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Proposed Specifications for SNF QRP Quality Measures and Standardized Data Elements

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DATA ELEMENTS

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Table of Contents

Chapter 1 Introduction	1
Chapter 2 IMPACT Act Measures Beginning with the FY 2020 SNF QRP	3
Section 1: Cross-Setting Measures Development Work: An Introduction	3
Section 2: Cross-Setting Pressure Ulcer Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	4
Measure Description	4
Purpose/Rationale for the Quality Measure	4
Denominator	8
Denominator Exclusions	8
Numerator	9
Measure Time Window.....	10
Items Included in the Quality Measure	10
Risk Adjustment Covariates.....	13
Quality Measure Calculation Algorithm.....	15
Section 3: An Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).....	17
Measure Description	17
Purpose/Rationale for the Quality Measure	17
Denominator	19
Numerator	20
Items Included in the Quality Measure	20
Risk Adjustment.....	21
Quality Measure Calculation Algorithm.....	24
Section 4: An Application of the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).....	26
Measure Description	26
Purpose/Rationale for the Quality Measure	26
Denominator	26
Numerator	27
Items Included in the Quality Measure	27
Risk Adjustment.....	28
Quality Measure Calculation Algorithm.....	32
Section 5: An Application of the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).....	33
Measure Description	33

Purpose/Rationale for the Quality Measure	33
Denominator	33
Numerator	34
Items Included in the Quality Measure	34
Risk Adjustment.....	35
Quality Measure Calculation Algorithm.....	38
Section 6: An Application of the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).....	39
Measure Description	39
Purpose/Rationale for the Quality Measure	39
Denominator	39
Numerator	40
Items Included in the Quality Measure	40
Risk Adjustment.....	41
Quality Measure Calculation Algorithm.....	45
Section 7: Measure updates for Potentially Preventable 30-Day Post-Discharge Measure for SNF QRP	46
Section 8: Measure Update for Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)	47
Chapter 3 Standardized Data Elements.....	49
Section 1: Standardized Patient Assessment Data Element Work: An Introduction	49
Section 2: Functional Status.....	50
Section 3: Cognitive Function	51
Standardized Data Elements to Assess Cognitive Impairment	51
Brief Interview for Mental Status (BIMS).....	52
Confusion Assessment Method (CAM©).....	54
Behavioral Signs and Symptoms	55
Mental Status (Depressed Mood).....	57
Standardized Data Elements to Assess Depressed Mood	57
Patient Health Questionnaire-2 (PHQ-2)	58
Section 4: Special Services, Treatments, and Interventions (Including Nutritional Approaches)	61
Standardized Data Elements to Assess for Special Services, Treatments, and Interventions.....	61
Chemotherapy (IV, Oral, Other)	61
Radiation	63
Oxygen Therapy (Continuous, Intermittent).....	64
Suctioning (Scheduled, As Needed)	65
Tracheostomy Care	67

Invasive Mechanical Ventilation	68
Non-invasive Mechanical Ventilation (Continuous Positive Airway Pressure [CPAP], Bilevel Positive Airway Pressure [BiPAP])	70
IV Medications.....	71
Transfusions.....	73
Dialysis (Hemodialysis, Peritoneal dialysis)	74
IV Access	75
Parenteral/IV Feeding	76
Feeding Tube	78
Mechanically Altered Diet.....	79
Therapeutic Diet.....	80
Section 5: Medical Conditions and Co-Morbidities.....	82
Section 6: Impairments	83
Standardized Data Elements to Assess Hearing and Vision Impairments	83
Hearing.....	83
Vision.....	85

Appendices

1	Data Elements Used in Calculation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	87
2	Pressure Ulcer Quality Measure Item Standardization: Data Elements Collected for Calculation of Quality Measures used in SNF, LTCH, and IRF Quality Reporting Programs.....	91
3	Reliability and Validity of Items used to Calculate Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	93

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Chapter 1

Introduction

In this document, we present specifications for the standardized patient assessment data elements and the following five (5) measures proposed for adoption for the SNF QRP through the FY 2018 SNF PPS proposed rule:

1. Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
2. Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633)
3. Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)
4. Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635)
5. Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636)

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Chapter 2

IMPACT Act Measures Beginning with the FY 2020 SNF QRP

Section 1: Cross-Setting Measures Development Work: An Introduction

The Improving Medicare Post-Acute Care Transformation Act (IMPACT Act), enacted October 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 quality measure domains, including but not limited to incidence of major falls, skin integrity, and function. The IMPACT Act requires the implementation of quality 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. This requirement refers to the collection of such data by means of the Minimum Data Set (MDS) 3.0 for SNFs, the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set for LTCHs, and the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for IRFs.

For more information on the statutory history of the SNF, LTCH, or IRF QRP, please refer to the FY 2015 final rules. 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 quality measures proposed for the SNF QRP:

Outcome Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, Measure Steward: CMS

Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633)

Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634)

Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635)

Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636)

Section 2: Cross-Setting Pressure Ulcer Measure: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

Measure Description

This quality measure reports the percent of patients/residents with Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that are new or worsened since admission. The measure is calculated using data from the MDS 3.0 assessment instrument for SNF residents, the LTCH CARE Data Set for LTCH patients, and the IRF-PAI for IRF patients. Data are collected separately in each of the three settings using standardized data elements. Data elements are referred to hereafter in this specification as items that have been harmonized across the MDS 3.0, LTCH CARE Data Set, and IRF-PAI. For residents or patients in SNFs, LTCHs and IRFs, this measure reports the percent of patient stays 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.

It is important to note that data collection and measure calculation for this measure are conducted separately for each of the three provider settings and will not be combined across settings.

For SNF residents, this measure is restricted to Medicare Part A residents. In IRFs, this measure is limited to Medicare (Part A and Medicare Advantage) patients. In LTCHs, this measure includes all patients.

Purpose/Rationale for the Quality Measure

This quality measure is proposed as a cross-setting quality measure to meet the requirements of the IMPACT Act of 2014 addressing the domain of skin integrity and changes in skin integrity. A pressure ulcer measure has previously been successfully implemented in NHs, SNFs, LTCHs and IRFs. The data for the pressure ulcer measure have been collected and submitted by LTCHs and IRFs (using the LTCH CARE Data Set and IRF-PAI, respectively) since October 1, 2012. Effective December 14, 2016, data for the pressure ulcer measure is publicly reported for LTCHs on CMS' Long-Term Care Hospital Compare at: <https://www.medicare.gov/longtermcarehospitalcompare/> and for IRFs on CMS' Inpatient Rehabilitation Facility Compare at: <https://www.medicare.gov/inpatientrehabilitationfacilitycompare/>.

In order to improve the quality measure and address recommendations provided by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP), the 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.

Second, the measure calculation has been amended to include M0300 items instead of M0800 items for the IRF QRP and LTCH QRP. This item calculation modification is intended to reduce redundancies in assessment items. To reflect these two changes, the measure is being proposed for FY 2018 federal rulemaking as: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.

This measure is intended to encourage SNFs, LTCHs, and IRFs to prevent pressure ulcer development or worsening, and to closely monitor and appropriately treat existing pressure ulcers.

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.^{1,2,3,4} Pressure ulcers interfere with activities of daily living and functional gains made during rehabilitation, predispose patients to osteomyelitis and septicemia, and are strongly associated with longer hospital stays, longer IRF stays, and mortality.^{5,6,7} 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.^{8,9}

Pressure ulcers typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, or bone.^{10,11,12} Elderly individuals in SNFs, LTCHs, and IRFs have a wide range of impairments 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 aids, feeding tubes, tracheostomies, percutaneous endoscopic gastrostomy

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- 1 Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." *Nurs N Z* 19(10): 20-24.
 - 2 Gorzoni, M. L. and S. L. Pires (2011). "Deaths in nursing homes." *Rev Assoc Med Bras* 57(3): 327-331.
 - 3 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.
 - 4 White-Chu, E. F., et al. (2011). "Pressure ulcers in long-term care." *Clin Geriatr Med* 27(2): 241-258.
 - 5 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.
 - 6 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>.
 - 7 Wang, H., et al. (2014). "Impact of pressure ulcers on outcomes in inpatient rehabilitation facilities." *Am J Phys Med Rehabil* 93(3): 207-216.
 - 8 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.
 - 9 Institute for Healthcare Improvement (IHI). Relieve the pressure and reduce harm. May 21, 2007. Available from <http://www.ihl.org/resources/pages/improvementstories/relievethethepressureandreduceharm.aspx>.
 - 10 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>.
 - 11 Reddy, M. (2011). "Pressure ulcers." *Clin Evid (Online)* 2011.
 - 12 Advancing Excellence in America's Nursing Homes (AEANH). Explore our goals.. n.d. Available from <https://www.nhqualitycampaign.org/goals.aspx>

tubes), a history of pressure ulcers, or presence of a pressure ulcer at admission are additional factors that increase pressure ulcer risk in elderly patients.^{13,14,15,16,17,18,19,20,21}

Pressure ulcers are high-cost adverse events across the spectrum of health care settings, from acute hospitals to home health.^{22,23,24} Pressure ulcer incidence rates vary considerably by clinical setting, ranging from 0.4% to 38% in acute care, 2.2% to 23.9% in SNFs and NHs, and 0% to 17% in home care.²⁵ No national survey of pressure ulcer incidence or prevalence has been conducted in LTCHs or IRFs. However, a study evaluating 2009 Medicare FFS claims data from post-acute care facilities found 15,995 secondary diagnosis claims of Stage 3 or 4 pressure ulcers in LTCHs; 2,342 secondary diagnosis claims of Stage 3 or 4 pressure ulcers in IRFs; and 9,939 secondary diagnosis claims of Stage 3 or Stage 4 pressure ulcers in SNFs.²⁶ Additionally, analysis conducted by RTI International examined the national incidence of new or worsened Stage 2, 3, or 4 pressure ulcers in LTCHs, SNFs, or IRFs at discharge compared with admission using discharges from January through December 2015. In LTCHs, RTI found a national incidence of 0.95 percent of new or worsened Stage 2 pressure ulcers, 0.65 percent of Stage 3 pressure ulcers, and 0.48 percent of Stage 4 pressure ulcers. In SNFs, RTI found a national incidence of 1.28 percent of new or worsened Stage 2 pressure ulcers, 0.26 percent of new or worsened Stage 3 pressure ulcers, and 0.05 percent of new or worsened Stage 4 pressure ulcers. In IRFs, RTI found a national incidence of 0.56 percent of new or worsened Stage 2 pressure ulcers, 0.09 percent of new or worsened Stage 3 pressure ulcers, and 0.01 percent of new or worsened Stage 4 pressure ulcers.

Pressure ulcers that are unstageable due to slough or eschar, unstageable due to non-removable dressing or device, and unstageable presenting as deep tissue injuries (DTI) are also potentially avoidable and considered to be important indicators of quality of care. Furthermore, some studies indicate that DTIs,

¹³ Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.

¹⁴ Agency for Healthcare Research and Quality (AHRQ). Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from <https://archive.ahrq.gov/news/newsletters/research-activities/jan09/0109RA22.html>

¹⁵ Cai, S., et al. (2013). "Obesity and pressure ulcers among nursing home residents." Med Care 51(6): 478-486.

¹⁶ 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]

¹⁷ MacLean DS. Preventing & managing pressure sores. Caring for the Ages. March 2003;4(3):34-7.

¹⁸ 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.

¹⁹ 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.

²⁰ Teno, J. M., et al. (2012). "Feeding tubes and the prevention or healing of pressure ulcers." Arch Intern Med 172(9): 697-701

²¹ 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.

²² Reddy, M. (2011). "Pressure ulcers." Clin Evid (Online) 2011.

²³ 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.

²⁴ Kandilov AMG, Coomer NM, Dalton K. (2014) The impact of hospital-acquired conditions on Medicare program payments. MMRR 4(4): E1-E23

²⁵ Institute for Healthcare Improvement (IHI). Relieve the pressure and reduce harm. May 21, 2007. Available from <http://www.ihl.org/resources/pages/improvementstories/relievethepressureandreduceharm.aspx>.

²⁶ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for Centers for Medicare & Medicaid Services. 2011.

if managed using appropriate care, can be resolved without deteriorating into Stage 3, or Stage 4 pressure ulcers.^{27,28}

The rate of unstageable pressure ulcers varies according to the type of unstageable pressure ulcer and setting. An analysis conducted by RTI International examined the national incidence of new or worsened unstageable pressure ulcers in LTCHs, IRFs, or SNFs at discharge compared with admission using discharges from January through December 2015. In LTCHs, RTI found a national incidence of 1.15 percent of new unstageable pressure ulcers due to slough/eschar, 0.05 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 1.01 percent of new DTIs. In SNFs, RTI found a national incidence of 0.40 percent of new unstageable pressure ulcers due to slough/eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.57 percent of new DTIs. In IRFs, RTI found a national incidence of 0.14 percent of new unstageable pressure ulcers due to slough/eschar, 0.02 percent of new unstageable pressure ulcers due to non-removable dressing/device, and 0.26 percent of new DTIs. There is some evidence to suggest that the proportion of pressure ulcers identified as DTI has increased over time. An international study spanning the time 2006 to 2009 found DTIs increased by three-fold, to nine percent of all observed ulcers in 2009 and that DTIs were more prevalent than either Stage 3 or 4 ulcers. During the same time period, the proportion of Stage 1 and 2 ulcers decreased, and the proportion of Stage 3 and 4 ulcers remained constant.²⁹

As reported in the Federal Register, in 2006 the average cost for a hospital stay related to pressure ulcers was \$40,381.³⁰ As of 2010, the cost for treatment of Stage 4 hospital acquired pressure ulcers and complications averaged \$129,248 per admission.³¹ Using data from 2009 and 2010, severe (Stage 3 and Stage 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.³²

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

²⁷ Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. *Ostomy Wound Management* 59(9) <http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patient>

²⁸ Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. *Ostomy Wound Management* 51(4) <http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury>

²⁹ VanGilder, C, MacFarlane, GD, Harrison, P, Lachenbruch, C, Meyer, S (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International Pressure Ulcer Prevalence Survey 2006-2009. *Advances in Skin & Wound Care*. 23(6): 254-261.

³⁰ 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.

³¹ Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., ... Vladeck, B. (2010). High Cost of Stage IV Pressure Ulcers. *American Journal of Surgery*, 200(4), 473-477. <http://doi.org/10.1016/j.amjsurg.2009.12.021>

³² Kandilov AMG, Coomer NM, Dalton K. (2014) The impact of hospital-acquired conditions on Medicare program payments. *MMRR* 4(4): E1-E23.

assessment instruments will be posted on the Web site at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/mds30raimanual.html>

Denominator

Specific denominator definitions for each setting are provided below.

IRF Denominator

The denominator is the total number of Medicare* (Part A and Medicare Advantage) patient stays with an IRF-PAI assessment in the measure target period, except those that meet the exclusion criteria.

*IRF-PAI data are submitted for Medicare patients (Part A and Medicare Advantage) only.

LTCH Denominator

The denominator is the number of patient stays with both an admission and planned or unplanned discharge LTCH CARE Data Set assessment with the discharge date in the measure target period, except those that meet the exclusion criteria.

SNF Denominator

The denominator is the number of Medicare Part A SNF stays in the selected time window for SNF residents ending during the selected time window, except those who meet the exclusion criteria.

Denominator Exclusions

Specific denominator exclusions for each setting are provided below.

IRF Denominator Exclusions:

1. Patient stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries, are missing at discharge; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1 = [-] or M0300D2 = [-]) and (M0300E1 = [-] or M0300E2 = [-]) and (M0300F1 = [-] or M0300F2 = [-]) and (M0300G1 = [-] or M0300G2 = [-]).
2. Patient stay is excluded if the patient died during the IRF stay; i.e., Item 44C = [0].

LTCH Denominator Exclusions:

1. Patient stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries, are missing on the planned or unplanned discharge assessment; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1 = [-] or M0300D2 = [-]) and (M0300E1 = [-] or M0300E2 = [-]) and (M0300F1 = [-] or M0300F2 = [-]) and (M0300G1 = [-] or M0300G2 = [-]).
2. Patient stay is excluded if the patient died during the LTCH stay; i.e., A0250 = [12].

SNF Denominator Exclusions:

1. Resident stay is excluded if data on new or worsened Stage 2, 3, 4, and unstageable pressure ulcers, including deep tissue injuries are missing at discharge; i.e., (M0300B1 = [-] or M0300B2 = [-]) and (M0300C1 = [-] or M0300C2 = [-]) and (M0300D1 = [-] or M0300D2 = [-]).

[-]) and (M0300E1= [-] or M0300E2=[-]) and (M0300F1= [-] or M0300F2=[-]) and (M0300G1= [-] or M0300G2=[-]).

2. Resident stay is excluded if the resident died during the SNF stay.

Numerator

Specific numerator definitions for each setting are provided below.

IRF Numerator

The numerator is the number of Medicare (Part A and Medicare Advantage) stays for which the IRF-PAI indicates one or more Stage 2-4 pressure ulcer(s), or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, that are new or worsened at discharge compared to admission.

- 1) Stage 2 (M0300B1) - (M0300B2) > 0, OR
- 2) Stage 3 (M0300C1) - (M0300C2) > 0, OR
- 3) Stage 4 (M0300D1) - (M0300D2) > 0, OR
- 4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR
- 5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR
- 6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

LTCH Numerator

The numerator is the number of stays for which the discharge assessment indicates one or more new or worsened Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, compared to admission.

