Proposed Measure Specifications and Standardized Data Elements for CY 2018 HH QRP Notice of Proposed Rule Making

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SECTION 1
CROSS-SETTING MEASURES DEVELOPMENT WORK: AN INTRODUCTION

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), enacted Oct. 6, 2014, directs the Secretary of Health and Human Services to "specify quality measures on which Post-Acute Care (PAC) providers are required under the applicable reporting provisions to submit standardized patient assessment data" in several domains, including functional status , skin integrity, and incidence of major falls. The IMPACT Act requires the implementation of measures to address these measure domains in home health agencies (HHAs), skilled nursing facilities (SNFs), long-term care hospitals (LTCHs), and inpatient rehabilitation facilities (IRFs).

The IMPACT Act also requires, to the extent possible, the submission of such quality measure data through the use of a PAC assessment instrument and the modification of such instrument as necessary to enable such use. For HHAs, the Outcome and Assessment Information Set (OASIS) will be used.

The reporting of quality data by HHAs is mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act ("the Act"). For more information on the statutory history of the HH Quality Reporting Program (QRP), please refer to https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html. More information on the IMPACT Act is available at https://www.govtrack.us/congress/bills/113/hr4994.

In this document, we present specifications for the following three (3) measures proposed for adoption for the HH QRP in the CY 2018 HH Prospective Payment System (PPS) Notice of Proposed Rule-Making (NPRM):

1. Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)

2. Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674)

3. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

SECTION 2
MEASURES AFFECTING THE CY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

2.1   Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)

2.1.1   Measure Description

The cross-setting function quality measure is a process measure that is an application of the quality measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure reports the percent of episodes with a Start of Care (SOC) /Resumption of Care (ROC) and a discharge functional assessment and a treatment goal that addresses function. The treatment goal provides evidence that a care plan with a goal has been established for the patient.

This process quality measure requires the collection of SOC/ROC and discharge functional status data by clinicians using standardized clinical assessment items or data elements that assess specific functional activities, that is, self-care and mobility activities. The self-care and mobility function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity. A higher score indicates greater independence. If an activity is not attempted, the reason that the activity did not occur is coded. For this quality measure, documentation of a goal for one of the function items reflects that the patient's care plan addresses function. The functional goal is recorded at start or resumption of care for at least one of the standardized self-care or mobility function items using the 6-level rating scale. Subsequent to the SOC/ROC assessment, goal setting and establishment of a care plan to achieve the goal, at the time of discharge the self-care and mobility functional performance is reassessed using the same 6-level rating scale, enabling the ability to re-assess the patient's functional abilities. This quality measure will be calculated using data from the Outcome and Assessment Information Set (OASIS).

2.1.2   Purpose/Rationale for the Measure

The National Committee on Vital and Health Statistics, Subcommittee on Health[1] noted: "[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations, that is, their functional status." This statement is supported by research showing that patient functioning is associated with important patient outcomes such as discharge destination and length of stay in inpatient settings[2] as well as

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[1]   Subcommittee on Health National Committee on Vital and Health Statistics, "Classifying and Reporting Functional Status" (2001).

[2]   Reistetter T. A., Graham J. E., Granger C. V., Deutsch A, Ottenbacher K. J. (2010). Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. Archives of Physical Medicine and Rehabilitation; 91:345-350.

risk of nursing home placement and hospitalization of older adults living the in community.[3] Functioning is important to patients and their family members.[4][5][6]

The primary goal of home care is to provide restorative care where improvement is expected, maintain function and health status when improvement is not expected, and/or facilitate transition to end-of-life care when appropriate.[7] Many patients who receive post-acute care (PAC) services, such as care provided by home health agencies (HHAs), have functional limitations and are at risk for further decline in function due to limited mobility and ambulation.[8]

Given the variation in patient populations across the PAC providers, the functional activities that are typically assessed by clinicians for each type of PAC provider may vary. For example, the activity of rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients who are chronically critically ill. However, certain functional activities, such as eating, oral hygiene, lying to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility, are important activities for patients/residents in each PAC setting. These activities are included in the cross-setting measure. The patient populations treated by home health agencies (HHAs) vary in their functional abilities at the time of the home health (HH) admission and their goals of care. For HH patients who are home-bound, achieving independence within the living environment and promoting community mobility may be the goal of care. For other HH patients, the goal of care may be to slow the rate of functional decline to avoid institutionalization.[9] The clinical practice guideline, Assessment of Physical Function,[10] recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. These quality measures will inform HH providers about opportunities to improve care in the area of self-care and function and strengthen incentives for quality improvement related to patient function.

Although functional assessment data are currently collected in HH, this data collection has employed different assessment instruments, scales, and items relative to other PAC providers. The data collected cover similar topics, but are not standardized across PAC settings. Further, the different sets of functional assessment items are coupled with different rating scales, making communication about patient functioning challenging when patients/residents transition from one type of provider to another. Collection of standardized functional assessment data across all PAC settings, using standardized data items, would establish a common language for patient/resident functioning, which may facilitate communication and care coordination as patients/residents transition from one type of provider to another. The collection of standardized

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3   Miller E.A., Weissert W. G. (2000) Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259-297.

4   Kurz, A. E., Saint-Louis, N., Burke, J. P., & Stineman, M. G. (2008). Exploring the personal reality of disability and recovery: a tool for empowering the rehabilitation process. Qual Health Res, 18(1), 90-105.

5   Kramer, A. M. (1997). Rehabilitation care and outcomes from the patient's perspective. Med Care, 35(6 Suppl), JS48-57.

6   Stineman, M. G., Rist, P. M., Kurichi, J. E., & Maislin, G. (2009). Disability meanings according to patients and clinicians: imagined recovery choice pathways. Quality of Life Research, 18(3), 389-398.

7   Riggs, J. S. & Madigan, E. A. (2012). Describing variation in home health care episodes for patients with heart failure. Home Health Care Management and Practice, 24(3): 146-152.

8   Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772-4.

9   Ellenbecker CH, Samia L, Cushman MJ, Alster K (2008). Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 13.

10 Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). (2012). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company, p. 89-103.

functional status data may also help improve patient/resident functioning during an episode of care by ensuring that basic daily activities are assessed at the start and end of each episode of care with the aim of determining whether at least one functional goal is established.

The functional assessment items included in the functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration (PAC PRD) version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize assessment of patient's/resident's status across acute and post-acute providers, including skilled nursing facilities (SNFs), HHAs, long-term care hospitals (LTCHs), and inpatient rehabilitation facilities (IRFs). The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge to determine patients'/residents' needs, evaluate patient/resident progress and prepare patients/residents and families for a transition to home or to another provider.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled "The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3."[11] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled "The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3"[12] and the report entitled "The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3."[13] The reports are available on CMS' Post-Acute Care Quality Initiatives webpage at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

2.1.3   Denominator Statement

Number of Medicare/Medicaid (including Advantage programs) covered home health episodes of care for patients who are at least 18 years of age, ending during the reporting period that do not meet the generic exclusions described below.

2.1.4   Denominator Details

All home health episodes of care, defined as a start/resumption of care assessment (OASIS item M0100) (Reason for Assessment) = 1 (Start of care) or 3 (Resumption of care)) paired with a corresponding discharge/transfer/death assessment (M0100 (Reason for Assessment) = 6 (Transfer to inpatient facility – not discharged), 7 (Transfer to inpatient facility

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[11]   Research Triangle International. The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set (Contract HHSM-500-2005-00291) 2012, August.

[12]   *IBID*

[13]   *IBID*

– discharged), 8 (Death at home), or 9 (Discharge from agency)), other than those covered by generic and measure-specific denominator exclusions.

2.1.5 Numerator Statement

The numerator for this quality measure is the number of home health quality episodes with functional assessment data for each self-care and mobility activity and at least one self-care or mobility goal.

2.1.6 Numerator Details

All three of the following are required for the patient to be counted in the numerator:

1. A valid numeric score indicating the patient's functional status, or a valid code indicating the activity was not attempted or could not be assessed for each of the functional assessment items on the SOC/ROC assessment;

2. A valid numeric score, which is a discharge goal indicating the patient's expected level of independence, for at least one self-care or mobility item on the SOC/ROC assessment; and

3. A valid numeric score indicating the patient's functional status, or a valid code indicating the activity was not attempted or could not be assessed, for each of the functional assessment items on the discharge assessment.

2.1.7 Incomplete Episode

For home health episodes ending in a qualifying admission to an inpatient facility [Transfer], or a Death at Home, the discharge functional status data would not be required for the episode to be included in the numerator. For episodes ending in transfer or death at home, the following are required for these patients to be counted in the numerator:

1. A valid numeric score indicating the patient's functional status, or a valid code indicating the activity was not attempted or could not be assessed for each of the functional assessment items on the SOC/ROC assessment; and

2. A valid numeric score, which is a discharge goal indicating the patient's expected level of independence, for at least one self-care or mobility item on the SOC/ROC assessment.

2.1.8 Items Included in the Quality Measure

An important consideration when measuring functional status is that certain activities may not be relevant or feasible to assess for all home health patients. For example, walking may not occur at the start or resumption of care because it is not safe for a patient to ambulate. In this situation, a clinician would code that a functional activity was not attempted because it was not safe or feasible for the patient to perform the activity.

The following functional status items are included in this measure:

<u>Self-Care Items</u>

Eating (GG0130A): The ability to use suitable utensils to bring food to the mouth and swallow food once the meal is presented on a table/tray. Includes modified food consistency.

Oral hygiene (GG0130B): The ability to use suitable items to clean teeth. [Dentures (if applicable): The ability to remove and replace dentures from and to the mouth, and manage equipment for soaking and rinsing them.]

Toileting hygiene (GG0130C): The ability to maintain perineal hygiene, adjust clothes before and after using the toilet, commode, bedpan or urinal. If managing an ostomy, include wiping the opening but not managing equipment.

<u>Mobility Items</u>

Sit to lying (GG0170B): The ability to move from sitting on side of bed to lying flat on the bed.

Lying to sitting on side of bed (GG0170C): The ability to safely move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support.

Sit to stand (GG0170D): The ability to safely come to a standing position from sitting in a chair or on the side of the bed.

Chair/bed-to-chair transfer (GG0170E): The ability to safely transfer to and from a bed to a chair (or wheelchair).

Toilet transfer (GG0170F): The ability to safely get on and off a toilet or commode.

For patients/residents who are walking, complete the following items:

Walk 50 feet with two turns (GG0170J): Once standing, the ability to walk at least 50 feet and make two turns.

Walk 150 feet (GG0170K): Once standing, the ability to walk at least 150 feet in a corridor or similar space.

For patients/residents who use a wheelchair, complete the following items:

Wheel 50 feet with two turns (GG0170R): Once seated in wheelchair/scooter, the ability to wheel at least 50 feet and make two turns.

Indicate the type of wheelchair/scooter used (GG0170RR).

1. Manual
2. Motorized

Wheel 150 feet (GG0170S): Once seated in wheelchair/scooter, the ability to wheel at least 150 feet in a corridor or similar space.

Indicate the type of wheelchair/scooter used (GG0170SS).

> 1. Manual
> 2. Motorized

Self-Care and Mobility Rating Scale: Codes and Code Definitions

6. **Independent** – Patient/resident completes the activity by him/herself with no assistance from a helper.

5. **Setup or clean-up assistance** – Helper SETS UP or CLEANS UP; patient/resident completes activity. Helper assists only prior to or following the activity.

4. **Supervision or touching assistance** – Helper provides VERBAL CUES or TOUCHING/ STEADYING assistance as patient/resident completes activity. Assistance may be provided throughout the activity or intermittently.

3. **Partial/moderate assistance** – Helper does LESS THAN HALF the effort. Helper lifts, holds, or supports trunk or limbs, but provides less than half the effort.

2. **Substantial/maximal assistance** – Helper does MORE THAN HALF the effort. Helper lifts, holds or supports trunk or limbs and provides more than half the effort.

1. **Dependent** – Helper does ALL of the effort. Patient/resident does none of the effort to complete the activity. Or the assistance of 2 or more helpers is required for the patient/resident to complete the activity.

If activity was not attempted, code reason:

07. Patient/resident refused

09. Not applicable

88. Not attempted due to **medical condition or safety concerns**

2.1.9 Risk Adjustment

This is a process measure and not risk-adjusted

2.1.10 Quality Measure Calculation Algorithm

1. For each provider, the records of patients meeting the inclusion criteria (i.e., denominator) discharged during the 12 month target time period are identified and counted. This count is the denominator.

3. The records of patients not transferred to an inpatient facility or who did not die at home are identified and the number of these episodes with complete SOC/ROC functional assessment data (codes 1 through 6 or 7, 9 or 88) AND at least one self-care or mobility goal (codes 1 through 6) AND complete discharge functional assessment data (codes 1 through 6 or 7, 9 or 88) is counted.

4. The records of patients who are transferred to an inpatient facility or who died at home are identified, and the number of these patient records with complete

SOC/ROC functional status data (codes 1 through 6 or 7, 9 or 88) AND at least one self-care or mobility goal (codes 1 through 6) is counted.

5. The counts from step 2 and step 3 are summed. The sum is the numerator count.

6. The numerator count is divided by the denominator count to calculate this quality measure, and converted to a percent value by multiplying by 100.

2.1.11 Denominator Exclusions

There are no measure-specific exclusions.

2.1.12 Numerator Exclusions

Medicare-certified home health agencies are currently required to collect and submit OASIS data only for adult (aged 18 and over), non-maternity Medicare and Medicaid patients (who are receiving skilled home health care. Therefore, maternity patients, patients less than 18 years of age, non-Medicare/Medicaid patients, and patients who are not receiving skilled home services are all excluded from the measure calculation. However, the OASIS items and related measures could potentially be used for other adult patients receiving services in a community setting, ideally with further testing. Publicly reported data for HHAs on CMS's Home Health Compare Web site require that the HHA have at least 20 observations for the quality measure and that the HHA has been in operation at least six months.

2.2 Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674)

2.2.1 Measure Description

The quality measure addressing the incidence of major falls is an Application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). This quality measure reports the percentage of quality episodes in which the patient experiences one or more falls with major injury (defined as bone fractures, joint dislocations, and closed-head injuries with altered consciousness, or subdural hematoma) during the home health episode.

The data for the measure would be submitted via the OASIS for home health patients. New OASIS items would need to be added. This quality measure is based on data reported for two items (See Appendix A). The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since start of care (SOC)/resumption of care (ROC). Because the home health measure is based on episode-level data reported at discharge, the item (J1800) for the OASIS asks whether the patient has experienced any falls since SOC/ROC. If the answer to J1800 is no, the next item (J1900) is skipped. If the answer to J1800 is yes, the next item (J1900) asks for the number of falls with a) no injury, b) injury (except major), and c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury).

2.2.2 Denominator Statement

All quality episodes that are eligible except those that meet the exclusions.

2.2.3 Denominator Details

All home health episodes of care, defined as a start/resumption of care assessment (OASIS item M0100) (Reason for Assessment) = 1 (Start of care) or 3 (Resumption of care)) paired with a corresponding discharge/transfer assessment (M0100 (Reason for Assessment) = 6 (Transfer to inpatient facility – not discharged), 7 (Transfer to inpatient facility – discharged), 8 (Death at home), or 9 (Discharge from agency)), other than those covered by generic and measure-specific denominator exclusions.

2.2.4 Numerator Statement

The numerator for this quality measure is the number of quality episodes in which the patient experienced one or more falls that resulted in major injury during the episode of care.

2.2.5 Numerator Details

Quality episodes in which the patients had an assessment that indicated one or more falls that resulted in major injury (J1900C = [Coding 1, 2]).

2.2.6   Items Included in the Quality Measure

The items used for this measure (See Appendix A) collect data that indicates whether or not a fall took place (J1800), and if so, the number of falls in each of the following categories (J1900):

Injury Related to Fall: Any documented injury that occurred as a result of, or was recognized within a short period of time (e.g., hours to a few days) after as, the fall and attributed to the fall.

Injury (Except Major): Includes skin tears, abrasions, lacerations, superficial bruises, hematomas, and sprains; or any fall-related injury that causes the patient to complain of pain.

Major Injury: Defined as a bone fracture, joint dislocation, closed-head injury with altered consciousness, or subdural hematoma.

Only the data on number of falls resulting in major injury are included to calculate this measure.

The item (J1900C) would assess whether patient had one or more falls that resulted in major injury since the time of admission to home health.

2.2.7   Risk Adjustment

This measure is not risk-adjusted.

2.2.8   Quality Measure Calculation Algorithm

The following steps would be used to calculate the measure. Since this measure is not risk-adjusted, only the agency observed score is computed.

Calculate the facility observed score (steps 1 through 3)

Step 1. Calculate the denominator count:

Calculate the number of quality episodes, except for those who meet the exclusion criteria.

Step 2. Calculate the numerator count:

Calculate the number of quality episodes during the selected time window for those who experienced one or more falls that resulted in major injury during the episode of care.

Step 3. Calculate the agency's observed score:

Divide the agency's numerator count by its denominator count to obtain the agency's observed score; that is, divide the result of step 2 by the result of step 1.

2.2.9 Denominator Exclusions

The quality episode is excluded if one of the following is true for all of the look-back scan assessments:

1. The occurrence of falls was not assessed OR

2. The assessment indicates that a fall occurred AND the number of falls with major injury was not assessed.

2.2.10 Numerator Exclusions

Medicare-certified home health agencies are currently required to collect and submit OASIS data only for adult (aged 18 and over), non-maternity Medicare and Medicaid patients who are receiving skilled home health care. Therefore, maternity patients, patients less than 18 years of age, non-Medicare/Medicaid patients, and patients who are not receiving skilled home services are all excluded from the measure calculation. However, the OASIS items and related measures could potentially be used for other adult patients receiving services in a community setting, ideally with further testing. Publicly reported data for HHAs on CMS's Home Health Compare Web site require that the HHA have at least 20 observations for the quality measure and that the HHA has been in operation at least six months.

