes, or does not appear to follow objects with eyes. Question C1c is coded 8 for *Unable to Assess* and 9 for *Unknown*.

Special Services, Treatments, and Interventions

Special services, treatments, and interventions can have a profound effect on an individual's health status, self-image, and quality of life. Reevaluation of special services, treatments and interventions received and performed is important to ensure the continued appropriateness of care and support care transitions. The assessment of special services, treatments, and interventions may also help to identify resource use intensity by capturing the medical complexity of patients/residents.

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 Special Services, Treatments, and Interventions.

- Hemodialysis
- IV (intravenous) Chemotherapy
- Radiation
- Central Line
- Total Parenteral Nutrition (TPN)
- Enteral Nutrition
- Vasoactive Medications
- Oxygen
- BiPAP/CPAP (bilevel or continuous positive airway pressure)
- Invasive Mechanical Ventilator: Weaning Status
- Suctioning
- Tracheostomy care

Hemodialysis

Hemodialysis is primarily used to provide replacement for lost kidney function. Hemodialysis may be needed for a short period, or, if the kidneys have permanently stopped function, may be needed permanently or until a kidney transplant is possible. Hemodialysis takes many hours multiple times per week. It is resource intensive and requires specialized nurses and technicians. Patient/resident vital signs must be monitored closely during treatment and there is frequent lab test. Therefore, patients/residents on hemodialysis have special needs and fewer choices at PAC discharge.

Data Element Specification

A similar data element, *Dialysis*, is currently collected in the MDS 3.0. This data element asks first if the resident received dialysis in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received dialysis in the past 14 days while a resident. The LCDS v3.0 also includes a data element to code for dialysis as being part of a patient's/resident's treatment plan. The data element *Hemodialysis* was tested in the PAC PRD.

Table: Assessment Instruments Using the *Hemodialysis* Data Element

Instrument	**Has Same or Similar Data Element**	**Data Element Variations**	**Other information**
Assessment used in PAC PRD	✓	2-day assessment period	
OASIS-C 2			
IRF-PAI v1.4			
LCDS v3.0	✓	If in treatment plan Data element is titled *Dialysis*	
MDS 3.0 v1.14	✓	14-day assessment period Data element is titled *Dialysis*	

CMS is soliciting comment on the *Hemodialysis* data element as shown below. This version differs from those in current use in both its title (i.e. *Hemodialysis* instead of *Dialysis*) and its content; the *Hemodialysis* data element would capture the presence of hemodialysis only, and not include peritoneal dialysis.

CMS is seeking comment on the cross-setting applicability of the *Hemodialysis* data element. Specifically, comment is requested on the following topics:

- Potential for improving quality
- Validity

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

O0100	Special Services, Treatments, and Interventions
☐	J. Hemodialysis

How Hemodialysis is Collected

The *Hemodialysis* data element can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received hemodialysis during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Hemodialysis is Coded

Coding for this data element is done by checking the box if, during the 3-day assessment period, the patient/resident received hemodialysis.

IV Chemotherapy

Chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. This treatment also indicates severity of illness. Intravenous (IV) chemotherapy requires more health care resources for inpatient and ambulatory care services than oral chemotherapy, which can be taken at home and allows for more patient flexibility.

Data Element Specification

The data element, *IV Chemotherapy* was collected in the PAC PRD and a similar data element, *Chemotherapy*, is currently in use in the MDS 3.0. This data element asks first if the resident received chemotherapy in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received chemotherapy in the past 14 days while a resident. A simplified version of this data element, which includes a single check box, is proposed.

Table: Assessment Instruments Using the *Chemotherapy* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2			
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	14-day assessment period Data element is titled *Chemotherapy*	

CMS is seeking comment on the cross-setting applicability of the data element, *IV Chemotherapy*, as shown below. This version differs from those in current use in its title (i.e. *IV Chemotherapy* instead of *Chemotherapy*) and its focus; the data element below would capture patient/resident use of IV chemotherapy specifically, and not include oral chemotherapy. Specifically, CMS is soliciting comment on the following topics:

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

In particular, CMS is soliciting comment on the usefulness or meaningfulness of assessing IV chemotherapy only versus all types of chemotherapy.