- 1) Stage 2 (M0300B1) - (M0300B2) > 0, OR
- 2) Stage 3 (M0300C1) - (M0300C2) > 0, OR
- 3) Stage 4 (M0300D1) - (M0300D2) > 0, OR
- 4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR
- 5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR
- 6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

SNF Numerator

The numerator is the number of complete resident Medicare Part A stays for which the discharge assessment indicates one or more new or worsened Stage 2-4 pressure ulcers, or unstageable pressure ulcers due to slough/eschar, non-removable dressing/device, or deep tissue injury, compared to admission.

- 1) Stage 2 (M0300B1) - (M0300B2) > 0, OR
- 2) Stage 3 (M0300C1) - (M0300C2) > 0, OR
- 3) Stage 4 (M0300D1) - (M0300D2) > 0, OR
- 4) Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR

- 5) Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR
- 6) Unstageable – Deep tissue injury (M0300G1) - (M0300G2) > 0

Measure Time Window

Specific measure time window descriptions for each setting are provided below.

IRF Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All IRF records, except those that meet the exclusion criteria, during the 12 months will be included in the denominator and are eligible for inclusion in the numerator. For patients with multiple records during the 12-month time window, each record is eligible for inclusion in the measure.

LTCH Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All LTCH stays, except those that meet the exclusion criteria, during the 12 months are included in the denominator and are eligible for inclusion in the numerator. For patients with multiple stays during the 12-month time window, each stay is eligible for inclusion in the measure.

SNF Time Window

The measure will be calculated quarterly using a rolling 12 months of data. For public reporting, the quality measure score reported for each quarter is calculated using a rolling 12 months of data. All Medicare Part A SNF stays, except those that meet the exclusion criteria, during the 12 months are included in the denominator and are eligible for inclusion in the numerator. For residents with multiple stays during the 12-month time window, each stay is eligible for inclusion in the measure.

Items Included in the Quality Measure

See **Appendix 1** for a summary of the M0300 items in instruments across settings.

IRF Items:

- Items from the time of discharge:
 - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission),
 - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission),
 - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission),
 - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission),

- M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission),
- M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure injuries that were present upon admission).
- In addition, items from the time of admission used to risk-adjust this quality measure:
 1. Functional Mobility Admission Performance:
 - GG0170C (Functional Mobility Admission Performance; Lying to Sitting on Side of Bed);
 2. Bowel Continence:
 - H0400 (Bowel Continence);
 3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:
 - I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or
 - I2900 (Diabetes Mellitus);
 4. Low Body Mass Index, based on Height (25A) and Weight (26A) at admission:
 - 25A (Height); and
 - 26A (Weight).

LTCH Items:

- Items from the planned or unplanned discharge assessment:
 - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission),
 - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission),
 - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission),
 - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission),
 - M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission),
 - M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure ulcers that were present upon admission).
- In addition, items from the admission assessment used to risk-adjust this quality measure:
 1. Functional Mobility Admission Performance:

- GG0170C (Functional Mobility; Lying to Sitting on Side of Bed);
2. Bowel Continence:
 - H0400 (Bowel Continence);
 3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:
 - I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or
 - I2900 (Diabetes Mellitus);
 4. Low Body Mass Index, based on Height and Weight:
 - K0200A (Height); and
 - K0200B (Weight).

SNF Items:

- Items from the discharge assessment:
 - M0300B1 (Number of Stage 2 pressure ulcers), M0300B2 (Number of these Stage 2 pressure ulcers that were present upon admission/entry or reentry),
 - M0300C1 (Number of Stage 3 pressure ulcers), M0300C2 (Number of these Stage 3 pressure ulcers that were present upon admission/entry or reentry),
 - M0300D1 (Number of Stage 4 pressure ulcers), M0300D2 (Number of these Stage 4 pressure ulcers that were present upon admission/entry or reentry),
 - M0300E1 (Number of unstageable pressure ulcers/injuries due to non-removable dressing/device), M0300E2 (Number of these unstageable pressure ulcers/injuries that were present upon admission/entry or reentry),
 - M0300F1 (Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar), M0300F2 (Number of these unstageable pressure ulcers that were present upon admission/entry or reentry),
 - M0300G1 (Number of unstageable pressure injuries presenting as deep tissue injury), M0300G2 (Number of these unstageable pressure injuries that were present upon admission/entry or reentry).
- In addition, items from the PPS 5-Day assessment used to risk-adjust this quality measure:
 1. Functional Mobility Admission Performance:
 - GG0170C (Mobility; Lying to Sitting on Side of Bed);
 2. Bowel Continence:
 - H0400 (Bowel Continence);
 3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:
 - I0900 (Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD)); or
 - I2900 (Diabetes Mellitus);
 4. Low Body Mass Index, based on Height and Weight:
 - K0200A (Height); and
 - K0200B (Weight).

Risk Adjustment Covariates

Specific covariate definitions for each setting are provided below.

IRF Risk Adjustment Covariates

For each patient stay covariate values are assigned either '0' for covariate condition not present or '1' for covariate condition present as reported at admission.

1. Functional Mobility Admission Performance:

Indicator of supervision/touching assistance or more assistance for the functional mobility item Lying to Sitting on Side of Bed at admission:

Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] = Substantial/maximal assistance, [03] = Partial/moderate assistance, [04] = Supervision or touching assistance, [07] = Patient refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)

Covariate = [0] (no) if GG0170C = [05, 06, -, ^] ([05] = Setup or clean-up assistance, [06] = Independent, [-] = No response available, [^] = Valid skip)

2. Bowel Continence

Bowel Continence (H0400) at admission

Covariate = [1] (yes) if H0400 = [1, 2, 3] ([1] = Occasionally incontinent, [2] = Frequently incontinent, [3] = Always incontinent)

Covariate = [0] (no) if H0400 = [0, 9, -, ^] ([0] = Always continent, [9] = Not rated, [-] = No response available, [^] = Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

Covariate = [1] (yes) if any of the following are true:

1. I0900 = [1] (checked)
2. I2900 = [1] (checked)

Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -] ([0] = No, [-] = No response available)

4. Low Body Mass Index, based on Height and Weight:

Covariate = [1] (yes) if BMI \geq [12.0] AND \leq [19.0]

Covariate = [0] (no) if BMI $<$ [12.0] OR $>$ [19.0]

Covariate = [0] (no) if 25A = [-] OR 26A = [-] ([-] = No response available)

Where: BMI = (weight * 703 / height²) = ([26A] * 703) / (25A²) and the resulting value is rounded to one decimal place.

LTCH Risk Adjustment Covariates

For each patient stay covariate values are assigned, either '0' for covariate condition not present or '1' for covariate condition present, as reported on the admission assessment.

1. Functional Mobility Admission Performance:

Supervision/touching assistance or more for the functional mobility item Lying to Sitting on Side of Bed

Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] = Substantial/maximal assistance, [03] = Partial/moderate assistance, [04] = Supervision or touching assistance, [07] = Patient refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)

Covariate = [0] (no) if GG0170C = [05, 06, -, ^] ([05] = Setup or clean-up assistance, [06] = Independent, [-] = No response available, [^] = Valid skip)

2. Bowel Continence:

Covariate = [1] (yes) if H0400 = [1, 2, 3] ([1] = Occasionally incontinent, [2] = Frequently incontinent, [3] = Always incontinent)

Covariate = [0] (no) if H0400 = [0, 9, -, ^] ([0] = Always continent, [9] = Not rated, [-] = No response available, [^] = Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

Covariate = [1] (yes) if any of the following are true:

I0900 = [1] (checked) I2900 = [1] (checked)

Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -] ([0] = No, [-] = No response available)

4. Low Body Mass Index, based on Height and Weight on the Admission assessment:

Covariate = [1] (yes) if $BMI \geq [12.0]$ AND $BMI \leq [19.0]$

Covariate = [0] (no) if $BMI < [12.0]$ OR $BMI > [19.0]$

Covariate = [0] (no) if K0200A = [-] OR K0200B = [-] ('-' = No response available)

Where: $BMI = (\text{weight} * 703 / \text{height}^2) = ([K0200B] * 703) / (K0200A^2)$ and the resulting value is rounded to one decimal place.

SNF Risk Adjustment Covariates

For each resident covariate values are assigned, either '0' for covariate condition not present or '1' for covariate condition present, as reported on the PPS 5-Day assessment.

1. Functional Mobility Admission Performance:

Covariate = [1] (yes) if GG0170C = [01, 02, 03, 04, 07, 09, 10, 88] ([01] = Dependent, [02] = Substantial/maximal assistance, [03] = Partial/moderate assistance, [04] = Supervision or touching assistance, [07] = Resident refused, [09] = Not applicable, [10] = Not attempted due to environmental limitations, [88] = Not attempted due to medical condition or safety concerns)

Covariate = [0] (no) if GG0170C = [05, 06, -, ^] ([05] = Setup or clean-up assistance, [06] = Independent, [-] = No response available, [^] = Valid skip)

2. Bowel Continence:

Covariate = [1] (yes) if H0400 = [1, 2, 3] (1 – Occasionally incontinent, 2 – Frequently incontinent, 3 – Always incontinent)

Covariate = [0] (no) if H0400 = [0, 9, -, ^] (0 – Always continent, 9 – Not rated, '[-]' – No response available, '[^]' – Valid skip)

3. Peripheral Vascular Disease / Peripheral Arterial Disease or Diabetes Mellitus:

Covariate = [1] (yes) if any of the following are true:

1. Active Peripheral Vascular Disease (PVD) or Peripheral Arterial Disease (PAD) in the last 7 days (I0900 = [1] (checked))
2. Active Diabetes Mellitus (DM) in the last 7 days (I2900 = [1] (checked))

Covariate = [0] (no) if I0900 = [0, -] AND I2900 = [0, -]

4. Low Body Mass Index, based on Height and Weight:

Covariate = [1] (yes) if BMI \geq [12.0] AND \leq [19.0]

Covariate = [0] (no) if BMI < [12.0] OR BMI > [19.0]

Covariate = [0] (no) if K0200A = [-] OR K0200B = [-] ('[-]' =No response available)

Where: BMI = (weight * 703 / height²) = ([K0200B] * 703) / (K0200A²) and the resulting value is rounded to one decimal place.

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

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

Step 1. Calculate the denominator count:

In the SNF setting, calculate the total number of complete Medicare Part A SNF stays ending in the measure time window, which do not meet the exclusion criteria.

In the LTCH setting, calculate the total number of stays with both an admission and discharge LTCH CARE Data Set assessment in the measure time window, which do not meet the exclusion criteria.

In the IRF setting, calculate the total number of stays with an IRF-PAI assessment in the measure time window, which do not meet the exclusion criteria.

Step 2. Calculate the numerator count:

In the SNF setting, calculate the total number of Medicare Part A SNF stays in the denominator with discharge assessment that indicates one or more new or worsened pressure ulcers.

In the LTCH setting, calculate the total number of patient stays whose discharge assessment indicates one or more new or worsened pressure ulcers compared to the admission assessment.

In the IRF setting, calculate the total number of patient stays whose IRF-PAI assessment indicates one or more new or worsened pressure ulcers at discharge compared to admission.

Step 3. Calculate the facility's observed score:

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

B. Calculate the expected score for each patient/resident (steps 4 and 5)

Step 4. Determine presence or absence of the pressure ulcer covariates for each patient/resident:

Assign covariate values, either '0' for covariate condition not present or '1' for covariate condition present, for each patient/resident for each of the four covariates as reported on the PPS 5-Day assessment for the SNF setting or the assessment at admission for the LTCH and IRF settings, as described in the Risk Adjustment section above.

Step 5. Calculate the expected score for each patient/resident with the following formula:

$$\text{Patient-/resident-level expected QM score} = 1 / [1 + e^{-x}] \quad (1)$$

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).

$$X = \beta_0 + \beta_1 * COVA + \beta_2 * COVB + \beta_3 * COVC + \beta_4 * COVD \quad (2)$$

Where β_0 is the logistic regression constant, β_1 is the logistic regression coefficient for the first covariate, $COVA$ is the patient/resident-level score for the first covariate, β_2 is the logistic regression coefficient for the second covariate, and $COVB$ is the patient-/resident-level score for the second covariate, etc. The regression constant and regression coefficients* are numbers obtained through statistical logistic regression analysis.

* Regression coefficients and constants are calculated separately for each facility type (SNF, LTCH, and IRF) and are updated each reporting period.

C. Calculate the facility-level expected score (step 6)

Step 6. Once an expected QM score has been calculated for all resident or patient stays for the SNF, LTCH and IRF settings, calculate the facility-level expected QM score by averaging all resident-/patient-level expected scores.

D. Calculate National mean observed QM score (steps 7 through 9)

Step 7. Calculate the national denominator count:

Calculate the total number of resident or patient stays retained after exclusions and sum to derive the national denominator count.

Step 8. Calculate the national numerator count:

Calculate the total number of resident or patient stays that triggered the QM and sum to derive the national numerator count.

Step 9. Calculate National mean observed QM score:

Divide the numerator count by its denominator count to obtain the national mean observed score; that is, divide the result of step 8 by the result of step 7.

E. Calculate the Facility-level adjusted score (step 10)

Step 10. Calculate the facility-level adjusted score based on the:

Facility-level observed QM score (step 3),
Facility-level expected QM score (step 6), and
National mean observed QM score (step 9).*

**The national mean observed QM score is updated separately for each facility type (SNF, LTCH, and IRF) for each reporting period.*

The calculation of the adjusted score uses the following equation:

$$Adj = 1 / [1 + e^{-y}] \quad (3)$$

where

Adj is the facility-level adjusted QM score, and
 $y = (\text{Ln}(\text{Obs}/(1-\text{Obs})) - \text{Ln}(\text{Exp}/(1-\text{Exp})) + \text{Ln}(\text{Nat}/(1-\text{Nat})))$
 Obs is the facility-level observed QM score,
 Exp is the facility-level expected QM score,
 Nat is the national mean observed QM score,
 Ln indicates a natural logarithm, and
 e is the base of natural logarithm.

Section 3: An Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633)

Measure Description

This proposed measure estimates the risk-adjusted mean change in *self-care* score between admission and discharge for residents discharged from a SNF.

Purpose/Rationale for the Quality Measure

This quality measure is proposed to meet the requirements of the IMPACT Act of 2014 addressing the domain of functional status, cognitive function, and changes in function and cognitive function. We finalized the same functional outcome measures for the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47111 through 47117). In developing these SNF functional outcome quality measures, we sought to build on our cross-setting function work by leveraging data elements currently collected in the MDS section GG, which would minimize additional data collection burden while increasing the feasibility of cross-setting item comparisons.

SNFs provide skilled services, such as skilled nursing or therapy services. Residents receiving care in SNFs include those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Treatment goals may include fostering residents' ability to manage their daily activities so that they can complete self-care and mobility activities as independently as possible, and, if feasible, return to a safe, active, and productive life in a community-based setting. Given that the primary goal of many SNF residents is improvement in function, SNF clinicians assess and document residents' functional status at admission and at discharge to evaluate not only the effectiveness of the rehabilitation care provided to individual residents but also the effectiveness of the SNF.

Examination of SNF data shows that SNF treatment practices directly influence resident outcomes. For example, therapy services provided to SNF residents have been found to be correlated with the functional improvement that SNF residents achieve (that is, functional outcomes).³³ Several studies found patients' functional outcomes vary based on treatment by physical and occupational therapists. Specifically, therapy was associated with significantly greater odds of improving mobility and self-care functional independence,³⁴ shorter length of stay,³⁵ and a greater likelihood of discharge to community.³⁶ Furthermore, Jung et al.³⁷ found that an additional hour of therapy treatment per week was associated with approximately a 3.1 percentage-point increase in the likelihood of returning to the community among residents with a hip fracture. Achieving these targeted resident outcomes, including

³³ Jette, D. U., R. L. Warren, & C. Wirtalla. (2005). The relation between therapy intensity and outcomes of rehabilitation in skilled nursing facilities. *Archives of Physical Medicine and Rehabilitation*, 86 (3), 373-9.

³⁴ Lenze, E. J., Host, H. H., Hildebrand, M. W., Morrow-Howell, N., Carpenter, B., Freedland, K. E., ... & Binder, E. F. (2012). Enhanced medical rehabilitation increases therapy intensity and engagement and improves functional outcomes in post acute rehabilitation of older adults: a randomized-controlled trial. *Journal of the American Medical Directors Association*, 13(8), 708-712.

³⁵ Medicare Payment Advisory Commission (US). (2016). Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission.

³⁶ Cary, M. P., Pan, W., Sloane, R., Bettger, J. P., Hoenig, H., Merwin, E. I., & Anderson, R. A. (2016). Self-Care and Mobility Following Postacute Rehabilitation for Older Adults With Hip Fracture: A Multilevel Analysis. *Archives of Physical Medicine and Rehabilitation*. <http://doi.org/10.1016/j.apmr.2016.01.012>

³⁷ Jung, H. Y., Trivedi, A. N., Grabowski, D. C., & Mor, V. (2016). Does More Therapy in Skilled Nursing Facilities Lead to Better Outcomes in Patients With Hip Fracture? *Physical therapy*, 96(1), 81-89.

improved self-care and mobility functional independence, reduced length of stay, and increased discharges to the community, is a core goal of SNFs.

