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Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements

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RTI INTERNATIONAL

FINAL SPECIFICATIONS FOR LTCH QRP QUALITY MEASURES AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS

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Introduction

In this document, we present specifications for the standardized patient assessment data elements and the following three (3) measures finalized for adoption for the LTCH QRP through the FY 2018 IPPS/LTCH PPS final rule:

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Chapter 2
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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 measure finalized for the LTCH QRP:

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

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

Measure Description

This cross-setting quality measure reports the percentage 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. This measure is a cross-setting quality measure to meet the requirements of the IMPACT Act addressing the domain of skin integrity and changes in skin integrity. This cross-setting quality 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 standardized across the MDS 3.0, LTCH CARE Data Set, and IRF-PAI. 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. See **Appendix 1** for additional information about measure and data element reliability and validity.

Purpose/Rationale for the Quality Measure

This quality measure is finalized 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 are 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 finalized for FY 2018 federal rulemaking as: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. This measure is intended to encourage IRFs, LTCHs, and SNFs 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

[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.

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 IRFs, LTCHs, and SNFs 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 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]

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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.ihi.org/resources/pages/improvementstories/relievethepressureandreduceharm.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

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.

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. See **Appendix 2 and 3** for further information on pressure ulcer incidence in PAC settings.

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, 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 IRFs, LTCHs, or SNFs at discharge compared with admission using discharges from January through December 2015. 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. 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

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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.ihi.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.

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-patien

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

dressing/device, and 0.57 percent of new DTIs. See **Appendix 2 and 3** for further information on pressure ulcer incidence in PAC settings. 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 assessment instruments will be posted on the Web site at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-QRP-Manual.html

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 all-payer 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.

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[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.

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 4 and 5** for a summary of the M0300 items in instruments across settings, and **Appendix 6** for a summary of the items used for risk adjustment.

IRF Items:

- Items from the time of discharge are listed below. These items are used to calculate the measure:
  - 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 are listed below:
  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 and Weight at admission:

   25A (Height); and

   26A (Weight).

LTCH Items:

- Items from the planned or unplanned discharge assessment are listed below. These items are used to calculate the measure.
  - 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 admission assessment used to risk-adjust this quality measure are listed below:

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 are listed below. These items are used to calculate the measure.:
  - 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 are listed below:

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).

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, 07, 09, 10, 88] ([01] = Dependent, [02] =Substantial/maximal 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 = [03, 04, 05, 06, -, ^] **([03] =Partial/moderate assistance, [04] =Supervision or touching assistance**, [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 (BMI), based on height (25A) and weight (26A):

   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 = [0, 00, -] OR 26A = [-] ([-] = Not assessed/no information)

   Where: BMI = (weight * 703 / height^2) = ([26A] * 703) / (25A^2) 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, 07, 09, 10, 88] ([01] = Dependent, [02] =Substantial/maximal 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 = [03, 04, 05, 06, -, ^] **([03] =Partial/moderate assistance, [04] =Supervision or touching assistance**, [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:

   3. I0900 = [1] (checked)
   4. I2900 = [1] (checked)

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

4. Low body mass index (BMI), based on height (K0200A) and weight (K0200B) on the Admission assessment:

   Covariate = [1] (yes) if BMI ≥ [12.0] AND ≤ [19.0]

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

   Covariate = [0] (no) if K0200A = [0, 00, -] OR K0200B = [-] ([-] = Not assessed/ no information)

   Where: BMI = (weight * 703 / 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, 07, 09, 10, 88] ([01] = Dependent, [02] =Substantial/maximal 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 = [03, 04, 05, 06, -, ^] **([03] =Partial/moderate assistance, [04] =Supervision or touching assistance**, [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 (BMI), based on height (K0200A) and weight (K0200B):

Covariate = [1] (yes) if BMI ≥ [12.0] AND ≤ [19.0]

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

Covariate = [0] (no) if K0200A = [0, 00, -] OR K0200B = [-] ([-] = Not assessed/ no information)

Where: BMI = (weight * 703 / height^2) = ([K0200B] * 703) / (K0200A^2) 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 IRF setting, calculate the total number of stays with an IRF-PAI assessment 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 ending in the measure time window, which do not meet the exclusion criteria.

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.

Step 2. Calculate the numerator count:
In the IRF setting, calculate the total number of patient stays in the denominator whose IRF-PAI assessment indicates one or more new or worsened pressure ulcers at discharge compared to admission.

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

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.

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 assessment at admission for the LTCH and IRF settings or the PPS 5-Day assessment for the SNF setting, as described in the Risk Adjustment section above.

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

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

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 $\beta 0$ is the logistic regression constant, $\beta 1$ is the logistic regression coefficient for the first covariate, *COVA* is the patient/resident-level score for the first covariate, $\beta 2$ 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 (IRF, LTCH, and SNF) 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 IRF, LTCH, and SNF 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 in the denominator 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 (IRF, LTCH, and SNF) 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 = (Ln(Obs/(1–Obs)) - Ln(Exp/(1–Exp)) + Ln(Nat/(1–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.

Multiply the risk-adjusted score (Adj) by 100 and round the percent value to one decimal place. If the digit in the second decimal place is 5 or greater, add 1 to the first decimal place, otherwise leave the first decimal place unchanged. Drop all of the digits following the first decimal place.

Facility-level recoding instructions: If the facility-level observed score (step 3) equals 0, then the facility-level risk-adjusted percent is set to 0.0. If the facility-level observed score (step 3) equals 1, then the facility-level risk-adjusted percent is set to 100.0.

Section 3: Public Display Period Update for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, Discharge to Community-Post Acute Care LTCH QRP, and Medicare Spending Per Beneficiary-Post Acute Care LTCH QRP Measures

In the FY 2017 IPPS/LTCH PPS Final Rule, CMS adopted the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP (81 FR 57215 through 57219), Discharge to Community-PAC LTCH QRP measure (81 FR 57207 through 57215), and Medicare Spending Per Beneficiary-PAC LTCH QRP measure (81 FR 57199 through 57207). The specifications for the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP and Discharge to Community-PAC LTCH QRP measure can be found at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Measure-Specifications-for-FY17-LTCH-QRP-Final-Rule.pdf. The specifications for the Medicare Spending Per Beneficiary-PAC LTCH QRP measure can be found at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/2016_04_06_mspb_pac_measure_specifications_for_rulemaking.pdf.

As previously adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57233 through 57236), confidential feedback reports for these 3 claims-based measures will be based on calendar years 2015 and 2016 and data collected for discharges beginning January 1, 2015 through December 31, 2016. In the FY 2018 IPPS/LTCH PPS Final Rule, CMS finalized a modification to the measurement period for public display of these measures, shifting from a calendar year to fiscal year cycle, beginning with public reporting of claims data for discharges in fiscal years 2016 and 2017.