☐	**D28a. IV Chemotherapy**

How IV Chemotherapy is Collected

The IV Chemotherapy data element can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received IV chemotherapy during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How IV Chemotherapy is Coded

Coding for this data element is done by checking the box if, within the 3-day assessment period, the patient/resident received IV chemotherapy agent administered as an antineoplastic. Each drug should be evaluated to determine its reason for use before coding. The drugs coded are those actually used for cancer treatment. For example, megestrol acetate is classified as an antineoplastic drug. One of its side effects is appetite stimulation and weight gain. If megestrol acetate is being given only for appetite stimulation, it should not be coded as chemotherapy in this data element, as the patient/resident is not receiving the medication for chemotherapy purposes in this situation.

Radiation

Radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. It is generally used to target solid tumors.

Data Element Specification

The data element, *Radiation* is currently collected in the MDS 3.0. This data element asks first if the resident received radiation in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received radiation in the past 14 days while a resident. A simplified version of this data element, which includes a single check box, is proposed.

Table: Assessment Instruments Using the *Radiation* Data element

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

CMS is soliciting comment on the *Radiation* data element as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Radiation*. Specifically, CMS is soliciting comment on the following topics:

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

☐	**B. Radiation**

How Radiation is Collected

The data element, *Radiation*, can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received radiation during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Radiation is Coded

Coding for this data element is done by checking the box if, within the 3-day assessment period, the patient/resident received intermittent radiation therapy, as well as radiation administered via radiation transplant.

Central Line Management

Central lines are a type of catheter inserted into a large vein to monitor hemodynamic status, to perform hemodialysis, and to administer medications, fluids, blood products, and total parenteral nutrition (TPN). Central lines require specialized nursing care and monitoring to ensure they do not get blocked and to prevent infection. Treatment with a central line will therefore influence the setting that a patient/resident is discharged to and will predict resource utilization.

Data Element Specification

The *Central Line Management* data element is not currently in use in any of the mandated PAC assessments, and was pilot tested only in the PAC PRD. The Central Line Management data element consists of a check box used to indicate whether a patient/resident has received central line management during the assessment period.

Table: Assessment Instruments Using the *Central Line Management* Data Element

Instrument	Has Same or Similar Data Element	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 *Central Line Management* data element, as shown below. CMS is seeking comment the cross-setting applicability of the data element, *Central Line Management*. 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 Central Line Management is Collected

The Central Line Management data element can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the

patient's/resident's medical record to determine whether or not the patient/resident received central line management during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Central Line Management is Coded

Coding for this data element is done by checking the box if, within the 3-day assessment period, the patient/resident had a central line managed during continuous or intermittent administration.

Total Parenteral Nutrition (TPN)

With Total Parenteral Nutrition (TPN), a patient is fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. TPN is often used following surgery, when feeding by mouth or digestive system is not possible, when a patient's digestive system cannot absorb nutrients due to chronic disease, or if a patient's nutritional requirement cannot be met by tube feeding and supplementation.

Data Element Specification

The data element, *Total Parenteral Nutrition* assesses whether a patient has received TPN during the assessment period. It is currently collected in the OASIS-C2, IRF-PAI, LCDS, and the MDS 3.0. The OASIS-C2 data element assesses if the patient is receiving parenteral nutrition at home. Section O of the IRF-PAI includes a check box data element to assess *Total Parenteral Nutrition*. The look-back period on this data element is 3 days. The LCDS includes a checklist, including a question asking if TPN is part of the patient's treatment plan. The MDS 3.0 includes a checklist, including questions asking if the resident received TPN in the past 14 days, while not a resident of the assessing facility, and if the resident received TPN in the past 14 days while a resident. This data element was also tested in the PAC PRD.