Among SNF residents receiving rehabilitation services, the amount of treatment received can vary. For example, the amount of therapy treatment provided varies by type (that is, for-profit versus not-for-profit) and location (that is, urban versus rural) of facility.^{38,39}

MedPAC⁴⁰ noted that while there was an overall increase in the share of intensive therapy days between 2002 and 2012, the for-profit and urban facilities had higher shares of intensive therapy than not-for-profit facilities and those located in rural areas. Data from 2011 to 2014 indicate that this variation is not explained by patient characteristics, such as activities of daily living, comorbidities and age, as SNF residents with stays in 2011 were more independent on average than the average SNF resident with stays in 2014. Because more intense therapy is associated with more functional improvement for certain beneficiaries, this variation in rehabilitation services supports the need to monitor SNF residents' functional outcomes. Therefore, we believe there is an opportunity for improvement in this area.

In addition, a recent analysis that examined the incidence, prevalence, and costs of common rehabilitation conditions found that back pain, osteoarthritis, and rheumatoid arthritis are the most common and costly conditions affecting more than 100 million individuals and costing more than \$200 billion per year.⁴¹ Persons with these medical conditions are admitted to SNFs for rehabilitation treatment.

The use of standardized mobility and self-care data elements would standardize the collection of functional status data, which could improve communication when residents are transferred between providers. Most SNF residents receive care in an acute care hospital prior to the SNF stay, and many SNF residents receive care from another provider after the SNF stay.

Recent research provides empirical support for the risk adjustment variables for these proposed quality measures. In a study of resident functional improvement in SNFs, Wysocki et al.⁴² found that several resident conditions were significantly related to resident functional improvement, including cognitive impairment, delirium, dementia, heart failure, and stroke. Also, Cary et al. found that several resident characteristics were significantly related to resident functional improvement, including age, cognitive function, self-care function at admission, and comorbidities.⁴³

³⁸ Grabowski, D. C., Feng, Z., Hirth, R., Rahman, M., & Mor, V. (2013). Effect of nursing home ownership on the quality of post-acute care: An instrumental variables approach. *Journal of Health Economics*, 32(1), 12-21.

³⁹ Medicare Payment Advisory Commission (US). (2016). Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission.

⁴⁰ Medicare Payment Advisory Commission (US). (2016). Report to the Congress: Medicare payment policy. Medicare Payment Advisory Commission.

⁴¹ Ma VY, Chan L, Carruthers KJ. Incidence, Prevalence, Costs, and Impact on Disability of Common Conditions Requiring Rehabilitation in the United States: Stroke, Spinal Cord Injury, Traumatic Brain Injury, Multiple Sclerosis, Osteoarthritis, Rheumatoid Arthritis, Limb Loss, and Back Pain. *Archives of Phys Med and Rehab* 2014

⁴² Wysocki, A., Thomas, K. S., & Mor, V. (2015). Functional Improvement Among Short-Stay Nursing Home Residents in the MDS 3.0. *Journal of the American Medical Directors Association*, 16(6), 470-474. <http://doi.org/10.1016/j.jamda.2014.11.018>.

⁴³ Cary, M. P., Pan, W., Sloane, R., Bettger, J. P., Hoenig, H., Merwin, E. I., & Anderson, R. A. (2016). Self-Care and Mobility Following Postacute Rehabilitation for Older Adults With Hip Fracture: A Multilevel Analysis. *Archives of Physical Medicine and Rehabilitation*. <http://doi.org/10.1016/j.apmr.2016.01.012>.

The functional assessment items used to calculate the four proposed quality measures are from the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize assessment of patients'/residents' status across acute and post-acute settings, including inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), SNFs, and home health agencies (HHAs). The CARE Item Set was developed and tested as part of the Post-Acute Care Payment Reform Demonstration. The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or at discharge to determine patients'/residents' needs, evaluate patient/resident progress, and prepare patients/residents and families for a transition to home or to another setting.

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."^{9,44}

Results of the reliability and validity testing conducted as part of the Post-Acute Care Payment Reform Demonstration found the functional status items to have acceptable reliability and validity in the acute and post-acute patient/resident populations. A description of the testing methodology and results are available in several reports, available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>.

The proposed quality measures described in this document focus on self-care and mobility activities. We recognize that inpatient rehabilitation programs focus on recovery across many areas of function at the level of body structure and function, activities, and participation; however, additional research is needed to develop quality measures for other areas of function status.

Denominator

The denominator is the number of SNF Medicare Part A resident stays, except those that meet the exclusion criteria.⁴⁵

Denominator Exclusions

This proposed quality measure has 7 exclusion criteria:

1. Residents with incomplete stays.

Rationale: It can be challenging to gather accurate discharge functional status data for residents who experience incomplete stays. Residents with incomplete stays include residents who are unexpectedly discharged to an acute care setting (short-stay acute hospital, critical access hospital, inpatient psychiatric facility, or long-term care hospital), because of a medical emergency; residents who die or leave a SNF against medical advice; residents discharged directly to another SNF; and residents with a length of stay of less than 3 days.

⁴⁴ Gage B, Constantine R, Aggarwal J, et al. 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: RTI International;2012.

⁴⁵ Please note that critical access hospital with swing beds are exempt from the SNF PPS and are not required to submit quality data under the SNF QRP by means of the MDS per the requirements set forth by the IMPACT Act.

2. Residents who are independent with all self-care activities at the time of admission.
Rationale: Residents who are independent with all self-care items at the time of admission are assigned the highest score on all self-care items, and thus, would not be able to show functional improvement on this same set of items at discharge.
3. Residents with the following medical conditions: coma; persistent vegetative state; complete tetraplegia; locked-in syndrome; severe anoxic brain damage, cerebral edema, or compression of brain.
Rationale: These residents are excluded because they may have limited or less predictable improvement with the selected self-care items.
4. Residents younger than 21 years.
Rationale: There is only limited evidence published about functional outcomes for individuals younger than 21 years.
5. Residents discharged to hospice.
Rationale: Resident goals may change during the SNF stay.
6. Residents who are not Medicare Part A beneficiaries.
Rationale: For the SNF QRP, MDS data are submitted for Medicare Part A beneficiaries.
7. Residents who do not receive physical or occupational therapy services.
Rationale: The focus of this proposed measure is functional improvement for residents admitted to the SNF with an expectation of functional improvement due to skilled services, including physical and occupational therapy. Some SNF residents may receive skilled care, but not physical or occupational therapy services, and these residents are not included in the measure calculation.

Numerator

The proposed measure does not have a simple form for the numerator. This measure estimates the risk-adjusted change in self-care score between admission and discharge among SNF Medicare Part A residents, except those that meet the exclusion criteria. The change in self-care score is calculated as the difference between the discharge self-care score and the admission self-care score.

Items Included in the Quality Measure

For this proposed quality measure, the following functional activities are assessed and rated at the time of admission and at discharge:

Self-Care Items

GG0130A. Eating: The ability to use suitable utensils to bring food and/or liquid to the mouth and swallow food and/or liquid once the meal is placed before the resident.

GG0130B. Oral hygiene: The ability to use suitable items to clean teeth. Dentures (if applicable): The ability to insert and remove dentures into and from the mouth, and manage denture soaking and rinsing with use of equipment.

GG0130C. Toilet hygiene: The ability to maintain perineal hygiene, adjust clothes before and after voiding or having a bowel movement. If managing an ostomy, include wiping the opening but not managing equipment.

GG0130E. Shower/bathe self: The ability to bathe self, including washing, rinsing, and drying self (excludes washing of back and hair). Does not include transferring in/out of tub/shower.

GG0130F. Upper body dressing: The ability to dress and undress above the waist; including fasteners, if applicable.

GG0130G. Lower body dressing: The ability to dress and undress below the waist, including fasteners; does not include footwear.

GG0130H. Putting on/taking off footwear: The ability to put on and take off socks and shoes or other footwear that is appropriate for safe mobility; including fasteners, if applicable.

Self-Care Rating Scale: Codes and Code Definitions

- 06. Independent** – Resident completes the activity by himself/herself with no assistance from a helper.
- 05. Setup or clean-up assistance** – Helper sets up or cleans up; resident completes activity. Helper assists only prior to or following the activity.
- 04. Supervision or touching assistance** – Helper provides verbal cues and/or touching/steading and/or contact guard assistance as resident 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 resident’s 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 resident’s trunk or limbs and provides more than half the effort.
- 01. Dependent** – Helper does ALL of the effort. Resident does none of the effort to complete the task. Or, the assistance of 2 or more helpers is required for the resident to complete the activity.

If the activity was not attempted, code the reason:

- 07. Patient refused**
- 09. Not applicable** – Not attempted and the patient did not perform this activity prior to the current illness, exacerbation, or injury.
- 10. Not attempted due to environmental limitations** (e.g., lack of equipment, weather constraints)
- 88. Not attempted due to medical condition or safety concerns**

Risk Adjustment

Residents treated in SNFs vary in terms of primary medical condition, demographic characteristics, and co-existing conditions. Residents may also have different expected improvement in function on the basis of these factors. Therefore, this proposed outcome measure is risk adjusted. Risk adjustment controls for specific resident characteristics (e.g., age or diagnosis) that may affect residents’ outcomes when comparing facilities.

Initially, an extensive set of risk adjustment variables was selected on the basis of a review of the literature and empirical findings from the PAC PRD analyses⁴⁶ as well as input from TEPs convened by

⁴⁶ Gage B, Morley M, Smith L, et al. Post-Acute Care Payment Reform Demonstration: Final Report Volume 4 of 4: RTI International;2012.

RTI.⁴⁷ Using this initial set of risk adjustment variables, we have been conducting regression analyses using the PAC PRD data to help identify the best set of risk adjustors on the basis of regression coefficients, statistical significance, sample sizes, and other indicators. Data on the reliability of CARE variables used for risk adjustment can be found in the report titled, *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing: Volume 2 of 3*.⁴⁸

The risk adjustors used for this proposed quality measure are the following:

- **Age group at SNF admission**
 - Younger than 54 years
 - 55 to 64 years
 - 65 to 74 years (reference category)
 - 75 to 84 years
 - 85 to 90 years
 - > 90 years of age and older
- **Admission self-care function score: continuous form**
- **Admission self-care function score: squared form**
- **Primary medical condition category**
 - Stroke
 - Non-traumatic brain dysfunction and traumatic brain dysfunction
 - Non-traumatic spinal cord dysfunction
 - Traumatic spinal cord dysfunction
 - Progressive neurological conditions
 - Other neurological conditions
 - Amputation
 - Hip and knee replacement (reference category)
 - Fractures and other multiple trauma
 - Other orthopedic conditions
 - Debility and cardiorespiratory conditions
 - Medically complex conditions
 - Other medical conditions
- **Interactions between primary medical condition category and SNF admission functional status**

⁴⁷ RTI International. Summary of Feedback from the Technical Expert Panel on the Development of Cross - Setting Functional Status Quality Measures;2014.

⁴⁸ Gage B, Smith L, Ross J, et al. The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing Volume 2 of 3; RTI International;2012.

- **Prior Surgery: Major surgery during the 100 days prior to the SNF admission**
- **Prior Functioning: Self-care**
 - Dependent
 - Some help
 - Independent, or unknown (reference category)
- **Prior Functioning: Indoor ambulation**
 - Dependent or some help
 - Independent, or unknown (reference category)
- **Prior Device Use: Walker use**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Wheelchair/scooter**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Mechanical lift**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Orthotics/prosthetics**
 - Yes
 - No, or unknown (reference category)
- **Presence of severe pressure ulcer at admission** (Stage 2 pressure ulcer)
- **Presence of severe pressure ulcer/injury at admission** (Stage 3, Stage 4 or Unstageable pressure ulcer/injury)
- **Cognitive Abilities: Brief Interview for Mental Status (BIMS) score**
 - Severely impaired
 - Moderately impaired
 - Intact (reference category)
- **Communication Impairment: Ability to express ideas and wants *and* Understanding verbal and non-verbal content**
 - Moderate to severe communication limitations: Rarely/never understands; or sometimes understands; or rarely/never understood; or unclear speech; or sometimes understood
 - Mild to no communication limitations: Usually understands or understands; and usually understood or understood (reference category)

- **Urinary Continence**
 - Occasionally or frequently incontinent or always incontinent
 - Continent or no urine output (reference category)
- **Bowel Continence**
 - Occasionally or frequently incontinent or always incontinent
 - Continent (reference category)
- **Tube feeding or total parenteral nutrition**
- **Comorbidities (hierarchical condition categories):**
 - Major Infections: Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock; and Other Infectious Diseases
 - Metastatic Cancer and Acute Leukemia
 - Diabetes: Diabetes with Chronic Complications; Diabetes without Complication; Type I Diabetes Mellitus
 - Other Significant Endocrine and Metabolic Disorders
 - Delirium and Encephalopathy
 - Dementia: Dementia With Complications; Dementia Without Complications
 - Tetraplegia (excluding complete tetraplegia) and paraplegia
 - Multiple Sclerosis
 - Parkinson´s and Huntington´s Diseases
 - Angina Pectoris
 - Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease
 - Hemiplegia, Other Late Effects of Cerebrovascular Accident: Hemiplegia/Hemiparesis; Late Effects of Cerebrovascular Disease, Except Paralysis
 - Dialysis Status and Chronic Kidney Disease - Stage 5
 - Urinary Obstruction and Retention
 - Amputations: Traumatic Amputations and Complications; Amputation Status, Lower Limb/Amputation Complications; Amputation Status, Upper Limb

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

1. Sum the scores of the admission self-care items to create an admission self-care score for each resident, after ‘activity not attempted’ values are recoded to 1 (score range: 7 to 42).
2. Sum the scores of the discharge self-care items to create a discharge self-care score for each resident, after ‘activity not attempted’ values are recoded to 1 (score range: 7 to 42).

3. Using stay-level records, identify the stay-level records of residents who meet the exclusion criteria and exclude them from analyses.
4. Calculate the difference between the admission self-care score (from step 1) and the discharge self-care score (from step 2) for each resident to create a change in self-care score for each resident.
5. Calculate an expected change in self-care score for each resident using regression coefficients from national data and each resident's admission characteristics (risk adjustors).
6. Calculate an average observed change in self-care score for each SNF. This is the facility-level observed change in self-care score.
7. Calculate an average expected change in self-care score for each SNF. This is the facility-level expected change in self-care score.
8. Calculate the difference between the facility-level observed change score and the facility-level expected change score to create an observed minus expected difference. A value that is 0 indicates the observed score and expected score are equal. A value that is higher than 0 indicates that the observed change score is higher (better) than expected. A value that is less than 0 indicates that the observed change score is lower (worse) than the expected score.
9. Add each SNF's difference value to the national average change in self-care score. This is the risk-adjusted mean self-care score.

Section 4: An Application of the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NOF #2634)

Measure Description

This proposed quality measure estimates the average risk-adjusted mean change in *mobility score* between admission and discharge for residents discharged from a SNF.

Purpose/Rationale for the Quality Measure

As noted above, SNFs provide rehabilitation services to many residents with a goal of improving resident functioning. This is the second functional outcome quality measure being proposed to meet the requirements of the IMPACT Act, addressing the domain of functional status, cognitive function, and changes in function and cognitive function.

Denominator

The denominator is the number of SNF Medicare Part A resident stays, except those that meet the exclusion criteria.⁴⁹

Denominator Exclusions

This proposed quality measure has 7 exclusion criteria:

1. Residents with incomplete stays.

Rationale: It can be challenging to gather accurate discharge functional status data for residents who experience incomplete stays. Residents with incomplete stays include residents who are unexpectedly discharged to an acute care setting (Short-stay Acute Hospital, Critical Access Hospital, Inpatient Psychiatric Facility, or Long-term Care Hospital), because of a medical emergency; residents who die or leave a SNF against medical advice; residents discharged directly to another SNF; and residents with a length of stay of less than 3 days.

2. Residents who are independent with all mobility activities at the time of admission.

Rationale: Residents who are independent with all mobility items at the time of admission are assigned the highest score on all mobility items, and thus, would not be able to show functional improvement on this same set of items at discharge.

3. Residents with the following medical conditions: coma; persistent vegetative state; complete tetraplegia; locked-in syndrome; severe anoxic brain damage, cerebral edema, or compression of brain.

Rationale: These residents are excluded because they may have limited or less predictable improvement with the selected mobility items.

4. Residents younger than 21 years.

Rationale: There is only limited evidence published about functional outcomes for individuals younger than 21 years.

⁴⁹ Please note that critical access hospital with swing beds are exempt from the SNF PPS and are not required to submit quality data under the SNF QRP by means of the MDS per the requirements set forth by the IMPACT Act.

5. Residents discharged to hospice.

Rationale: Resident goals may change during the SNF stay.

6. Residents who are not Medicare Part A beneficiaries.

Rationale: For the SNF QRP, MDS data are submitted for Medicare Part A beneficiaries.

7. Residents who do not receive physical or occupational therapy services.

Rationale: The focus of this proposed measure is functional improvement for residents admitted to the SNF with an expectation of functional improvement due to skilled services, including physical and occupational therapy. Some SNF residents may receive skilled care, but not physical or occupational therapy services, and these residents are not included in the measure calculation.

Numerator

The measure does not have a simple form for the numerator. This measure estimates the risk-adjusted change in mobility score between admission and discharge among SNF Medicare Part A residents, except those that meet the exclusion criteria. The change in mobility score is calculated as the difference between the discharge mobility score and the admission mobility score.

Items Included in the Quality Measure

For the proposed quality measure, the following functional activities are assessed and rated at the time of admission and discharge:

Mobility Items

GG0170A. Roll left and right: The ability to roll from lying on back to left and right side, and roll back to back on the bed.

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

GG0170C. 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, no back support.