Chapter 3
Ventilator Weaning (Liberation) Measures Beginning with the FY 2020 LTCH QRP

This section describes final specifications for two ventilator weaning (liberation) quality measures for Long-Term Care Hospitals (LTCHs). The Centers for Medicare & Medicaid Services (CMS) solicits public comments on these quality measure specifications to inform ongoing quality measure development and implementation for the CMS LTCH Quality Reporting Program (QRP). The quality measures described in this section focus on ventilator weaning processes and outcomes.

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act required the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), to include quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures, such as alignment with the CMS Quality Strategy, which incorporates the three broad aims of the National Quality Strategy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

Invasive mechanical ventilation care was identified through technical expert panels and public comment periods as a gap in the LTCH QRP measure set and aligns with the National Quality Strategy Priority and the CMS Quality Strategy Goal of "promoting the most effective prevention and treatment practices" by reducing the risk of complications from unnecessarily prolonged mechanical ventilation.

Section 1: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay

Measure Description

This measure assesses facility-level compliance with Spontaneous Breathing Trial (SBT), including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) breathing trial, by Day 2 of the Long-Term Care Hospital (LTCH) stay for patients on invasive mechanical ventilation support upon admission, and for whom at admission weaning attempts were expected or anticipated. This measure is calculated and reported separately for the following two components:

Component 1, "Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay": the percentage of patients who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

Component 2, "Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay": the percentage of patients found ready for SBT (including TCT or CPAP breathing trial) for whom an SBT (including TCT or CPAP breathing trial) was performed by Day 2 of LTCH stay.

Patients included in Component 2 comprise a subset of the population in Component 1. While all patients admitted on invasive mechanical ventilation are included in the denominator for Component 1, only those patients who were found ready for SBT (including TCT and CPAP breathing trial) are included in the denominator for Component 2

Definitions

- **Invasive mechanical ventilation support** is defined as the use of a device to assist or control pulmonary ventilation, inclusive of the weaning period, either intermittently or continuously through a tracheostomy or by endotracheal intubation. Note: Lung expansion devices such as intermittent positive-pressure breathing (IPPB), nasal positive end-expiratory pressure (nasal PEEP), and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).
- **Day 1 of the LTCH stay** is the day of admission.
- **Day 2 of the LTCH stay** is defined as the second day of the patient's LTCH stay.
- **"Weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom weaning attempts are expected or anticipated at admission (e.g. patients admitted for the purpose of weaning).
- **"Non-weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom at admission weaning attempts are NOT expected or anticipated (*e.g.*, patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning *must* be based on documentation found in the patient's medical record at admission.
- **SBT** is a trial of unassisted breathing during the day and full ventilator support at night, administered to patients with endotracheal tubes. This includes TCT or CPAP breathing trial.
- **TCT** is a trial of unassisted breathing via a tracheostomy collar (mask) with aerosol (mist), administered to patients with tracheostomy tubes. TCT would apply only to patients with tracheostomy tubes.
- **CPAP breathing trial** is a trial of unassisted breathing for a certain period of time administered while the patient is wearing any type of continuous positive airway pressure respiratory support device that prevents the airways from closing by delivering slightly pressurized air through a mask continuously or via electronic cycling throughout the breathing cycle.
- **"Documentation"** indicates explicit physician, registered nurses, or respiratory therapist documentation of the reason that a patient was not deemed ready for SBT (including TCT or CPAP breathing trial) within the given time frame. Documentation must be dated by Day 2 of the LTCH stay.

Purpose/Rationale for the Quality Measure

This ventilator-related process quality measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay, is important for encouraging implementation of evidence-based weaning guidelines as early during the LTCH patient stay as is beneficial to patients, in order to decrease LTCH patient exposure to adverse ventilator-associated morbidity and mortality.

Patients on invasive mechanical ventilation comprise a substantial proportion of LTCH patient admissions, and thus present a critical focus for assessment of high quality care. In 2012, about 22,000 or 15.8% of all LTCH discharges received PMV services during the LTCH stay.[33]

Although often necessary for life support, invasive mechanical ventilation is not without risk of harm to patients, and these risks increase as duration of ventilation continues.[34, 35, 36] Studies have shown that invasive mechanical ventilation of critically ill patients is associated with higher rates of mortality[37] [38] [39]and morbidity, including ventilator-associated pneumonia,[40, 41, 42, 43, 44] ventilator-associated lung

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[33] MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.

[34] Boles, J. M., Bion, J., Connors, A., Herridge, M., Marsh, B., Melot, C., ... & Welte, T. (2007). Weaning from mechanical ventilation. European Respiratory Journal, 29(5), 1033-1056.

[35] Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

[36] Peñuelas, O., Frutos-Vivar, F., Fernández, C., Anzueto, A., Epstein, S. K., Apezteguía, C., ... & Desmery, P. (2011). Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation. American journal of respiratory and critical care medicine, 184(4), 430-437.

[37] Cox, C. E., & Carson, S. S. (2012, August). Medical and Economic Implications of Prolonged Mechanical Ventilation and Expedited Post–Acute Care. In Seminars in respiratory and critical care medicine (Vol. 33, No. 04, pp. 357-361). Thieme Medical Publishers.

[38] Esteban, A., Anzueto, A., Frutos, F., Alía, I., Brochard, L., Stewart, T. E., ... & Arroliga, A. C. (2002). Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA, 287(3), 345-355.

[39] Kahn, J. M., Benson, N. M., Appleby, D., Carson, S. S., & Iwashyna, T. J. (2010). Long-term acute care hospital utilization after critical illness. JAMA, 303(22), 2253-2259.

[40] Cook, D. J., Walter, S. D., Cook, R. J., Griffith, L. E., Guyatt, G. H., Leasa, D., ... & Brun-Buisson, C. (1998). Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients. Annals of internal medicine, 129(6), 433-440.

[41] Papazian, L., Bregeon, F., Thirion, X., Gregoire, R., Saux, P., Denis, J. P., ... & Gouin, F. (1996). Effect of ventilator-associated pneumonia on mortality and morbidity. American journal of respiratory and critical care medicine, 154(1), 91-97.

[42] Vincent, J. L., Bihari, D. J., Suter, P. M., Bruining, H. A., White, J., Nicolas-Chanoin, M. H., ... & Hemmer, M. (1995). The prevalence of nosocomial infection in intensive care units in Europe: results of the European Prevalence of Infection in Intensive Care (EPIC) Study. JAMA, 274(8), 639-644.

[43] Safdar, N., Dezfulian, C., Collard, H. R., & Saint, S. (2005). Clinical and economic consequences of ventilator-associated pneumonia: a systematic review. Critical care medicine, 33(10), 2184-2193.