Table: Assessment Instruments Using the *Total Parenteral Nutrition* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓		
OASIS-C2	✓	7-day assessment period	
IRF-PAI v1.4	✓	3-day assessment period	
LCDS v3.0	✓		
MDS 3.0 v1.14	✓	7-day assessment period	

CMS is soliciting comment on the *Total Parenteral Nutrition* data element, as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Total Parenteral Nutrition*. 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 Total Parenteral Nutrition is Collected

The data element, *Total Parenteral Nutrition* can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received total parenteral nutrition during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Total Parenteral Nutrition is Coded

Coding for this data element is done by checking the box if, within the 3-day assessment period, the patient/resident received TPN administered continuously or intermittently.

Enteral Nutrition

Enteral nutrition refers to the delivery of a nutritionally complete feed, containing protein, carbohydrate, fat, water, minerals and vitamins, directly into the stomach, duodenum, or jejunum. It is typically used for patients/residents who have a functional gastrointestinal tract but are unable to maintain an adequate or safe oral intake. The data element, *Enteral Nutrition*, assesses if the patient/resident received enteral nutrition during the assessment period.

Data Element Specification

Enteral Nutrition is currently collected in the OASIS-C2, with a question asking if the patient is receiving enteral nutrition at home. A related data element, *Feeding tube – nasogastric or abdominal (PEG)*, is included in the MDS 3.0 and assesses a patient's use of a feeding tube in the past 14 days while not a resident, and in this same time period while a resident. In the IRF-PAI, a *Swallowing Status* data element also captures some information related to enteral nutrition through the response option "Tube/Parenteral Feeding."

Table: Assessment Instruments Using the *Enteral Nutrition* Data element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD			
OASIS-C2	✓		
IRF-PAI v1.4	✓	*Swallowing Status ("Tube/Parenteral Feeding")*	
LCDS v3.0			
MDS 3.0 v1.14	✓	*Feeding tube*	

CMS is soliciting comment on the *Enteral Nutrition* data element, as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Enteral Nutrition*. Specifically, CMS is soliciting comment on the following topics:

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

☐	3 -	Enternal Nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)

How Enteral Nutrition is Collected

The data element *Enteral Nutrition* can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received enteral nutrition during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Enteral Nutrition Data is Coded

Coding for this data element is done by checking the box if, during the 3-day assessment period, the patient/resident received enteral nutrition.

Vasoactive Medications

Vasoactive medications (e.g., pressors, dilators, continuous medication for pulmonary edema) are drugs that increase or decrease blood pressure and/or heart rate. Because patients on these medications can experience extreme changes in blood pressure or heart rate, use of these medications requires close monitoring and observation. The data element, *Vasoactive Medications* assesses if the patient received vasoactive medications during the assessment period.

Data Element Specification

None of the existing PAC assessments include a data element to capture the use of vasoactive medications. The MDS 3.0 does have a data element for *IV Medications*, which captures a subset of patients/residents who receive vasoactive medications. In the PAC PRD, IV vasoactive medications were assessed with a check box item.

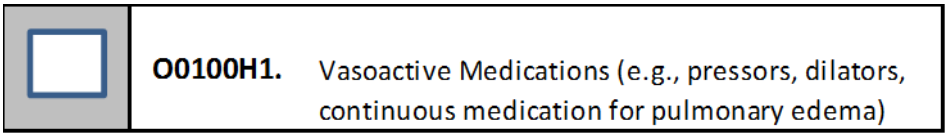
Table: Assessment Instruments Using the *Vasoactive Medications* Data Element

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

CMS is soliciting comment on the *Vasoactive Medications* data element, as shown below. This version of the data element differs from that in current use in that it is specific to vasoactive medications, but not limited to IV vasoactive medications.

CMS is seeking comment on the cross-setting applicability of the data element, *Vasoactive Medication*. 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 Vasoactive Medications is Collected

This data element can be collected by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident is receiving this treatment as part of his or her plan of care during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Vasoactive Medications is Coded

Coding for this data element is done by checking the box if, during the 3-day assessment period, the patient/resident is receiving vasoactive medication.