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

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

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

GG0170G. Car transfer: The ability to transfer in and out of a car or van on the passenger side. Does not include the ability to open/close door or fasten seat belt.

GG0170I. Walk 10 feet: Once standing, the ability to walk at least 10 feet (3 meters) in room, corridor, or similar space.

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

GG0170K. Walk 150 feet: Once standing, the ability to walk at least 150 feet (45 meters) in corridor or similar space.

GG0170L. Walking 10 feet on uneven surfaces: The ability to walk 10 feet on uneven or sloping surfaces (indoor or outdoor), such as turf or gravel.

GG0170M. 1 step (curb): The ability to step over a curb and/or up and down one step

GG0170N. 4 steps: The ability to go up and down four steps with or without a rail.

GG0170P. 12 steps: The ability to go up and down 12 steps with or without a rail.

GG0170O. Picking up object: The ability to bend/stoop from a standing position to pick up a small object, such as a spoon, from the floor.

Mobility Rating Scale: Codes and Code Definitions

- 06. Independent** – Resident completes the activity by himself/herself with no assistance from a helper.
- 05. Setup or clean-up assistance** – Helper sets up or cleans up; resident completes activity. Helper assists only prior to or following the activity.
- 04. Supervision or touching assistance** – Helper provides verbal cues and/or touching/steading and/or contact guard assistance as resident 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 resident's 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 resident's trunk or limbs and provides more than half the effort.
- 01. Dependent** – Helper does ALL of the effort. Resident does none of the effort to complete the task. Or, the assistance of 2 or more helpers is required for the resident to complete the activity.

If the activity was not attempted, code the reason:

- 07. Patient refused**
- 09. Not applicable** – Not attempted and the patient did not perform this activity prior to the current illness, exacerbation, or injury.
- 10. Not attempted due to environmental limitations** (e.g., lack of equipment, weather constraints)
- 88. Not attempted due to medical condition or safety concerns**

Risk Adjustment

Residents treated in SNFs vary in terms of primary medical condition, demographic characteristics, and co-existing conditions. Residents may also have different expected improvement in function on the basis of these factors. Therefore, this proposed outcome measure is risk adjusted. Risk adjustment controls for specific resident characteristics (e.g., age or diagnosis) that may affect residents' outcomes when comparing facilities.

Initially, an extensive set of risk adjustment variables was selected on the basis of a review of the literature and empirical findings from the PAC PRD analyses⁵⁰ as well as input from TEPs convened by

⁵⁰ Gage B, Morley M, Smith L, et al. Post-Acute Care Payment Reform Demonstration: Final Report Volume 4 of 4: RTI International;2012.

RTI.⁵¹ Using this initial set of risk adjustment variables, we have been conducting regression analyses using the PAC PRD data to help identify the best set of risk adjustors on the basis of regression coefficients, statistical significance, sample sizes, and other indicators. Data on the reliability of CARE variables used for risk adjustment can be found in the report titled *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing: Volume 2 of 3*.⁵²

The risk adjustors used for this proposed quality measure are the following:

- **Age group at SNF admission**
 - Younger than 54 years
 - 55 to 64 years
 - 65 to 74 years (reference category)
 - 75 to 84 years
 - 85 to 90 years
 - 90 years or older
- **Admission mobility function score: continuous score**
- **Admission mobility function score: squared form**
- **Primary medical condition category**
 - Stroke
 - Non-traumatic brain dysfunction and Traumatic brain dysfunction
 - Non-traumatic spinal cord dysfunction
 - Traumatic spinal cord dysfunction
 - Progressive neurological conditions
 - Other neurological conditions
 - Amputation
 - Hip and knee replacements (reference category)
 - Fractures and other multiple trauma
 - Other orthopedic conditions
 - Debility, cardiorespiratory conditions
 - Medically complex conditions
 - Other medical conditions
- **Interaction of medical condition category and admission mobility score and primary**

⁵¹ RTI International. Summary of Feedback from the Technical Expert Panel on the Development of Cross - Setting Functional Status Quality Measures;2014.

⁵² Gage B, Smith L, Ross J, et al. The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing Volume 2 of 3; RTI International;2012.

- **Prior Surgery: Major surgery during the 100 days prior to the SNF admission**
- **Prior Functioning: Indoor Mobility (ambulation)**
 - Dependent
 - Some help
 - Independent, or unknown (reference category)
- **Prior Functioning: Stairs**
 - Dependent
 - Some help
 - Independent, or unknown (reference category)
- **Prior Functioning: Functional Cognition**
 - Dependent
 - Independent, some help, or unknown (reference category)
- **Prior Device Use: Walker**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Wheelchair/scooter**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Mechanical lift**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Orthotics/prosthetics**
 - Yes
 - No, or unknown (reference category)
- **Communication Impairment: Ability to express ideas and wants *and* Understanding verbal and non-verbal content**
 - Moderate to severe communication impairment: Rarely/never understands; or sometimes understands; or rarely/never understood; or unclear speech; or sometimes understood.
 - Mild communication impairment: Usually understands or usually understood
 - No communication impairment (reference category)
- **Cognitive Abilities: Brief Interview for Mental Status (BIMS) score:**
 - Severely impaired
 - Moderately impaired
 - Intact (reference category)

- **Urinary Continence**
 - Occasionally or frequently incontinent, or always incontinent
 - Continent or no urine output (reference category)
- **Bowel Continence**
 - Always incontinent
 - Occasionally or frequently incontinent Continent (reference category)
- **Presence of stage 2 pressure ulcer at admission**
- **Presence of severe pressure ulcer/injury at admission** (Stage 3, Stage 4, or Unstageable pressure ulcer/injury)
- **Tube feeding or total parenteral nutrition**
- **History of Falls: history of one or more falls in the 6 months prior to admission**
- **Comorbidities (hierarchical condition categories)**
 - Central nervous system (CNS) Infections: Bacterial, Fungal, and Parasitic Central Nervous System Infections; Viral and Late Effects Central Nervous System Infections
 - Other Infectious Diseases (HCC 7)
 - Metastatic Cancer and Acute Leukemia
 - Lymphoma and Other Cancers
 - Other Major Cancers: Colorectal, Bladder, and Other Cancers; Other Respiratory and Heart Neoplasms; Other Digestive and Urinary Neoplasms; Other Neoplasms
 - Dementia: Dementia With Complications; Dementia Without Complications
 - Mental Health Disorders: Schizophrenia; Major Depressive, Bipolar, and Paranoid Disorders; Reactive and Unspecified Psychosis; Personality Disorders
 - Tetraplegia (excluding complete tetraplegia) and paraplegia
 - Multiple Sclerosis
 - Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease
 - Hemiplegia/Other Late Effects of Cerebrovascular Accident: Hemiplegia/Hemiparesis; Late Effects of Cerebrovascular Disease, Except Paralysis
 - Aspiration, Bacterial, and Other Pneumonias: Aspiration and Specified Bacterial Pneumonias; Pneumococcal Pneumonia, Empyema, Lung Abscess
 - Legally Blind
 - Dialysis Status and Chronic Kidney Disease - Stage 5
 - Chronic Kidney Disease - Stages 1-4, Unspecified: Chronic Kidney Disease, Severe (Stage 4); Chronic Kidney Disease, Moderate (Stage 3); Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)
 - Major Fracture, Except of Skull, Vertebrae, or Hip

- Amputations: Traumatic Amputations and Complications; Amputation Status, Lower Limb/Amputation Complications; Amputation Status, Upper Limb

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

1. Sum the scores of the admission mobility items to create an admission mobility score for each resident, after 'activity not attempted' values are recoded to 1 (score range: 15 to 90).
2. Sum the scores of the discharge mobility items to create a discharge mobility score for each resident, after 'activity not attempted' values are recoded to 1 (score range: 15 to 90).
3. Using SNF stay records, identify the records of residents who meet the exclusion criteria and exclude them from analyses.
4. Calculate the difference between the admission mobility score (from step 1) and the discharge mobility score (from step 2) for each resident to create a change in mobility score for each resident.
5. Calculate an expected change in mobility score for each resident using regression coefficients from national data and each resident's admission characteristics (risk adjustors).
6. Calculate an average observed change in mobility score for each SNF (using the resident data calculated in step 4. This is the facility-level observed change in mobility score.
7. Calculate an average expected change in mobility score for each SNF (using the resident data from step 5. This is the facility-level expected change in mobility score.
8. Calculate the difference between the facility-level observed change score and the facility-level expected change score to create an observed minus expected difference. A value that is 0 indicates the observed score and expected score are equal. A value that is higher than 0 indicates that the observed change score is higher (better) than expected. A value that is less than 0 indicates that the observed change score is lower (worse) than the expected score.
9. Add each SNF's difference value to the national average change in mobility score. This is the risk-adjusted mean mobility score.

Section 5: An Application of the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NOF #2635)

Measure Description

This proposed quality measure estimates the percentage of SNF residents who meet or exceed an expected discharge self-care score.

Purpose/Rationale for the Quality Measure

As noted above, SNFs provide rehabilitation services to many residents with a goal of improving resident functioning. This is the third quality measure being proposed to meet the requirements of the IMPACT Act, addressing the domain of functional status, cognitive function, and changes in function and cognitive function.

Denominator

The denominator is the number of SNF Medicare Part A resident stays, except those that meet the exclusion criteria.⁵³

Denominator Exclusions

This proposed quality measure has 6 exclusion criteria:

1. Residents with incomplete stays.

Rationale: It can be challenging to gather accurate discharge functional status data for residents who experience incomplete stays. Residents with incomplete stays include residents who are unexpectedly discharged to an acute care setting (Short-stay Acute Hospital, Critical Access Hospital, Inpatient Psychiatric Facility, or Long-term Care Hospital), because of a medical emergency; residents who die or leave a SNF against medical advice; residents discharged directly to another SNF; and residents with a length of stay of less than 3 days.

2. Residents with the following medical conditions: coma; persistent vegetative state; complete tetraplegia; locked-in syndrome; severe anoxic brain damage, cerebral edema, or compression of brain.

Rationale: These residents are excluded because they may have limited or less predictable improvement with the selected self-care items.

3. Residents younger than 21 years.

Rationale: There is only limited evidence published about functional outcomes for individuals younger than 21 years.

4. Residents discharged to hospice.

Rationale: Resident goals may change during the SNF stay.

5. Residents who are not Medicare Part A beneficiaries.

Rationale: For the SNF QRP, MDS data are submitted for Medicare Part A beneficiaries.

⁵³ Please note that critical access hospital with swing beds are exempt from the SNF PPS and are not required to submit quality data under the SNF QRP by means of the MDS per the requirements set forth by the IMPACT Act.

6. Residents who do not receive physical or occupational therapy services.

Rationale: The focus of this proposed measure is functional improvement for residents admitted to the SNF with an expectation of functional improvement due to skilled services, including physical and occupational therapy. Some SNF residents may receive skilled care, but not physical or occupational therapy services, and these residents are not included in the measure calculation.

Numerator

The numerator is the number of Medicare Part A residents in an SNF, except those that meet the exclusion criteria, with a discharge self-care score that is equal to or higher than the calculated expected discharge self-care score.

Items Included in the Quality Measure

The following functional activities are assessed and rated at the time of admission and discharge:

Self-Care Items

GG0130A. Eating: The ability to use suitable utensils to bring food and/or liquid to the mouth and swallow food and /or liquid once the meal is placed before the resident.

GG0130B. Oral hygiene: The ability to use suitable items to clean teeth. Dentures (if applicable): The ability to insert and remove dentures into and from the mouth, and manage denture soaking and rinsing with use of equipment.

GG0130C. Toilet hygiene: The ability to maintain perineal hygiene, adjust clothes before and after voiding or having a bowel movement. If managing an ostomy, include wiping the opening but not managing equipment.

GG0130E. Shower/bathe self: The ability to bathe self, including washing, rinsing, and drying self (excludes washing of back and hair). Does not include transferring in or out of tub/shower.

GG0130F. Upper body dressing: The ability to dress and undress above the waist; including fasteners, if applicable

GG0130G. Lower body dressing: The ability to dress and undress below the waist, including fasteners. Does not include footwear.

GG0130H. Putting on/taking off footwear: The ability to put on and take off socks and shoes or other footwear that are appropriate for safe mobility; including fasteners, if applicable.

Self-Care Rating Scale: Codes and Code Definitions

- 06. Independent** – Resident completes the activity by himself/herself with no assistance from a helper.
- 05. Setup or clean-up assistance** – Helper sets up or cleans up; resident completes activity. Helper assists only prior to or following the activity.
- 04. Supervision or touching assistance** – Helper provides verbal cues and/or touching/steading and/or contact guard assistance as resident 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 resident's 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 resident’s trunk or limbs and provides more than half the effort.
- 01. Dependent** – Helper does ALL of the effort. Resident does none of the effort to complete the task. Or, the assistance of 2 or more helpers is required for the resident to complete the activity.

If the activity was not attempted, code the reason:

- 07. Patient refused**
- 09. Not applicable** – Not attempted and the patient did not perform this activity prior to the current illness, exacerbation, or injury.
- 10. Not attempted due to environmental limitations** (e.g., lack of equipment, weather constraints)
- 88. Not attempted due to medical condition or safety concerns**

Risk Adjustment

Residents treated in SNFs vary in terms of primary medical condition, demographic characteristics, and co-existing conditions. Residents may also have different expected improvement in function on the basis of these factors. Therefore, this proposed outcome measure is risk adjusted. Risk adjustment controls for specific resident characteristics (e.g., age or diagnosis) that may affect residents’ outcomes when comparing facilities.

Initially, an extensive set of risk adjustment variables was selected on the basis of a review of the literature and empirical findings from the PAC PRD analyses⁵⁴ as well as input from TEPs convened by RTI.⁵⁵ Using this initial set of risk adjustment variables, we have been conducting regression analyses using the PAC PRD data to help identify the best set of risk adjustors on the basis of regression coefficients, statistical significance, sample sizes, and other indicators. Data on the reliability of CARE variables used for risk adjustment can be found in the report titled *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing: Volume 2 of 3*.⁵⁶

The risk adjustors used for this proposed quality measure are the following:

- **Age group at SNF admission**
 - Younger than 54 years
 - 55 to 64 years
 - 65 to 74 years (reference category)
 - 75 to 84 years
 - 85 to 90 years
 - > 90 years of age and older

⁵⁴ Gage B, Morley M, Smith L, et al. Post-Acute Care Payment Reform Demonstration: Final Report Volume 4 of 4: RTI International;2012.

⁵⁵ RTI International. Summary of Feedback from the Technical Expert Panel on the Development of Cross - Setting Functional Status Quality Measures;2014.

⁵⁶ Gage B, Smith L, Ross J, et al. The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing Volume 2 of 3: RTI International;2012.

- **Admission self-care function score: continuous form**
- **Admission self-care function score: squared form**
- **Primary medical condition category**
 - Stroke
 - Non-traumatic brain dysfunction and traumatic brain dysfunction
 - Non-traumatic spinal cord dysfunction
 - Traumatic spinal cord dysfunction
 - Progressive neurological conditions
 - Other neurological conditions
 - Amputation
 - Hip and knee replacement (reference category)
 - Fractures and other multiple trauma
 - Other orthopedic conditions
 - Debility and cardiorespiratory conditions
 - Medically complex conditions
 - Other medical conditions
- **Interactions between primary medical condition category and SNF admission functional status**
 - **Prior Surgery: Major surgery during the 100 days prior to the SNF admission**
 - **Prior Functioning: Self-care**
 - Dependent
 - Some help
 - Independent, or unknown (reference category)
 - **Prior Functioning: Indoor ambulation**
 - Dependent or some help
 - Independent, or unknown (reference category)
 - **Prior Device Use: Walker use**
 - Yes
 - No, or unknown (reference category)

- **Prior Device Use: Wheelchair/scooter**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Mechanical lift**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Orthotics/prosthetics**
 - Yes
 - No, or unknown (reference category)
- **Presence of severe pressure ulcer at admission** (Stage 2 pressure ulcer)
- **Presence of severe pressure ulcer/injury at admission** (Stage 3, Stage 4 or Unstageable pressure ulcer/injury)
- **Cognitive Abilities: Brief Interview for Mental Status (BIMS) score**
 - Severely impaired
 - Moderately impaired
 - Intact (reference category)
- **Communication Impairment: Ability to express ideas and wants *and* Understanding verbal and non-verbal content**
 - Moderate to severe communication limitations: Rarely/never understands; or sometimes understands; or rarely/never understood; or speech is unclear; or sometimes understood
 - Mild to no communication limitations: Usually understands or understands; and Usually understood or understood; (reference category)
- **Urinary Continence**
 - Occasionally or frequently incontinent or always incontinent
 - Continent or no urine output (reference category)
- **Bowel Continence**
 - Occasionally or frequently incontinent or always incontinent
 - Continent (reference category)
- **Tube feeding or total parenteral nutrition**
- **Comorbidities (hierarchical condition categories):**
 - Major Infections: Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock; and Other Infectious Diseases
 - Metastatic Cancer and Acute Leukemia
 - Diabetes: Diabetes with Chronic Complications; Diabetes without Complication; Type I Diabetes Mellitus

- Other Significant Endocrine and Metabolic Disorders
- Delirium and Encephalopathy
- Dementia: Dementia With Complications; Dementia Without Complications
- Tetraplegia (excluding complete tetraplegia) and paraplegia
- Multiple Sclerosis
- Parkinson’s and Huntington’s Diseases
- Angina Pectoris
- Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease
- Hemiplegia, Other Late Effects of Cerebrovascular Accident: Hemiplegia/Hemiparesis; Late Effects of Cerebrovascular Disease, Except Paralysis
- Dialysis Status and Chronic Kidney Disease - Stage 5
- Urinary Obstruction and Retention
- Amputations: Traumatic Amputations and Complications; Amputation Status, Lower Limb/Amputation Complications; Amputation Status, Upper Limb

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

1. Sum the scores of the discharge self-care items to create a discharge self-care score for each resident, after ‘activity not attempted’ codes are recoded to 1 (score range: 7 to 42). This is the resident’s observed discharge score.
2. Calculate an expected discharge self-care score for each SNF resident using a statistical model that estimates the average effect of the risk adjustors (resident demographic and admission clinical characteristics) across all SNFs.
3. Identify the stay-level records of residents who meet the exclusion criteria and exclude them from analyses.
4. Compare each resident’s observed and expected discharge self-care score and classify the difference as
 - a. Observed discharge score is equal to or higher than the expected discharge score, or
 - b. Observed discharge score is lower than the expected discharge score.
5. Sum the number of residents whose observed discharge score is the same as or higher than the expected discharge score. This is the numerator.
6. The denominator is the total number of residents in the SNF who do not meet the exclusion criteria.
7. The percent is calculated as the numerator divided by the denominator and then multiplied by 100.