2.3 Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

2.3.1 Quality Measure Description

This proposed quality measure reports the percent of quality episodes in which the patient has one or more Stage 2-4 pressure ulcers, or an unstageable ulcer, present at discharge that are new or worsened since the beginning of the quality episode.[14] The measure is calculated using data from the OASIS. For home health patients, this measure reports the percent of quality episodes with reports of Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that were not present or were at a lesser stage on admission.

2.3.2 Purpose/Rationale for Quality Measure

This quality measure is proposed to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), in the HH QRP measure set beginning with the CY 2020 HH QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contains updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of "Skin integrity and changes in skin integrity." In order to recommendations provided by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP), the current quality measure has been modified in two ways. First, the measure has been modified to incorporate the addition of unstageable pressure ulcers due to slough or eschar, unstageable pressure ulcers due to non-removable dressing or device, and unstageable pressure ulcers presenting as deep tissue injuries in the numerator. This measure is being proposed across PAC settings, including HH, IRF, SNF, and LTCH settings.

Second, the measure calculation has been amended to include M1311 items instead of M1313 items for the HH QRP. This item calculation modification is intended to reduce redundancies in assessment items. To reflect these two changes, the measure is being proposed for CY 2018 federal rulemaking as: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.

Regardless of setting or provider type, pressure ulcers are recognized as a serious medical condition. Considerable evidence exists regarding the seriousness of pressure ulcers, and the relationship between pressure ulcers and pain, decreased quality of life, and increased mortality in aging populations.[15] [16] [17] [18] Pressure ulcers interfere with activities of daily living and

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[14] For the purposes of payment determination in the Home Health Quality Reporting Program, quality episodes are defined by pairing a SOC/ROC assessment with an end of care (EOC) assessment. EOC assessments include Discharge from Agency, Transfer to an Inpatient Facility and Death at Home.

[15] Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." Nurs N Z 19(10): 20-24.

[16] Gorzoni, M. L. and S. L. Pires (2011). "Deaths in nursing homes." Rev Assoc Med Bras 57(3): 327-331.

[17] Thomas, J. M., et al. (2013). "Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality." J Am Geriatr Soc 61(6): 902-911.

functional gains made during rehabilitation, predispose patients to osteomyelitis and septicemia, and are strongly associated with longer hospital stays, longer IRF stays, and mortality.[19] [20] [21] Additionally, patients with acute care hospitalizations related to pressure ulcers are more likely to be discharged to long-term care facilities (e.g., a nursing facility, an intermediate care facility, or a nursing home) than hospitalizations for all other conditions.[22] [23]

Pressure ulcers typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, or bone.[5] [9] [24] Elderly individuals receiving home health care have a wide range of impairments and/or medical conditions that increase their risk of developing pressure ulcers, including but not limited to, impaired mobility or sensation, malnutrition or under-nutrition, obesity, stroke, diabetes, dementia, cognitive impairments, circulatory diseases, and dehydration. The use of wheelchairs and medical devices (e.g., hearing aid, feeding tubes, tracheostomies), a history of pressure ulcers, or presence of a pressure ulcer at admission are additional factors that increase pressure ulcer risk in elderly patients.[1] [5] [6] [8] [25] [26] [27] [28] [29] [30] [31]

Pressure ulcers are high-cost adverse events across the spectrum of health care settings, from acute hospitals to home health.[5] [8] [10] Pressure ulcer incidence rates vary considerably by clinical setting, ranging from 0.4% to 38% in acute care, 2.2% to 23.9% in skilled nursing facilities [SNFs] and nursing homes [NHs], and 0% to 17% in home health.[8] [9] As reported in the Federal Register, in 2006 the average cost for a hospital stay related to pressure ulcers was $40,381[32] The Advancing Excellence in America's Nursing Homes Campaign reported that it

18   White-Chu, E. F., et al. (2011). "Pressure ulcers in long-term care." Clin Geriatr Med 27(2): 241-258.
19   Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744-51.
20   Park-Lee E, Caffrey C. Pressure ulcers among nursing home residents: United States, 2004 (NCHS Data Brief No. 14). Hyattsville, MD: National Center for Health Statistics, 2009. Available from http://www.cdc.gov/nchs/data/databriefs/db14.htm.
21   Wang, H., et al. (2014). "Impact of pressure ulcers on outcomes in inpatient rehabilitation facilities." Am J Phys Med Rehabil 93(3): 207-216.
22   Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500-2005-000181 TO 0002. 2010.
23   Institute for Healthcare Improvement (IHI). Relieve the pressure and reduce harm. May 21, 2007. Available from http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/FSRelievethePressureandReduceHarm.htm.
24   Russo CA, Steiner C, Spector W. Hospitalizations related to pressure ulcers among adults 18 years and older, 2006 (Healthcare Cost and Utilization Project Statistical Brief No. 64). December 2008. Available from http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.pdf.
25   Agency for Healthcare Research and Quality (AHRQ). Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from http://www.ahrq.gov/research/jan09/0109RA22.htm.
26   Cai, S., et al. (2013). "Obesity and pressure ulcers among nursing home residents." Med Care 51(6): 478-486.
27   DeJong, G., et al. (2014). "Factors Associated with Pressure Ulcer Risk in Spinal Cord Injury Rehabilitation." Am J Phys Med Rehabil. 2014 May 29. [Epub ahead of print]
28   MacLean DS. Preventing & managing pressure sores. Caring for the Ages. March 2003;4(3):34-7. Available from http://www.amda.com/publications/caring/march2003/policies.cfm.
29   Michel, J. M., et al. (2012). "As of 2012, what are the key predictive risk factors for pressure ulcers? Developing French guidelines for clinical practice." Ann Phys Rehabil Med 55(7): 454-465.
30   National Pressure Ulcer Advisory Panel (NPUAP) Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. Adv Skin Wound Care. 2001;14(4):208-15.
31   Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.
32   Centers for Medicare & Medicaid Services (CMS). Medicare program; changes to the hospital inpatient prospective payment system and fiscal year 2008 rates. Fed Register. August 22, 2007;72(162):47205.

can cost as much as $19,000 to treat a single Stage 4 pressure ulcer.[33] Using data from 2009 and 2010, severe (Stage 3 and 4) pressure ulcers acquired during a hospital stay were estimated to have increased CMS payments across 90-day episodes of care by at least $18.8 million a year.[34]

The terminology and definitions developed by the National Pressure Ulcer Advisory Panel (NPUAP) for the care of pressure ulcers are often used to inform the PAC patient and resident assessment instruments and corresponding assessment manuals, specifically the IRF-PAI, the LTCH CARE Data Set, the MDS for SNFs, and the OASIS for HHAs. Considering the recent updates made by the NPUAP to their Pressure Ulcer Staging System, CMS intends to continue the adaptation of NPUAP terminology for coding the patient and resident assessment instruments. CMS will provide guidance which emphasizes that terminology related to these wounds may include injuries, as well as pressure ulcers, while retaining current holistic assessment instructions definitions and terminology. Further guidance and information on adaptation of the NPUAP guidelines, and definitions, and terminology, via assessment manuals and assessment instruments will be posted on the Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html.

2.3.3 Denominator

The denominator is the number of quality episodes, except those that meet the exclusion criteria. HH quality episodes are defined by pairing assessments completed at the start or resumption of care with assessments completed at discharge.

2.3.4 Denominator Exclusions

1. Episodes that end in a death at home or transfer to an inpatient facility are excluded from this measure as OASIS data collection that occurs at these time points does not contain the items needed to compute this measure.

2. Episodes without an assessment completed at the start or resumption of care and an assessment completed at discharge are excluded.

3. Episodes are excluded if the discharge assessment does not have a usable response for M1311a, M1311b, M1311c, M1311d, M1311e or M1311f.

2.3.5 Numerator

The numerator is the number of completed quality episodes for patients whose assessment at discharge indicates one or more new or worsened Stage 2-4 or unstageable pressure ulcers compared to the start or resumption of care assessment.

Where on any discharge assessment:

1. Stage 2 (M1311A1) **-** (M1311A2) > 0, OR

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[33]   Advancing Excellence in America's Nursing Homes (AEANH). Explore our goals. n.d. Available from https://www.nhqualitycampaign.org/goals.aspx.

[34]   Kandilov AMG, Coomer NM, Dalton K. (2014) The impact of hospital-acquired conditions on Medicare program payments. MMRR 4(4): E1-E23

2. Stage 3 (M1311B1) **-** (M1311B2) > 0, OR

3. Stage 4 (M1311C1) **-** (M1311C2) > 0, OR

4. Unstageable – Non-removable dressing/device (M1311D1) - (M1311D2) > 0, OR

5. Unstageable – Slough and/or eschar (M1311E1) - (M1311E2) > 0, OR

6. Unstageable – Deep tissue injury (M1311F1) - (M1311F2) > 0

2.3.6   Items Included in the Quality Measure

- **M1311A1**. Number of Stage 2 pressure ulcers, **M1311A2**. Number of these Stage 2 pressure ulcers that were present at most recent SOC/ROC

- **M1311B1**. Number of Stage 3 pressure ulcers, **M1311B2.** Number of <u>these</u> Stage 3 pressure ulcers that were present at most recent SOC/ROC

- **M1311C1**. Number of Stage 4 pressure ulcers, **M1311C2.** Number of <u>these</u> Stage 4 pressure ulcers that were present at most recent SOC/ROC

- **M1311D1**. Number of unstageable pressure ulcers/injuries due to non-removable dressing/device, **M1311D2**. Number of <u>these</u> unstageable pressure ulcers/injuries that were present at most recent SOC/ROC

- **M1311E1.** Unstageable: Slough and/or eschar, **M1311E2.** Number of <u>these</u> unstageable pressure ulcers that were present at most recent SOC/ROC

- **M1311F1**. Unstageable: Deep tissue injury, **M1311F2.** Number of <u>these</u> unstageable pressure injuries that were present at most recent SOC/ROC

2.3.7   Risk Adjustment Factors

This measure will be risk-adjusted based on an evaluation of potential risk factors and their statistically significant impact on the outcome. Proposed risk factor covariates include:

1. Indicator of supervision/touching assistance or more at SOC/ROC for functional mobility item Lying to Sitting on Side of Bed (GG0170C):
   Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 88]
   Covariate = [0] (no) if GG0170C = [05, 06, -]

2. Indicator of bowel incontinence at least occasionally at SOC/ROC (M1620):
   Covariate = [1] if M1620 = [2, 3, 4, 5]
   Covariate = [0] if M1620 = [0, 1, NA, UK]

3. Have diabetes mellitus, peripheral vascular disease or peripheral arterial disease:
   Covariate = [1] (yes) if any of the following are true at SOC/ROC: M1028 = [1] (checked) or M1028 = [2] (checked)
   Covariate = [0] (no) if M1028 = [^] (Valid skip)

4. Indicator of Low Body Mass Index, based on Height (M1060a) and Weight (M1060b)at SOC/ROC
   Covariate = [1] (yes) if BMI ≥ [12.0] AND ≤ [19.0]
   Covariate = [0] (no) if BMI > [19.0]

Covariate = [0] (no) if M1060a = [-] OR M1060b = [-] OR BMI < [12.0], ('-'= No response available)

Where: BMI = (weight * 703 / height2) = ((M1060b) * 703) / (M1060a2) and the resulting value is rounded to one decimal.

2.3.8   Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

A. Calculate the agency observed score (steps 1 through 3)

Step 1. Calculate the denominator count:

Calculate the total number of quality episodes with a selected target OASIS assessment in the measure time window that do not meet the exclusion criteria.

Step 2. Calculate the numerator count:

Calculate the total number of quality episodes in the denominator whose OASIS assessments indicates one or more new or worsened pressure ulcers at discharge compared to start or resumption of care.

Step 3. Calculate the agency's observed rate:

Divide the agency's numerator count by its denominator count to obtain the agency's observed rate; that is, divide the result of step 2 by the result of step 1.

B. Calculate the predicted rate for each quality episode (steps 4 and 5)

Step 4. Determine presence or absence of the pressure ulcer risk factors for each patient:

If dichotomous risk factor covariates are used, assign covariate values, either '0' for covariate condition not present or '1' for covariate condition present, for each quality episode for each of the covariates as reported at SOC/ROC, as described in the section above. In some cases the actual values for a risk factor covariate may be used, e.g., the number of pressure ulcers present at each level at SOC/ROC or the total number of pressure ulcers present across all levels or the number of unstageable pressure ulcers.

Step 5. Calculate the predicted rate for each quality episode with the following formula:

[1] Episode-level predicted QM rate = 1/ [1+e⁻ˣ]

Where e is the base of natural logarithms and X is a linear combination of the constant and the logistic regression coefficients times the covariate scores (from Formula [2], below).

[2] QM triggered (yes=1, no=0) = B0 + B1*COVA + B2*COVB + … BN*COVN

Where B0 is the logistic regression constant, B1 is the logistic regression coefficient for the first covariate (where applicable), COVA is the episode-level rate for the first covariate, B2 is the logistic regression coefficient for the second covariate, and COVB is the episode-level rate for the second covariate (where applicable), etc. The

regression constant and regression coefficients* are numbers obtained through statistical logistic regression analysis.

* Regression coefficients and constants are updated each reporting period.

C. Calculate the agency predicted rate (step 6)

Step 6. Once a predicted QM rate has been calculated for all quality episodes, calculate the mean agency-level predicted QM rate by averaging all episode-level predicted values for that agency.

D. Calculate national predicted rate (step 7)

Step 7. Calculate the national predicted rate:

Once a predicted QM value has been calculated for all episodes, calculate the mean national-level predicted QM rate by averaging all episode-level predicted values. Note that the sample will include only those quality episodes with non-missing data for the component covariates.

E. Calculate the agency's risk-adjusted rate (step 8)

Step 8. Calculate the agency-level risk-adjusted rate based on the:

agency-level observed QM rate (step 3),
agency-level mean predicted QM rate (step 6), and
*national mean predicted QM rate (step 7), using the following formula:
agency risk adjusted rate = agency observed rate + national predicted rate – agency predicted rate
*The national predicted QM rates are updated each reporting period.

SECTION 3
STANDARDIZED DATA ELEMENTS

3.1   Standardized Patient Assessment Data Element Work: An Introduction

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires CMS to develop, implement, and maintain standardized patient assessment data elements for PAC settings. The goals of implementing cross-setting standardized patient assessment data elements are to facilitate care coordination, interoperability, and improve outcomes of Medicare beneficiaries and other patients receiving post-acute care. Existing PAC assessment instruments (i.e., Outcome and Assessment Information Set (OASIS) for HHAs, Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs, LTCH CARE Data Set (LCDS) for LTCHs, and the Minimum Data Set (MDS) for SNFs) often collect data items pertaining to similar concepts, but the individual data elements -- questions and response options -- vary by assessment instrument. With a few exceptions, the data elements collected in these assessment instruments are not currently standardized or interoperable, therefore, patient responses across the assessment instruments cannot be compared easily. The IMPACT Act further requires that the assessment instruments described above be modified to include core data elements on health assessment categories and that such data be standardized and interoperable. Implementation of a core set of standardized assessment items across PAC settings has important implications for Medicare beneficiaries and other patients receiving post-acute care, families, providers, and policymakers. CMS is proposing standardized patient assessment data elements for five categories specified in the IMPACT Act. These categories are:

1. Functional status, such as mobility and self-care

2. Cognitive function (e.g., able to express ideas and to understand normal speech) and mental status (e.g., depression and dementia)

3. Special services, treatments, and interventions (e.g., need for ventilator, dialysis, chemotherapy, and total parenteral nutrition)

4. Medical conditions and co-morbidities (e.g., diabetes, heart failure, and pressure ulcers)

5. Impairments (e.g., incontinence; impaired ability to hear, see, or swallow)

In the following sections, we present specifications and evidence of support for the standardized patient assessment data elements proposed in the HH QRP.

3.2 Functional Status

Beginning with the CY 2020 HH QRP, we are proposing that the submission of the data used in the measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631). This process measure has been finalized in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111) for the IRF QRP, the FY 2016 SNF PPS final rule (80 FR 46444 through 46453) for the SNF QRP, and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) for the LTCH QRP. We believe this measure meets the requirement for the collection of standardized data in the area of Functional Status. This cross-setting function process measure requires the collection of admission and discharge functional status data using standardized clinical assessment items, or data elements, which assess specific functional activities, that is, self-care and mobility activities. These activities are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. For more information about this proposed quality measure, we refer readers to Section 2.

3.3 Cognitive Function

Impairments in cognitive function can result from a number of underlying conditions, including dementia, Alzheimer's Disease, stroke, brain injury, side effects of medication, metabolic and/or endocrine imbalances, and delirium.[35] Cognitive impairments may affect a patient or resident's ability to recover from illness or injury, or they may be a sign of an acute condition (e.g., hypoxia) that requires immediate intervention. Cognitive impairment that manifests with behavioral symptoms—or that impairs a patient's ability to communicate, prompting behavioral disturbances—may put the patient or resident or others in the care setting at risk for injury or assault, or may signal unmet patient or resident needs (e.g. pain management). Screening for the presence of impairment can help ensure appropriate and timely intervention.