Oxygen (intermittent or continuous)

Oxygen therapy provides a patient/resident with extra oxygen when conditions (e.g., COPD, pneumonia, severe asthma) prevent the patient/resident from getting enough oxygen from breathing. The data element, *Oxygen*, assesses if the patient received oxygen therapy.

Data Element Specification

The *Oxygen* data element is included in the OASIS-C2 and the MDS 3.0. This data element asks first if the resident received oxygen in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received oxygen in the past 14 days while a resident.

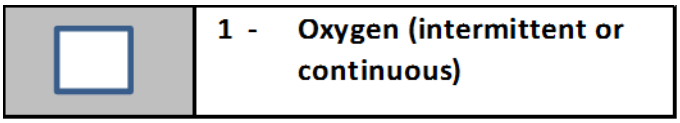
Table: Assessment Instruments Using the *Oxygen* (intermittent or continuous) Data element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	Collected High O2 Concentration Delivery System with FiO2>40%	
OASIS-C2	✓		
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	14-day assessment period	

CMS is soliciting comment on the *Oxygen* data element, as shown below.

CMS is seeking comment on the cross-setting applicability of the *Oxygen* 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 Oxygen is Collected

The data element, *Oxygen* can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient received oxygen within the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Oxygen is Coded

Coding for this data element is done by checking the box if, during the 3-day assessment period, the patient/resident is receiving oxygen.

BiPAP/CPAP

CPAP (continuous positive airway pressure) and BiPAP (bilevel positive airway pressure) are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air through a mask continuously or via electronic cycling throughout the breathing cycle. A BiPAP/CPAP mask enables the individual to support his or her own respiration by providing enough pressure when the individual inhales to keep his or her airways open, unlike ventilators that "breathe" for the individual. They can be used for sleep apnea or for more serious conditions like COPD or respiratory failure.

Data Element Specification

The data element, *BiPAP/CPAP* assesses if the patient received bilevel positive airway pressure or continuous positive airway pressure during the assessment period. It is currently collected in the OASIS-C2, LCDS, and the MDS 3.0. The OASIS-C2 assessment data element includes a checkbox item for respiratory treatments, of which continuous/bi-level positive airway pressure is included. The LCDS includes a checklist, including an item asking if a non-invasive ventilator (BIPAP, CPAP) is part of the patient's treatment plan. The MDS 3.0 includes a checklist, including an item asking if the resident received treatment with a BiPAP/CPAP. This data element asks first if the resident used BIPAP/CPAP in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident used BIPAP/CPAP in the past 14 days while a resident. A checkbox item for *Non-invasive Ventilation (CPAP)* was tested in the PAC PRD.

Table: Assessment Instruments Using *BiPAP/CPAP* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	*Non-invasive ventilation (CPAP)*	
OASIS-C2	✓		
IRF-PAI v1.4			
LCDS v3.0	✓	*Non-invasive Ventilator (BIPAP, CPAP)*	
MDS 3.0 v1.14	✓	14-day assessment period	

CMS is soliciting comment on the *BiPAP/CPAP* data element as shown below.

CMS is seeking comment on the cross-setting applicability of the *BiPAP/CPAP* 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

In particular, CMS seeks comment on:

- The cross-setting applicability of the combined BiPAP/CPAP data element and whether there is a need for two separate data elements.

☐	**G. BiPAP/CPAP**

How BiPAP/CPAP is Collected

The *BiPAP/CPAP* data element can be coded by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received BiPAP/CPAP support during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How BiPAP/CPAP is Coded

Coding for this data element is done by checking the box if, within the 3-day assessment period, the patient/resident is received any type of BiPAP/CPAP respiratory support devices, including if a ventilator or respirator is being used as a substitute for BiPAP/CPAP, or patient/resident places or removes his/her own BiPAP/CPAP mask.

Invasive Mechanical Ventilator: Weaning Status

Weaning from mechanical ventilation is the process of reducing ventilator support, ultimately resulting in a patient/resident breathing spontaneously and being extubated. Many complications associated with invasive ventilation increase in likelihood with duration of ventilation; therefore, it is important to wean patients/residents from mechanical ventilation as quickly as possible.