Section 6: An Application of the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NOF #2636)

Measure Description

This proposed quality measure estimates the percentage of SNF residents who meet or exceed an expected discharge mobility score.⁵⁷

Purpose/Rationale for the Quality Measure

As noted above, SNFs provide rehabilitation services to many residents with a goal of improving resident functioning. This is the fourth quality measure being proposed to meet the requirements of the IMPACT Act, addressing the domain of functional status, cognitive function, and changes in function and cognitive function.

Denominator

The denominator is the number of SNF Medicare Part A resident stays, except those that meet the exclusion criteria.

Denominator Exclusions

This proposed quality measure has 6 exclusion criteria:

1. Residents with incomplete stays.

Rationale: It can be challenging to gather accurate discharge functional status data for residents who experience incomplete stays. Residents with incomplete stays include residents who are unexpectedly discharged to an acute care setting (Short-stay Acute Hospital, Critical Access Hospital, Inpatient Psychiatric Facility, or Long-term Care Hospital), because of a medical emergency; residents who die or leave a SNF against medical advice; residents discharged directly to another SNF; and residents with a length of stay of less than 3 days.

2. Residents with the following medical conditions: coma; persistent vegetative state; complete tetraplegia; locked-in syndrome; severe anoxic brain damage, cerebral edema, or compression of brain.

Rationale: These residents are excluded because they may have limited or less predictable improvement with the selected mobility items.

3. Residents younger than 21 years.

Rationale: There is only limited evidence published about functional outcomes for individuals younger than 21 years.

4. Residents discharged to hospice.

Rationale: Resident goals may change during the IRF stay.

5. Residents who are not Medicare Part A beneficiaries.

Rationale: For the SNF QRP, MDS data are submitted for Medicare Part A beneficiaries.

⁵⁷ Please note that critical access hospital with swing beds are exempt from the SNF PPS and are not required to submit quality data under the SNF QRP by means of the MDS per the requirements set forth by the IMPACT Act.

6. Residents who do not receive physical or occupational therapy services.

Rationale: The focus of this proposed measure is functional improvement for residents admitted to the SNF with an expectation of functional improvement due to skilled services, including physical and occupational therapy. Some SNF residents may receive skilled care, but not physical or occupational therapy services, and these residents are not included in the measure calculation.

Numerator

The numerator is the number of Medicare Part A residents in an SNF, except those that meet the exclusion criteria, with a discharge mobility score that is equal to or higher than a calculated expected discharge mobility score.

Items Included in the Quality Measure

For the proposed quality measure, the following functional activities are assessed and rated at the time of admission and discharge:

Mobility Items

GG0170A. Roll left and right: The ability to roll from lying on back to left and right side, and roll back to back on the bed.

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

GG0170C. 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, no back support.

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

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

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

GG0170G. Car transfer: The ability to transfer in and out of a car or van on the passenger side. Does not include the ability to open/close door or fasten seat belt.

GG0170I. Walk 10 feet: Once standing, the ability to walk at least 10 feet (3 meters) in room, corridor, or similar space.

GG0170J. Walk 50 feet with two turns: The ability to walk 50 feet and make two turns.

GG0170K. Walk 150 feet (45 m): Once standing, the ability to walk at least 150 feet (45 meters) in corridor or similar space.

GG0170L. Walking 10 feet on uneven surfaces: The ability to walk 10 feet on uneven or sloping surfaces (indoor or outdoor), such as turf or gravel.

GG0170M. 1 step (curb): The ability to step over a curb and/or up and down one step.

GG0170N. 4 steps: The ability to go up and down four steps, with or without a rail.

GG0170O. 12 steps: The ability to go up and down 12 steps, with or without a rail.

GG0170P. Picking up object: The ability to bend/stoop from a standing position to pick up a small object, such as a spoon from the floor.

Mobility Rating Scale: Codes and Code Definitions

- 06. Independent** – Resident completes the activity by himself/herself with no assistance from a helper.
- 05. Setup or clean-up assistance** – Helper sets up or cleans up; resident completes activity. Helper assists only prior to or following the activity.
- 04. Supervision or touching assistance** – Helper provides verbal cues and/or touching/steading and/or contact guard assistance as resident 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 resident’s 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 resident’s trunk or limbs and provides more than half the effort.
- 01. Dependent** – Helper does ALL of the effort. Resident does none of the effort to complete the task. Or, the assistance of 2 or more helpers is required for the resident to complete the activity.

If the activity was not attempted, code the reason:

- 07. Patient refused**
- 09. Not applicable** – Not attempted and the patient did not perform this activity prior to the current illness, exacerbation, or injury.
- 10. Not attempted due to environmental limitations** (e.g., lack of equipment, weather constraints)
- 88. Not attempted due to medical condition or safety concerns**

Risk Adjustment

Residents treated in SNFs vary in terms of primary medical condition, demographic characteristics, and co-existing conditions. Residents may also have different expected improvement in function on the basis of these factors. Therefore, this proposed outcome measure is risk adjusted. Risk adjustment controls for specific resident characteristics (e.g., age or diagnosis) that may affect residents’ outcomes when comparing facilities.

Initially, an extensive set of risk adjustment variables was selected on the basis of a review of the literature and empirical findings from the PAC PRD analyses⁵⁸ as well as input from TEPs convened by RTI.⁵⁹ Using this initial set of risk adjustment variables, we have been conducting regression analyses using the PAC PRD data to help identify the best set of risk adjustors on the basis of regression coefficients, statistical significance, sample sizes, and other indicators. Data on the reliability of CARE variables used for risk adjustment can be found in the report titled *The Development and Testing of the*

⁵⁸ Gage B, Morley M, Smith L, et al. Post-Acute Care Payment Reform Demonstration: Final Report Volume 4 of 4: RTI International;2012.

⁵⁹ RTI International. Summary of Feedback from the Technical Expert Panel on the Development of Cross - Setting Functional Status Quality Measures;2014.

The risk adjustors used for this proposed quality measure are the following:

- **Age group at SNF admission**
 - Younger than 54 years
 - 55 to 64 years
 - 65 to 74 years (reference category)
 - 75 to 84 years
 - 85 to 90 years
 - 90 years or older
- **Admission mobility function score: continuous score**
- **Admission mobility function score: squared form**
- **Primary medical condition category**
 - Stroke
 - Non-traumatic brain dysfunction and Traumatic brain dysfunction
 - Non-traumatic spinal cord dysfunction
 - Traumatic spinal cord dysfunction
 - Progressive neurological conditions
 - Other neurological conditions
 - Amputation
 - Hip and knee replacements (reference category)
 - Fractures and other multiple trauma
 - Other orthopedic conditions
 - Debility and cardiorespiratory conditions
 - Medically complex conditions
 - Other medical conditions
- **Interaction of primary medical condition and admission mobility score**
- **Prior Surgery: Major surgery during the 100 days prior to the SNF admission**
- **Prior Functioning: Indoor Mobility (ambulation)**
 - Dependent
 - Some help

⁶⁰ Gage B, Smith L, Ross J, et al. The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing Volume 2 of 3; RTI International;2012.

- Independent, or unknown (reference category)
- **Prior Functioning: Stairs**
 - Dependent
 - Some help
 - Independent, or unknown (reference category)
- **Prior Functioning: Functional Cognition**
 - Dependent
 - Independent, some help, or unknown (reference category)
- **Prior Device Use: Walker**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Wheelchair/scooter**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Mechanical lift**
 - Yes
 - No, or unknown (reference category)
- **Prior Device Use: Orthotics/prosthetics**
 - Yes
 - No, or unknown (reference category)
- **Communication Impairment: Ability to express ideas and wants *and* Understanding verbal and non-verbal content**
 - Moderate to severe communication impairment: Rarely/never understands; or sometimes understands; or rarely/never understood; or speech is unclear or sometimes understood.
 - Mild communication impairment: Usually understands or usually understood
 - No communication impairment (reference category)
- **Cognitive Abilities: Brief Interview for Mental Status (BIMS) score:**
 - Severely impaired
 - Moderately impaired
 - Intact (reference category)
- **Urinary Continence**
 - Occasionally or frequently incontinent, or always incontinent
 - Continent or no urine output (reference category)

- **Bowel Continence**
 - Always incontinent
 - Occasionally or frequently incontinent Continent (reference category)
- **Presence of stage 2 pressure ulcer at admission**
- **Presence of severe pressure ulcer/injury at admission** (Stage 3, Stage 4, or Unstageable pressure ulcer/injury)
- **Tube feeding or total parenteral nutrition**
- **History of Falls: history of one or more falls in the 6 months prior to admission**
- **Comorbidities (hierarchical condition categories)**
 - Central nervous system (CNS) Infections: Bacterial, Fungal, and Parasitic Central Nervous System Infections; Viral and Late Effects Central Nervous System Infections
 - Other Infectious Diseases (HCC 7)
 - Metastatic Cancer and Acute Leukemia
 - Lymphoma and Other Cancers
 - Other Major Cancers: Colorectal, Bladder, and Other Cancers; Other Respiratory and Heart Neoplasms; Other Digestive and Urinary Neoplasms; Other Neoplasms
 - Dementia: Dementia With Complications; Dementia Without Complications
 - Mental Health Disorders: Schizophrenia; Major Depressive, Bipolar, and Paranoid Disorders; Reactive and Unspecified Psychosis; Personality Disorders
 - Tetraplegia (excluding complete tetraplegia) and paraplegia
 - Multiple Sclerosis
 - Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease
 - Hemiplegia/Other Late Effects of Cerebrovascular Accident: Hemiplegia/Hemiparesis; Late Effects of Cerebrovascular Disease, Except Paralysis
 - Aspiration, Bacterial, and Other Pneumonias: Aspiration and Specified Bacterial Pneumonias; Pneumococcal Pneumonia, Empyema, Lung Abscess
 - Legally Blind
 - Dialysis Status and Chronic Kidney Disease - Stage 5
 - Chronic Kidney Disease - Stages 1-4, Unspecified: Chronic Kidney Disease, Severe (Stage 4); Chronic Kidney Disease, Moderate (Stage 3); Chronic Kidney Disease, Mild or Unspecified (Stages 1-2 or Unspecified)
 - Major Fracture, Except of Skull, Vertebrae, or Hip
 - Amputations: Traumatic Amputations and Complications; Amputation Status, Lower Limb/Amputation Complications; Amputation Status, Upper Limb

Quality Measure Calculation Algorithm

The following steps are used to calculate the measure:

1. Sum the scores of the discharge mobility items to create a discharge mobility score for each resident, after 'activity not attempted' values are recoded to 1 (score range: 15 to 90). This is the resident's observed discharge score.
2. Calculate an expected discharge mobility score for each SNF resident using a statistical model that estimates the average effect of the risk adjustors (resident demographic and admission clinical characteristics) across all SNFs.
3. Identify the stay-level records of residents who meet the exclusion criteria and exclude them from analyses.
4. Compare each resident's observed and expected discharge mobility score and classify the difference as
 - a. Observed discharge score is equal to or higher than the expected discharge score, or
 - b. Observed discharge score is lower than the expected discharge score.
5. Sum the number of residents whose observed discharge score is the same as or higher than the expected discharge score. This is the numerator.
6. The denominator is the total number of residents in the SNF who do not meet the exclusion criteria.
7. The percent is calculated as the numerator divided by the denominator and then multiplied by 100.

Section 7: Measure updates for Potentially Preventable 30-Day Post-Discharge Measure for SNF QRP

The Potentially Preventable 30-Day Post-Discharge Readmission Measure for SNF QRP was adopted in the FY 2017 SNF PPS Final Rule (81 FR 52030 through 52034). The measure specifications for this measure can be found at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Measure-Specifications-for-FY17-SNF-QRP-Final-Rule.pdf>.

CMS is proposing to make the following modifications to the years of data and public reporting dates for this measure.

- We propose to increase the measurement period for this measure from one year to two years. This change will increase the number of SNFs with 25 stays or more, which is the minimum number of stays required for public reporting. Furthermore, this modification will align the SNF measure more closely with the IRF and LTCH post-discharge PPR measures developed to meet the IMPACT Act requirements, which are calculated on two consecutive years of data.
- For public reporting of this measure, we also propose to shift this measure from calendar year to fiscal year, beginning with publicly reporting on claims data for discharges in fiscal years 2016 and 2017.

Section 8: Measure Update for Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

The Discharge to Community-Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) measure was adopted in the FY 2017 SNF PPS Final Rule (81 FR 52021 through 52029). The specifications for this measure can be found at:

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Measure-Specifications-for-FY17-SNF-QRP-Final-Rule.pdf>.

CMS is proposing a modification to the measurement period for public reporting of this measure. We propose to shift this measure from calendar year to fiscal year, beginning with public reporting of claims data for discharges in fiscal year 2017.

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Chapter 3

Standardized Data Elements

Section 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 SNF QRP.

Section 2: Functional Status

Beginning with the FY 2020 SNF 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), that we finalized in the FY 2016 SNF PPS final rule (80 FR 46444 through 46453), also 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 quality measure, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

Section 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.⁶¹ 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.⁶² 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.^{64 65 66} 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.

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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- ⁶¹ 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>
- 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 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).
- ⁶⁴ Casey, D. A., Antimisiaris, D., & O’Brien, J. (2010). Drugs for Alzheimer’s disease: are they effective? *Pharmacy and Therapeutics* 35(4): 208.
- ⁶⁵ 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.
- ⁶⁶ 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).

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 SNFs

The BIMS is currently a central component of the cognitive function data elements submitted by SNF providers through the MDS 3.0 and, as a screening tool, has been shown to accurately predict formal diagnoses of impaired cognitive function in nursing homes.⁶⁷ The assessment of cognitive function in SNF residents is essential due to the substantial number of residents affected by cognitive impairments and its potential to impact care, health, and cost outcomes. BIMS data from the PAC PRD⁶⁸ show that approximately 33 percent of Medicare FFS SNF residents are moderately to severely cognitively impaired. Furthermore, the BIMS has been shown to be an efficient assessment that is feasible to administer under the time constraints faced by NH staff, and suitable for use by all levels of staff that contribute to resident assessment, including paraprofessionals.⁶⁹ Results of the BIMS' screening for cognitive impairment can be used to initiate appropriate therapy in a timely fashion, to establish a baseline for identifying changes in cognitive function over time, and to inform staff about a resident's ability to understand and participate in treatments during their stay and about what supports and services will likely be needed at the time of discharge. The standardized assessment of cognitive function using the BIMS data elements would provide important information for care planning, care transitions, patient safety, and resource use in SNFs.

⁶⁷ MacDougall EE, Mansbach WE, Clark K, Mace RA. (2014). The brief cognitive assessment tool (BCAT): cross-validation in a community dwelling older adult sample. *Int Psychogeriatr.* 1-8.

⁶⁸ 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.

⁶⁹ Saliba D, Buchanan J, Edelen MO, et al. (2012). MDS 3.0: Brief Interview for Mental Status. *J Am Med Dir Assoc* 13(7):611-617.