A substantial proportion of PAC patients and residents experience cognitive impairment, delirium, and behavioral distress. Testing from the PAC PRD found that about one-third of patients and residents in PAC settings were classified as having moderately or severely impaired cognitive function.[36,37] About one-third exhibited disorganized thinking and altered level of consciousness, and about one-half exhibited inattention. Fewer than 7 percent of patients and residents exhibited signs and symptoms of behavioral distress in the PAC PRD.

Therapeutic interventions can improve patient outcomes, and evidence suggests that treatment (e.g., drugs, physical activity) can stabilize or delay symptom progression in some patients, thereby improving quality of life.[38,39,40] In addition, assessments help PAC providers to better understand the needs of their patients by establishing a baseline for identifying changes in cognitive function and mental status (e.g., delirium), elucidating the patient's ability to understand and participate in treatments during their stay, highlighting safety needs (e.g., to prevent falls), and identifying appropriate support needs at the time of discharge. The standardized assessment of patient or resident cognition supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, enabling the transfer of accurate health information.

3.3.1 Standardized Data Elements to Assess Cognitive Impairment

CMS has identified several data elements as applicable for cross-setting use in standardized assessment of cognitive impairment. The proposed data elements comprise:

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[35] National Institute on Aging. (2013). Assessing Cognitive Impairment in Older Patients: A Quick Guide for Primary Care Physicians. Available at https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients

[36] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[37] This estimate is based on responses to the Brief Interview for Mental Status (BIMS) in a study of patient/residents in the Post-Acute Care Payment Reform Demonstration (Gage et al., 2012).

[38] Casey, D. A., Antimisiaris, D., & O'Brien, J. (2010). Drugs for Alzheimer's disease: are they effective? Pharmacy and Therapeutics 35(4): 208.

[39] Bherer, L., Erickson, K. I., & Liu-Ambrose, T. (2013). A review of the effects of physical activity and exercise on cognitive and brain functions in older adults. J of Aging Research. 2013.

[40] Langa, K. M., & Levine, D. A. (2014). The diagnosis and management of mild cognitive impairment: a clinical review. JAMA 312(23): 2551-2561.

1. The Brief Interview for Mental Status (BIMS);

2. The Confusion Assessment Method (CAM©); and

3. Behavioral Signs & Symptoms

It should be noted that the data elements proposed involve different aspects of cognition (e.g., short term memory, executive function), types of data (e.g., interview, performance-based), and are collected by various modes (e.g., clinician assessed, patient reported).

3.3.2   Brief Interview for Mental Status (BIMS)

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

Relevance to HHAs

The OASIS-C2 does not include a performance-based cognitive assessment. The proposed performance-based cognitive assessment, the BIMS, would provide important baseline information about cognitive function when patients are discharged to the HH setting. In the PAC PRD, two-thirds of patients in the HH setting (67.5 percent) were cognitively intact or borderline functioning, but 18.6 percent were moderately impaired, and 11.2 percent fell into a severely impaired category.[41] Although patients treated in HHAs, when compared to those admitted to other settings, were least likely to have severe cognitive impairment, cognitive function predicts changes in functional status (i.e., activities of daily living) among patients receiving HH, and can affect the ability of HH patients to safely manage their medication regimens.[42,43] Cognitive impairment is also associated with re-hospitalization among elderly patients receiving home health care.[44] Therefore assessing cognitive function among patients in a home health setting is important.

[41]   Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Mallinson, T. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

[42]   Scharpf, T. P., & Madigan, E. A. (2010). Functional status outcome measures in home health care patients with heart failure. Home Health Care Services Quarterly 29(4): 155-170.

[43]   Ellenbecker, C. H., Samia, L., Cushman, M. J., & Alster, K. (2008). Patient safety and quality in home health care. In R. G. Hughes (Ed.), Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville MD: Agency for Healthcare Research and Quality.

[44]   Tao, H., & Ellenbecker, C. H. (2013). Is OASIS effective in predicting rehospitalization for home health care elderly patients? Home Health Care Management & Practice 25(6): 250-255.

Section C	Cognitive Patterns
C0100. Should Brief Interview for Mental Status (C0200-C0500) be Conducted?	
Attempt to conduct interview with all patients.	
Enter Code ☐	0. No (patient is rarely/never understood) → *Skip to C1310, Signs and Symptoms of Delirium (from CAM©)* 1. Yes → *Continue to C0200, Repetition of Three Words*
Brief Interview for Mental Status (BIMS)	
C0200. Repetition of Three Words	

Enter Code ☐	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 after the first attempt
	   0. None
	   1. One
	   2. Two
	   3. Three
	 After the patient's first attempt, repeat the words using cues (*"sock: something you wear; blue: a color; bed: a piece of furniture"*). You may repeat the words up to two more times.

C0300. Temporal Orientation (orientation to year, month, and day)	

Enter Code ☐	Ask patient: *"Please tell me what year it is right now."*
	   A. Able to report correct year
	     0. Missed by > 5 years or no answer
	     1. Missed by 2-5 years
	     2. Missed by 1 year
	     3. Correct

Enter Code ☐	Ask patient: *"What month are we in right now?"*
	   B. Able to report correct month
	     0. Missed by > 1 month or no answer
	     1. Missed by 6 days to 1 month
	     2. Accurate within 5 days

Enter Code ☐	Ask patient: *"What day of the week is today?"*
	   C. Able to report correct day of the week
	     0. Incorrect or no answer
	     1. Correct

C0400. Recall	

Enter Code ☐	Ask patient: *"Let's go back to an earlier question. What are those three words that I asked you to repeat?"* If unable to remember a word, give cue (something to wear; a color; a piece of furniture) for that word.
	   A. Able to recall "sock"
	     0. No- could not recall
	     1. Yes, after cueing ("something to wear")
	     2. Yes, no cue required

Enter Code ☐	**B. Able to recall "blue"**
	     0. No- could not recall
	     1. Yes, after cueing ("a color")
	     2. Yes, no cue required

Enter Code ☐	**C. Able to recall "bed"**
	     0. No- could not recall
	     1. Yes, after cueing ("a piece of furniture")
	     2. Yes, no cue required

C0500. BIMS Summary Score	
Enter Score ☐☐	Add scores for questions C0200-C0400 and fill in total score (00-15) Enter 99 if the patient was unable to complete the interview

Current use

    The BIMS data elements are currently used in the MDS 3.0 and the IRF-PAI.

Evidence supporting use of the BIMS

    The BIMS data elements were tested in the PAC PRD, where they showed substantial to almost perfect reliability of 0.71 to 0.91 (weighted kappas) when used across all four PAC settings. The lowest agreement was on the "repetition of three words" memory data element, with a kappa of 0.71, which still falls within the range of substantial agreement. PAC PRD testing found evidence of strong reliability of the BIMS data elements in the IRF setting. In addition, the BIMS data elements were also found to be predictive of cost.[45] The BIMS data

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[45] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at

elements were also included in the national MDS 3.0 test in nursing homes and showed almost perfect reliability. [46] Agreement ranged from 0.862 to 0.994 (standard kappa). The BIMS data elements were found to be highly correlated (0.906) with a gold-standard measure of cognitive function, the Modified Mini-Mental Status (3MS) exam.[47]

3.3.3 Confusion Assessment Method (CAM©)

The Confusion Assessment Method (CAM) screens for certain types of cognitive impairment, including delirium and reversible confusion. Delirium, when undetected or untreated, can increase the likelihood of complications, rehospitalization, and death compared to patients/residents without delirium.[48] The CAM is available free of charge, for public use.

Although multiple versions of the CAM have been developed, CMS is proposing that the Short version be adopted for standardized patient assessment data elements. The Short CAM contains only four items (i.e., items 1 to 4) from the original Confusion Assessment Method (Long CAM). These items focus on an acute change in mental status, inattention, disorganized thinking, and altered level of consciousness.

Relevance to HHAs

The OASIS-C2 does not screen for delirium through use of assessments such as the CAM. However, it is important to do so in that delirium is common among home health populations; analyses of PAC PRD data have shown that HHAs have more patients with signs and symptoms of delirium than other PAC settings.[49] In PAC PRD testing, 52.9 percent of HH patients showed inattention, 37.0 percent showed disorganized thinking, and 14.0 percent showed altered level of consciousness as assessed by the CAM.[50] Among HHAs participating in the PAC PRD, the CAM demonstrated moderate-to-high inter-rater reliability for the inattention (kappa = 0.59), disorganized thinking (kappa = 0.79), and altered level of consciousness/alertness (kappa = 0.54) questions.[51] Delirium may interfere with a patient's ability to engage in self-care, medication management, therapeutic activities, and activities of daily living. As such, assessing patients for signs and symptoms of delirium is critical for care planning and decision making in the HH setting.

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https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[46] Chodosh, J., Edelen, M. O., Buchanan, J. L., Yosef, J. A., Ouslander, J. G., Berlowitz, D. R., ... & Saliba, D. (2008). Nursing home assessment of cognitive impairment: development and testing of a brief instrument of mental status. J of the Am Geriatrics Society 56(11): 2069-2075.

[47] Saliba, D., Buchanan, J., Edelen, M. O., Streim, J., Ouslander, J., Berlowitz, D., & Chodosh, J. (2012). MDS 3.0: Brief interview for mental status. J of the Am Med Directors Association 13(7): 611-617.

[48] Marcantonio, E. R., Kiely, D. K., Simon, S. E., John Orav, E., Jones, R. N., Murphy, K. M., & Bergmann, M. A. (2005). Outcomes of older people admitted to postacute facilities with delirium. J of the Am Geriatrics Society 53(6): 963-969.

[49] RAND analysis of unpublished data from the PAC PRD Public Comments sample, 2008-2010.

[50] *Ibid*

[51] Smith, L., Gage, B., Deutsch, A., Hand, L., Etlinger, A., Ross, J., … Barch, D. (2012). Continuity assessment record and evaluation (CARE) item set: Additional interrater provider-type specific reliability analyses. Research Triangle Park, NC: RTI International.

Section C	Cognitive Patterns
C1310. Signs and Symptoms of Delirium (from CAM©) Code after completing Brief Interview for Mental Status and reviewing medical record.	
A. Acute Onset Mental Status Change	

Enter Code ☐	Is there evidence of an acute change in mental status from the patient's baseline? 0. No 1. Yes

Coding:	↓ Enter Code in Boxes
0. Behavior not present 1. Behavior continuously present, does not fluctuate 2. Behavior present, fluctuates (comes and goes, changes in severity)	☐ B. **Inattention** - Did the patient have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said?
	☐ C. **Disorganized Thinking** - Was the patient's thinking disorganized or incoherent (rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject)?
	☐ D. **Altered Level of Consciousness** - Did the patient have altered level of consciousness as indicated by any of the following criteria? ■ **vigilant** - startled easily to any sound or touch ■ **lethargic** - repeatedly dozed off when being asked questions, but responded to voice or touch ■ **stuporous** - very difficult to arouse and keep aroused for the interview ■ **comatose** - could not be aroused

Confusion Assessment Method. © 1988, 2003, Hospital Elder Life Program. All rights reserved. Adapted from: Inouye SK et al. Ann Intern Med. 1990; 113:941-8. Used with permission.

Current use

The Short CAM data elements are currently collected in the MDS 3.0 and the LCDS, and the scoring is based on staff observations of delirium. While the Short CAM data elements are used in both assessment tools, the response options currently differ. The current version of the LCDS includes two response options (yes/no, indicating that the behavior is present or not present), whereas the MDS 3.0 offers three response options (behavior continuously present, does not fluctuate; behavior present, fluctuates; 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.

Evidence supporting use of the CAM

The four elements in the Short CAM have been shown to be effective in identifying delirium in validated research studies.[52] The Short CAM was tested in the PAC PRD and found to be reliable across all four settings.[53] The "Inattention" and "Disorganized Thinking" questions had substantial inter-rater reliability agreement (kappa range of 0.70 to 0.73) and the "Altered Level of Consciousness" question showed moderate agreement (kappa of 0.58).[54]

A version of the CAM, with the addition of an item to assess psychomotor retardation, was tested in the national MDS 3.0 test in nursing homes. Reliabilities were substantial or almost

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[52] Waszynski, C. M. (2007). How to try this: Detecting delirium. AJN 107(12): 50-59.
[53] Smith, L., Gage, B., & Deutsch, A. (2012). Continuity Assessment Record and Evaluation (CARE) Item Set: additional provider-type specific interrater reliability analyses. Centers for Medicare & Medicaid Services Contract No. RTI International.
[54] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

perfect. Overall average kappa ranged from 0.893 to 0.850 and items ranged from 0.784 to 0.902 (standard kappa).[55]

3.3.4   Behavioral Signs and Symptoms

Behavioral disturbances can require additional resources from providers. They can disrupt care, result in poorer patient outcomes, and place the patient at risk for injury, isolation, and inactivity. Assessment and documentation of these disturbances can help inform care planning and patient transitions. For example, standardized assessment of behavioral symptoms would foster attention to the patient's needs and limitations early in the care planning process, and could trigger addition clinical assessment (e.g., for pain or depression) that could address underlying causes of behavioral disturbances.

The Behavioral Signs and Symptoms data elements 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. These assessed behavioral disturbances can indicate unrecognized needs and care preferences and are associated commonly with dementia and other cognitive impairment, but associated less commonly with adverse drug events, mood disorders, and other conditions.

Relevance to HHAs

The proposed Behavioral Signs and Symptoms data elements would provide important information for the home health setting. These proposed data elements assess whether the patient has exhibited any behavioral symptoms during the assessment period, which may suggest that follow-up is needed to assess the underlying cause of these symptoms (e.g., cognitive impairment, issues related to medication, neurological or mood disorders). Overall, disruptive behaviors are documented infrequently among HH patients, with 0.8 percent of HH patients assessed in the PAC PRD study exhibiting physical behavioral symptoms directed toward others, and 2.2 percent exhibiting verbal behavioral symptoms towards others.[56] However, disruptive behaviors may be more common among HH patients with dementia. In a sample of home care patients aged 50 and older in Ontario, 21.5 percent were diagnosed with dementia; among these patients, 3.9 percent exhibited physically abusive symptoms, 11.4 percent exhibited verbally abusive symptoms, and 10 percent exhibited a severe Aggressive Behavior Score (a composite measure of verbally abusive, physically abusive, socially inappropriate/disruptive, or resists care behaviors).[57] The burden of care is considerably higher for patients with behavioral disturbances.[58,59] Further, the behavior of these patients may place themselves and others in

[55]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[56]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[57]   Maxwell, C. J., Vu, M., Hogan, D. B., Patten, S. B., Jantzi, M., Kergoat, M. J., … & Hirdes, J. P. (2013). Patterns and determinants of dementia pharmacotherapy in a population-based cohort of home care clients. Drugs & Aging, 30(7), 569-585.

[58]   Black, W., & Almeida, O. P. (2004). A systematic review of the association between the Behavioral and Psychological Symptoms of Dementia and burden of care. International Psychogeriatrics 16(3):295-315.

danger. Despite the low incidence of these behavioral disturbances in the HH setting, assessing patients for these symptoms would help with care planning, resource planning, and patient and caregiver safety.

Proposed Data Elements for the Assessment of Cognitive Function:
Behavioral Signs and Symptoms

Section E	Behavior Symptoms

E0200. Behavioral Symptom - Presence & Frequency
Note presence of symptoms and their frequency.

↓ Enter Codes in Boxes

Coding:
0. Behavior not exhibited
1. Behavior of this type occurred 1 to 3 days
2. Behavior of this type occurred 4 to 6 days, but less than daily
3. Behavior of this type occurred daily

A. Physical behavioral symptoms directed toward others (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)

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

C. Other behavioral symptoms not directed toward others (e.g., physical symptoms such as hitting or scratching self, pacing, rummaging, public sexual acts, disrobing in public, throwing or smearing food or bodily wastes, or verbal/vocal symptoms like screaming, disruptive sounds)

Current use

The Behavioral Signs and Symptoms data elements are currently in use in the MDS 3.0.

Evidence supporting use of Behavioral Signs and Symptoms

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

The Behavioral Signs and Symptoms data elements were tested in the national MDS 3.0 test in nursing homes with three response options per data element (Not present in last 5 days, present 1-2 days, present 3 or more days). Reliabilities were almost perfect and ranged from 0.964 to 0.984 (standard kappa).[60] The Behavioral Signs and Symptoms data elements were also validated against a gold-standard measure of behavior disturbance, the Cohen Mansfield Agitation Inventory (CMAI), where kappas ranged from 0.532 to 0.856.

3.3.5 Mental Status (Depressed Mood)

Depression is the most common mental health condition in older adults, yet under-recognized and thus under-treated. Existing data show that depressed mood is relatively common in patients and residents receiving PAC services. The PAC PRD found that about 9 percent of

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[59] Ornstein, K., & Gaugler, J. E. (2012). The problem with "problem behaviors": a systematic review of the association between individual patient behavioral and psychological symptoms and caregiver depression and burden within the dementia patient-caregiver dyad. International Psychogeriatrics 24(10):1536-1552.

[60] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

individuals in PAC were classified as having likely depression.[61] The prevalence varied from a low of 7 percent of beneficiaries in SNFs to a high of 11 percent in IRFs.[62]

Diagnosis and treatment of depression can lead to significant improvement of symptoms, as measured on depression assessment scales. Depressive symptoms improve in 60 to 80 percent of elderly patients taking an antidepressant medication.[63] Psychosocial treatments of depression in older adults have been shown to be more effective than no treatment, based on self-rated and clinician-rated measures of depression.[64,65]

Assessments of the signs and symptoms of depression help PAC providers to better understand the needs of their patients and residents by prompting further evaluation (i.e., to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. The standardized assessment of depression among PAC patients and residents supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, further enabling the transfer of accurate health information.