[44] Buczko, W. (2009). Ventilator-associated pneumonia among elderly Medicare beneficiaries in long-term care hospitals. Health care financing review, 31(1), 1.

injury,[45, 46, 47] ventilator -induced diaphragm dysfunction,[48, 49] psychological distress[50, 51, 52] and post-traumatic stress disorder,[53] disability[54] and decreased functional status,[55, 56] and chronic critical illness syndrome.[57] Mechanical ventilation is also associated with increased costs. Studies in the ICU setting indicate that patients who require mechanical ventilation can have up to 50% higher costs than patients who do not receive mechanical ventilation.[58] Patients on prolonged ventilation (≥21 days) incur even greater health care costs; the estimated cost per one-year survival for patients who are ventilated for ≥ 21 days is $423,596.[59]

Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is associated with improved patient health outcomes. In LTCHs, fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications/events, enhanced rehabilitation opportunities, and

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45 Meade, M. O., & Cook, D. J. (1995). The aetiology, consequences and prevention of barotrauma: a critical review of the literature. Clinical Intensive Care, 6(4), 166-173.

46 Meade, M. O., Cook, D. J., Kernerman, P., & Bernard, G. (1997). How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury. Critical care medicine, 25(11), 1915-1922.

47 Slutsky, A. S., & Tremblay, L. N. (1998). Multiple system organ failure: is mechanical ventilation a contributing factor?. American journal of respiratory and critical care medicine, 157(6), 1721-1725.

48 Levine, S., Nguyen, T., Taylor, N., Friscia, M. E., Budak, M. T., Rothenberg, P., ... & Rubinstein, N. A. (2008). Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans. New England Journal of Medicine, 358(13), 1327-1335.

49 Demoule, A., Molinari, N., Jung, B., Prodanovic, H., Chanques, G., Matecki, S., ... & Jaber, S. (2016). Patterns of diaphragm function in critically ill patients receiving prolonged mechanical ventilation: a prospective longitudinal study. Annals of intensive care, 6(1), 75.

50 Rose, L., Nonoyama, M., Rezaie, S., & Fraser, I. (2014). Psychological wellbeing, health related quality of life and memories of intensive care and a specialised weaning centre reported by survivors of prolonged mechanical ventilation. Intensive and Critical Care Nursing, 30(3), 145-151.

51 Schou, L., & Egerod, I. (2008). A qualitative study into the lived experience of post-CABG patients during mechanical ventilator weaning. Intensive and Critical Care Nursing, 24(3), 171-179.

52 Rotondi, A. J., Chelluri, L., Sirio, C., Mendelsohn, A., Schulz, R., Belle, S., ... & Pinsky, M. R. (2002). Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. Critical care medicine, 30(4), 746-752.

53 Jubran, A., Lawm, G., Duffner, L. A., Collins, E. G., Lanuza, D. M., Hoffman, L. A., & Tobin, M. J. (2010). Post-traumatic stress disorder after weaning from prolonged mechanical ventilation. Intensive care medicine, 36(12), 2030-2037.

54 Barnato, A. E., Albert, S. M., Angus, D. C., Lave, J. R., & Degenholtz, H. B. (2011). Disability among elderly survivors of mechanical ventilation. American journal of respiratory and critical care medicine, 183(8), 1037-1042.

55 Scheinhorn, D. J., Hassenpflug, M. S., Votto, J. J., Chao, D. C., Epstein, S. K., Doig, G. S., ... & Petrak, R. A. (2007). Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. CHEST Journal, 131(1), 85-93.

56 Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

57 *Ibid.*

58 Dasta, J. F., McLaughlin, T. P., Mody, S. H., & Piech, C. T. (2005). Daily cost of an intensive care unit day: the contribution of mechanical ventilation. Critical care medicine, 33(6), 1266-1271.

59 Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

shorter LOS.[60] Ventilator liberation has been associated with lower post-discharge mortality, even among the elderly, [61, 62] and fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications/events, enhanced rehabilitation opportunities, and a shorter length of stay.[63] However, prior studies have shown that some physicians may underestimate the probability of weaning success.[64, 65] Based on studies and observations of implementation of regular assessment for SBTs and weaning protocols in ICUs, adherence to the recommended weaning processes, including prompt assessment of weaning readiness and initiation of SBTs, appears quite variable, likely due to differences in clinicians' intuitive thresholds for determination of patients' readiness to wean.[66 67] Clinician delays in recognizing that weaning may be possible and in beginning assessment of weaning readiness are two common causes of weaning delays.[68]

In 2005, an international task force convened and developed recommendations to address the entire weaning process. This task force recommended that weaning be considered as soon as possible,[69] because failure to assess the patient for readiness to wean may lead to undue prolonged mechanical ventilation,[70] thus exposing patients unnecessarily to adverse ventilator-associated morbidity and

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60 Hassenpflug, M., Vela, D., Sandoval, R., Nelson, D. R., Sasse, S. A., & Steckart, M. J. (2015). Post-ICU Mechanical Ventilation: Outcomes Of The Revised Therapist-Implemented Patient-Specific (TIPS©) Weaning Protocol. In B44. INVASIVE AND NON-INVASIVE MECHANICAL VENTILATION (pp. A3166-A3166). American Thoracic Society.

61 Dermot Frengley, J., Sansone, G. R., Shakya, K., & Kaner, R. J. (2014). Prolonged mechanical ventilation in 540 seriously ill older adults: effects of increasing age on clinical outcomes and survival. Journal of the American Geriatrics Society, 62(1), 1-9.

62 Stearn-Hassenpflug, M., Steckart, M., & Nelson, D. (2013). 678: Post-ICU Mechanical Ventilation: Trends in Mortality and 12-month Post-discharge Survival. Critical Care Medicine, 41(12), A166.

63 Hassenpflug, M., Vela, D., Sandoval, R., Nelson, D. R., Sasse, S. A., & Steckart, M. J. (2015). Post-ICU Mechanical Ventilation: Outcomes Of The Revised Therapist-Implemented Patient-Specific (TIPS©) Weaning Protocol. In B44. INVASIVE AND NON-INVASIVE MECHANICAL VENTILATION (pp. A3166-A3166). American Thoracic Society.

64 MacIntyre, N. R. (2013). The Ventilator Discontinuation Process: An Expanding Evidence BaseDiscussion. Respiratory care, 58(6), 1074-1086.

65 Strickland, J. H., & Hasson, J. H. (1993). A computer-controlled ventilator weaning system: a clinical trial. Chest, 103(4), 1220-1226.

66 MacIntyre, N. R. (2013). The Ventilator Discontinuation Process: An Expanding Evidence BaseDiscussion. Respiratory care, 58(6), 1074-1086.

67 Kollef, M. H., Shapiro, S. D., Silver, P., John, R. E. S., Prentice, D., Sauer, S., ... & Baker-Clinkscale, D. (1997). A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. Critical care medicine, 25(4), 567-574.

68 Boles, J. M., Bion, J., Connors, A., Herridge, M., Marsh, B., Melot, C., ... & Welte, T. (2007). Weaning from mechanical ventilation. European Respiratory Journal, 29(5), 1033-1056.