Data Element Specification

The data elements in the *Invasive Mechanical Ventilator: Weaning Status* section were tested in the PAC PRD and are currently collected in the LCDS. The data elements in the LCDS ask respondents to select all respiratory treatments that apply to the patient, including data elements for *Invasive Mechanical Ventilator: weaning, and Invasive Mechanical Ventilator: non-weaning.*

Table: Assessment Instruments Using *Invasive Mechanical Ventilator: Weaning Status* at Discharge Data Elements

Instrument	Has Same or Similar Data Element	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 *Invasive Mechanical Ventilator: Weaning Status* data element, as shown below.

CMS is seeking comment on the cross-setting applicability of the data element, *Invasive Mechanical Ventilator: Weaning Status* data elements. Specifically, CMS is soliciting comment on the following topics:

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

☐	**D14. Ventilator - Weaning**
☐	**D15. Ventilator - Non-Weaning**

How Invasive Mechanical Ventilator: Weaning Status is Collected

The data element can be coded by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident has been weaning or not weaning from this treatment during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Invasive Mechanical Ventilator: Weaning Status is Coded

Coding for the data elements is done by checking the box if, during the 3-day assessment period, the patient/resident is receiving invasive mechanical ventilation. The appropriate box is checked, based on whether the patient/resident is weaning, or not, from mechanical ventilation.

Suctioning

Suctioning is used to clears secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube.

Data Element Specification

The data element, *Suctioning*, assesses whether a patient/resident received suctioning during the assessment period. As currently collected in the MDS 3.0, the *Suctioning* data element exists as a checklist. This data element asks first if the resident received suctioning in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received suctioning in the past 14 days while a resident. In the PAC PRD, suctioning was assessed with a data element asking if patients/residents use a *Trach Tube with Suctioning*.

Table: Assessment Instruments Using the *Suctioning* Data Element

Instrument	Has Same or Similar Data Element	Data Element Variations	Other information
Assessment used in PAC PRD	✓	Trach Tube with Suctioning	
OASIS-C2			
IRF-PAI v1.4			
LCDS v3.0			
MDS 3.0 v1.14	✓	14-day assessment period	

CMS is soliciting comment on the *Suctioning* data element as shown below.

CMS is seeking comment on the cross-setting applicability of the *Suctioning* data element, as shown below. Specifically, CMS is soliciting comment on the following topics:

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

☐	**D. Suctioning**

How Suctioning is Collected

The *Suctioning* data element can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical record to determine whether or not the patient/resident received suctioning during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Suctioning is Coded

Coding for this data element is done by checking the box if, during the 3-day assessment period, the patient/resident received tracheal and/or nasopharyngeal suctioning but not oral suctioning. This data element may also be coded if the patient/resident performs his/her own tracheal and/or nasopharyngeal suctioning.

Tracheostomy Care

A tracheostomy provides an air passage to help a patient breathe when the usual route for breathing is obstructed or impaired. Care for a tracheostomy, including suctioning and cleaning, is important to preserve patency and prevent infection. This is an involved process that must be conducted regularly.

Data Element Specification

The data element, *Tracheostomy Care*, assesses whether a patient/resident received tracheostomy care during the assessment period. As currently collected in the MDS 3.0, the *Tracheostomy care* data element exists as a checklist. This data element asks first if the resident received tracheostomy care in the past 14 days while not a resident of the assessing facility. Next, the data element asks if the resident has received tracheostomy care in the past 14 days while a resident. A simplified version of this data element, which includes a single check box, is proposed.

Table: Assessment Instruments Using *Tracheostomy Care* Data element

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

CMS is soliciting comment on the *Tracheostomy Care* data element, as shown below.

CMS is seeking comment on the cross-setting applicability of the *Tracheostomy Care* 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

☐	**E. Tracheostomy Care**

How Tracheostomy Care is Collected

The *Tracheostomy Care* data element can be administered by any clinician with knowledge of the patient's/resident's medical history. The assessor reviews the patient's/resident's medical

record to determine whether or not the patient/resident has received tracheostomy care during the 3-day assessment period. This data element can be collected at admission to and at discharge from the PAC setting.