3.3.6   Standardized Data Elements to Assess Depressed Mood

CMS has identified the Patient Health Questionnaire (PHQ-2) data elements for standardization for assessment of depressed mood.

3.3.7   Patient Health Questionnaire-2 (PHQ-2)

The Patient Health Questionnaire-2 (PHQ-2) data elements use a summed item scoring approach to screen for signs and symptoms of depressed mood in patients and residents by assessing the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure).[66] 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.

Relevance to HHAs

The PHQ-2 is currently included in OASIS-C2. Assessors are required to report on whether or not patients have been screened for the signs and symptoms of depression. The PHQ-2 items are included on the assessment form as an optional aide to complete the screening during the assessment process, but HHAs are not required to use this particular assessment of the signs and symptoms of depression. However, the PHQ-2 is

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[61]   This estimate is based on patient responses to a question about being sad in the two weeks prior to the assessment interview in a study of patient/residents in the PAC PRD (Gage et al., 2012). If they responded "often" or "always," they were considered to have depression.

[62]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[63]   Lebowitz, B. D., Pearson, J. L., Schneider, L. S., Reynolds, C. F., Alexopoulos, G. S., Bruce, M. L., ... & Mossey, J. (1997). Diagnosis and treatment of depression in late life: Consensus statement update. JAMA 278(14): 1186-1190.

[64]   Scogin, F., & McElreath, L. (1994). Efficacy of psychosocial treatments for geriatric depression: a quantitative review. J Consult Clin Psychol 62(1):69-74.

[65]   Wei, W., Sambamoorthi, U., Olfson, M., Walkup, J. T., & Crystal, S. (2005). Use of psychotherapy for depression in older adults. Am J of Psychiatry 162(4): 711-717.

[66]   American Psychiatric Association. Diagnostic and Statistic Manual of Mental Disorders. 1980.

now being proposed as a required assessment instrument for the purposes of standardization. Depression is common among HH patients. According to PAC PRD data, 9.2 percent of HH patients screened positive for signs and symptoms depression.[67] Identifying and treating depression in home care can decrease short-term risk of re-hospitalization. A study conducted with 477 patients newly admitted to home care found that, although depression was not associated with overall hospitalization rates, the hospitalization rate for depressed patients was more than twice as high as the rate for non-depressed patients during the first two weeks of home care.[68] Depression in HH patients has also been associated with an increased risk of falls.[69] In addition, a two-year panel study found that potential depression at year 1, as assessed by PHQ-2, was associated with greater health care expenditures from home health services during the second year.[70] Among HHAs participating in the PAC PRD, the PHQ-2 demonstrated moderate to high inter-rater reliability.[71] Given the prevalence of depression among HH patients and its effect on patient outcomes, assessment of depression is clinically relevant in the home health setting.

Proposed Data Elements for the Assessment of Cognitive Function: PHQ-2

(M1731) Patient Health Questionnaire 2 (PHQ-2 ©)					
Say to the patient: "Over the last two weeks, how often have you been bothered by any of the following problems?"					
PHQ-2©*	Not at all 0 - 1 day	Several days 2 - 6 days	More than half of the days 7 – 11 days	Nearly every day 12 – 14 days	NA Unable to respond
a) Little interest or pleasure in doing things?	☐0	☐1	☐2	☐3	☐NA
b) Feeling down, depressed, or hopeless?	☐0	☐1	☐2	☐3	☐NA
*Copyright© Pfizer Inc. All rights reserved. Reproduced with permission.					

Current use

The PHQ-2 data elements are currently in use in the OASIS-C2. The PHQ-9 data elements, which include the two questions used in the PHQ-2 plus additional items, are in use in MDS 3.0.

Evidence supporting use of PHQ-2

The PHQ-2 is a brief, reliable screening tool for assessing signs and symptoms of depression. Among studies conducted in primary care centers with large samples of adults, the PHQ-2 has performed well as both a screening tool for identifying symptoms of depression and to assess depression severity.[72,73] It has also been shown to be sensitive to changes in a patient's mood. Across 15 studies that assessed the diagnostic accuracy of the PHQ-2 against a recognized gold-standard instrument for the diagnosis of major depression in adults, sensitivity estimates (based on the summed-item approach to scoring and a cutoff score of 3) have varied, ranging

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[67] Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Manning, J. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

[68] Sheeran, T., Byers, A. L., & Bruce, M. L. (2010). Depression and increased short-term hospitalization risk among geriatric patients receiving home health care services. Psychiatric Services 61(1): 78-80.

[69] Byers AL, Sheeran T, Mlodzianowski AE, Meyers, BS, Nassisi, P., & Bruce, ML. (2008). Depression and risk for adverse falls in older home health care patients. Research in Gerontological Nursing 1(4): 245–251.

[70] Choi, S., Hasche, L., & Nguyen, D. (2015). Effects of depression on the subsequent year's healthcare expenditures among older adults: Two-year panel study. Psychiatric Quarterly 86: 225–241.

[71] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[72] Li, C., Friedman, B., Conwell, Y., & Fiscella, K. (2007). Validity of the Patient Health Questionnaire 2 (PHQ-2) in identifying major depression in older people. J of the A Geriatrics Society 55(4): 596-602.

[73] Löwe, B., Kroenke, K., & Gräfe, K. (2005). Detecting and monitoring depression with a two-item questionnaire (PHQ-2). J of Psychosomatic Research 58(2): 163-171.

between 39 percent and 97 percent (median value = 77 percent); specificity estimates (based on the summed-item approach to scoring and a cutoff score of 3) have been higher and more stable, ranging between 74 percent and 97 percent (median value = 90 percent).[74,75,76,77,78,79,80,81,82,83,84,85,86,87,88] Thus, the specificity of the PHQ-2 appears to be comparable to that of the longer form PHQ-9, although the slightly lower sensitivity of the PHQ-2 means that more cases of depressive symptoms are likely to be missed using this brief instrument compared with the PHQ-9. The PHQ-2 was tested in the PAC PRD and found to be reliable in beta testing across the four PAC settings (kappas ranged from 0.74 to 0.91).[89] It is thus a viable option for standardization, with the benefits of the shorter assessment counterbalancing the limitation of the lower sensitivity.

The PHQ-9 was also tested in the national MDS 3.0 test in nursing homes. For the two presence items in the PHQ-2 (little interest in doing things; feeling down, depressed or hopeless), kappa statistics were almost perfect and ranged from 0.981 to 0.988.[90] The PHQ-9 was also

[74] Arroll, B., Goodyear-Smith, F., Crengle, S., Gunn, J., Kerse, N., Fishman, T., ... & Hatcher, S. (2010). Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. Ann Fam Med 8(4): 348-353.

[75] Bhana, A., Rathod, S. D., Selohilwe, O., Kathree, T., & Petersen, I. (2015). The validity of the Patient Health Questionnaire for screening depression in chronic care patients in primary health care in South Africa. BMC Psych 15(1): 118.

[76] Boyle, L. L., Richardson, T. M., He, H., Xia, Y., Tu, X., Boustani, M., & Conwell, Y. (2011). How do the PHQ-2, the PHQ-9 perform in aging services clients with cognitive impairment? Int Jof Geriatric Psych 26(9): 952-960.

[77] Chagas, M. H., Crippa, J. A., Loureiro, S. R., Hallak, J. E., Meneses-Gaya, C. D., Machado-de-Sousa, J. P., ... & Tumas, V. (2011). Validity of the PHQ-2 for the screening of major depression in Parkinson's disease: two questions and one important answer. Aging & Mental Health 15(7): 838-843.

[78] Chen, S., Chiu, H., Xu, B., Ma, Y., Jin, T., Wu, M., & Conwell, Y. (2010). Reliability and validity of the PHQ-9 for screening late-life depression in Chinese primary care. Int J of Geriatric Psychiatry 25(11): 1127-1133.

[79] de Lima Osório, F., Vilela Mendes, A., Crippa, J. A., & Loureiro, S. R. (2009). Study of the discriminative validity of the PHQ-9 and PHQ-2 in a sample of Brazilian women in the context of primary health care. Perspectives in Psych Care 45(3): 216-227.

[80] Hanwella, R., Ekanayake, S., & de Silva, V. A. (2014). The validity and reliability of the Sinhala translation of the Patient Health Questionnaire (PHQ-9) and PHQ-2 Screener. Depression research and treatment.

[81] Inagaki, M., Ohtsuki, T., Yonemoto, N., Kawashima, Y., Saitoh, A., Oikawa, Y., ... & Yamada, M. (2013). Validity of the PHQ-9 and PHQ-2 in general internal medicine primary care at a Japanese rural hospital: a cross-sectional study. Gen Hosp Psychiatry 35(6): 592-597.

[82] Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9. J Gen Intern Med 16(9): 606-613.

[83] Anand, A., Li, Y., Wang, Y., Wu, J., Gao, S., Bukhari, L., ... & Lowe, M. J. (2005). Activity and connectivity of brain mood regulating circuit in depression: a functional magnetic resonance study. Biological Psychiatry 57(10): 1079-1088.

[84] Phelan, E., Williams, B., Meeker, K., Bonn, K., Frederick, J., LoGerfo, J., & Snowden, M. (2010). A study of the diagnostic accuracy of the PHQ-9 in primary care elderly. BMC Fam Practice 11(1): 63.

[85] Suzuki, K., Kumei, S., Ohhira, M., Nozu, T., & Okumura, T. (2015). 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 10(3): e0119147.

[86] Thombs, B. D., Ziegelstein, R. C., & Whooley, M. A. (2008). Optimizing detection of major depression among patients with coronary artery disease using the patient health questionnaire: data from the heart and soul study. J of Gen Int Med 23(12): 2014-2017.

[87] Xiong, N., Fritzsche, K., Wei, J., Hong, X., Leonhart, R., Zhao, X., ... & Fischer, F. (2015). Validation of patient health questionnaire (PHQ) for major depression in Chinese outpatients with multiple somatic symptoms: a multicenter cross-sectional study. J of Affective Disorders 174: 636-643.

[88] Zuithoff, N. P., Vergouwe, Y., King, M., Nazareth, I., van Wezep, M. J., Moons, K. G., & Geerlings, M. I. (2010). The PHQ-9 for detection of major depressive disorder in primary care: consequences of current thresholds in a crosssectional study. BMC Fam Practice 11(1): 98.

[89] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[90] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

found to have agreement with Modified Schedule for Affective Disorders and Schizophrenia (m-SADS), a gold-standard measure for mood disorder, in residents without severe cognitive impairment (weighted kappa=0.685) and with the Cornell Depression Scale, a gold-standard measure for mood disorder, in residents with severe cognitive impairment (correlation=0.63).[91]

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[91] *Ibid.*

3.4   Special Services, Treatments, and Interventions (Including Nutritional Approaches)

Some medical conditions require complex clinical care, consisting of special services, treatments, and interventions. The implementation of these interventions typically indicates conditions of a more serious nature and can be life-sustaining. Patients and residents who need them may have few clinical alternatives. Conditions requiring the use of special services, treatments, and interventions can have a profound effect on an individual's health status, self-image, and quality of life. Providers should be aware of the patient or resident's clinical needs in order to plan the provision of these important therapies and 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.

3.4.1   Standardized Data Elements to Assess for Special Services, Treatments, and Interventions

CMS has identified data elements for cross-setting standardization of assessment for 15 special services, treatments, and interventions in the areas of cancer, respiratory, and other treatments, as well as nutritional approaches. The proposed data elements are:

1.   Chemotherapy (IV, Oral, Other);
2.   Radiation;
3.   Oxygen therapy (Continuous, Intermittent);
4.   Suctioning (Scheduled, As needed);
5.   Tracheostomy Care
6.   Invasive Mechanical Ventilator;
7.   Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP]; Continuous Positive Airway Pressure [CPAP]);
8.   Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other);
9.   Transfusions;
10.   Dialysis (Hemodialysis, Peritoneal dialysis);
11.   Intravenous (IV) Access (Peripheral IV, Midline, Central line, Other);
12.   Parenteral/IV Feeding;
13.   Feeding Tube;
14.   Mechanically Altered Diet; and
15.   Therapeutic Diet.
16.   Chemotherapy (IV, Oral, Other)

Chemotherapy is a type of cancer treatment that uses medications to destroy cancer cells. This treatment indicates that a patient has a malignancy (cancer) and therefore has a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection (due to a suppressed immune system), anemia, and an increased risk of bleeding (due to low platelet counts). Oral chemotherapy can be as potent as chemotherapy given by IV but can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling, and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. The need for chemotherapy predicts

resource intensity, both because of the complexity of administering these potent, toxic drug combinations following specific protocols and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

Relevance to HHAs

Neither chemotherapy in general, nor specific routes of chemotherapy administration, are currently assessed in the OASIS-C2. However, cancer is fairly common among HH patients. According to data from the National Home and Hospice Care Survey (NHHCS), 9 percent of HH patients aged 65 and older had malignant neoplasms.[92] Another study of elderly patients newly admitted to HHAs found that 11 percent had a referral diagnosis of cancer.[93] Oral and intravenous chemotherapy in the home for patients being treated for cancer has become increasingly common due to patient preference, its cost-effectiveness, and increasing demand for oncology services.[94] Further, there is some evidence for the benefits of oncology home care; one study found that lung cancer patients who received oncology home care reported less distress and greater social independence compared to those who received usual outpatient care.[95] Assessing the receipt of chemotherapy is important in the HH setting for care planning and defining case mix.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Chemotherapy

Section O	Special Treatments, Procedures, and Programs		
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.			
		3. Performed during the first 3 days at SOC/ROC	
		Check all that apply ↓	
A. **Chemotherapy** (if checked, please specify below) A2a. IV A3a. Oral A10a. Other		☐ ☐ ☐ ☐	

Current use

Chemotherapy data elements are currently used in the MDS 3.0. The items document whether the resident received chemotherapy in the past 14 days while not a resident of the assessing facility, and also if the resident has received chemotherapy in the past 14 days while a resident, but do not assess the route of chemotherapy.

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[92] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.
[93] Bruce, M. L., McAvay, G. J., Raue, P. J., Brown, E. L., Meyers, B. S., … Weber, C. (2002). Major depression in elderly home health care patients. American Journal of Psychiatry 159(8): 1367-1374.
[94] Chavis-Parker, P. (2015). Safe chemotherapy in the home environment. Home Health Care Now 33(5): 246-251.
[95] McCorkle, R., Benoliel, J. Q., Donaldson, G., Georgiadou, F., Moinpour, C., & Goodell, B. (1989). A randomized clinical trial of home nursing care for lung cancer patients. Cancer 64(6): 1375-1382.

Evidence supporting use of Chemotherapy (IV, Oral, Other)

An IV Chemotherapy data element was found to be feasible for cross-setting use in the PAC PRD.[96] A checkbox for chemotherapy during the last 14 days was shown to have reliabilities of 0.695 and 0.8 in studies of MDS 2.0 in nursing homes.[97]

3.4.2 Radiation

Radiation is a type of cancer treatment that uses high-energy radiation to shrink tumors and kill cancer cells by damaging their DNA. However, it can also damage normal cells, leading to side effects such as fatigue, skin irritation or damage, hair loss, nausea, and delayed side effects such as fibrosis (scar tissue formation), damage to the bowels if radiation was delivered to the abdominal region, memory loss, and infrequently, a second cancer due to radiation exposure. Radiation is a mainstay of cancer treatment; about half to two-thirds of all patients with cancer receive radiation therapy at some point in their treatment course.[98, 99] The indications range from early-stage cancer treated with curative intent to palliative radiation therapy, such as to treat metastatic cancer; tumors that are pressing on the spine or growing within bones, causing severe pain; or shrinking a tumor near the esophagus, which can inhibit swallowing. There are many types of radiation, such as external-beam radiation therapy and internal radiation therapy (brachytherapy that is delivered from sources placed inside or on the body), and systemic radiation therapy (in which the patient swallows or receives an injection of a radioactive substance).

Relevance to HHAs

Radiation treatment is not currently assessed in the OASIS-C2. However, as mentioned above, cancer is fairly common among HH patients. According to data from the National Home and Hospice Care Survey (NHHCS), 9 percent of HH patients aged 65 and older had malignant neoplasms.[100] Another study of elderly patients newly admitted to HHAs found that 11 percent had a referral diagnosis of cancer.[101] A 2006 study of home health utilization among older adults with cancer found that approximately 29 percent of older patients' access home health care following a cancer diagnosis.[102] Thus, assessing the receipt of radiation treatment for cancer is important in the HH setting for care planning and defining case mix.

[96] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[97] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[98] Yamada, Y. Principles of Radiotherapy. (2009). In Cancer rehabilitation: principles and practice. Eds. Stubblefield Michael D. and O'dell Michael W.

[99] National Cancer Institute. (2010). Radiation Therapy for Cancer. Available at https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet

[100] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.

[101] Bruce, M. L., McAvay, G. J., Raue, P. J., Brown, E. L., Meyers, B. S., … Weber, C. (2002). Major depression in elderly home health care patients. American Journal of Psychiatry 159(8): 1367-1374.

[102] Locher, J. L., Kilgore, M. L,. Morrisey. M. A., Ritchie, C. S. (2006). Patterns and predictors of home health and hospice use by older adults with cancer. Journal of the American Geriatric Society 54(8): 1206-1211.

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC**
		Check all that apply ↓
B. Radiation		☐

Current use

A version of this data element, Radiation, is currently collected in the MDS 3.0. The items document whether the resident received radiation in the past 14 days while not a resident of the assessing facility, and also if the resident has received radiation in the past 14 days while a resident.