69 *Ibid.*

70 MacIntyre, N. R., Epstein, S. K., Carson, S., Scheinhorn, D., Christopher, K., & Muldoon, S. (2005). Management of patients requiring prolonged mechanical ventilation: report of a NAMDRC consensus conference. CHEST Journal, 128(6), 3937-3954.

mortality.[71] Evidence continues to support early patient assessment using weaning criteria and performance of a spontaneous breathing trial as soon as it medically appropriate for the patient.[72, 73, 74]

In a study of ventilator weaning in an LTCH by Jubran and colleagues,[75] 32% of newly admitted LTCH patients on invasive mechanical ventilation were able to breathe unassisted during the first 5 days following admission[76], suggesting that many ICU patients sent to LTCHs for "failure to wean" from the ventilator may not have undergone ventilator weaning attempts during the latter part of their stay in an ICU.[77] That a substantial portion of newly admitted LTCH patients could be weaned within 5 days underscores the need to assess patients' ability to breathe without assistance soon after admission, in order to identify individuals who are able to discontinue invasive mechanical ventilation.

Because invasive mechanical ventilation should be discontinued as soon as patients are capable of breathing independently,[78] unnecessarily prolonged mechanical ventilation can be an indicator of poor quality care.[79] This quality measure is designed to encourage adherence to evidence-based and consensus based guidelines through implementation of trials of unassisted breathing and early assessment of weaning criteria. The anticipated improvement in quality is an improvement in timeliness of weaning and ventilator liberation for patients admitted to LTCHs on invasive mechanical ventilation. Additionally, facilities can use results of this measure to improve early compliance with evidence-based weaning guidelines and develop ventilator weaning quality improvement programs.

Denominator

The target population for this measure is patients who were on invasive mechanical ventilation support upon admission to the LTCH, for whom weaning attempts were expected or anticipated at admission. If a patient has more than one LTCH stay during the reporting period, each discharge will be reported and included in the measure calculation. The denominator will be calculated separately according to each of the component groups below:

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71 Hess, D. R., & MacIntyre, N. R. (2011). Ventilator discontinuation: why are we still weaning?.

72 Frutos-Vivar, F., & Esteban, A. (2014). Our paper 20 years later: how has withdrawal from mechanical ventilation changed?. Intensive care medicine, 40(10), 1449-1459.

73 MacIntyre, N. R. (2013). The Ventilator Discontinuation Process: An Expanding Evidence BaseDiscussion. Respiratory care, 58(6), 1074-1086.

74 McConville, J. F., & Kress, J. P. (2012). Weaning patients from the ventilator. New England Journal of Medicine, 367(23), 2233-2239.

75 Jubran, A., Grant, B. J., Duffner, L. A., Collins, E. G., Lanuza, D. M., Hoffman, L. A., & Tobin, M. J. (2013). Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial. JAMA, 309(7), 671-677.

76 *Ibid.*

77 Kahn, J. M., & Carson, S. S. (2013). Generating evidence on best practice in long-term acute care hospitals. JAMA, 309(7), 719-720.

78 Blackwood, B., Alderdice, F., Burns, K., Cardwell, C., Lavery, G., & O'Halloran, P. (2011). Use of weaning protocols for reducing duration of mechanical ventilation in critically ill adult patients: Cochrane systematic review and meta-analysis. Bmj, 342, c7237.

79 MacIntyre, N. R. (2013). The Ventilator Discontinuation Process: An Expanding Evidence BaseDiscussion. Respiratory care, 58(6), 1074-1086.

- **Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay**

  The denominator for Component 1 is patients who were on invasive mechanical ventilation upon admission to an LTCH, for whom weaning attempts are expected or anticipated at admission.

- **Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay**

  The denominator for Component 2 is the subset of patients in the denominator of Component 1, who were assessed and deemed ready for SBT by Day 2 of the LTCH stay.

For patients with more than one LTCH stay during the reporting period, each admission and discharge is reported and included in the measure calculation. For example, if an LTCH patient is transferred to a short-stay acute care hospital for a procedure, surgery, or some other reason(s), returns to the LTCH within three (3) calendar days, and is subsequently discharged from the LTCH, this is considered one "patient stay." However, if this patient's "stay" at the short-stay acute care hospital exceeds three (3) calendar days, whereby day one begins on the day of transfer from the LTCH to the short-stay acute care hospital, regardless of the hour of transfer, then a new LTCH CARE Data Set Admission Assessment is conducted upon return of the patient to the LTCH, and a second LTCH CARE Data Set Discharge Assessment accompanies the second discharge. Admission and Discharge (Planned or Unplanned) Assessments are completed for this patient for the first stay, and Admission and Discharge (Planned or Unplanned) Assessments are completed for the second stay. Both stays for this patient are included in the measure calculation and reporting.

Denominator Exclusions

This measure (both Component 1 and Component 2) excludes patients with missing data and invasively mechanically ventilated patients identified as non-weaning at the time of admission to an LTCH. Patients who may be identified as non-weaning by LTCHs include patients who are considered chronically ventilated as defined by evidence-based guidelines for ventilator liberation[80] or patients with an acute or chronic condition that negates any expectation or anticipation of weaning attempts at admission (e.g., amyotrophic lateral sclerosis, or severe neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning must be based on documentation found in the patient's medical record.

After patient-level exclusions are applied, LTCHs with denominator counts of less than 20 in the sample during the reporting period will be excluded from public reporting, owing to small sample size.

Denominator exclusion details

Patients are excluded from the target population (i.e., denominator) if they meet either of the following criteria:

1. O0150A. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 0 (i.e., No, not on invasive mechanical ventilation support), OR:

[80] MacIntyre, N. R. (2001). Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. Chest Journal, 120(6_suppl), 375S-396S.

2. O0150A. Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 2, Yes, non-weaning (i.e., No weaning attempts are expected or anticipated at admission)

Numerator

The numerator represents patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay and, if deemed ready, who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

The numerator will be computed and reported separately according to each of the components below. Each component numerator is the number of patients in the following components:

Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of the LTCH Stay

The numerator represents the number of patients admitted on invasive mechanical ventilation during the reporting period who were assessed for readiness for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay

For the purpose of this measure component, a patient is considered in the numerator if the LTCH reports, on the LTCH CARE Data Set Admission Assessment, either of the following combinations of items:

O0150B = 1 (Yes) AND O0150C = 1 (Yes). Assessed for readiness for SBT by day 2 of the LTCH stay and Deemed medically ready for a SBT by day 2 of the LTCH stay.

OR

O0150B = 1 (Yes) AND O0150D= 1 (Yes): Assessed for readiness for SBT by day 2 of the LTCH stay and documentation of reason(s) that patient was deemed medically unready for a SBT by day 2 of the LTCH stay.

The sum of the numbers of patients in these two groups represents the number of patients admitted on invasive mechanical ventilation who were assessed for readiness for SBT by day 2 of the LTCH stay, as reported on the Admission Assessment.

Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay

The numerator represents the number of patients admitted on invasive mechanical ventilation during the reporting period who were ready for SBT and who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

For the purpose of this measure component, a patient is considered in the numerator if the LTCH reports on the LTCH CARE Data Set Admission Assessment item O0150E = 1 (Yes), SBT performed by day 2 of the LTCH stay.

Compliance with SBT (including TCT or CPAP breathing trial) by day 2 of LTCH stay is reported as a percentage and is calculated and reported for these two numerator components separately.

Items Included in the Quality Measure

For this quality measure, the following ventilator weaning items are assessed at the time of admission:

O0150	Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay
O0150A	Invasive Mechanical Ventilation Support upon Admission to the LTCH
O0150B	Assessed for readiness for SBT by day 2 of the LTCH stay
O0150C	Deemed medically ready for SBT by day 2 of the LTCH stay
O0150D	Is there documentation of reason(s) in the patient's medical record that the patient was deemed medically unready for SBT by day 2 of the LTCH stay?
O0150E	SBT performed by day 2 of the LTCH stay

Risk Adjustment

This measure is not risk-adjusted or stratified.

Quality Measure Calculation Algorithm

Component 1, Percentage of Patients Assessed for Readiness for SBT by Day 2 of LTCH Stay

$$= \frac{A + B}{C - D} x\ 100$$

where

A = Number of patients who were deemed ready for SBT by Day 2 of the LTCH Stay
B = Number of patients with documentation that the patient was deemed medically unready for SBT by Day 2 of the LTCH stay
C = All patients admitted on invasive mechanical ventilator support for any duration during the reporting period
D = Patients for whom weaning attempts were NOT expected or anticipated at admission

Steps for Calculation

1. Of patients admitted to the LTCH during the reporting period, identify all patients who were on invasive mechanical ventilation support upon admission to the LTCH. This is the target population.
2. Of patients identified in (1) above, identify the subset of patients for whom weaning attempts are not expected or anticipated at admission. These patients are excluded from the measure.
3. Of the patients identified in (1) above, identify the subset of patients for whom weaning attempts were expected or anticipated at admission. This is the denominator for Component 1 of the measure.
4. Of the patients identified in (3) above, identify the subset of patients who were found ready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.

5. Of the patients identified in (3) above, identify the subset of patients who were assessed and documented as being unready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay.
6. The numerator for Component 1 is the sum of the number of patients identified in (4) and (5) above.
7. Calculate the percentage of patients who were assessed for SBT by Day 2 of the LTCH stay by dividing the number of patients in (6) by the number of patients in (3).

Component 2, Percentage of Patients Ready for SBT Who Received SBT by Day 2 of LTCH Stay

$$= \frac{E}{F} x\ 100$$

where

E = Number of patients who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH Stay
F = Number of patients who were deemed ready for SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH Stay

1. The group of patients identified in (4) above is the denominator for Component 2 of the measure.
2. Of the patients identified in (8) above, identify the number of patients who received an SBT (including TCT or CPAP breathing trial) by Day 2 of the LTCH stay. This is the numerator for component 2 of the measure.
3. Divide the results of Step (9) by Step (8).

Section 2: Ventilator Liberation Rate

Measure Description

This measure reports facility-level Ventilator Liberation Rate for patients admitted to an LTCH requiring invasive mechanical ventilation support, *and* for whom weaning attempts were expected or anticipated as reported on the Admission Assessment. The Ventilator Liberation Rate is defined as the percentage of patients who are alive and fully liberated (weaned) at discharge.

Data will be collected using items added to the LTCH CARE Data Set Admission, Planned Discharge and Unplanned Discharge Assessments. A patient is considered fully liberated (weaned) if he or she does not require any invasive mechanical ventilation support for at least 2 consecutive calendar days immediately prior to the date of discharge.

Definitions

- **Invasive mechanical ventilation support** is defined as the use of a device to assist or control pulmonary ventilation, inclusive of the weaning period, either intermittently or continuously through a tracheostomy or by endotracheal intubation. Note: Lung expansion devices such as intermittent positive-pressure breathing (IPPB), nasal positive end-expiratory pressure (nasal PEEP), and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).
- **Day 1 of the LTCH stay** is the day of admission.
- **Day 2 of the LTCH stay** is defined as the second day of the patient's LTCH stay.
- **"Weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom weaning attempts are expected or anticipated at admission (e.g. patients admitted for the purpose of weaning).
- **"Non-weaning"** patients are those patients on invasive mechanical ventilation upon admission to the LTCH, for whom at admission weaning attempts are NOT expected or anticipated (*e.g.*, patients who are chronically ventilated in the community or a facility, or have progressive neuromuscular disease such as amyotrophic lateral sclerosis, or irreversible neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning *must* be based on documentation found in the patient's medical record at admission.
- **A patient is considered fully liberated (weaned)** if he or she is alive and does not require any invasive mechanical ventilation support for at least two consecutive calendar days immediately prior to the day of discharge from the LTCH.
- **A patient is considered not fully liberated (weaned)** if he or she is not alive or requires invasive mechanical ventilation support for any duration of time during the two consecutive calendar days immediately prior to the day of discharge from the LTCH.

Purpose/Rationale for the Quality Measure

Patients on invasive mechanical ventilation comprise a substantial proportion of LTCH patient admissions, and thus present a critical focus for assessment of high quality care. In 2012, about 22,000 or 15.8% of all LTCH discharges received PMV services during the LTCH stay.[81]

Although often necessary for life support, invasive mechanical ventilation is not without risk of harm to patients, and these risks increase as duration of ventilation continues.[82, 83, 84] Studies have shown that invasive mechanical ventilation of critically ill patients is associated with higher rates of mortality[85] [86] [87] and morbidity, including ventilator-associated pneumonia,[88, 89, 90, 91, 92] ventilator-associated lung

[81] MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.

[82] Boles, J. M., Bion, J., Connors, A., Herridge, M., Marsh, B., Melot, C., ... & Welte, T. (2007). Weaning from mechanical ventilation. European Respiratory Journal, 29(5), 1033-1056.

[83] Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

[84] Peñuelas, O., Frutos-Vivar, F., Fernández, C., Anzueto, A., Epstein, S. K., Apezteguía, C., ... & Desmery, P. (2011). Characteristics and outcomes of ventilated patients according to time to liberation from mechanical ventilation. American journal of respiratory and critical care medicine, 184(4), 430-437.

[85] Cox, C. E., & Carson, S. S. (2012, August). Medical and Economic Implications of Prolonged Mechanical Ventilation and Expedited Post–Acute Care. In Seminars in respiratory and critical care medicine (Vol. 33, No. 04, pp. 357-361). Thieme Medical Publishers.

[86] Esteban, A., Anzueto, A., Frutos, F., Alía, I., Brochard, L., Stewart, T. E., ... & Arroliga, A. C. (2002). Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA, 287(3), 345-355.