How Tracheostomy Care is Coded

This data element is coded if the patient/resident received cleansing of the tracheostomy and/or cannula during the 3-day assessment period. This data element may be coded if the patient/resident performs his/her own tracheostomy care.

References

1. Chodosh J, Edelen MO, Buchanan JL, et al. Nursing home assessment of cognitive impairment: development and testing of a brief instrument of mental status. *Journal of the American Geriatrics Society.* 2008;56(11):2069-2075.

2. Saliba D, Buchanan J, Edelen MO, et al. MDS 3.0: Brief interview for mental status. *Journal of the American Medical Directors Association.* 2012;13(7):611-617.

3. Inouye SK, Kosar CM, Tommet D, et al. The CAM-S: development and validation of a new scoring system for delirium severity in 2 cohorts. *Annals of internal medicine.* 2014;160(8):526-533.

4. Klapow J, Kroenke K, Horton T, Schmidt S, Spitzer R, Williams JB. Psychological disorders and distress in older primary care patients: a comparison of older and younger samples. *Psychosomatic Medicine.* 2002;64(4):635-643.

5. Kroencke K, Spitzer R, Williams J. The phq-9: Validity of a brief depression severity measure [Electronic version]. *Journal of General Internal Medicine.* 2001;16(9):606-613.

6. Löwe B, Kroenke K, Herzog W, Gräfe K. Measuring depression outcome with a brief self-report instrument: sensitivity to change of the Patient Health Questionnaire (PHQ-9). *Journal of affective disorders.* 2004;81(1):61-66.

7. Ruo B, Rumsfeld JS, Hlatky MA, Liu H, Browner WS, Whooley MA. Depressive symptoms and health-related quality of life: the Heart and Soul Study. *Jama.* 2003;290(2):215-221.

8. Williams JW, Pignone M, Ramirez G, Stellato CP. Identifying depression in primary care: a literature synthesis of case-finding instruments. *General hospital psychiatry.* 2002;24(4):225-237.

9. Ell K, Unützer J, Aranda M, Sanchez K, Lee P-J. Routine PHQ-9 depression screening in home health care: Depression prevalence, clinical and treatment characteristics, and screening implementation. *Home Health Care Services Quarterly.* 2006;24(4):1-19.

10. Saliba D, DiFilippo S, Edelen MO, Kroenke K, Buchanan J, Streim J. Testing the PHQ-9 interview and observational versions (PHQ-9 OV) for MDS 3.0. *Journal of the American Medical Directors Association.* 2012;13(7):618-625.

11. Williams LS, Brizendine EJ, Plue L, et al. Performance of the PHQ-9 as a screening tool for depression after stroke. *Stroke.* 2005;36(3):635-638.

12. Fann JR, Bombardier CH, Dikmen S, et al. Validity of the Patient Health Questionnaire‐9 in Assessing Depression Following Traumatic Brain Injury. *The Journal of head trauma rehabilitation.* 2005;20(6):501-511.

13. Gilbody S, Richards D, Brealey S, Hewitt C. Screening for depression in medical settings with the Patient Health Questionnaire (PHQ): a diagnostic meta-analysis. *Journal of general internal medicine.* 2007;22(11):1596-1602.

14. Manea L, Gilbody S, McMillan D. Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. *Canadian Medical Association Journal.* 2012;184(3):E191-E196.

15. Moriarty AS, Gilbody S, McMillan D, Manea L. Screening and case finding for major depressive disorder using the Patient Health Questionnaire (PHQ-9): a meta-analysis. *General hospital psychiatry.* 2015;37(6):567-576.