Evidence supporting use of Radiation

In studies of the MDS 2.0, a checkbox for radiation during the last 14 days was shown to have reliabilities of 1 and 0.66.[103]

3.4.3   Oxygen Therapy (Continuous, Intermittent)

Oxygen therapy provides a patient/resident with supplemental oxygen when medical conditions (e.g., chronic obstructive pulmonary disease [COPD], pneumonia, severe asthma) prevent the patient or resident from adequately oxygenating their bloodstream. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment: a reliable source of oxygen, various delivery systems (e.g., oxygen concentrator, liquid oxygen containers, and high-pressure systems), and the patient interface (e.g., nasal cannula, various types of masks). Accessories are also required (e.g., regulators, filters, tubing, etc.). While the equipment is generally the same for both sub-elements of this data element (continuous vs. intermittent), the main differences between delivering oxygen intermittently versus continuously are the severity of the underlying illness (which often requires more hours per day of oxygen therapy), and the bedside nursing care to set up the oxygen delivery system if the patient is unable (whether physically or cognitively) to do so independently.

The proposed Oxygen (Continuous, Intermittent) data elements assess if the patient received oxygen therapy and whether the oxygen was delivered continuously (typically defined as >=14 hours per day) or intermittently.

Relevance to HHAs

The OASIS-C2 currently asks about oxygen therapy, but does not differentiate between intermittent and continuous oxygen. Assessing the receipt of intermittent and continuous oxygen therapy is important in the HH setting for care planning and resource allocation. HH patients may have a medical condition that requires supplemental oxygen. A study by Dwyer et al. found

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[103]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

that 2.4 percent of individuals receiving home health care had pneumonia.[104] Data from the National Home and Hospice Care Survey (NHHCS) indicated that 15 percent of home health patients aged 65 and older had chronic obstructive pulmonary disease (COPD) and allied conditions.[105] Pneumonia and COPD are the fourth and fifth most common diagnoses of Medicare beneficiaries discharged to the home health setting.[106] According to a RAND analysis of 2013 OASIS data, 13.9 percent of patients in the home health setting were receiving oxygen therapy.[107]

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Oxygen Therapy

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC** Check all that apply ↓
C. **Oxygen Therapy** (if checked, please specify below) C2a. Continuous C3a. Intermittent		☐ ☐ ☐

Current use

Related data elements are collected in the OASIS-C2 and the MDS 3.0. In the MDS, the items document whether the resident received oxygen therapy in the past 14 days while not a resident of the assessing facility, and also if the resident has received oxygen therapy in the past 14 days while a resident.

Evidence supporting use of Oxygen Therapy (Continuous, Intermittent)

A related data element on high concentration oxygen use (FiO2>40%) was used and found feasible for cross-setting use in the PAC PRD.[108] In nursing homes, a checkbox for oxygen therapy during the last 5 days was shown to have reliability ranging from 0.925 to 0.955 in the national MDS 3.0 test.[109] Oxygen therapy data elements during the last 14 days were shown to have reliabilities ranging from of 0.81 to 0.87 in studies of MDS 2.0.[110]

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[104] Dwyer, L. L., Harris-Kojetin, L. D., Valverde, R. H., Frazier, J. M., Simon, A. E., Stone, N. D., & Thompson, N. D. (2013). Infections in long-term care populations in the United States. Journal of the American Geriatric Society 61(3): 341-349.

[105] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.

[106] The National Association for Home Care & Hospice (2010). Basic statistics about home care. Washington DC: Author.

[107] RAND analysis of 2013 OASIS data.

[108] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[109] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[110] *Ibid.*

3.4.4 Suctioning (Scheduled, As Needed)

Suctioning is used to clear secretions from the airway when a person cannot clear those secretions on his or her own due to a variety of reasons, including excess production of secretions from a pulmonary infectious process or neurological deficits that inhibit the ability to cough, swallow, etc. 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. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions that can lead to aspiration pneumonias (a common condition in patients with inadequate gag reflexes) and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as needed, such as when secretions become so prominent that gurgling or choking is noted, or a sudden desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents patients from clearing their secretions effectively, which also means they are in need of increased nursing care more generally (such as after a stroke or during an acute respiratory infection).

Relevance to HHAs

The OASIS-C2 does not currently assess suctioning, although many HH patients have medical conditions that may necessitate this procedure. As mentioned above, a cross-sectional study by Dwyer et al. found that 2.4 percent of individuals receiving home health care had pneumonia.[111] According to data from the National Home and Hospice Care Survey (NHHCS), 15 percent of home health patients aged 65 and older had chronic obstructive pulmonary disease (COPD) and allied conditions.[112] Pneumonia and COPD are the fourth and fifth most common diagnoses of Medicare beneficiaries discharged to the home health setting.[113] These conditions may require suctioning to clear secretions from the patient's airway that they are not able to clear themselves. As such, assessing the receipt of suctioning is important in the HH setting for care planning and defining case mix.

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[111] Dwyer, L. L., Harris-Kojetin, L. D., Valverde, R. H., Frazier, J. M., Simon, A. E., Stone, N. D., & Thompson, N. D. (2013). Infections in long-term care populations in the United States. Journal of the American Geriatric Society 61(3): 341-349.

[112] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.

[113] The National Association for Home Care & Hospice (2010). Basic statistics about home care. Washington DC: Author.

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC** Check all that apply ↓
D. **Suctioning** (if checked, please specify below) D2a. Scheduled D3a. As needed		☐ ☐ ☐

Current use

Related Suctioning data elements are collected in the MDS 3.0. The items document whether the resident received Suctioning in the past 14 days while not a resident of the assessing facility, and also if the resident has received Suctioning in the past 14 days while a resident.

Evidence supporting use of Suctioning (Scheduled, As Needed)

In the PAC PRD, suctioning was assessed as part of Trach Tube with Suctioning data element, which evaluated whether patients or residents had a tracheostomy tube or needed suctioning. This related data element was found feasible for cross-setting use in the PAC PRD.[114] A checkbox for suctioning during the last 14 days was shown to have reliabilities of 0.89 and 0.775 in studies of MDS 2.0.[115]

3.4.5   Tracheostomy Care

A tracheotomy is a surgical procedure that consists of making a direct airway opening (tracheostomy) into the trachea (windpipe). Tracheostomies are created primarily for reasons such as to bypass an obstructed upper airway; in chronic cases, to enable the removal of secretions from the airway; and to deliver oxygen to the patient's lungs. For example, patients with a need for long-term ventilation (such as those in a persistent vegetative state or those who require long-term ventilator weaning but are alert and oriented); patients with tumors of the upper airway; patients with severe neck, mouth, or chest wall injuries; patients with degenerative neuromuscular diseases such as amyotrophic lateral sclerosis (ALS); patients with spinal cord injuries; and patients with airway burns are just some of the examples of the indications for a tracheostomy. Generally, in all of these cases we note that suctioning is necessary to ensure that the tracheostomy is clear of secretions, which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, permanent or temporary, warrants careful monitoring and immediate intervention should the tracheostomy become occluded, or in the case of a temporary tracheostomy, the devices used become dislodged.

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[114]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[115]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

For patients with a tracheostomy, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is a critical part of their care plans. Regular cleansing is important to prevent infection, such as pneumonia, and to prevent any occlusions with which there are risks for inadequate oxygenation. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the tracheostomy is performed by the patient) in general the presence of such a device is associated with increased patient risk, and clinical care services will necessarily include close monitoring since to ensure that no life threatening events occur as a result of the tracheostomy, often considered part of the patient's life line.

The data element, Tracheostomy Care, assesses whether a patient/resident received tracheostomy care during the assessment period.

Relevance to HHAs

Tracheostomy care is not currently assessed in OASIS-C2. However, tracheostomy care is becoming more routinely performed in the home.[116, 117] Caring for a tracheostomy, including suctioning and cleaning, preserves patency and prevents infection. In general, use of a tracheostomy care protocol for patients with a tracheostomy lead to decreased morbidity and mortality.[118,119] Effective management of a tracheostomy in the hospital and PAC settings has a significant positive impact on the quality of life. Patients with deficits in respiratory drive or in respiratory muscle strength, such as those with stroke, could require extended ventilation and tracheostomy care. One study of home care clients in Canada found approximately 17 percent of patients had a diagnosis of stroke.[120] This data element is relevant in facilitating care coordination and supporting care transitions. The tracheostomy care element will ensure those receiving services continue to receive appropriate care and support throughout care transitions, including the transition from another PAC setting into HH.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Tracheostomy Care

Section O	Special Treatments, Procedures, and Programs
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.	
	3. **Performed during the first 3 days at SOC/ROC** Check all that apply ↓
E. **Tracheostomy Care**	☐

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[116]   Gershon, R. R. M., Pearson, J. M., Sherman, M. F., Samar, S. M., Canton, A. N., & Stone, P. W. (2009). The prevalence and risk factors for percutaneous injuries in registered nurses in the home health care sector. American Journal of Infection Control 37(7): 525-533.

[117]   Lewarski, J. S. (2005). Long-term care of the patient with a tracheostomy. Respiratory Care 50(4): 534 –537.

[118]   Garrubba, M., Turner, T., & Grieveson, C. (2009). Multidisciplinary care for tracheostomy patients: a systematic review. Critical Care 13(6): R177.

[119]   Cetto, R., Arora, A., Hettige, R., Nel, M., Benjamin, L., Gomez, C. M., … & Narula, A. A. (2011). Improving tracheostomy care: a prospective study of the multidisciplinary approach. Clinical Otolaryngology 36(5): 482-488.

[120]   Mitchell, L. A., Hirdes, J., Poss, J. W., Siegers-Boyd, C., Caldarelli, H., & Martin, L. (2015). Informal caregivers of clients with neurological conditions: profiles, patterns and risk factors for distress from a home care prevalence study. BMC health services research, 15(1), 350.

A version of this data element currently exists in the MDS 3.0. The items document whether the resident received Tracheostomy Care in the past 14 days while not a resident of the assessing facility, and also if the resident has received Tracheostomy Care in the past 14 days while a resident.

Evidence supporting use of Tracheostomy Care

In two studies of the MDS 2.0, a checkbox for tracheostomy care during the last 14 days was shown to have reliability of 1.[121]

3.4.6 Invasive Mechanical Ventilation

Invasive mechanical ventilation includes any type of electrically or pneumatically powered closed-system mechanical support devices, to ensure adequate ventilation of the patient who is unable to support his or her own respiration. Patients receiving closed-system ventilation include those receiving ventilation via a tracheostomy, as well as those patients with an endotracheal tube (e.g., nasally or orally intubated). Depending on the patient's underlying diagnosis, clinical condition, and prognosis, he or she may or may not be a candidate for weaning off the ventilator. For instance, certain medical conditions such as lung infections are expected to improve or resolve to a point where the patient can support his or her own respiration, whereas chronic neurodegenerative diseases are likely to progress over time and therefore preclude the patient from weaning and eventually having the tube removed.

Ventilation in this manner is a resource-intensive therapy associated with life threatening conditions without which the patient would not survive. However, ventilator use has inherent risks requiring close monitoring and failure to adequately care for the patient who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical and/or surgical condition.

Relevance to HHAs

The OASIS-C2 currently assesses respiratory treatments used at home, with "ventilator (continually or at night)" as one response option. This data element will provide more specific information on whether the HH patient is receiving invasive mechanical ventilation specifically. Since there is no national registry for home ventilation in the United States, it is difficult to account for the number of patients using invasive mechanical ventilation in the HH setting, but estimates suggest that the number of patients receiving home ventilation is increasing in the United States.[122, 123] Goals of home invasive mechanical ventilation include sustaining and extending life, enhancing the quality of life, reducing morbidity, improving or sustaining physical and psychological functioning, and providing cost-effective care.[124,125] However,

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[121] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[122] Divo, M. J., Murray, S., Cortopassi, F., & Celli, B. R. (2010). Prolonged mechanical ventilation in Massachusetts: the 2006 prevalence survey. Respiratory care, 55(12), 1693-1698.

[123] King, A. C. (2012). Long-term home mechanical ventilation in the United States. Respiratory care, 57(6), 921-932.

[124] AARC Clinical Practice Guideline (2007). Long-Term Invasive Mechanical Ventilation in the Home - 2007 Revision & Update. Respiratory Care 52(1): 1056-1062.

invasive mechanical ventilation is one of the most advanced and complicated types of medical treatment provided outside a hospital setting.[126,127] Potential major complications include pneumonia, injury to the lung due to excessive air pressure, fluid overload, and blood clot in a lung artery.[128] Assessing the use of invasive mechanical ventilation in the HH setting is important for care planning, clinical decision support, care coordination, understanding of medical complexity, and resource use planning.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Invasive Mechanical ventilation

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC**
		Check all that apply ↓
F. **Invasive Mechanical Ventilator** (ventilator or respirator)		☐

Current use

Invasive mechanical ventilation is currently assessed in the MDS 3.0, the OASIS-C2, and the LCDS. In the MDS, the items document whether the resident used a ventilator or respirator in the past 14 days while not a resident of the assessing facility, and also if the resident used a ventilator or respirator in the past 14 days while a resident. The OASIS-C2 assessment data element includes a checkbox item for respiratory treatments used at home, in which "ventilator (continually or at night)" is included. The LCDS has two items that specify whether the invasive mechanical ventilator is weaning or non-weaning.

Evidence supporting use of Invasive Mechanical Ventilation

Checkbox items for ventilator (weaning and non-weaning) were tested in the PAC PRD and were found to be feasible for cross-setting use.[129] A version of the item was tested in the MDS 3.0 National Evaluation Study and had perfect reliability (1.0).[130]

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[125]   King, A. C. (2012). Long-term home mechanical ventilation in the United States. Respiratory care, 57(6), 921-932.

[126]   Dybwik, K., Nielsen, E. W., & Brinchmann, B. S. (2011). Home mechanical ventilation and specialised health care in the community: Between a rock and a hard place. BMC Health Services Research, 11: 115. doi: 10.1186/1472-6963-11-115

[127]   Lewarski, J. S., & Gay, P. C. (2007). Current issues in home mechanical ventilation. Chest. 132(2): 671–676.

[128]   Klompas, M., Khan, Y., Kleinman, K., Evans, R. S., Lloyd, J. F., Stevenson, K., . . . CDC Prevention Epicenters Program. (2011). Multicenter evaluation of a novel surveillance paradigm for complications of mechanical ventilation. PLoS One, 6(3), e18062. doi:10.1371/journal.pone.0018062

[129]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[130]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

3.4.7 Non-invasive Mechanical Ventilation (Continuous Positive Airway Pressure [CPAP], Bilevel Positive Airway Pressure [BiPAP])

CPAP and BiPAP 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 provides breathing support through the provision of positive airway pressure that prevents airways from collapsing down during the respiratory cycle. Non-invasive mechanical ventilation differs from invasive mechanical ventilation because the interface with the patient is a mask rather than an endotracheal tube that is passed into the windpipe. CPAP and BiPAP have a variety of clinical indications, from obstructive sleep apnea, to acute respiratory infections, to progressive neuromuscular decline leading to respiratory failure. The key difference between CPAP and BiPAP is that CPAP delivers the same amount of positive airway pressure throughout the breathing cycle while BiPAP, as the name implies, delivers two different pressure levels, a higher pressure to support inhalation and a lower pressure to prevent the airways from collapsing during exhalation. These interventions signify underlying medical conditions in the patient who requires their use.

Relevance to HHAs

The OASIS-C2 currently assesses BiPAP/CPAP treatment. However, it does not differentiate between BiPAP treatment and CPAP treatment. According to 2013 OASIS data, 2.6 percent of HH patients were on either BiPAP or CPAP treatment.[131] CPAP or BiPAP masks enable individuals to support their own breathing cycle. They can be used for sleep apnea or more serious conditions like COPD or respiratory failure. Non-invasive ventilation is a common tool in the management of acute and chronic respiratory failure in home settings. Complications related to mask use may include mask discomfort and skin rashes; other complications include pressure and blood flow issues, such as general discomfort, ear or sinus pain, gastric insufflation, nasal dryness, congestion, and obstruction. More serious complications include aspiration and hemodynamic compromise, the latter in patients with compromised cardiac output.[132] Non-invasive mechanical ventilation can be more difficult for patients who rely on long-term ventilator support when compared to invasive mechanical ventilation.[133] Considering the use of noninvasive mechanical ventilation is therefore important to assess in HHAs for purposes of case mix adjustment and care planning.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: Non-invasive Mechanical Ventilation

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC**
		Check all that apply ↓
G. **Non-invasive Mechanical Ventilator** (BiPAP/CPAP) (if checked, please specify below)		☐
G2a. BiPAP		☐
G2b. CPAP		☐

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[131] RAND analysis of 2013 OASIS data.
[132] Gay, P. C. (2009). Complications of noninvasive ventilation in acute care. Respiratory Care 54(2): 246-257.
[133] King, A. C. (2012). Long-term home mechanical ventilation in the United States. Respiratory Care 57(6): 921-932.

Current use

The *BiPAP/CPAP* data elements assess if the patient received bilevel positive airway pressure or continuous positive airway pressure during the assessment period. They are currently collected in the OASIS-C2, LCDS, and the MDS 3.0. The OASIS-C2 assessment data elements include a checkbox item for respiratory treatments, in which continuous/bi-level positive airway pressure is included. The LCDS uses a checklist format, including an item asking if a non-invasive ventilator (BIPAP, CPAP) is part of the patient's treatment plan. In the MDS, the items document whether the resident used BiPAP/CPAP in the past 14 days while not a resident of the assessing facility, and also if the resident used BiPAP/CPAP in the past 14 days while a resident.