Proposed Data Elements for the Assessment of Cognitive Function: The BIMS

Section C		Cognitive Patterns	
C0100. Should Brief Interview for Mental Status (C0200-C0500) be Conducted?			
Attempt to conduct interview with all residents			
Enter Code	<input type="checkbox"/>	0. No (resident is rarely/never understood) → Skip to and complete C0700-C1000, Staff Assessment for Mental Status	
	<input type="checkbox"/>	1. Yes → Continue to C0200, Repetition of Three Words	
Brief Interview for Mental Status (BIMS)			
C0200. Repetition of Three Words			
Enter Code	<input type="checkbox"/>	Ask resident: "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 first attempt	
	<input type="checkbox"/>	0. None	
	<input type="checkbox"/>	1. One	
	<input type="checkbox"/>	2. Two	
	<input type="checkbox"/>	3. Three	
After the resident's first attempt, repeat the words using cues ("sock, something to 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)			
Ask resident: "Please tell me what year it is right now."			
Enter Code	<input type="checkbox"/>	A. Able to report correct year	
	<input type="checkbox"/>	0. Missed by > 5 years or no answer	
	<input type="checkbox"/>	1. Missed by 2-5 years	
	<input type="checkbox"/>	2. Missed by 1 year	
	<input type="checkbox"/>	3. Correct	
Ask resident: "What month are we in right now?"			
Enter Code	<input type="checkbox"/>	B. Able to report correct month	
	<input type="checkbox"/>	0. Missed by > 1 month or no answer	
	<input type="checkbox"/>	1. Missed by 6 days to 1 month	
	<input type="checkbox"/>	2. Accurate within 5 days	
Ask resident: "What day of the week is today?"			
Enter Code	<input type="checkbox"/>	C. Able to report correct day of the week	
	<input type="checkbox"/>	0. Incorrect or no answer	
	<input type="checkbox"/>	1. Correct	
C0400. Recall			
Ask resident: "Let's go back to an earlier question. What were 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.			
Enter Code	<input type="checkbox"/>	A. Able to recall "sock"	
	<input type="checkbox"/>	0. No - could not recall	
	<input type="checkbox"/>	1. Yes, after cueing ("something to wear")	
	<input type="checkbox"/>	2. Yes, no cue required	
Enter Code	<input type="checkbox"/>	B. Able to recall "blue"	
	<input type="checkbox"/>	0. No - could not recall	
	<input type="checkbox"/>	1. Yes, after cueing ("a color")	
	<input type="checkbox"/>	2. Yes, no cue required	
Enter Code	<input type="checkbox"/>	C. Able to recall "bed"	
	<input type="checkbox"/>	0. No - could not recall	
	<input type="checkbox"/>	1. Yes, after cueing ("a piece of furniture")	
	<input type="checkbox"/>	2. Yes, no cue required	
C0500. BIMS Summary Score			
Enter Score	<input type="text"/>	Add scores for questions C0200-C0400 and fill in total score (00-15)	
	<input type="text"/>	Enter 99 if the resident 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 also demonstrated feasibility of the BIMS for use in SNFs and found evidence of strong reliability of the BIMS data elements in the SNF setting. In addition, the BIMS data elements were also found to be predictive of cost.⁷⁰ The BIMS data

⁷⁰ 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.⁷¹ 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.⁷²

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.⁷³ 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 SNFs

The four-item Short CAM is currently used, in combination with other data elements, to assess SNF residents' mental status. The CAM allows trained facility staff to identify delirium with sensitivity and specificity, even in populations with a high prevalence of dementia.⁷⁴ As assessed in the PAC PRD using the CAM,⁷⁵ the following proportions of SNF residents showed the following signs or symptoms of delirium: 47.4 percent of residents in SNFs exhibited inattention; 34.9 percent had disorganized thinking; and 14.9 percent had an altered level of consciousness. Assessing mental status of SNF residents has several benefits, including establishing a baseline for recognizing changes in mental status, highlighting threats to patient safety (e.g., risk of falls), and helping clinicians to identify appropriate treatment and supports to be incorporated into care plans. SNF residents with delirium are more likely to experience new complications and be re-hospitalized, and less likely to be discharged to the community within 30 days.⁷⁶ The standardized assessment of cognitive impairment, including delirium and reversible confusion, using the Short CAM data elements would provide important information for care planning, care transitions, patient safety, and resource use in SNFs.

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

⁷¹ 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.

⁷² 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.

⁷³ 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.

⁷⁴ Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. (1990). Clarifying confusion: the confusion assessment method. A new method for detection of delirium. *Ann Intern Med.* 113(12):941-948.

⁷⁵ Unpublished data from the PAC PRD Public Comments sample, 2008-2010.

⁷⁶ Marcantonio, E. R., Kiely, D. K., Simon, S. E., Orav, E. J., et al. (2005). Outcomes of older people admitted to postacute facilities with delirium. *J of Am Geriatr Soc* 53(6): 963-969.

Proposed Data Elements for the Assessment of Cognitive Function: CAM

C1310. Signs and Symptoms of Delirium (from CAM[©])	
Code after completing Brief Interview for Mental Status or Staff Assessment, and reviewing medical record	
A. Acute Onset Mental Status Change	
Enter Code <input type="checkbox"/>	Is there evidence of an acute change in mental status from the resident's baseline? 0. No 1. Yes
Coding: 0. Behavior not present 1. Behavior continuously present, does not fluctuate 2. Behavior present, fluctuates (comes and goes, changes in severity)	↓ Enter Codes in Boxes <input type="checkbox"/>
	B. Inattention - Did the resident have difficulty focusing attention, for example, being easily distractible or having difficulty keeping track of what was being said? <input type="checkbox"/>
	C. Disorganized Thinking - Was the resident's thinking disorganized or incoherent (rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject)? <input type="checkbox"/>
	D. Altered Level of Consciousness - Did the resident have altered level of consciousness, as indicated by any of the following criteria? <ul style="list-style-type: none"> ■ 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 <input type="checkbox"/>
<small>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.</small>	

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.⁷⁷ The Short CAM was tested in the PAC PRD and found to be reliable across all four settings.⁷⁸ 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).⁷⁹

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 perfect. Overall average kappa ranged from 0.893 to 0.850 and items ranged from 0.784 to 0.902 (standard kappa).⁸⁰

Behavioral Signs and Symptoms

Behavior 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.

⁷⁷ Waszynski, C. M. (2007). How to try this: Detecting delirium. *AJN* 107(12): 50-59.

⁷⁸ 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.

⁷⁹ 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.

⁸⁰ 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>.

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 additional 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 SNFs

The Behavioral Signs and Symptoms data elements provide important information about resource use in SNFs. These symptoms may disrupt the living environment and impact the safety and privacy of other residents, caregivers, and staff. Among SNFs studied in the PAC PRD, 1.5 percent of SNF residents were physically aggressive towards others; 2.6 percent were verbally aggressive towards others; and 1.7 percent exhibited another concerning behavior towards themselves.⁸¹ The standardized assessment of behavioral disturbances with the Behavioral Signs and Symptoms data elements would provide useful information for care planning, resource use, and patient and staff safety in SNFs.

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

Behavioral Symptoms							
E0200. Behavioral Symptom - Presence & Frequency							
Note presence of symptoms and their frequency							
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	<div style="text-align: center;">↓ Enter Codes in Boxes</div> <table border="1" style="width: 100%;"> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>A. Physical behavioral symptoms directed toward others (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>B. Verbal behavioral symptoms directed toward others (e.g., threatening others, screaming at others, cursing at others)</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>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)</td> </tr> </table>	<input type="checkbox"/>	A. Physical behavioral symptoms directed toward others (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)	<input type="checkbox"/>	B. Verbal behavioral symptoms directed toward others (e.g., threatening others, screaming at others, cursing at others)	<input type="checkbox"/>	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)
<input type="checkbox"/>	A. Physical behavioral symptoms directed toward others (e.g., hitting, kicking, pushing, scratching, grabbing, abusing others sexually)						
<input type="checkbox"/>	B. Verbal behavioral symptoms directed toward others (e.g., threatening others, screaming at others, cursing at others)						
<input type="checkbox"/>	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

⁸¹ Unpublished data from the PAC PRD Public Comments sample, 2008-2010.

kappa)⁸². 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.

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 individuals in PAC were classified as having likely depression.⁸³ The prevalence varied from a low of 7 percent of beneficiaries in SNFs to a high of 11 percent in IRFs.⁸⁴

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.⁸⁵ 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.^{86 87}

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.

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.

⁸² 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>.

⁸³ 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.

⁸⁴ 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.

⁸⁵ 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.

⁸⁶ Scogin, F., & McElreath, L. (1994). Efficacy of psychosocial treatments for geriatric depression: a quantitative review. J Consult Clin Psychol 62(1):69-74.

⁸⁷ 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.

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).⁸⁸ 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 SNFs

Major depressive disorder is common in SNF residents, with a prevalence of 7.3 percent for SNFs, as assessed in the PAC PRD.⁸⁹ When signs and symptoms of depression are identified, treatments are available to alleviate suffering and improve clinical outcomes, prevent recurrence of symptoms, and improve quality of life. The PHQ-2 is a subset of the PHQ-9, which is currently used by SNF providers to screen for the signs and symptoms of depression. The PHQ-9 is reported in the MDS 3.0. The standardized assessment of screening for the signs and symptoms of depression using the PHQ-2 (which are the first two items in the PHQ-9) would provide important information for care planning, care transitions, and resource use in SNFs.

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

D0200. Resident Mood Interview (PHQ-9 [©])																						
Say to resident: "Over the last 2 weeks, have you been bothered by any of the following problems?"																						
If symptom is present, enter 1 (yes) in column 1, Symptom Presence.																						
If yes in column 1, then ask the resident: "About how often have you been bothered by this?"																						
Read and show the resident a card with the symptom frequency choices. Indicate response in column 2, Symptom Frequency.																						
1. Symptom Presence 0. No (enter 0 in column 2) 1. Yes (enter 0-3 in column 2) 9. No response (leave column 2 blank)	2. Symptom Frequency 0. Never or 1 day 1. 2-6 days (several days) 2. 7-11 days (half or more of the days) 3. 12-14 days (nearly every day)	<table border="1"> <thead> <tr> <th>1. Symptom Presence</th> <th>2. Symptom Frequency</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">↓ Enter Scores in Boxes ↓</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>	1. Symptom Presence	2. Symptom Frequency	↓ Enter Scores in Boxes ↓		<input type="checkbox"/>															
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A. Little interest or pleasure in doing things																						
B. Feeling down, depressed, or hopeless																						
C. Trouble falling or staying asleep, or sleeping too much																						
D. Feeling tired or having little energy																						
E. Poor appetite or overeating																						
F. Feeling bad about yourself - or that you are a failure or have let yourself or your family down																						
G. Trouble concentrating on things, such as reading the newspaper or watching television																						
H. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual																						
I. Thoughts that you would be better off dead, or of hurting yourself in some way																						
D0300. Total Severity Score																						
Enter Score	Add scores for all frequency responses in Column 2, Symptom Frequency. Total score must be between 00 and 27.																					
<input type="text"/>	Enter 99 if unable to complete interview (i.e., Symptom Frequency is blank for 3 or more items).																					

Note: This image shows the PHQ-9. The first two items of the PHQ-9 – A and B – comprise the PHQ-2, which are the data elements proposed for standardization across PAC settings.

⁸⁸ American Psychiatric Association. (1980). Diagnostic and Statistical Manual of Mental Disorders.
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.

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 depression and to assess depression severity.^{90 91} 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 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).^{92 93 94 95}

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- ⁹⁰ 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.
- ⁹¹ 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.
- ⁹² 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.
- ⁹³ 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.
- ⁹⁴ 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.
- ⁹⁵ 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.

96 97 98 99 100 101 102 103 104 105 106 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).¹⁰⁷ 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 0.988.¹⁰⁸ The PHQ-9 was also 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).¹⁰⁹

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- 96 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.
- 97 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.
- 98 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*, 2014.
- 99 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.
- 100 Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9. *J Gen Intern Med* 16(9): 606-613.
- 101 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.
- 102 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.
- 103 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.
- 104 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.
- 105 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.
- 106 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 cross-sectional study. *BMC Fam Practice* 11(1): 98.
- 107 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.
- 108 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>.
- 109 *Ibid.*

Section 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.

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.

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 SNFs

In one study using MDS data, approximately 1 in 10 nursing home residents were estimated to have a cancer affecting their health.¹¹⁰ However, chemotherapy is not a prevalent treatment for SNF residents. According to a RAND analysis of 2013 MDS data, 0.5 percent of SNF residents were receiving IV chemotherapy. Despite low prevalence of IV chemotherapy, this and other chemotherapy treatments are expensive and resource intensive. Therefore the standardized assessment of whether the resident is receiving chemotherapy would provide important information for care planning, clinical decision making, and resource use in SNFs.

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

Section 0		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 last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01		1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
		Check all that apply		
Cancer Treatments		↓	↓	↓
A. Chemotherapy (if checked, please specify below)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A2a. IV				<input type="checkbox"/>
A3a. Oral				<input type="checkbox"/>
A10a. Other				<input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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.

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.¹¹¹ 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.¹¹²

¹¹⁰ Johnson, V. M. P., Teno J. M., Bourbonniere, M., & Mor, V. (2005). Palliative Care Needs of Cancer Patients in U.S. Nursing Homes. *J of Pall Med* 8(2): 273-279.
¹¹¹ 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.
¹¹² 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>.

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.^{113 114} 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 SNFs

Radiation is an important therapy for particular types of cancer and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. According to a RAND analysis of 2013 MDS data, 0.3% of SNF residents were receiving radiation treatment. Despite low prevalence, assessment of radiation treatment upon admission to a SNF is important for coordinating special services, equipment, and staff required to deliver possible increase in intensity and quantity of skilled nursing care. Receipt of radiation therapy typically indicates a higher level of resident acuity. Therefore, the standardized assessment of whether the resident is receiving Radiation would provide important information for care planning, clinical decision making, and resource use in SNFs.

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

Section O Special Treatments, Procedures, and Programs			
O0100. Special Treatments, Procedures, and Programs - Continued			
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
	Check all that apply		
B. Radiation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

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.

¹¹³ Yamada, Y. (2009). Principles of Radiotherapy. In Cancer rehabilitation: principles and practice. Eds. Stubblefield Michael D. and O'dell Michael W.

¹¹⁴ National Cancer Institute. (2010). Radiation Therapy for Cancer. Available at <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/radiation-fact-sheet>

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 0.66.¹¹⁵

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 SNFs

A large portion of SNF residents receive oxygen therapy; a RAND analysis of 2013 MDS data found that 23.1 percent of SNF residents were on oxygen therapy. Residents with community-acquired pneumonia are routinely discharged to SNFs to complete their recovery. SNFs also have a high burden of residents with chronic obstructive pulmonary disease (COPD), particularly those who have severe COPD. Taken together, this indicates an increased burden and nursing need in SNFs for caring with residents with oxygen and other respiratory needs. The standardized assessment of whether a resident is receiving Oxygen Therapy would provide important information for care planning, clinical decision making, care transitions, and resource use in SNFs.

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>.

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 - Continued			
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
	Check all that apply		
Respiratory Treatments	↓	↓	↓
C. Oxygen Therapy (if checked, please specify below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C2a. Continuous			<input type="checkbox"/>
C3a. Intermittent			<input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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.¹¹⁶ 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.¹¹⁷ Oxygen therapy data elements during the last 14 days were shown to have reliabilities ranging from 0.81 to 0.87 in studies of MDS 2.0.¹¹⁸

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

¹¹⁶ 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.

¹¹⁷ 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>.

¹¹⁸ *Ibid.*

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 SNFs

A RAND analysis of 2013 MDS data found that 1.3 percent of SNF residents received suctioning. Suctioning is important to improve patient comfort, improve oxygenation, relieve mucus obstructions during respiratory infections, and to prevent aspiration pneumonias. Pneumonia itself is also a cause of excess secretions, which is a concern in the SNF setting: the attack rate for pneumonia is highest among those in nursing homes.¹¹⁹ One study found that 33 of 1,000 nursing home residents per year required hospitalization for treatment of pneumonia, compared with 1.14 of 1,000 elderly adults living in the community.¹²⁰ The standardized assessment of whether Suctioning is being performed for a resident would provide important information for care planning, clinical decision making, care transitions, and resource use in SNFs.

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

Section O		Special Treatments, Procedures, and Programs		
O0100. Special Treatments, Procedures, and Programs - Continued				
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission	
	Check all that apply			
D. Suctioning (if checked, please specify below)	↓	↓	↓	
D2a. Scheduled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D3a. As Needed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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

¹¹⁹ National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination. (2013). Chapter 8: Long-Term Care Facilities. <https://health.gov/hcq/pdfs/hai-action-plan-ltcf.pdf>

¹²⁰ Marik, P. E., and Kaplan D (2003). "Aspiration pneumonia and dysphagia in the elderly." CHEST Journal 124 (1):328-36.

data element was found feasible for cross-setting use in the PAC PRD.¹²¹ A checkbox for suctioning during the last 14 days was shown to have reliabilities of 0.89 and 0.775 in studies of MDS 2.0.¹²²

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.

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 SNFs

While only 1.3 percent of SNF residents received Tracheostomy Care,¹²³ maintenance and support of tracheostomies require increased resources, as above with suctioning, among other things. Residents with tracheostomies are at relatively high risk of hospital acquired infections or other complications, and require close monitoring to ensure that their tracheostomy is patent, enabling the resident to breathe or be mechanically ventilated through the tracheostomy. The standardized assessment of whether Tracheostomy Care is being performed for a resident would provide important information for care planning, clinical decision making, care transitions, and resource use in SNFs.

¹²¹ 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.

¹²² 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>.

¹²³ A RAND analysis of 2013 MDS data.

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

Section 0	Special Treatments, Procedures, and Programs		
00100. Special Treatments, Procedures, and Programs - Continued			
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
	↓ Check all that apply ↓		
E. Tracheostomy Care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

Current use

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 1.¹²⁴

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.

Assessment of this item will be accomplished by a new quality measure, “Spontaneous Breathing Trial (SBT),” which will be included in the Admission assessment only and will replace the assessment of invasive mechanical ventilation (weaning versus non-weaning) in the extant LCDS. The quality measure

¹²⁴ 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>.

will allow a more accurate and nuanced assessment of the patient’s candidacy for weaning from the ventilator, as well as document the steps taken to allow the patient a trial of spontaneous breathing, if appropriate. Specifically, the first subquestion of the item asks if the patient is on invasive mechanical ventilation support and, if yes, whether it is weaning or non-weaning support. If it is weaning, the next part of the item asks if the patient was assessed for readiness for SBT by day 2 of the LTCH stay. If deemed medically ready, the assessor documents if SBT was performed by day 2 of the LTCH stay and, if deemed medically unready for SBT by day 2, the item asks for documentation of the reason.