[87] Kahn, J. M., Benson, N. M., Appleby, D., Carson, S. S., & Iwashyna, T. J. (2010). Long-term acute care hospital utilization after critical illness. JAMA, 303(22), 2253-2259.

[88] Cook, D. J., Walter, S. D., Cook, R. J., Griffith, L. E., Guyatt, G. H., Leasa, D., ... & Brun-Buisson, C. (1998). Incidence of and risk factors for ventilator-associated pneumonia in critically ill patients. Annals of internal medicine, 129(6), 433-440.

[89] Papazian, L., Bregeon, F., Thirion, X., Gregoire, R., Saux, P., Denis, J. P., ... & Gouin, F. (1996). Effect of ventilator-associated pneumonia on mortality and morbidity. American journal of respiratory and critical care medicine, 154(1), 91-97.

[90] Vincent, J. L., Bihari, D. J., Suter, P. M., Bruining, H. A., White, J., Nicolas-Chanoin, M. H., ... & Hemmer, M. (1995). The prevalence of nosocomial infection in intensive care units in Europe: results of the European Prevalence of Infection in Intensive Care (EPIC) Study. JAMA, 274(8), 639-644.

[91] Safdar, N., Dezfulian, C., Collard, H. R., & Saint, S. (2005). Clinical and economic consequences of ventilator-associated pneumonia: a systematic review. Critical care medicine, 33(10), 2184-2193.

[92] Buczko, W. (2009). Ventilator-associated pneumonia among elderly Medicare beneficiaries in long-term care hospitals. Health care financing review, 31(1), 1.

injury,[93, 94, 95] ventilator induced diaphragm dysfunction,[96, 97] psychological distress[98, 99, 100] and post-traumatic stress disorder,[101] disability[102] and decreased functional status,[103, 104] and chronic critical illness syndrome.[105] Mechanical ventilation is also associated with increased costs. Studies in the ICU setting indicate that patients who require mechanical ventilation can have up to 50% higher costs than patients who do not receive mechanical ventilation.[106] Patients on prolonged ventilation (≥ 21 days) incur even greater health care costs; the estimated cost per one-year survival for patients who are ventilated for ≥ 21 days is $423,596.[107]

Discontinuation of invasive mechanical ventilation, known as weaning or liberation, is feasible for many ventilated patients, and is associated with improved health outcomes. Although attempts to liberate patients from invasive mechanical ventilation in LTCHs have variable success, expectations of

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93 Meade, M. O., & Cook, D. J. (1995). The aetiology, consequences and prevention of barotrauma: a critical review of the literature. Clinical Intensive Care, 6(4), 166-173.

94 Meade, M. O., Cook, D. J., Kernerman, P., & Bernard, G. (1997). How to use articles about harm: the relationship between high tidal volumes, ventilating pressures, and ventilator-induced lung injury. Critical care medicine, 25(11), 1915-1922.

95 Slutsky, A. S., & Tremblay, L. N. (1998). Multiple system organ failure: is mechanical ventilation a contributing factor?. American journal of respiratory and critical care medicine, 157(6), 1721-1725.

96 Levine, S., Nguyen, T., Taylor, N., Friscia, M. E., Budak, M. T., Rothenberg, P., ... & Rubinstein, N. A. (2008). Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans. New England Journal of Medicine, 358(13), 1327-1335.

97 Demoule, A., Molinari, N., Jung, B., Prodanovic, H., Chanques, G., Matecki, S., ... & Jaber, S. (2016). Patterns of diaphragm function in critically ill patients receiving prolonged mechanical ventilation: a prospective longitudinal study. Annals of intensive care, 6(1), 75.

98 Rose, L., et al. (2014). "Psychological wellbeing, health related quality of life and memories of intensive care and a specialised weaning centre reported by survivors of prolonged mechanical ventilation." Intensive Crit Care Nurs 30(3): 145-151.

99 Schou, L., & Egerod, I. (2008). A qualitative study into the lived experience of post-CABG patients during mechanical ventilator weaning. Intensive and Critical Care Nursing, 24(3), 171-179.

100 Rotondi, A. J., Chelluri, L., Sirio, C., Mendelsohn, A., Schulz, R., Belle, S., ... & Pinsky, M. R. (2002). Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit. Critical care medicine, 30(4), 746-752.

101 Jubran, A., Lawm, G., Duffner, L. A., Collins, E. G., Lanuza, D. M., Hoffman, L. A., & Tobin, M. J. (2010). Post-traumatic stress disorder after weaning from prolonged mechanical ventilation. Intensive care medicine, 36(12), 2030-2037.

102 Barnato, A. E., Albert, S. M., Angus, D. C., Lave, J. R., & Degenholtz, H. B. (2011). Disability among elderly survivors of mechanical ventilation. American journal of respiratory and critical care medicine, 183(8), 1037-1042.

103 Scheinhorn, D. J., Hassenpflug, M. S., Votto, J. J., Chao, D. C., Epstein, S. K., Doig, G. S., ... & Petrak, R. A. (2007). Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. CHEST Journal, 131(1), 85-93.

104 Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

105 *Ibid.*

106 Dasta, J. F., McLaughlin, T. P., Mody, S. H., & Piech, C. T. (2005). Daily cost of an intensive care unit day: the contribution of mechanical ventilation. Critical care medicine, 33(6), 1266-1271.

107 Cox, C. E., Carson, S. S., Lindquist, J. H., Olsen, M. K., Govert, J. A., & Chelluri, L. (2007). Differences in one-year health outcomes and resource utilization by definition of prolonged mechanical ventilation: a prospective cohort study. Critical Care, 11(1), R9.

successful ventilator liberation are high for many LTCH patients.[108, 109, 110] A recent meta-analysis of weaning attempts in ICU patients with PMV found a pooled weaning rate in US ICUs of 47% (95% CI 42-51). The analysis included nine studies (4,769 patients); weaning rates reported for included studies varied from 13% to 56%.[111] These findings have also been observed in LTCHs, where higher weaning rates have been associated with lower post-discharge mortality.[112, 113] In LTCHs, fewer days of mechanical ventilation may lead to decreased risk of ventilator-associated complications, enhanced rehabilitation opportunities, and shorter LOS.[114]

Unnecessarily prolonged mechanical ventilation increases the risk of negative patient outcomes and can be an indicator of poor quality care or of persistent illness.[115] Based on the evidence, improving weaning processes and increasing weaning rates are expected to mitigate the risk of harm associated with invasive mechanical ventilation, thus contributing to more favorable clinical outcomes for patients[116,117] and decreased costs.[118]

This quality measure, Ventilator Liberation Rate, will assess the proportion of patients discharged alive from an LTCH who are fully liberated (weaned), thereby promoting weaning efforts and encouraging quality management of LTCH patients on invasive mechanical ventilation. Kahn et al. noted that inclusion of a liberation outcome measure is key to providing a truly patient-centered measure related to invasive mechanical ventilation weaning among LTCH patients.[119]

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[108] Scheinhorn, D. J., Hassenpflug, M. S., Votto, J. J., Chao, D. C., Epstein, S. K., Doig, G. S., ... & Petrak, R. A. (2007). Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. CHEST Journal, 131(1), 85-93.