Evidence supporting use of Non-invasive Mechanical Ventilation (CPAP, BiPAP)

A checkbox item for Non-invasive Ventilation (CPAP) was tested in the PAC PRD and was found to be feasible for cross-setting use.[134]

3.4.8   IV Medications

Intravenous (IV) medications are drugs or biologics that are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a tube placed into the vein, including one that allows the fluids to enter the circulation through one of the larger heart vessels or more peripherally through a vein, e.g., commonly referred to as central midline, or peripheral ports.

This data element is important to collect, as IV medications are more resource intensive to administer than oral medications and signify a higher patient complexity (and often higher severity of illness). The clinical indications for each of the sub-types of IV medications proposed (antibiotics, anticoagulants, and other) are very different. IV antibiotics are used for severe infections when a) the bioavailability of the oral form of the medication would be inadequate to kill the pathogen; b) an oral form of the medication does not exist; or c) the patient is unable to take the medication by mouth. Due to growing concern about antimicrobial resistance, antibiotic stewardship initiatives are aimed at increasing evidence-based antibiotic prescribing and decreasing antibiotic overuse. While the particular antibiotic(s) would not be collected, collecting data on the use of IV antibiotics overall in the four PAC settings would assist with monitoring the implementation of evidence-based prescribing guidelines moving forward.

IV anticoagulants refers to anti-clotting medications ("blood thinners") often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are therefore at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. When a patient is on an IV anticoagulant, they require frequent monitoring of laboratory values to ensure appropriate anticoagulation status.

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[134]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

Relevance to HHAs

The OASIS-C2 currently assesses intravenous or infusion therapy in a single item, but does not assess specific types of IV medications. However, IV antibiotic use in the HH setting is becoming increasingly common due to patient placement difficulties and costs associated with skilled facilities.[135] Further, there is evidence that an IV medication adjunct to treatment can reduce the likelihood of hospital readmission for HH patients with heart failure.[136] Thus, it is important to assess the fact of IV administration in addition to the type of IV medications being administered within the HH setting for care planning and defining case mix.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: IV Medications

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
	3. **Performed during the first 3 days at SOC/ROC**	
	Check all that apply ↓	
H. **IV Medications** (if checked, please specify below) H3a. Antibiotics H4a. Anticoagulation H10a. Other	☐ ☐ ☐ ☐	

Current use

An IV Medications data element is currently in use in the MDS 3.0 but without the sub-elements specifying types of IV Medication. The items document whether the resident received IV Medication in the past 14 days while not a resident of the assessing facility, and also if the resident has received IV Medication in the past 14 days while a resident.

Evidence supporting use of IV Medications

A similar data element, IV Vasoactive Medications, was tested in the PAC PRD and found to be feasible across PAC settings. This data element was specific to the IV administration of vasoactive drugs (e.g., pressors, dilators, continuous medication for pulmonary edema) that increase or decrease blood pressure and/or heart rate.

In nursing homes, a checkbox for IV medications during the last 5 days was shown to have reliability of 0.952 in the national MDS 3.0 test and IV medications during the last 14 days was shown to have reliabilities of 0.92 and 0.564 in studies of MDS 2.0.[137]

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[135] Bossaer, J. B. & Lewis, P. O. (2012). Antibiotic use in home health: A primer. Home Health Care Management & Practice 24(1): 50-55.

[136] Sherrod, M. M., Graulty, R., Crawford, M., & Cheek, D. J. (2009). Intravenous heart failure medications: An update for home health clinicians. Home Healthcare Nurse 27(10): 610-619.

[137] Saliba, D., & Buchanan, J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. 2008. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf

3.4.9 Transfusions

Transfusions are the administration of blood or blood products (e.g. platelets, synthetic blood products) into the bloodstream. Blood transfusions are highly protocolized, with multiple safety checks and monitoring required during and after the infusion to avoid adverse events. Coordination with the facility's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require additional nursing staff and care coordination, and impacts planning for transitions of care, as transfusions are not performed in all PAC settings.

Relevance to HHAs

The OASIS-C2 currently assesses intravenous or infusion therapy in a single item, but does not assess blood transfusions specifically. Blood transfusions can be safely administered in the home. Common diagnoses for patients receiving home transfusions are cancer, chronic anemia, AIDS, and bone marrow transplantation.[138] Further, as the population continues to age and more adults require care in the HH setting it is likely that the demand for these services will continue to rise.[139] Advantages for home transfusion include offering patients the physical and psychological comfort of receiving services in their home, lower costs, fewer clerical errors, minimizing the need of the patient to travel for care, and no risk of nosocomial infection.[140,141,142] Noted concerns in the past, specifically distance from emergency services in the event of an adverse event, appear to be minimized as evidenced by recent studies; work to date suggests that transfusions at home can be administered safely to maximize benefits for patients in this PAC setting.[143] Assessing transfusion therapy with the HH setting is important for care planning and defining case mix.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Transfusions

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. **Performed during the first 3 days at SOC/ROC** **Check all that apply** ↓
I. Transfusions		☐

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138   Benson, K., Popovsky, M. A., Hines, D., Hume, H., Oberman, H. A., Glassman, A. B., …& Anderson, K. C. (1998). Nationwidel survey of home transfusion practices. Transfusion 38(1): 90-96.
139   Ibid
140   *Ibid*
141   Benson, K. (2006). Home is where the heart is: Do blood transfusions belong there too? Transfusion Medicine Reviews 20(3): 218-229.
142   Niscola, P., Tendas, A., Giovannini, M., Cupelli, L., Trawinska, M. M. Palombi, M., … Perrotti, A. (2012).Transfusions at home in patients with myelodysplastic syndromes. Leukemia Research 36(6): 684-688.
143   Benson, K. (2006). Home is where the heart is: Do blood transfusions belong there too? Transfusion Medicine Reviews 20(3): 218-229.

The Transfusions data element is currently collected in the MDS 3.0, using a checkbox format. The items document whether the resident received Transfusions in the past 14 days while not a resident of the assessing facility, and also if the resident has received Transfusions in the past 14 days while a resident.

Evidence supporting use of Transfusions

In nursing homes, a checkbox for transfusions in the past 5 days was shown to have reliability of 0.666 in the national MDS 3.0 test.[144] A checkbox for transfusions in the last 14 days was shown to have reliabilities of 0.57 and 0.304 when tested in two studies of MDS 2.0.[145]

3.4.10 Dialysis (Hemodialysis, Peritoneal dialysis)

Dialysis is used primarily in the case of end stage kidney failure. It is a process by which waste, salt, and excess water are from the body and key electrolytes such as sodium, potassium, and bicarbonate are maintained at a safe level. Hemodialysis is conducted using an artificial kidney, an external hemodialyzer, which filters the blood. During peritoneal dialysis, the dialysate is injected into the peritoneal (abdominal) cavity, excess fluid and waste products are drawn out of the blood and into the dialysate, and the fluid is then drained. Hemodialysis sessions are typically performed three times a week and last up to four hours each. Peritoneal dialysis can be performed continuously overnight or intermittently during the day.

Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients receiving hemodialysis are often transported to a dialysis center, if the service is not offered at the PAC setting. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during, and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and, as with hemodialysis, close monitoring is required.

Relevance to HHAs

The OASIS-C2 does not currently have a separate item assessing dialysis. Rather, it is included in a more general category of "Intravenous or infusion therapy (excludes TPN)." An analysis of PAC PRD data suggests that 1.3 percent of patients in the home health setting were receiving hemodialysis.[146] Including an item specifically assessing dialysis therapy with the HH setting is important for care planning and defining case mix.

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[144]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[145]   *Ibid.*

[146]   Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Manning, J. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs		
Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. Performed during the first 3 days at SOC/ROC
		Check all that apply ↓
J. **Dialysis** (if checked, please specify below)		☐
J2a. Hemodialysis		☐
J3a. Peritoneal dialysis		☐

Current use

A Dialysis data element is currently collected in the MDS 3.0. The items document whether the resident received Dialysis in the past 14 days while not a resident of the assessing facility, and also if the resident has received Dialysis in the past 14 days while a resident. These data elements use a checkbox format to indicate peritoneal or renal dialysis including hemofiltration treatments, Slow Continuous Ultrafiltration (SCUF), Continuous Arteriovenous Hemofiltration (CAVH), and Continuous Ambulatory Peritoneal Dialysis (CAPD).

Evidence supporting use of Dialysis (Hemodialysis, Peritoneal dialysis)

In nursing homes, a data element assessing dialysis in the past 5 days was tested in the national MDS 3.0 test and shown to have almost perfect reliability (0.908 to 0.927).[147] Dialysis in the last 14 days was also shown to have almost perfect reliability (0.92 to 0.965) in studies of MDS 2.0.[148]

3.4.11 IV Access

Intravenous (IV) access refers to a catheter inserted into a vein for a variety of clinical reasons, including long-term medication treatment, hemodialysis, large volumes of blood or fluid, frequent access for blood samples, intravenous fluid administration, total parenteral nutrition (TPN), or in some instances the measurement of central venous pressure.

The data elements associated with IV Access distinguish between peripheral access and central access. Further, different types of central access are specified. The rationale for distinguishing between a peripheral IV and central IV access is that central lines confer higher risks associated with life threatening events such as pulmonary embolism, infection and bleeding. Patients with central lines, including those peripherally inserted or who have subcutaneous central line "port" access, always require vigilant nursing care to ensure patency of the lines and importantly to ensure that such invasive lines are free from any potentially life-threatening events such as infection, air embolism, as well as bleeding from an open lumen.

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[147] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[148] *Ibid.*

The OASIS-C2 currently only has an option for "Intravenous or infusion therapy (excludes TPN)." The proposed data element includes additional detail about the type of IV access, such as distinguishing between peripheral IV and central IV access. As noted above, this distinction is important in that central lines confer higher risks associated with life threatening events. Analyses of PAC PRD data suggest that 1.5 percent of patients in the home health setting were receiving care for central line.[149] Furthermore, a study of patients receiving home health care found that 3 percent were receiving IV therapy or parenteral nutrition.[150] Adding this data element will provide important information on different types of IV access, which is important for resource planning and care transitions.

Proposed Data Elements for the Assessment of Special Services, Treatments, and Interventions: IV Access

Section O	Special Treatments, Procedures, and Programs	
O0100. Special Treatments, Procedures and Programs		
Check all of the following treatments, procedures, and programs that were performed during the first 3 days at SOC/ROC.		
		3. Performed during the first 3 days at SOC/ROC
		Check all that apply ↓
O. IV Access (if checked, please specify below)		☐
O2a. Peripheral IV		☐
O3a. Midline		☐
O4a. Central line (e.g., PICC, tunneled, port)		☐
O10a. Other		

Current use

The IV Access data elements as proposed are not currently included in any of the PAC assessments.

Evidence supporting use of IV Access

The IV Access data elements were not tested in the PAC PRD but that study did test a related data element, Central Line Management, which was found feasible for cross-setting use.

3.4.12 Parenteral/IV Feeding

Patients can be fed parenterally (i.e. intravenously) to bypass the usual process of eating and digestion. The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins. Parenteral/IV feeding 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.

The need for parenteral/IV feeding indicates a clinical complexity that prevents the patient from meeting his/her nutritional needs enterally and is more resource intensive than other

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[149]   Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Mallinson, T. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

[150]   Shang, J., Larson, E., Liu, J., & Stone, P. (2015). Infection in home health care: Results from national Outcome and Assessment Information Set data. American Journal of Infection Control 43(5): 454-459.

forms of nutrition, as it often involves monitoring of blood chemistries and maintenance of a central line. Therefore, assessing a patient's need for parenteral feeding is important for resource use and care planning. In addition to the risks associated with central and peripheral intravenous access, parenteral/IV feeding is associated with significant risks such as embolism and sepsis.

Relevance to HHAs

The OASIS-C2 currently assesses whether a patient receives parenteral nutrition at home. Analysis of 2013 OASIS data, 0.2 percent of patients in the home health setting were receiving total parenteral nutrition treatment.[151] Home parenteral nutrition is needed when patients do not have adequate or functional gastrointestinal tract to maintain fluids, electrolytes, and nutrition. Similar to enteral nutrition, patients receiving it rely on the intervention as a life-sustaining effort in and out of the hospital.[152] However, home parenteral nutrition is a complex method of feeding that has been associated with a host of short- and long-term complications.[153] Assessing receipt of parenteral nutrition would provide important information for resource use and care planning in the HH setting.

A nutritional assessment of older adults receiving Medicare home health services found that 12.0 percent of patients were malnourished and 51.0 percent were at risk for malnourishment.[154] Malnourished/ at-risk malnourished individuals are more likely to experience hospitalization, emergency room and home health aide utilization, and mortality.[155] A study by Corkins et al. found that discharges to home health care were twice as likely among malnourished hospitalized patients.[156] When a patient is unable to receive enteral nutrition, parenteral nutrition is a beneficial treatment of malnutrition in the HH setting.[157]

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Parenteral/IV Feeding

Section K	Swallowing/Nutritional Status	
K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days at SOC/ROC.		
		1. Performed during the first 3 days at SOC/ROC Check all that apply ↓
A. Parenteral/IV feeding		☐

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[151] RAND analysis 2013 OASIS data.
[152] Jeejeebhoy, K. N. (2001). Total parenteral nutrition: potion or poison?. The American Journal of Clinical Nutrition, 74(2), 160-163.
[153] Kumpf, V. J., & Tillman, E. M. (2012). Home parenteral nutrition: Safe transition from hospital to home. Nutrition in clinical practice, 27(6), 749-757.
[154] Yang, Y., Brown, C. J., Burgio, K. L., Kilgore, M. L., Ritchie, C. S., Roth, D. L., & West, D. S. (2011). Undernutrition at baseline and health services utilization and mortality over a 1-year period in older adults receiving medicare home health services. Journal of the American Medical Directors Association 12(4): 287-294.
[155] *Ibid*
[156] Corkins, M. R., Guenter, P., DiMaria-Ghalili, R. A., Jensen, G. L., Malone, A., Miller, S., … and the American Society for Parenteral and Enteral Nutrition. Malnutrition diagnoses in hospitalized patients: United States, 2010. Journal of Parenteral and Enteral Nutrition 38(2): 186-195.
[157] Jeejeebhoy, K. N. (2001). Total parenteral nutrition: potion or poison?. The American Journal of Clinical Nutrition, 74(2), 160-163.

Current use

Versions of the Parenteral/IV Feeding data element are currently collected in the OASIS-C2, IRF-PAI, LCDS, and the MDS 3.0. The OASIS-C2 data element assesses whether 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 (TPN) with a 3-day look-back period. The LCDS includes a checklist with a question asking whether TPN is part of the patient's treatment plan at admission. In the MDS, the items document whether the resident received Parenteral/IV Feeding in the past 7 days while not a resident of the assessing facility, and also if the resident has received Parenteral/IV Feeding in the past 7 days while a resident.

Evidence supporting use of Parenteral/IV Feeding

A similar data element, the Total Parenteral Nutrition, was tested in the PAC PRD and found to be feasible across PAC settings. Parental/IV feeding in the last 5 days was shown to have almost perfect reliability (0.946 to 0.951) in the national MDS 3.0 test in nursing homes.[158] Parental/IV in the last 7 days was shown to have fair (0.213) and almost perfect (0.83) reliabilities in studies of the MDS 2.0.[159]

3.4.13 Feeding Tube

The Feeding Tube data element refers to enteral nutrition, which is the delivery of a nutritionally complete diet 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. This data element assesses if the patient/resident received enteral nutrition during the assessment period.

Relevance to HHAs

This data element is currently collected in the OASIS-C2, with a question asking if the patient is receiving enteral nutrition at home. Analysis of 2013 OASIS data found that 1.4 percent of patients in the home health setting received enteral nutrition treatment.[160] While the proportion of patients who received enteral tube feeding is not high, patients receiving it rely on the intervention as a life-sustaining effort in and out of the hospital.[161] Home enteral nutrition is also expected to become more popular, due to increased awareness of therapeutic nutrition, developments in artificial nutrition, higher proportions of elderly people in the population, and a reduction in the number of hospital beds.[162,163] While inserting

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[158]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[159]   *Ibid.*

[160]   RAND analysis of 2013 OASIS data.

[161]   Majka, A. J., Wang, Z., Schmitz, K. R., Niesen, C. R., Larsen, R. A., Kinsey, G. C., ... & Murad, M. H. (2014). Care coordination to enhance management of long-term enteral tube feeding: a systematic review and meta-analysis. Journal of Parenteral and Enteral Nutrition, 38(1), 40-52.

[162]   Alivizatos, V., Gavala, V., Alexopoulos, P., Apostolopoulos, A., & Bajrucevic, S. (2012). Feeding tube-related complications and problems in patients receiving long-term home enteral nutrition. Indian Journal of Palliative Care, 18(1), 31.

[163]   Majka, A. J., Wang, Z., Schmitz, K. R., Niesen, C. R., Larsen, R. A., Kinsey, G. C., ... & Murad, M. H. (2014). Care coordination to enhance management of long-term enteral tube feeding: a systematic review and meta-analysis. Journal of Parenteral and Enteral Nutrition, 38(1), 40-52.

feeding tubes is usually related to minor morbidity, long-term use can contribute to various complications and impact quality of life.[164]

A nutritional assessment of older adults receiving Medicare home health services found that 12 percent of patients were malnourished and 51 percent were at risk for malnourishment.[165] Malnourished/ at-risk malnourished individuals are more likely to experience hospitalization, emergency room and home health aide utilization, and mortality.[166] A study by Corkins et al. found that discharges to home health care were twice as likely among malnourished hospitalized patients.[167] Enteral tube feeding is an effective method for providing nutrients to individuals across PAC settings, including in the HH setting.[168]

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Feeding Tube

Section K	Swallowing/Nutritional Status	
K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days at SOC/ROC.		
		1. Performed during the first 3 days at SOC/ROC Check all that apply ↓
B. **Feeding tube** – nasogastric or abdominal (e.g., PEG)		☐

Current use

A version of the Feeding Tube data element is currently used in three existing PAC assessments. The data element Enteral Nutrition is currently collected in the OASIS-C2, with a question asking if the patient is receiving enteral nutrition at home. In the MDS, the items document whether the resident used a Feeding tube in the past 7 days while not a resident of the assessing facility, and also if the resident has used a Feeding tube in the past 7 days while a resident. In the IRF-PAI, a Swallowing Status data element captures some information related to enteral nutrition through the response option "Tube/Parenteral Feeding."