Relevance to SNFs

Although invasive mechanical ventilation is not common in the SNF setting, with less than one percent of residents on ventilator or respirator,¹²⁵ invasive mechanical ventilation is resource-intensive and can indicate the complexity of the resident’s underlying medical condition. The standardized assessment of whether the resident is on Invasive Mechanical Ventilation would provide important information for care planning, clinical decision making, care transitions, and resource use in SNFs.

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 - Continued				
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission	
	Check all that apply			↓
F. Invasive Mechanical Ventilator (ventilator or respirator)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Note: The checkbox in Column 3 is the data element being proposed for standardization.

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.

¹²⁵ RAND analysis of 2013 MDS data.

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.¹²⁶ A version of the item was tested in the MDS 3.0 National Evaluation Study and had perfect reliability (1.0).¹²⁷

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 SNFs

A RAND analysis of 2013 MDS data found that 2.8 percent of SNF residents received Non-invasive Mechanical Ventilation (BiPAP/CPAP). However, there is a trend of increased mechanical ventilation use in SNFs. One projection estimates that discharges to SNF for residents on mechanical ventilation can be expected to rise from 91,000 in year 2000 to nearly 220,000 by 2020.¹²⁸ A study on Medicare patients who were hospitalized for acute respiratory failure found that 23 percent were discharged into a nursing home or skilled nursing facility.¹²⁹ In fact, skilled nursing facilities also may be a better setting for weaning from mechanical ventilation. A study on 1,127 patients in seven Florida locations found that “a number of patients can be weaned from mechanical ventilation via tracheostomy in Skilled Nursing Facilities even when these patients were deemed unweanable in the acute care and/or LTACs [Long-Term Acute Care hospitals].”¹³⁰ The standardized assessment of Non-Invasive Mechanical Ventilation, including BiPAP and CPAP, would provide important information for care planning, care transitions, and resource use in SNFs.

¹²⁶ 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.

¹²⁷ 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>.

¹²⁸ Zilberberg, M., & Shorr, A. F. (2008). Prolonged acute mechanical ventilation and hospital bed utilization in 2020 in the United States: implications for budgets, plan and personnel planning. *BMC Health Serv Res* 8:242.

¹²⁹ Hajizadeh, N., Goldfeld, K., & Crothers, K. A. (2014). What happens to advanced stage COPD patients who get intubated for CPD exacerbation? A one-year retrospective follow up study of Medicare beneficiaries using CMS data. American Thoracic Society 2014 International Conference.

¹³⁰ Ferrer, G., Vallejo, I., & Casper, M (2016). Weaning from mechanical ventilation in skilled nursing facility: a multicenter study. *CHEST* 149(4 S)A536.

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 - Continued			
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
↓ Check all that apply ↓			
G. Non-invasive Mechanical Ventilator (BiPAP/CPAP) (if checked, please specify below) G2a. BiPAP G3a. CPAP	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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.¹³¹

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)

¹³¹ 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.

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.

Relevance to SNFs

A RAND analysis of 2013 MDS data found that 7.9 percent of SNF residents received IV Medications. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC; knowing not only whether or not residents are receiving IV medication but also the type of medication will be helpful in the SNF setting. The standardized assessment of IV Medications, including the type of medications, would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs.

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 - Continued				
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01		1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
		Check all that apply		
		↓	↓	↓
Other Treatments				
H. IV Medications (if checked, please specify below)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
H3a. Antibiotics				<input type="checkbox"/>
H4a. Anticoagulation				<input type="checkbox"/>
H10a. Other				<input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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 2.0.¹³²

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. Receipt of transfusions is also important to assess for case mix adjustment due to the need for added resources and to the extent that receipt of transfusions indicates a more medically complex patient.

Relevance to SNFs

One study found that 3.5 percent of residents had received a blood transfusion sometime during their stay at a SNF.¹³³ Knowing about prior transfusions is important for management as well, as transfusions require close monitoring due to possibility of infection or complications. Transfusions are resource-intensive, requiring coordination among the blood bank and bedside care staff, and close monitoring is necessary to prevent adverse reactions, which may range from mild to severe. The standardized assessment of whether the resident requires Transfusions would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs.

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 - Continued				
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission	
	Check all that apply			
I. Transfusions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Note: The checkbox in Column 3 is the data element being proposed for standardization.

Current use

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

¹³² 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>

¹³³ Rogers, M. A. M., Blumberg, N., Heal, J. M., Langa, K. M. (2011). Utilization of blood transfusion among older adults in the United States. *Transfusion* 51(4):710-718.

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.¹³⁴ 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 2.0.¹³⁵

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 removed 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 different facility, or, at a minimum, to a different part of the hospital if the LTCH is adjacent to a dialysis center. 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 SNFs

Currently, the MDS gathers information about dialysis, but it does not distinguish between the types of dialysis. According to a RAND analysis of 2013 MDS data, 3.0 percent of SNF residents received dialysis. Each type of dialysis (i.e., hemodialysis, peritoneal dialysis) has advantages and disadvantages: peritoneal dialysis (PD) can be done overnight, allowing the patients to spend daytime in other activities rather than traveling for hemodialysis, and it offers cost savings (about \$20,000 lower per year), though both kinds are covered by Medicare. It is important to track patients who receive this service because they are at risk for infection, and likely have chronic diseases that will require ongoing care. The standardized assessment of Dialysis (Hemodialysis, Peritoneal dialysis) would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs.

¹³⁴ 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>

¹³⁵ *Ibid.*

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

Section O	Special Treatments, Procedures, and Programs		
O0100. Special Treatments, Procedures, and Programs - Continued			
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
	↓ Check all that apply ↓		
J. Dialysis (if checked, please specify below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
J2a. Hemodialysis		<input type="checkbox"/>	<input type="checkbox"/>
J2b. Hemodialysis received in facility, in an ESRD certified unit		<input type="checkbox"/>	
J2c. Hemodialysis received in facility, not in an ESRD certified unit		<input type="checkbox"/>	
J2d. Hemodialysis received outside of facility		<input type="checkbox"/>	
J3a. Peritoneal dialysis		<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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).¹³⁶ Dialysis in the last 14 days was also shown to have almost perfect reliability (0.92 to 0.965) in studies of MDS 2.0.¹³⁷

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

¹³⁶ 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>

¹³⁷ *Ibid.*

potentially life-threatening events such as infection, air embolism, as well as bleeding from an open lumen.

Relevance to SNFs

In SNFs studied in the PAC PRD, 3.0 percent of residents were on central line management treatment,¹³⁸ one type of IV access. The standardized assessment of IV Access would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in SNFs. See “IV Medications” sections of this document for more information.

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 - Continued				
Check all of the following treatments, procedures, and programs that were performed during the last 14 days (columns 1 and 2) and during the first 3 days of admission (column 3) following the instructions for each column provided below				
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 14 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 14 DAYS. If resident last entered 14 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 14 days</i> 3. Performed during first 3 days of admission Complete only if A0310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission	
	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				<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Note: The checkboxes in Column 3 are the data elements being proposed for standardization.

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.

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 forms of nutrition, as

¹³⁸ 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.

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 care planning and case mix adjustment. 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 SNFs

Parental/IV feeding is not common in the SNF setting. However, this service is important for treating a population at risk for undernutrition, which is present in SNF residents: a 2015 review found that approximately 20 percent of nursing home residents had some form of malnutrition.¹³⁹ Another review of nursing home surveys found that for chronically institutionalized older people, from 5 to 18 percent of nursing home residents had energy intakes below need, and up to half of these individuals were underweight.¹⁴⁰ Malnutrition has been linked to development of pressure sores,¹⁴¹ and increases risk of mortality in or failure to return home from a SNF.¹⁴² The standardized assessment of Parenteral/IV Feeding would provide important information for care planning, care transitions, and resource use in SNFs.

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

K0510. Nutritional Approaches			
Check all of the following nutritional approaches that were performed during the last 7 days (Column 1 and Column 2) and during the first 3 days of admission (Column 3)			
1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission	
<p>Performed while NOT a resident of this facility and within the last 7 days. Only check column 1 if resident entered (admission or reentry) IN THE LAST 7 DAYS. If resident last entered 7 or more days ago, leave column 1 blank</p> <p>2. While a Resident Performed while a resident of this facility and within the last 7 days</p> <p>3. Performed during first 3 days of admission Complete only if AO310B = 01</p>			
Check all that apply			
↓	↓	↓	↓
A. Parenteral/IV feeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

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.

¹³⁹ Bell, C. L., Lee., A. S., & Tamura, B. K. (2015). Malnutrition in the nursing home. *Curr Opin Clin Nutr Metab Care* 18(1):17-23.

¹⁴⁰ Rudman, D., & Feller, A. G. (1989). Protein-calorie undernutrition in the nursing home. *J of Am Ger Soc* 37(2):173-183.

¹⁴¹ Shahin, E. S. M., Meijers, J. M. M., Schols, J. M. G. A., et al. (2010). The relationship between malnutrition parameters and pressure ulcers in hospitals and nursing homes. *Nutrition* 26(9): 886-889.

¹⁴² Hakkarainen, T. W., Arabi, S., Willis, M. M., Davidson, G. H., and Flum, D. R. (2016). Outcomes of patients discharged to skilled nursing facilities after acute care hospitalizations. *Ann Surg* 263(2):280-285.

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.¹⁴³ 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 2.0.¹⁴⁴

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 SNFs

Patients/residents with severe malnutrition are at higher risk for a variety of complications.¹⁴⁵ According to a RAND analysis of 2013 MDS data, 4.3 percent of SNF patients were on Enteral Nutrition treatment. The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in the SNF setting.¹⁴⁶ Additionally, the standardized assessment of enteral nutrition is useful for the purposes of care planning, care transitions, and resource use in SNFs, as enteral nutrition is most often used in medically complex patients and is a relatively resource-intensive feeding method, requiring frequent monitoring and administration.

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

K0510. Nutritional Approaches			
Check all of the following nutritional approaches that were performed during the last 7 days (Column 1 and Column 2) and during the first 3 days of admission (Column 3)			
1. While NOT a Resident	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
<p>Performed <i>while NOT a resident</i> of this facility and within the <i>last 7 days</i>. Only check column 1 if resident entered (admission or reentry) IN THE LAST 7 DAYS. If resident last entered 7 or more days ago, leave column 1 blank</p> <p>2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 7 days</i></p> <p>3. Performed during first 3 days of admission Complete only if AO310B = 01</p>			
Check all that apply			
	↓	↓	↓
B. Feeding tube - nasogastric or abdominal (e.g., PEG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

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

¹⁴³ 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>

¹⁴⁴ *Ibid.*

¹⁴⁵ Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). The link between nutritional status and clinical outcome: can nutritional intervention modify it? *Am J of Clinical Nutrition* 47(2): 352-356.

¹⁴⁶ McWhirter, J. P., & Pennington, C. R. (1994). Incidence and recognition of malnutrition in hospital. *BMJ*, 308(6934): 945-948.

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 2.0, the Feeding Tube data element, collected in the last 7 days, was also shown to have almost perfect reliability (0.98).¹⁴⁷

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 SNFs

Dysphagia is a common health care issue among nursing home residents and can lead to complications including aspiration pneumonia or death.^{148 149} While 40 percent to 60 percent of nursing home residents have clinical evidence of dysphagia,^{150 151} it may be even more common than recognized. In one study, 45 out of 82 nursing home residents were “found to have some degree of dysphagia,” but only 10 of those 45 had been referred to a specialist (speech pathologist or occupational therapist) previously.¹⁵² Many SNF residents have mechanically altered diets, which are used to facilitate oral intake among residents with signs and symptoms of swallowing disorders. Based on MDS 3.0 assessments in the third quarter of 2016, 34.2 percent of active nursing home residents received a mechanically altered diet nationally.¹⁵³ Although resident’s clinical condition may benefit from a mechanically altered diet, resident’s preferences and overall clinical goals should also be considered as these diets can also diminish an individual’s sense of dignity and self-worth and diminish pleasure from eating. Residents may also be inappropriately placed on a mechanically altered diet – one study found that while 31 percent of residents in two SNFs were prescribed a mechanically altered diet, most of them were able to eat at a higher level.¹⁵⁴ The standardized assessment of whether a SNF resident requires a

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 Marik, P.E., Kaplan, D. (2003). Aspiration pneumonia and dysphagia in the elderly. *Chest* 124(1):328-336.

¹⁴⁹ Tanner, D.C. (2010). Lessons from nursing home dysphagia malpractice litigation *J Gerontol Nurs* 36 (3):41-46.

¹⁵⁰ *Ibid.*

¹⁵¹ Carrau, R., Murry, T. (2006). Comprehensive management of swallowing disorders. San Diego: Plural 75-81.

¹⁵² Kayser-Jones, J. & Pengilly, K. (1999). Dysphagia among nursing home residents. *Geriatr Nurs* 20(2):77-82.

¹⁵³ CMS. (2016). MDS 3.0 Frequency Report. 2016 Third Quarter. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report.html> Accessed January 2017.

¹⁵⁴ Groher, M.E. & McKaig, T.N. (1995). Dysphagi and dietary levels in skilled nursing facilities. *J Am Geriatr Soc* 43(5):528-532.

mechanically altered diet would provide important information for care planning, care transitions, patient safety, and resource use in SNFs.

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

K0510. Nutritional Approaches			
Check all of the following nutritional approaches that were performed during the last 7 days (Column 1 and Column 2) and during the first 3 days of admission (Column 3)			
	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 7 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 7 DAYS. If resident last entered 7 or more days ago, leave column 1 blank 2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 7 days</i> 3. Performed during first 3 days of admission Complete only if AO310B = 01	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
	Check all that apply		
C. Mechanically altered diet - require change in texture of food or liquids (e.g., pureed food, thickened liquids)	↓ <input type="checkbox"/>	↓ <input type="checkbox"/>	↓ <input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

Current use

The Mechanically Altered Diet data element is currently collected in the MDS 3.0. It uses a 7-day look-back period to assess if a patient received a mechanically altered diet while a resident or before admission to the facility.

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).¹⁵⁵

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 SNF 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 SNFs

Therapeutic diets are often used to eliminate, reduce, or increase certain substances in the diet as part of the treatment for many conditions and are common among SNF residents. Currently, almost half (48.1%) of nursing home residents received a therapeutic diet nationally, according to the third quarter 2016 MDS 3.0 frequency report.¹⁵⁶ The standardized assessment of whether a resident requires a

¹⁵⁵ 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>.

¹⁵⁶ CMS. (2016). MDS 3.0 Frequency Report, 2016 Third Quarter. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report.html> Accessed January 2017.

Therapeutic Diet would provide important information for care planning, clinical decision making, care transitions, and resource use in SNFs.

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

K0510. Nutritional Approaches			
Check all of the following nutritional approaches that were performed during the last 7 days (Column 1 and Column 2) and during the first 3 days of admission (Column 3)			
1. While NOT a Resident Performed <i>while NOT a resident</i> of this facility and within the <i>last 7 days</i> . Only check column 1 if resident entered (admission or reentry) IN THE LAST 7 DAYS. If resident last entered 7 or more days ago, leave column 1 blank.	1. While NOT a Resident	2. While a Resident	3. Performed during first 3 days of admission
2. While a Resident Performed <i>while a resident</i> of this facility and within the <i>last 7 days</i>	Check all that apply		
3. Performed during first 3 days of admission Complete only if AO310B = 01	↓	↓	↓
D. Therapeutic diet (e.g., low salt, diabetic, low cholesterol)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note: The checkbox in Column 3 is the data element being proposed for standardization.

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).¹⁵⁷

¹⁵⁷ 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>

Section 5: Medical Conditions and Co-Morbidities

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), which was finalized for adoption into the SNF QRP in the FY 2016 SNF PPS final rule, and for the other PAC quality reporting programs in the, the FY 2014 IRF PPS final rule, FY 2014 IPPS/LTCH PPS final rule, and 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 Chapter 2, Section 2 of this document.

Section 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.

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)

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.¹⁵⁸ About 51 percent of nursing facility patients and residents are estimated to have moderate to severe hearing impairment.¹⁵⁹ 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.^{160 161}

¹⁵⁸ 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.

¹⁵⁹ 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.

¹⁶⁰ 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).

¹⁶¹ 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

Relevance to SNFs

Inadequate hearing is common among residents in SNFs. According to a study on hearing loss, 51 percent of nursing home residents had a moderate to severe loss.¹⁶² The assessment of hearing allows SNFs the opportunity to treat these impairments or improve the ability to hear (e.g., with devices), supporting better outcomes. Problems with hearing can contribute to sensory deprivation, social isolation, and mood and behavior disorders, and unaddressed communication problems related to hearing impairment can be mistaken for confusing or cognitive impairment.^{163 164 165 166} In addition, nursing home residents with better hearing are also likely to spend more time in occupational therapy than those with hearing impairment, which might help accelerate their recovery.¹⁶⁷ The standardized assessment of hearing in a resident would provide important information for communication, ensuring safety, care planning, care transitions, and resource use in SNFs.