[109] Rose, L., & Fraser, I. M. (2012). Patient characteristics and outcomes of a provincial prolonged-ventilation weaning centre: a retrospective cohort study. Canadian respiratory journal, 19(3), 216-220.

[110] Hassenpflug, M., Vela, D., Sandoval, R., Nelson, D. R., Sasse, S. A., & Steckart, M. J. (2015). Post-ICU Mechanical Ventilation: Outcomes Of The Revised Therapist-Implemented Patient-Specific (TIPS©) Weaning Protocol. In B44. INVASIVE AND NON-INVASIVE MECHANICAL VENTILATION (pp. A3166-A3166). American Thoracic Society.

[111] Damuth, E., Mitchell, J. A., Bartock, J. L., Roberts, B. W., & Trzeciak, S. (2015). Long-term survival of critically ill patients treated with prolonged mechanical ventilation: a systematic review and meta-analysis. The Lancet Respiratory Medicine, 3(7), 544-553.

[112] Dermot Frengley, J., Sansone, G. R., Shakya, K., & Kaner, R. J. (2014). Prolonged mechanical ventilation in 540 seriously ill older adults: effects of increasing age on clinical outcomes and survival. Journal of the American Geriatrics Society, 62(1), 1-9.

[113] Stearn-Hassenpflug, M., Steckart, M., & Nelson, D. (2013). 678: Post-ICU Mechanical Ventilation: Trends in Mortality and 12-month Post-discharge Survival. Critical Care Medicine, 41(12), A166.

[114] Hassenpflug, M., Vela, D., Sandoval, R., Nelson, D. R., Sasse, S. A., & Steckart, M. J. (2015). Post-ICU Mechanical Ventilation: Outcomes Of The Revised Therapist-Implemented Patient-Specific (TIPS©) Weaning Protocol. In B44. INVASIVE AND NON-INVASIVE MECHANICAL VENTILATION (pp. A3166-A3166). American Thoracic Society.

[115] MacIntyre, N. R. (2013). The Ventilator Discontinuation Process: An Expanding Evidence BaseDiscussion. Respiratory care, 58(6), 1074-1086.

[116] Blackwood, B., Burns, K. E., Cardwell, C. R., & O'Halloran, P. (2014). Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically ill adult patients. The Cochrane Library.

[117] Jubran, A., Grant, B. J., Duffner, L. A., Collins, E. G., Lanuza, D. M., Hoffman, L. A., & Tobin, M. J. (2013). Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial. JAMA, 309(7), 671-677.

[118] Dasta, J. F., McLaughlin, T. P., Mody, S. H., & Piech, C. T. (2005). Daily cost of an intensive care unit day: the contribution of mechanical ventilation. Critical care medicine, 33(6), 1266-1271.

[119] Kahn, J. M., & Carson, S. S. (2013). Generating evidence on best practice in long-term acute care hospitals. JAMA, 309(7), 719-720.

Denominator

The target population is patients discharged from an LTCH AND who were on invasive mechanical ventilation support upon admission to the LTCH, for whom at admission weaning attempts were expected or anticipated.

For patients with more than one LTCH stay during the reporting period, each admission and discharge is included in the measure calculation and reporting. For example, if an LTCH patient is transferred to a short-stay acute care hospital for a procedure, surgery, or some other reason(s), returns to the LTCH within three (3) calendar days, and is subsequently discharged from the LTCH, this is considered one "patient stay." However, if this patient's "stay" at the short-stay acute care hospital exceeds three (3) calendar days, whereby day one begins on the day of transfer from the LTCH to the short-stay acute care hospital, regardless of the hour of transfer, then a new LTCH CARE Data Set Admission Assessment is conducted upon return of the patient to the LTCH, and a second LTCH CARE Data Set Discharge Assessment accompanies the second discharge. Admission and Discharge (Planned or Unplanned) Assessments are completed for this patient for the first stay, and Admission and Discharge (Planned or Unplanned) Assessments are completed for the second stay. Both stays for this patient are included in the measure calculation and reporting.

Denominator Exclusions

This measure excludes patients with missing data and invasively mechanically ventilated patients identified as non-weaning at the time of admission to an LTCH. Patients who may be considered non-weaning include patients who are considered chronically ventilated as defined by evidence-based guidelines for ventilator liberation[120] or patients with an acute or chronic condition that may negate any expectation or anticipation of weaning attempts at admission (e.g., amyotrophic lateral sclerosis, or severe neurological injury or disease or dysfunction such as high (C2) spinal cord injury). Consideration of a patient as non-weaning must be based on documentation found in the patient's medical record by Day 2 of LTCH stay.

After patient-level exclusions are applied, LTCHs with denominator counts of less than 20 patient stays during the reporting period will be excluded from public reporting, owing to a small sample size.

Denominator exclusion details

Patients are excluded from the target population (i.e., denominator) if they meet either of the following criteria:

1. O0150A. Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 0 (i.e., No, not on invasive mechanical ventilation support), OR:
2. O0150A. Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH = 2, Yes, non-weaning (i.e., No weaning attempts are expected or anticipated at admission)

[120] MacIntyre, N. R. (2001). Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. Chest Journal, 120(6_suppl), 375S-396S.

Numerator

The numerator represents the number of patients who were reported as fully liberated (weaned) at discharge on the Planned or Unplanned Discharge Assessments.

A patient is included in the numerator if the LTCH reports that Item O0250A (Invasive Mechanical Ventilator: Weaning Status at Discharge) = 1 (Fully liberated at discharge) on the LTCH CARE Data Set Planned or Unplanned Discharge Assessments.

Items Included in the Quality Measure

For this quality measure, the following items are assessed at the time of admission:

A0900	Birth Date
GG0100B	Prior Functioning: Everyday Activities. Indoor Mobility (Ambulation)
I0103	Metastatic Cancer
I0104	Severe Cancer
I0605	Severe Left Systolic/Ventricular Dysfunction (known ejection fraction ≤ 30%).
I4900	Hemiplegia or Hemiparesis
I5000	Paraplegia
I5101	Complete Tetraplegia
I5102	Incomplete Tetraplegia
I5110	Other Spinal Cord Disorder/Injury
I5200	Multiple Sclerosis (MS)
I5450	Amyotrophic Lateral Sclerosis
I5455	Other Progressive Neuromuscular Disease
I5470	Severe Anoxic Brain Damage, Cerebral Edema, or Compression of Brain
I5480	Other Severe Neurological Injury, Disease, or Dysfunction
I7100	Lung Transplant
I7101	Heart Transplant
I7102	Liver Transplant
I7103	Kidney Transplant
I7104	Bone Marrow Transplant
O0100H	IV Medications
O0100H2a	Vasoactive Medications (e.g. continuous infusions of vasopressors or inotropes)
O0100J	Dialysis
O0150A	Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of LTCH Stay: Invasive Mechanical Ventilation Support upon Admission to the LTCH

The following item is assessed at the time of discharge for patients with Planned or Unplanned Discharge Assessments:

O0200A	Ventilator Liberation Rate: Invasive Mechanical Ventilator: Liberation Status at Discharge

Risk Adjustment

This measure is risk-adjusted to account for various risk factors using a statistical risk model.