Evidence supporting use of Feeding Tube

In the national MDS 3.0 test in nursing homes, the Feeding Tube data element, collected for the last 5 days, was shown to have almost perfect reliability (0.886). In studies of the MDS

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[164] Alivizatos, V., Gavala, V., Alexopoulos, P., Apostolopoulos, A., & Bajrucevic, S. (2012). Feeding tube-related complications and problems in patients receiving long-term home enteral nutrition. Indian Journal of Palliative Care, 18(1), 31.

[165] Yang, Y., Brown, C. J., Burgio, K. L., Kilgore, M. L., Ritchie, C. S., Roth, D. L., & West, D. S. (2011). Undernutrition at baseline and health services utilization and mortality over a 1-year period in older adults receiving medicare home health services. Journal of the American Medical Directors Association 12(4): 287-294.

[166] *Ibid*

[167] Corkins, M. R., Guenter, P., DiMaria-Ghalili, R. A., Jensen, G. L., Malone, A., Miller, S., … and the American Society for Parenteral and Enteral Nutrition. Malnutrition diagnoses in hospitalized patients: United States, 2010. Journal of Parenteral and Enteral Nutrition 38(2): 186-195.

[168] Ojo, O. (2015). The challenges of home enteral tube feeding: a global perspective. Nutrients, 7(4), 2524-2538.

2.0, the Feeding Tube data element, collected in the last 7 days, was also shown to have almost perfect reliability (0.98).[169]

3.4.14 Mechanically Altered Diet

A mechanically altered diet is one that is specifically prepared to alter the texture or consistency of food to facilitate oral intake. Examples include soft solids, puréed foods, ground meat, and thickened liquids. A mechanically altered diet should not automatically be considered a therapeutic diet.

The provision of a mechanically altered diet is resource intensive, as it signifies difficulty swallowing/eating safety (dysphagia). Often, nurses are required to slowly feed patients meals consisting of a mechanically altered diet rather than having them eat independently.

Relevance to HHAs

The OASIS-C2 currently collects data on a patient's ability to feed him- or herself independently, but requires a liquid, pureed, or ground meat diet. However, the OASIS-C2 does not have a more general item on whether the patient receives a mechanically altered diet. There is some evidence that dysphagia, which is difficulty or discomfort in swallowing, may affect many HH patients. The prevalence of dysphagia is high among dementia and stroke patients.[170] Data from the 2013-2014 National Study of Long-Term Care Providers showed that 31.4 percent of home health patients had a diagnosis of Alzheimer's disease or other dementias.[171] Further, a large study of stroke patients aged 18 years and older found that 11.5 percent were discharged to the home health setting.[172] This speaks to the importance of assessing whether HH patients receive a mechanically altered diet.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Mechanically Altered Diet

Section K	Swallowing/Nutritional Status	
K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days at SOC/ROC.		
		1. **Performed during the first 3 days at SOC/ROC** **Check all that apply** ↓
C. **Mechanically altered diet –** require change in texture of food or liquids (e.g., pureed foods, thickened liquids)		☐

[169] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[170] Sura, L., Madhavan, A., Carnaby, G., & Crary, M. A. (2012). Dysphagia in the elderly: Management and nutritional considerations. Clinical Interventions in Aging, 7, 287-298.

[171] Harris-Kojetin, L., Sengupta, M., Park-Lee, E., et al. (2016). Long-term care providers and services users in the United States: Data from the National Study of Long-Term Care Providers, 2013–2014. National Center for Health Statistics. Vital and Health Statistics, 3(38).

[172] Bettger, J. P., McCoy, L., Smith, E. E., Fonarow, G. C., Schwamm, L. H. & Peterson, E. D. (2015) Contemporary trends and predictors of postacute service use and routine discharge home after stroke. Journal of the American Heart Association 4(2): e001038.

Current use

The Mechanically Altered Diet data element is currently collected in the MDS 3.0. The items document whether the resident received a Mechanically Altered Diet in the past 7 days while not a resident of the assessing facility, and also if the resident has received a Mechanically Altered Diet in the past 7 days while a resident.

Evidence supporting use of Mechanically Altered Diet

In the national MDS 3.0 test and studies of MDS 2.0 in nursing homes, the Mechanically Altered Diet data element was shown to have almost perfect reliability (0.82 to 0.960).[173]

3.4.15 Therapeutic Diet

A therapeutic diet is a diet intervention ordered by a health care practitioner as part of the treatment for a disease or clinical condition manifesting an altered nutritional status, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium).

The Therapeutic Diet data element is important to collect in the HH setting in order to distinguish therapeutic diet from various other nutritional approaches. It is less resource intensive from the bedside nursing perspective but does signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC settings of whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

Relevance to HHAs

Therapeutic diet is not currently assessed in OASIS-C2. However, the standardized assessment of therapeutic diets is relevant to patients in HH settings due to an aging population and high prevalence of chronic diseases that will result in increased need for this type of diet. In particular, as the population ages, and the HH population grows, greater demand for therapeutic diets can be expected.[174] Physiological changes of aging can affect food intake, in addition to chronic disease conditions.[175] Many disease specific-conditions could necessitate therapeutic diet. These include diabetes mellitus, cardiovascular disease, chronic kidney disease, and obesity, among others.[176] According to data from the National Home and Hospice Care Survey (NHHCS), 32 percent of home health patients aged 65 and older had diabetes mellitus and 39 percent had heart disease.[177] Similarly, data from the 2013-2014 National Study of Long-Term Care Providers showed that 45.2 percent of home health patients had a diagnosis of diabetes.[178]

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[173] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[174] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.

[175] Dorner, B. (2010). Position of the American Dietetic Association: individualized nutrition approaches for older adults in health care communities. Journal of the American Dietetic Association, 110(10), 1549-1553.

[176] *Ibid*

[177] Jones, A. L., Harris-Kojetin, L., & Valverde, R. (2012). Characteristics and use of home health care by men and women aged 65 and over. National health statistics reports; no. 52. Hyattsville, MD: National Center for Health Statistics.

[178] Harris-Kojetin, L., Sengupta, M., Park-Lee, E., et al. (2016). Long-term care providers and services users in the United States: Data from the National Study of Long-Term Care Providers, 2013–2014. National Center for Health Statistics. Vital and Health Statistics, 3(38).

Because management of these common conditions typically necessitates some type of therapeutic diet, receipt of a therapeutic diet is important to assess in HH settings.

Proposed Data Element for the Assessment of Special Services, Treatments, and Interventions: Therapeutic Diet

Section K	Swallowing/Nutritional Status	
K0520. Nutritional Approaches Check all of the following nutritional approaches that were performed during the first 3 days at SOC/ROC.		
		1. Performed during the first 3 days at SOC/ROC Check all that apply ↓
D. **Therapeutic diet** - (e.g., low salt, diabetic, low cholesterol)		☐

Current use

This Therapeutic Diet data element is currently collected in the MDS 3.0. The items document whether the resident received a Therapeutic Diet in the past 7 days while not a resident of the assessing facility, and also if the resident has received a Therapeutic Diet in the past 7 days while a resident.

Evidence supporting use of Therapeutic Diet

In the national MDS 3.0 test and studies of MDS 2.0 in nursing homes, the Therapeutic Diet data element was shown to have substantial to almost perfect reliability (0.797 to 0.931).[179]

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[179] Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

3.5 Medical Condition and Comorbidity Data

Standardized data elements to satisfy the IMPACT Act category of Medical conditions and comorbidities are already submitted for calculation of the measure the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). This measure was finalized for adoption into the IRF QRP in the FY 2012 IRF PPS final rule (76 FR 47876 through 47878), adopted as a non-risk-adjusted application of the NQF-endorsed version in the CY 2013 OPPS/ASC Final Rule (77 FR 68500 through 68507), adopted as the risk adjusted, NQF-endorsed version in FY 2014 IRF PPS Final Rule (78 FR 47911 through 47912), and adopted in the FY 2016 IRF PPS final rule (80 FR 47089 through 47096) to fulfill IMPACT Act requirements. Further, an application of the pressure ulcer measure was adopted for use in the LTCH QRP in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for the FY 2014 payment determination and subsequent years, and the NQF-endorsed version of the measure was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863) for the FY 2015 payment determination and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736), that same measure was readopted for use as a cross-setting measure to address the IMPACT Act domain of skin integrity and changes in skin integrity. Finally, in the FY 2016 SNF PPS Final Rule (80 FR 46433 through 46440), an NQF-endorsed pressure ulcer measure was adopted for use in the SNF QRP for use as a cross-setting measure to address the IMPACT Act of 2014 domain of skin integrity and changes in skin integrity. This quality measure has also been adopted for the HH QRP in the CY 2016 HH PPS final rule. The standardized data elements used to calculate and risk adjust this measure fall under the IMPACT Act category "medical conditions and comorbidities," listed in section 1899B(b)(1)(B) of the Act, which includes pressure ulcers and diabetes. The data elements proposed for use in the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, are also related to the category of medical conditions and comorbidities, are described in Section2 of this document.

3.6 Impairments

Hearing and vision impairments are common conditions that, if unaddressed, affect patients' and residents' activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions such as cognition. Hearing impairments may cause difficulty in communication of important information concerning the patient's or resident's condition, preferences, and care transitions; vision impairments have been associated with increased risk of falls. Both types of impairment can also interfere with comprehension of and adherence to discharge plans. Onset of hearing and vision impairments can be gradual, so accurate screening tools and follow-up evaluations are essential to determining which patients and residents need hearing- or vision-specific medical attention or assistive devices, and to ensuring that person-directed care plans are developed to accommodate a patient or resident's needs during post-acute care and at discharge.

Assessments pertaining to sensory status aids PAC providers in better understanding the needs of their patients and residents by establishing a diagnosis of hearing or vision impairment, elucidating the patient or resident's ability and willingness to participate in treatments or use assistive devices during their stay, and identifying appropriate ongoing therapy and support needs at the time of discharge. The standardized assessment of vision impairment among PAC patients and residents supports clinical decision-making, early clinical intervention, person-centered care, and improved care continuity and coordination. The use of valid and reliable standardized assessments can aid in the communication of information within and across providers, further enabling the transfer of accurate health information.

3.6.1 Standardized Data Elements to Assess Hearing and Vision Impairments

CMS has identified two data elements for cross-setting standardized assessment of hearing and vision impairment. The proposed data elements are:

1. Hearing (Ability to Hear)
2. Vision (Ability to See in Adequate Light)
3. Hearing

Hearing impairment is one of the most common complaints in adults over the age of 60 and is a major contributor to difficulties in speech comprehension.[180] About 51 percent of nursing facility patients and residents are estimated to have moderate to severe hearing impairment.[181] Data from the PAC PRD suggest that severe hearing impairment affects 1 to 2 percent of Medicare FFS beneficiaries in the four types of PAC.[182,183]

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[180] Peelle, J. E., Troiani, V., Grossman, M., & Wingfield, A. (2011). Hearing loss in older adults affects neural systems supporting speech comprehension. J of Neuroscience 31(35): 12638-12643.

[181] Garahan, M. B., Waller, J. A., Houghton, M., Tisdale, W. A., & Runge, C. F. (1992). Hearing loss prevalence and management in nursing home residents. J Am Geriatrics Society 40(2): 130-134.

[182] Hearing impairments were classified into categories from mildly impaired to severely impaired. The percentages reported here refer to severe impairment of hearing, defined as "Absence of useful hearing" (Gage et al., 2012).

[183] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at

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Hearing impairment among HH patients[184] can adversely affect their ability to follow the instructions of HH health care providers. This may be due directly to the hearing loss (i.e., not being able to hear the instructions) and/or due indirectly to cognitive impairments associated with hearing loss (i.e., not being able to understand or remember the instructions). Among HHAs participating in the PAC PRD, the Ability to Hear item demonstrated moderate inter-rater reliability (weighted kappa = 0.73).[185] In a sample of community-dwelling older adults, hearing loss was associated with lower scores on measures of mental status, memory, and executive functioning.[186] In a nationally representative sample, hearing loss was independently associated with past-year hospitalization and having more hospitalizations.[187] This suggests that severe hearing impairment may increase the likelihood of rehospitalization among HH patients. Possible mechanisms include the effects of hearing loss on social isolation, health-related oral literacy, and cognitive decline. In addition, severe hearing impairment can adversely affect HH patients' ability to function safely within their home environment (e.g., respond to warnings, or hear doorbells and alarms). It has also been associated with increased likelihood of falls.[188,189] Therefore, assessing HH patients' ability to hear—and treatment of hearing loss symptoms—can help improve quality of life and care planning.

Proposed Data Element for the Assessment of Impairments: HEARING

Section B	Hearing, Speech, and Vision
B0200. Hearing	
Enter Code	**Ability to hear** (with hearing aid or hearing appliance if normally used)
	0. **Adequate**: No difficulty in normal conversation, social interaction, listening to TV
	1. **Minimal difficulty**: Difficulty in some environments (e.g., when person speaks softly or setting is noisy)
	2. **Moderate difficulty**: Speaker has to increase volume and speak distinctly
	3. **Highly impaired**: Absence of useful hearing

Current use

The Hearing data element (Ability to Hear) is currently collected in the MDS 3.0.

Evidence supporting use of Hearing

The Hearing data element tested in the PAC PRD includes one question regarding hearing ability, which showed high reliability across PAC settings (unweighted kappa = 0.78). The MDS 3.0 version of the Hearing data element also had almost perfect agreement in the MDS

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[184] Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Manning, J. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

[185] Smith, L., Gage, B., Deutsch, A., Hand, L., Etlinger, A., Ross, J., … Barch, D. (2012). Continuity assessment record and evaluation (CARE) item set: Additional interrater provider-type specific reliability analyses. Research Triangle Park, NC: RTI International.

[186] Lin, F. R., Ferrucci, L., Metter, E. J., An, Y., Zonderman, A. B., & Resnick, S. M. (2011). Hearing loss and cognition in the Baltimore Longitudinal Study of Aging. Neuropsychology 25(6): 763-770.

[187] Genther, D. J., Frick, K. D., Chen, D., Betz, J., & Lin, F. R. (2013). Association of hearing loss with hospitalization and burden of disease in older adults. JAMA 309(22): 2322-2324.

[188] Lin, F. R., & Ferrucci, L. (2012). Hearing loss and falls among older adults in the United States. Archives of Internal Medicine 172(4): 369-371.

[189] Kamil, R. J., Betz, J., Power, B. B., Pratt, S., Kritchevsky, S., Ayonayon, H. N., … Health ABC Study (2016). Associations of hearing impairment with incident frailty and falls in older adults. Journal of Aging and Health 28(4): 644-660.

3.0 national test in nursing homes (weighted kappa = 0.938 and 0.894).[190] In MDS 2.0 testing, the Hearing data element showed moderate to good reliability (0.575 – 0.88).[191]

3.6.2   Vision

Visual impairment can be caused not only by age-related diseases (e.g., age-related macular degeneration [AMD], cataract, glaucoma, and diabetic retinopathy) but also due to nearsightedness, farsightedness, loss of near vision with age, and/or untreated disease.[192] In addition to conditions affecting the eye itself, visual deficits can also be caused by other conditions such as stroke and traumatic brain injury. The PAC PRD study found that between 1 and 3 percent of Medicare FFS beneficiaries among the four types of PAC providers had the most extreme category of visual impairment assessed, having "No vision or object identification questionable." [193]

Relevance to HHAs

Severe vision impairment can adversely affect HH patients' mobility and their ability to function safely within their home environment (e.g., ability to see obstacles in their path), including risk of falls.[194] According to PAC PRD data, 2.1 percent of HH patients have severe vision impairment.[195] A study by Jaffee et al. (2016) of 1,900 adult medicine inpatients at an urban hospital found that insufficient vision was associated with post-discharge falls among participants aged 65 years or older (adjusted odds ratio [AOR] 3.38, 95% confidence interval [CI] 1.42–8.05), but not among participants younger than 65 years (AOR 1.44, 95% CI 0.89–2.32).[196] Severe vision impairment can also adversely impact many aspects of HH patients' self-care (e.g., reading medication labels; performing certain ADLs/IADLs, mobility). For example, patients with visual impairment have more difficulty reading medication labels and instructions and likely need more assistance managing their medications. Assessing the ability to see among HH patients is important to support care management and planning.

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[190]   Saliba, D., & Buchanan, J. (2008). Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[191]   *Ibid.*

[192]   Cimarolli, V. R., Boerner, K., Brennan-Ing, M., Reinhardt, J. P., & Horowitz, A. (2012). Challenges faced by older adults with vision loss: a qualitative study with implications for rehabilitation. Clin Rehab 26(8): 748-757.

[193]   Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

[194]   Jaffee, E. G., Arora, V. M., Matthiesen, M. I., Hariprasad, S. M., Meltzer, D. O., & Press, V. G. (2016). Postdischarge falls and readmissions: Associations with insufficient vision and low health literacy among hospitalized seniors. Journal of Health Communication 21 (Suppl 2): 135-140.