Proposed Data Element for the Assessment of Impairments: Hearing

B0200. Hearing	
Enter Code	Ability to hear (with hearing aid or hearing appliances if normally used)
<input type="checkbox"/>	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 3.0 national test in nursing homes (weighted kappa = 0.938 and 0.894).¹⁶⁸ In MDS 2.0 testing, the Hearing data element showed moderate to good reliability (0.575 – 0.88).¹⁶⁹

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

- ¹⁶² Garahan, M.B., Waller, J.A., Houghton, M., Tisdale, W.A., Runge, C.F. (1992). Hearing Loss Prevalence and Management in Nursing Home Residents. *Journal of the American Geriatrics Society* 40(2):130-134.
- ¹⁶³ Cacciatore, F., Napoli, C., Abete, P. et al. (1999). Quality of life determinants and hearing function in an elderly population: Osservatorio Geriatrico Campano study group. *Gerontology* 45: 323-328.
- ¹⁶⁴ Carabellese, C., Appollonio, I., Rozzini, R. (1995). Sensory impairment and quality of life in a community elderly population. *J Am Geriatr Soc* 41:401-407.
- ¹⁶⁵ Lin, F. R., Metter, J., O'Brien, R. K., Resnick, S. M., et al. (2011). Hearing loss and dementia. *Arch Neurol* 68:214-220.
- ¹⁶⁶ Cohen-Mansfield, J. A., & Taylor, J. W. (2004). Hearing aid use in nursing homes Part I: prevalence rates of hearing impairment & hearing aid use. *JAMDA* 5:283-288.
- ¹⁶⁷ Cimarolli, V.R., Jung, S. (2016). Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc* 17(10):939-942.
- ¹⁶⁸ 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>.
- ¹⁶⁹ *Ibid.*

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.¹⁷⁰ 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.”¹⁷¹

Relevance to SNFs

Inadequate vision is common in residents in SNFs. Among nursing home residents, two studies have found 38 and 57 percent of residents experience visual impairment.^{172 173} The assessment of vision allows SNFs the opportunity to address these impairments or improve the ability to see, supporting better outcomes. Additionally, assessment of this information is useful for ensuring safety in the SNF setting, as impaired vision increases the risk of falls.^{174 175} If uncorrected, vision impairment can limit the enjoyment of everyday activities such as reading newspapers, books or correspondence, and maintaining and enjoying hobbies and other activities. The standardized assessment of vision in a resident would provide important information for patient safety, communication, care planning, care transitions, and resource use in SNFs.

Proposed Data Element for the Assessment of Impairments: Vision

B1000. Vision	
Enter Code <input type="checkbox"/>	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).

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- ¹⁷⁰ 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.
- ¹⁷¹ 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.
- ¹⁷² Owlsey, C., McGwin, G., Scilley, K., Meek, G. C., Dyer, A., Seker, D. (2007). The visual status of older persons residing in nursing homes. *Arch Ophthalmol* 127(7):925-930.
- ¹⁷³ West, S. K., Friedman, D., Muoz, B., et al. (2003). A randomized trial of visual impairment interventions for nursing home residents: study design, baseline, characteristics, and visual loss. *Ophthalmic Epidemiol* 10(3):193-209.
- ¹⁷⁴ Ivers, R. Q., Norton, R., Cumming, R. G., Butler, M., & Campbell, A. J. (2000). Visual impairment and risk of hip fracture. *Am J Epidemiol*. 152(7): 633-639.
- ¹⁷⁵ Freeman, E. E., Munoz, B., Rubin, G., West, S. K. (2007). Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci* 48(10): 4445-4450.

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 homes¹⁷⁶. 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).¹⁷⁷

¹⁷⁶ 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>.

¹⁷⁷ 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

Data Elements Used in Calculation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

SNF		IRF		LTCH	
M0300 – 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.	
Enter number <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C Stage 3	Enter number <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C Stage 3	Enter number <input type="text"/>	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C Stage 3
Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> Stage 2 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
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.	
Enter number <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number <input type="text"/>	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4
Enter number <input type="text"/>	2: Number of <u>these</u> 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 <input type="text"/>	2: Number of <u>these</u> Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number <input type="text"/>	2: Number of <u>these</u> Stage 3 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
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.	
Enter number <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number <input type="text"/>	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device

(continued)

SNF		IRF		LTCH	
Enter number <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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.
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.	
Enter number <input type="text"/>	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar	Enter number <input type="text"/>	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar	Enter number <input type="text"/>	1: Number of unstageable pressure ulcers/injuries due to non-removable dressing/device. If 0 skip to M0300F, Unstageable – Slough and/or eschar
Enter number <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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.
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.	
Enter number <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.
G. Unstageable - Deep tissue injury		G. Unstageable - Deep tissue injury		G. Unstageable - Deep tissue injury	
Enter number <input type="text"/>	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1030, Number of Venous and Arterial Ulcers	Enter number <input type="text"/>	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention	Enter number <input type="text"/>	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention
Enter number <input type="text"/>	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 <input type="text"/>	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 <input type="text"/>	2: Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.

(continued)

SNF Risk Adjustment Covariates	IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates
Functional Mobility Admission Performance		
<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Resident refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>	<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>	<p>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.</p> <p>06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent</p> <p>If activity was not attempted, code reason:</p> <p>07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns</p>
Bowel Continence		
<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated</p>	<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated</p>	<p>H0400. Bowel Continence</p> <p>0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated</p>
Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) or Diabetes		
<p>I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)</p> <p>0. Did not have PVD or PAD in the last 7 days 1. Had PVD or PAD in the last 7 days</p> <p>I2900. Diabetes Mellitus (DM)</p> <p>0. Did not have DM in the last 7 days 1. Had DM in the last 7 days</p>	<p>I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)</p> <p>0. Does not have PVD or PAD 1. Have PVD or PAD</p> <p>I2900. Diabetes Mellitus (DM)</p> <p>0. Does not have DM 1. Has DM</p>	<p>I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)</p> <p>0. Does not have PVD or PAD 1. Have PVD or PAD</p> <p>I2900. Diabetes Mellitus (DM)</p> <p>0. Does not have DM 1. Has DM</p>
Height and Weight (Low Body Mass Index)		
<p>K0200A (Height); and K0200B (Weight).</p>	<p>25A (Height); and 26A (Weight).</p>	<p>K0200A (Height); and K0200B (Weight).</p>

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Appendix 2
**Pressure Ulcer Quality Measure Item Standardization: Data
Elements Collected for Calculation of Quality Measures used in
SNF, LTCH, and IRF Quality Reporting Programs**

SNF, LTCH, and IRF PAC Settings: Items Collected at Discharge				
Item	Item Description	Proposed MDS 3.0 (effective 10/1/2018)	Proposed LTCH CARE Data Set v4.00 (effective 4/1/2018)	Proposed IRF-PAI v2.0 (effective 10/1/2018)
M0300	Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage			
<i>A</i>	Number of Stage 1 pressure ulcers	X	X	X
<i>B1</i>	Number of Stage 2 pressure ulcers	X	X	X
<i>B2</i>	Number of these Stage 2 pressure ulcers that were present upon admission	X	X	X
<i>C1</i>	Number of Stage 3 pressure ulcers	X	X	X
<i>C2</i>	Number of these Stage 3 pressure ulcers that were present upon admission	X	X	X
<i>D1</i>	Number of Stage 4 pressure ulcers	X	X	X
<i>D2</i>	Number of these Stage 4 pressure ulcers that were present upon admission	X	X	X
<i>E1</i>	Number of unstageable pressure ulcers/injuries due to non-removable dressing/device	X	X	X
<i>E2</i>	Number of these unstageable pressure ulcers/injuries that were present upon admission	X	X	X
<i>F1</i>	Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar	X	X	X
<i>F2</i>	Number of these unstageable pressure ulcers that were present upon admission	X	X	X
<i>G1</i>	Number of unstageable pressure injuries presenting as deep tissue injury	X	X	X
<i>G2</i>	Number of these unstageable pressure injuries that were present upon admission	X	X	X

X = Item is present

Appendix 3

Reliability and Validity of Items used to Calculate Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

The assessment items used in the quality measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury have undergone rigorous reliability and validity testing. The goal of reliability testing is to ensure that items on an assessment obtain consistent results when assessed by different individuals. Validity testing determines if an item measures what it intends to measure. Testing of pressure ulcer assessment items conducted across post-acute care settings indicated high inter-rater reliability of the items. In addition, testing showed that inclusion of unstageable pressure ulcers in the measure increased variability of scores in IRFs, LTCHs, and SNFs and may improve the ability of the measure to distinguish between high and low performing facilities. Also, support from Technical Expert Panels (TEP), the National Pressure Ulcer Advisory Panel (NPUAP), and public commenters offer construct validity. A brief summary of testing conducted on the pressure ulcer assessment items is provided below.

Item-Level Reliability Testing (MDS 3.0)

Item reliability for data elements assessing pressure ulcers, including unstageable pressure ulcers, was tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.¹⁷⁸ The project consisted of a representative sample of for-profit and not-for-profit facilities, and hospital-based and freestanding facilities, which included 71 community nursing facilities in 8 states and 19 Veterans Affairs (VA) nursing homes. The sample included 3,822 residents from community nursing homes and 764 residents from VA nursing homes. The RAND pilot test of the MDS 3.0 items showed good reliability and are applicable to the IRF-PAI as well as the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set because the items tested are the same as those used in the IRF-PAI and LTCH CARE Data Set. Furthermore, the MDS 3.0 testing results are appropriate to apply to the evaluation of the LTCH and IRF items because the items are identical across assessments, and there is significant overlap in the populations cared for by these providers. The short stay nursing home NQF endorsed measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), was endorsed by NQF to include the IRF and LTCH settings using this MDS data as evidence of reliability and validity.

Across the pressure ulcer items, average gold-standard to gold standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate “almost perfect” agreement using the Landis and Koch standard for strength of agreement.¹⁷⁹ We believe that the kappa statistics comparing gold-standard nurse to facility nurse responses should be sufficient for evaluation of the validity of these items as well. The results of this study are publicly available on the CMS website.

¹⁷⁸ Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0*. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf>.

¹⁷⁹ Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159-174.

More specifically, the RAND project found a high level of inter-rater reliability for assessment items used to calculate the pressure ulcer quality measure, including assessment items for unstageable pressure ulcers. The study included the following results¹⁸⁰:

- Number of existing stage 2 pressure ulcers: Kappa statistic = 0.993 (weighted)
- Number of stage 2 ulcers present on admission: Kappa statistic= 0.966 (weighted)
- Percent agreement for number of stage 3, stage 4, and nonstageable ulcers existing and present on admission was 100%

Item-Level Reliability Testing (CARE/PAC PRD)

Additional inter-rater reliability testing of pressure ulcer items similar to those used to calculate the quality measure in the IRF, LTCH and SNF settings was conducted as a part of the PAC PRD.¹⁸¹ For the pressure ulcer item “Does this patient have one or more unhealed pressure ulcer(s) at stage 2 or higher or unstageable?” The kappa score across all settings (acute, IRF, LTCH, SNF and HHA) was 0.845, indicating almost perfect agreement. Setting specific scores are presented below. Kappa statistics for IRF, LTCH, SNF and HHA ranged from 0.58 to 0.92 indicating “moderate” to “almost perfect” agreement.

For the pressure ulcer items collecting number of pressure ulcers present at assessment by stage, the kappa scores across all settings (acute, HHA, IRF, LTCH, SNF) were:

- Stage 2 Pressure Ulcers = 0.815
- Stage 3 Pressure Ulcers = 0.852
- Stage 4 Pressure Ulcers = 0.780

For the pressure ulcer item “Number of pressure ulcers present at admission by stage- Unstageable”, the kappa score across settings was 0.652, indicating substantial agreement. A setting specific score was only provided for the LTCH setting (kappa= 0.417, moderate agreement) as the sample size for most individual settings was too small to report (< 15).

Results of the PAC PRD study are publicly available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html>

Additional Testing

RTI performed additional testing of the measure to compare the performance of the measure with proposed changes to the measure as currently specified.¹⁸² Testing of the proposed measure, including adding unstageable pressure ulcers to the quality measure, increased performance scores in all settings

¹⁸⁰ Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0. Appendices*. Contract No. 500-00-0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from http://www.geronet.med.ucla.edu/centers/borun/Appendix_A-G.pdf

¹⁸¹ Smith, L., Deutsch, A., Hand, L., Etlinger, A., Ross, J., Abbate, J., Gage-Croll, Z., Barch, D., Gage, B. (2012, September). Continuity Assessment Record and Evaluation (CARE) Item Set: Additional Provider-Type Specific Interrater Reliability Analyses. Contract No. HHSM-500-2005-00291. Research Triangle Park, NC: RTI

¹⁸² Schwartz, M., Barch, D. H., Kaur, R., Pardasaney, P. K., Seibert, J. H., Kandilov, A. M., Frank, J. M., et al. (2016, January). The development of a cross-setting pressure ulcer measure: Addition of unstageable pressure ulcers and transition to M0300 items. Prepared for Centers for Medicare & Medicaid Services.

(with scores increasing by 0.1% in IRF settings and 1.7% in NH/SNF settings) and increased the variability of measures scores. This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing facilities. RTI presented the results of their findings during the July 18, 2016 TEP. Information regarding this study are also included in the TEP Summary Report.

Testing results by setting are as follows:

- In NH/SNFs for reporting period Q1 2012, the mean risk-adjusted score increased from the original measure of 1.8% to 3.5% when we transitioned to M0300 items and added unstageable pressure ulcer items to the measure.
- LTCH: In the mean LTCH risk-adjusted score increased from the original measure of 2.6% to 2.8% for reporting period Q2 2014 when we transition to M0300 items and add unstageable pressure ulcer items.
- IRF: The mean IRF risk-adjusted score increased from the original measure of 0.9% to 1.0% for reporting period Q1 2015 when we transition to M0300 items and add unstageable pressure ulcer items.

Construct Validity

A TEP meeting was held on July 18, 2016 to discuss potential changes to the measure, including changes in the data elements used to calculate the measure. During the TEP meeting, RTI presented analyses to show the impact of a transition to calculation of the measure using M0300/M1313 items and inclusion of unstageable pressure ulcers in the measure calculation. Overall, the TEP was supportive of the data element changes as well as inclusion of unstageable pressure ulcers in the measure calculation, indicating construct validity.

Specific feedback from TEP members regarding the potential transition to M0300/M1313 items is excerpted here:

Some TEP members expressed preference for the M0300 items over the M0800 items due to differences in wording. The M0800 items collect data on “worsening in pressure ulcer status,” while the M0300 items collect data on “current number of unhealed pressure ulcers.” One TEP member stated a preference for the neutral wording of the M0300 items over the M0800 items, which could potentially be interpreted to assign blame for the worsened pressure ulcers. Another TEP member stated a preference for the perceived clarity of the M0300 items, which collect both the current number of pressure ulcers and the number that were present on admission, over the M0800 items, which require the data abstracter to perform a mental calculation to determine the number of new or worsened pressure ulcers, thus providing an opportunity for error.

None of the TEP members stated preference of the use of M0800 items instead of M0300 items in calculation of the proposed quality measure and none of the members expressed objections to the modification. However, the TEP requested that consistent training across all post-acute care settings be made available to providers to support the proposed measure if implemented. The TEP summary report is publicly available and is soon to be available on CMS’ website.¹⁸³

¹⁸³ Seibert, J., Frank, J., Free, L., Waldron, D. (2016, December). Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs),

Also, prior cross-setting TEP meetings held in June and November 2013 yielded support for the inclusion of unstageable pressure ulcers in the quality measure. During these meetings, TEP members concurred that newly-acquired unstageable pressure ulcers, including suspected deep tissue injuries, should be captured in the quality measure for pressure ulcers. The TEP also advised that if a Stage 1 or 2 pressure ulcer becomes unstageable due to slough or eschar, it should be considered worsened in the quality measure for pressure ulcers. CMS and the measure development contractor received additional feedback from technical and clinical advisors and the National Pressure Ulcer Advisory Panel (NPUAP) in January 2014 supporting inclusion of unstageable pressure ulcers in the measure numerator.

Functional Mobility Risk Adjustment in SNF

Since the IMPACT Act requires submission of standardized assessment data, there is a need to standardize risk adjustment for the measure Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury across settings. In the SNF setting, G0110A1 is used to measure limitations in bed mobility in the pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). However, in the proposed measure, the risk adjuster item G0110A1. Activities of Daily Living (ADL) Assistance: Bed Mobility Self-Performance will be replaced with the item GG0170C. Mobility: Lying to Sitting on Side of Bed for the SNF setting measure in order to align with the risk adjuster items used in the LTCH and IRF setting measures. Using data from SNF discharges between October 1, 2016 through December 15, 2016, RTI conducted testing on the comparability of assessment items G0110A1 and GG0170C. Testing results indicate high concordance for those coded as high risk for limitations in bed mobility using both items at 93.85 percent. Overall concordance for high and low risk for limitations in bed mobility using both items was 89.45 percent. The correlation between the G0110A1 and GG0170C assessment items in the SNF population was found to be of medium effect, according to Cohen's standard (Spearman coefficient=0.324).

Additional testing was conducted to provide a comparison of incidence of new or worsened pressure ulcers according to how residents are characterized using the different bed mobility items: G0110A1 and GG0170C. The percent of individuals who had a new or worsened pressure ulcer and were coded as high risk for limitations in bed mobility using the item G0110A1 was 3.28, while the percent of individuals who had a new or worsened pressure ulcer and were coded as high risk for limitations in bed mobility using the item GG0170C was 3.35. Similar rates of new or worsened pressure ulcers among both groups indicates support for the replacement of G0110A1 with GG0170C to increase harmonization across settings.