16. Wittkampf KA, Naeije L, Schene AH, Huyser J, van Weert HC. Diagnostic accuracy of the mood module of the Patient Health Questionnaire: a systematic review. *General hospital psychiatry.* 2007;29(5):388-395.
17. Fann JR, Berry DL, Wolpin S, et al. Depression screening using the Patient Health Questionnaire‐9 administered on a touch screen computer. *Psycho‐Oncology.* 2009;18(1):14-22.
18. Huang FY, Chung H, Kroenke K, Delucchi KL, Spitzer RL. Using the patient health questionnaire‐9 to measure depression among racially and ethnically diverse primary care patients. *Journal of general internal medicine.* 2006;21(6):547-552.
19. Löwe B, Schenkel I, Carney-Doebbeling C, Göbel C. Responsiveness of the PHQ-9 to psychopharmacological depression treatment. *Psychosomatics.* 2006;47(1):62-67.
20. Löwe B, Unützer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the patient health questionnaire-9. *Medical care.* 2004;42(12):1194-1201.
21. Suzuki K, Kumei S, Ohhira M, Nozu T, Okumura T. Screening for Major Depressive Disorder with the Patient Health Questionnaire (PHQ-9 and PHQ-2) in an Outpatient Clinic Staffed by Primary Care Physicians in Japan: A Case Control Study. *PloS one.* 2015;10(3):e0119147.
22. Löwe B, Spitzer RL, Gräfe K, et al. Comparative validity of three screening questionnaires for DSM-IV depressive disorders and physicians' diagnoses. *Journal of affective disorders.* 2004;78(2):131-140.
23. Saliba D, Buchanan J. Development and validation of a revised nursing home assessment tool: MDS 3.0. *Santa Monica (CA): RAND Health.* 2008.
24. Thomas KS, Wysocki A, Intrator O, Mor V. Finding Gertrude: The Resident's Voice in Minimum Data Set 3.0. *Journal of the American Medical Directors Association.* 2014;15(11):802-806.
25. Banerjee S, Macdonald A. Mental disorder in an elderly home care population: associations with health and social service use. *The British Journal of Psychiatry.* 1996;168(6):750-756.
26. Hyer L. Depression in Long‐Term Care. *Clinical Psychology: Science and Practice.* 2005;12(3):280-299.
27. Jones RN, Marcantonio ER, Rabinowitz T. Prevalence and correlates of recognized depression in US nursing homes. *Journal of the American Geriatrics Society.* 2003;51(10):1404-1409.
28. Parmelee PA, Katz IR, Lawton MP. Incidence of depression in long-term care settings. *Journal of Gerontology.* 1992;47(6):M189-M196.
29. Teresi J, Abrams R, Holmes D, Ramirez M, Eimicke J. Prevalence of depression and depression recognition in nursing homes. *Social psychiatry and psychiatric epidemiology.* 2001;36(12):613-620.
30. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *Journal of affective disorders.* 2009;114(1):163-173.
31. Wells TS, Horton JL, LeardMann CA, Jacobson IG, Boyko EJ. A comparison of the PRIME-MD PHQ-9 and PHQ-8 in a large military prospective study, the Millennium Cohort Study. *Journal of affective disorders.* 2013;148(1):77-83.

32. Yueh B, Souza PE, McDowell JA, et al. Randomized trial of amplification strategies. *Archives of Otolaryngology–Head & Neck Surgery.* 2001;127(10):1197-1204.
33. Horowitz A. Depression and Vision and Hearing Impairments in Later Life. *Generations.* 2003;27(1):32-38.
34. Jones GC, Rovner BW, Crews JE, Danielson ML. Effects of depressive symptoms on health behavior practices among older adults with vision loss. *Rehabilitation Psychology.* 2009;54(2):164-172.
35. Inouye SK, Bogardus ST, Charpentier PA, et al. A Multicomponent Intervention to Prevent Delirium in Hospitalized Older Patients. *New England Journal of Medicine.* 1999;340(9):669-676.
36. Inouye SK, Baker DI, Fugal P, Bradley EH, for the HDP. Dissemination of the Hospital Elder Life Program: Implementation, Adaptation, and Successes. *Journal of the American Geriatrics Society.* 2006;54(10):1492-1499.
37. Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Investigative ophthalmology & visual science.* 2007;48(10):4445-4450.