[195]   Gage B., Ingber, M. J., Morley M., Smith L., Deutsch, A., Kline, T., … & Manning, J. (2012). Post-acute care payment reform demonstration: Final report (Volume 4 of 4). Research Triangle Park, NC: RTI International.

[196]   Jaffee, E. G., Arora, V. M., Matthiesen, M. I., Hariprasad, S. M., Meltzer, D. O., & Press, V. G. (2016). Postdischarge falls and readmissions: Associations with insufficient vision and low health literacy among hospitalized seniors. Journal of Health Communication 21 (Suppl 2): 135-140.

Proposed Data Element for the Assessment of Impairments: VISION

B1000. Vision	
Enter Code ▢	**Ability to see in adequate light (**with glasses or other visual appliances)
	0. **Adequate:** sees fine detail, such as regular print in newspapers/books
	1. **Impaired:** sees large print, but not regular print in newspapers/books
	2. **Moderately impaired:** limited vision; not able to see newspaper headlines but can identify objects
	3. **Highly impaired:** object identification in question, but eyes appear to follow objects
	4. **Severely impaired:** no vision or sees only light, colors or shapes; eyes do not appear to follow objects

Current use

The Vision data element (Ability to See in Adequate Light) is currently collected in the MDS 3.0. The data element contains five response options ranging from 0 (adequate) to 4 (severely impaired).

Evidence supporting use of Vision

The MDS 3.0 Vision data element has been shown to perform reliably in screening for vision impairment (weighted kappa = 0.917) in the national MDS 3.0 test in nursing homes.[197] In studies of MDS 2.0, the Vision data element was shown to have moderate to almost perfect reliability ranging from 0.581 to 0.85. The Vision data element is also linked to performance with readily available materials (i.e., newspaper). Finally, the Vision 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).[198]

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[197] Saliba, D., & Buchanan, J. Development and validation of a revised nursing home assessment tool: MDS 3.0. Santa Monica, CA: Rand Corporation. 2008. Available at http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.

[198] Gage, B., Morley, M., Smith, L., Ingber, M. J., Deutsch, A., Kline, T., ... & Kelleher, C. (2012). Post-acute care payment reform demonstration: Final report. Research Triangle Park, NC: RTI International. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/PAC_Payment_Reform_Demo_Final.html.

APPENDIX 1:
FUNCTION ITEMS INCLUDED IN THE PROCESS FUNCTION QUALITY MEASURE FOR HH, IRF, SNF, AND LTCH QUALITY REPORTING PROGRAMS

Table 1 shows the items included in the function quality measures that are process measures. For the HH, IRF, SNF and LTCH settings, the cross-setting measure, an *Application* of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed), is listed.

Table 1
Function Items Included in the Process Function Quality Measures for HH,IRF, SNF, and LTCH QRPs

Item Identifier	Item Name	HH QRP	IRF QRP	SNF QRP	LTCH QRP	
		Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)*
SELF-CARE GG0130						
A	Eating	✓	✓	✓	✓	✓
B	Oral hygiene	✓	✓	✓	✓	✓
C	Toileting hygiene	✓	✓	✓	✓	✓
D	Wash upper body	—	—	—	—	✓
E	Shower/bathe self	—	—	—	—	—
F	Upper body dressing	—	—	—	—	—
G	Lower body dressing	—	—	—	—	—

(continued)

Table 1 (continued)
Function Items Included in the Process Function Quality Measures for HH, IRF, SNF, and LTCH QRPs

Item Identifier	Item Name	HH QRP	IRF QRP	SNF QRP	LTCH QRP	
		Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	Percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)*
H	Putting on/ taking off footwear	—	—	—	—	—
MOBILITY GG0170						
A	Roll left and right	—	—	—	—	✓
B	Sit to lying	✓	✓	✓	✓	✓
C	Lying to sitting on side of bed	✓	✓	✓	✓	✓
D	Sit to stand	✓	✓	✓	✓	✓
E	Chair/bed-to-chair transfer	✓	✓	✓	✓	✓
F	Toilet transfer	✓	✓	✓	✓	✓
G	Car transfer	—	—	—	—	—
H	*Does the patient walk?*	✓	✓	✓	✓	✓
I	Walk 10 feet	—	—	—	—	✓
J	Walk 50 feet with two turns	✓	✓	✓	✓	✓
K	Walk 150 feet	✓	✓	✓	✓	✓
L	Walking 10 feet on uneven surface	—	—	—	—	—

(continued)

Table 1 (continued)
Function Items Included in the Process Function Quality Measures for HH, IRF, SNF, and LTCH QRPs

Item Identifier	Item Name	HH QRP Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed	IRF QRP Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed	SNF QRP Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	LTCH QRP Application of percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)	LTCH QRP Percent of long-term care hospital patients with an admission and discharge functional assessment and a care plan that addresses function (NQF #2631; endorsed)*
M	1 step (curb)	—	—	—	—	—
N	4 steps	—	—	—	—	—
O	12 steps	—	—	—	—	—
P	Picking up object	—	—	—	—	—
Q	*Does patient use wheelchair/ scooter?*	✓	✓	✓	✓	✓
R	Wheel 50 feet with two turns	✓	✓	✓	✓	✓
RR	Type of wheelchair/ scooter	✓	✓	✓	✓	✓
S	Wheel 150 feet	✓	✓	✓	✓	✓
SS	Type of wheelchair/ scooter	✓	✓	✓	✓	✓

NOTES:

✓ = Item is included in the quality measure.

— = Item is not included in the quality measure.

* This process measure was adopted for the LTCH QRP through the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).

APPENDIX 2:
SUPPLEMENTAL INFORMATION TO THE ASSESSMENT ITEMS USED TO CALCULATE THE ADOPTED HH FUNCTION QUALITY MEASURES

Standardized functional assessment items are included in the *Section GG* of the Quality Indicator section of the Outcome and Assessment Information Set (OASIS) proposed for implementation starting January 1, 2019. These standardized items are used to collect data to calculate the adopted quality measures intended to meet the IMPACT Act requirement for measure domain: functional status, cognitive function, and changes in function and cognitive function. The quality measure Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) rely on the collection of data using these standardized items derived from the Continuity Assessment Record and Evaluation (CARE) Item Set. The standardized items used to calculate the adopted quality measures will enable CMS to assess functional change in an IRF care setting.

The standardized items included within the OASIS do not duplicate existing items on the OASIS currently in use for data collection on functional assessment. While many of the standardized items have labels that are similar to existing items on the OASIS, there are several key differences between the two sets that may result in variation in the patient assessment results. Key differences include: (1) the data collection and associated data collection instructions; (2) the rating scales used to score a patient's level of independence; and (3) the item definitions.

Supplemental information discussing the standardized items used to calculate the adopted function quality measures is listed below.

1. Data Collection and Data Collection Instructions for the Standardized Function Items:

   - The breath of the standardized items used to assess function reflects the intent to measure function with greater precision for low-functioning patients as well as high-functioning patients.

   - For the standardized items, the assessment period is three (3) calendar days. When patient functioning varies, the patient's *usual* performance (rather than *most dependent*) will need to be reported on the standardized items included in the OASIS. Standardized functional assessment items are also included in Section GG of the MDS 3.0, IRF PAI, and the LTCH CARE Data Set.

   - The standardized function items reflect best practice clinical assessment of daily activities that occur as part of the start of care (SOC) /resumption of care (ROC) and/or discharge assessment workflow.

     - Activities assessed at admission occur in order to set discharge goals and activities are assessed at discharge in order to optimize a safe transition to home or the next care setting.

     - Examples include: "Sit to stand" and "Roll left and right" are bed mobility activities that are often assessed at SOC/ROC in most HHAs. "Car transfers," "Walking 10 feet on an uneven surface" and "Picking up an object from a standing position" are activities that are often assessed at discharge.

2. Rating Scales Used to Assess Functional Activities:

- The standardized items include 7 self-care activities and 17 mobility activities that are rated on a 6-level rating scale ranging from "6" meaning "Independent" to "1" that refers to dependent (Figure 1).

- A higher score on the rating scale means greater independence.

- Three special codes (07, 09, 88) are available to report that a patient did not attempt an activity and to identify the rationale for why a patient did not attempt an activity (e.g., safety concerns, patient refused), which is important information when examining patient outcomes.

- Supervision and touching assistance with *no lifting* assistance is coded at a level 4 on the rating scale. Supervision assistance is coded at a level of 4 to reflect the supervision that is often needed during the entire time of completing an activity.

- The level titled "Dependent" is defined to include only patients who are completely dependent. That is, if a patient is coded "Dependent," then that patient does not assist with completing an activity.

Figure 1.
Rating Scale for Standardized Functional Assessment Items

CODING:
Safety and **Quality of Performance** - If helper assistance is required because patient's performance is unsafe or of poor quality, score according to amount of assistance provided.

Activities may be completed with or without assistive devices.

06. **Independent** - Patient completes the activity by him/herself with no assistance from a helper.
05. **Setup or clean-up assistance** - Helper SETS UP or CLEANS UP; patient completes activity. Helper assists only prior to or following the activity.
04. **Supervision or touching assistance** - Helper provides VERBAL CUES or TOUCHING/STEADYING assistance as patient completes activity. Assistance may be provided throughout the activity or intermittently.
03. **Partial/moderate assistance** - Helper does LESS THAN HALF the effort. Helper lifts, holds or supports trunk or limbs, but provides less than half the effort.
02. **Substantial/maximal assistance** - Helper does MORE THAN HALF the effort. Helper lifts or holds trunk or limbs and provides more than half the effort.
01. **Dependent** - Helper does ALL of the effort. Patient does none of the effort to complete the activity. Or, the assistance of 2 or more helpers is required for the patient to complete the activity.

If activity was not attempted, code the reason:
07. **Patient refused**
09. **Not applicable**
88. Not attempted due to **medical condition or safety concerns**

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3. Definitions for the Standardized Items:

- The standardized items include assessment and scoring methods to allow for variation. For example, a score is reported for four walking items with different distances (10, 50 and 150 feet) and different types of surfaces (even and uneven surfaces) and includes the capacity for coding two wheelchair items, if applicable.

- The standardized items have specified definitions. For example, the standardized function item for assessing "Eating" does not include tube feeding administration. If an individual is solely receiving nutrition by tube feeding and the staff administers his tube feedings and he does not eat by mouth, the standardized "Eating" item would be coded as the "Activity was not attempted due to medical condition or safety concerns" (code = 88).

- For personal hygiene, one standardized item focuses on a single activity, "Oral hygiene," which is not intermixed with other personal hygiene activities. The focus of this item enables the ability to identify activity-specific limitations, areas requiring clinical focus, and set activity-specific goals.

APPENDIX 3:
DATA ELEMENTS USED IN CALCULATION OF CHANGES IN SKIN INTEGRITY POST-ACUTE CARE: PRESSURE ULCER/INJURY QM

SNF		IRF		LTCH		HH	
M0300/M1311 – Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage							
B. Stage 2: Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.		**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.		**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.		**A1. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister.	
Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M1311B1, Stage 3
Enter number ☐	2: Number of these Stage 2 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission/ entry or reentry.	Enter number ☐	2: Number of these Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these Stage 2 pressure ulcers that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.
C. Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.		**C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.		**C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.		**B1. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.	
Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4.	Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4.	Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4.	Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M1311C1, Stage 4.
Enter number ☐	2: Number of these Stage 3 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry	Enter number ☐	2: Number of these Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of these Stage 3 pressure ulcers that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.

SNF		IRF		LTCH		HH	
D. Stage 4: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.		**D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.		**D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling		**C1. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.	
Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device.	Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device.	Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device.	Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M1311D1, Unstageable non-removable dressing/device.
Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.
E. Unstageable – Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.		**E. Unstageable** – Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.		**E. Unstageable** – Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.		**D1. Unstageable** – Non-removable dressing/device: Known but not stageable due to non-removable dressing/device.	
Enter number ☐	1: Number of unstageable pressure ulcers/injuries non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar.	Enter number ☐	1: Number of unstageable pressure ulcers/injuries non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar.	Enter number ☐	1: Number of unstageable pressure ulcers/injuries non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar.	Enter number ☐	1: Number of unstageable pressure ulcers/injuries non-removable dressing/device. If 0 skip to M1311E1, Unstageable – Slough and/or eschar.
Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/injuries that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.

SNF		IRF		LTCH		HH	
F. Unstageable – slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.		**F. Unstageable –** slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.		**F. Unstageable –** slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.		**E1. Unstageable –** slough and/or eschar: Known but not stageable due to coverage of wound bed by slough and/or eschar.	
Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury.	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury.	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury.	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M1311F1, Unstageable – Deep tissue injury.
Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.
G. Unstageable – Deep tissue injury:		**G. Unstageable –** Deep tissue injury		**G. Unstageable –** Deep tissue injury:		**F1. Unstageable –** Deep tissue injury:	
Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1030, Number of Venous and Arterial Ulcers.	Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention.	Enter number ☐	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention.	Enter number ☐	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1322
Enter number ☐	2. Number of <u>these</u> unstageable pressure injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.	Enter number ☐	2. Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure injuries that were present at most recent SOC/ROC. Enter how many were noted at the time of most recent SOC/ROC.

RISK ADJUSTMENT COVARIATES USED IN CALCULATION OF CHANGES IN SKIN INTEGRITY POST-ACUTE CARE: PRESSURE ULCER/INJURY QM

SNF Risk Adjustment Covariates	IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates	HH Risk Adjustment Covariates
Functional Mobility Admission Performance			
GG0170C. Mobility: Lying to Sitting on Side of Bed: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Resident refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed:** The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed**: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed**: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns

SNF Risk Adjustment Covariates	IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates	HH Risk Adjustment Covariates
Bowel Continence			
H0400. Bowel Continence 0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated	**H0400. Bowel Continence** 0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated	**H0400. Bowel Continence** 0. Always continent 1. Occasionally incontinent (one episode of bowel incontinence) 2 Frequently incontinent (2 or more episodes of bowel incontinence, but at least one continent bowel movement) 3 Always incontinent (no episodes of continent bowel movements) 4 Not rated, patient had an ostomy or did not have a bowel movement for the entire 3 days	**M1620. Bowel Incontinence** 0. Very rarely or never has bowel incontinence 1. Less than once weekly 2. One to three times weekly 3. Four to six times weekly 4. On a daily basis 5. More often than once daily NA. Patient has ostomy for bowel elimination

(continued)

SNF Risk Adjustment Covariates	IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates	HH Risk Adjustment Covariates
Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) or Diabetes			
I0900. Peripheral Vascular Disease (PVD) /Peripheral Arterial Disease (PAD) 0. Did not have PVD or PAD in the last 7 days 1. Had PVD or PAD in the last 7 days **I2900 Diabetes Mellitus (DM)** 0. Did not have DM in the last 7 days 1. Had DM in the last 7 days	**I0900. Peripheral Vascular Disease (PVD) /Peripheral Arterial Disease (PAD)** 0. Does not have PVD or PAD 1. Have PVD or PAD **I2900 Diabetes Mellitus (DM)** 0. Does not have DM 1. Has DM	**I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)** 0. Does not have PVD or PAD 1. Have PVD or PAD **I2900. Diabetes Mellitus (DM)** 0. Does not have DM 1. Has DM	**I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)** 2. Does not have PVD or PAD 3. Have PVD or PAD **I2900. Diabetes Mellitus (DM)** 1. Does not have DM 2. Has DM
Height and Weight (Low Body Mass Index)			
K0200A (Height); and K0200B (Weight).	**25A (Height); and 26A (Weight).**	**K0200A (Height); and K0200B (Weight).**	**(M1060) Height and Weight** a. Height (in inches). Record most recent height measure since the most recent SOC/ROC b. Weight (in pounds). Base weight on most recent measure in last 30 days; measure weight consistently, according to standard agency practice

APPENDIX 5:
PRESSURE ULCER QUALITY MEASURE ITEM STANDARDIZATION: DATA ELEMENTS COLLECTED FOR CALCULATION OF QUALITY MEASURES USED IN HH, SNF, LTCH, AND IRF QUALITY REPORTING PROGRAMS

		SNF, LTCH, IRF and HH PAC Settings: Items Collected at Discharge			
Item	**Item Description**	**Proposed MDS (effective 10/1/2018)**	**Proposed LTCH CARE Data Set (effective 4/1/2018)**	**Proposed IRF-PAI (effective 10/1/2018)**	**Proposed OASIS (effective 01/01/2019)**
M0300/ M1311	**Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage**				
A/(M1322)	Number of Stage 1 pressure ulcers	X	X	X	X
B1/A1	Number of Stage 2 pressure ulcers	X	X	X	X
B2/A2	Number of these Stage 2 pressure ulcers that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X
C1/B1	Number of Stage 3 pressure ulcers	X	X	X	X
C2/B2	Number of these Stage 3 pressure ulcers that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X
D1/C1	Number of Stage 4 pressure ulcers	X	X	X	X
D2/C2	Number of these Stage 4 pressure ulcers that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X
E1/D1	Number of unstageable pressure ulcers/injuries due to non-removable dressing/device	X	X	X	X
E2/D2	Number of these unstageable pressure ulcers/injuries that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X
F1/E1	Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar	X	X	X	X
F2/E2	Number of these unstageable pressure ulcers that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X
G1/F1	Number of unstageable pressure injuries presenting as deep tissue injury	X	X	X	X
G2/F2	Number of these unstageable pressure injuries that were present upon admission/at the time of most recent SOC/ROC	X	X	X	X

X = Item is present