We are developing, subsequent to measure testing and data analysis, a statistical risk model based on hierarchical logistic regression to predict the probability of full ventilator liberation at discharge for patients discharged from the LTCH alive. Patient characteristics related to admission and a marker for the specific discharging LTCH are included in the equation.

The equation is hierarchical in that both individual patient characteristics are accounted for, as well as the clustering of patient characteristics by LTCH. The statistical model estimates both the average predictive effect of the patient characteristics across all facilities, and the degree to which each LTCH has an effect on ventilator liberation that differs from that of the average LTCH. The LTCH effects are assumed to be randomly distributed around the average (according to a normal distribution). When computing the LTCH effect, hierarchical modeling accounts for the potential predictors of ventilator liberation in LTCHs, on average, such as patient characteristics, the observed LTCH rate, and the number of LTCH stays eligible for inclusion in the measure. The estimated LTCH effect is determined mostly by the LTCH's own data if the number of patient discharges is relatively large (as the estimate would be relatively precise), but is adjusted toward the average if the number of patient discharges is small (as that would yield a less precise estimate).

We are testing the following risk adjustment model:

Let Y_{ij}, denote the outcome (equal to 1 if patient *i* is alive and fully liberated at LTCH discharge, 0 otherwise) for a patient *i* at LTCH *j*; Z_{ij} denotes a set of risk adjustment variables. We assume the outcome is related to the risk adjusters via a logit function with dispersion:

$$\text{logit}(\text{Prob}(Y_{ij}=1)) = \alpha_j + \beta_i * Z_{ij} + \varepsilon_{ij}$$
$$\alpha_j = \mu + \omega_j\,;\ \omega_j \sim N(0, \tau^2) \qquad (1)$$

where $Z_{ij} = (Z_1, Z_2, \ldots Z_k)$ is a set of *k* patient-level risk adjustment variables; α_j represents the LTCH-specific intercept; μ is the adjusted average outcome across all LTCHs; τ^2 is the between-LTCH variance component; and $\varepsilon \sim N(0,\sigma^2)$ is the error term.

The hierarchical logistic regression model is estimated using SAS software (PROC GLIMMIX: SAS/STAT User's Guide, SAS Institute Inc.).

The estimated equation is used twice in the measure. The sum of the probabilities of ventilator liberation of all patients in the LTCH measure, including both the effects of patient characteristics and the LTCH, is the "predicted number" of liberated patients after adjusting for the LTCH's case mix. The same equation is used without the LTCH effect to compute the "expected number" of liberated patients for the same patients at the average LTCH. This is shown in equation 2.

$$\text{logit}(\text{Prob}(Y_{ij}=1)) = \beta_0 + \beta_i * Z_{ij} + \varepsilon_{ij} \qquad (2)$$

The ratio of the predicted-to-expected number of fully liberated patients is a measure of the degree to which ventilator liberation rates are higher or lower than what would otherwise be expected. This standardized risk ratio is then multiplied by the mean observed ventilator liberation rate for all LTCH stays included in the measure. As a result, this yields the risk-adjusted ventilator liberation rate for each LTCH. Please note that the estimation procedure is recalculated for each measurement period. Re-

estimating the models for each measurement period allows the estimated effects of the patient characteristics to vary over time as patient case-mix and medical treatment patterns change.

Risk adjustment variables include variables for age; prior functional status; selected conditions and comorbidities; special treatments and programs; and medications from the LTCH CARE Data Set V4.00 as provided below.

The following variables will be used as risk adjusters for initial measure testing:

1. Age
2. Prior Functioning: Everyday Activities
3. Metastatic cancer
4. Severe cancer
5. Left ventricular assistive device with known ejection fraction ≤ 30%
6. Progressive Neuromuscular Disease
7. Severe Neurological Injury, Disease, or Dysfunction
8. Post-transplant (lung, heart, liver, kidney, and bone marrow)
9. Vasoactive medication (i.e. continuous infusions of vasopressors or inotropes)
10. Dialysis

Quality Measure Calculation Algorithm

Risk-adjusted ventilator liberation rate:

1. Identify all patients discharged (alive or expired) during the reporting period from an LTCH.
2. Of patients discharged (alive or expired) from the LTCH during the reporting period, identify all patients who were admitted on invasive mechanical ventilation support upon admission to an LTCH. This is the target population.
3. Of patients identified in (2), identify the subset of patients for whom weaning attempts are not expected or anticipated at admission. These patients are excluded from the measure.
4. Of the patients identified in (2), identify the subset of patients for whom weaning attempts were expected or anticipated at admission. This is the denominator.
5. Of patients identified in (4), identify the subset of patients who are reported as alive and fully liberated (weaned) at discharge on the Planned or Unplanned Discharge Assessments. This is the numerator.
6. Identify presence or absence of risk factors for each patient identified in (4).
7. Calculate the predicted number of patients ($pred_j$) who are reported as alive and fully liberated (weaned) at discharge for each LTCH using the hierarchical logistic regression model specified in 3.4.7.
8. Calculate the expected number of patients (exp_j) who are reported as alive and fully liberated (weaned) at discharge for each LTCH using the logistic regression model specified in 3.4.7.
9. Calculate the LTCH standardized risk ratio (SRR_j) using the following equation: $SRR_j = pred_j/exp_j$.

10. Calculate the risk-adjusted LTCH ventilator liberation rate by multiplying the standardized risk ratio by the overall national observed ventilator liberation rate times 100.

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Chapter 4
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. The categories specified in the IMPACT Act 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 finalized in the LTCH QRP.

We are finalizing the standardized patient assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. The standardized patient assessment data that we proposed for these clinical categories are collected and used to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF # 0678) measure and the 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) measure.

We will not finalize the standardized patient assessment data element proposals due to the substantial comments requesting the delay for standardized patient assessment data element implementation coupled with extensive comments on the increase in burden the proposed standardized patient assessment data element policy would impose on facilities, and the need for time to prepare and implement training, manuals, and reports. We intend to adopt standardized patient assessment data elements for the three categories of Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments no later than in the FY 2020 IPPS/LTCH PPS proposed rule.

Section 2: Functional Status

Beginning with the FY 2020 LTCH QRP, we are finalizing that the submission of the admission and discharge performance 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 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), also meets the requirement for the collection of standardized patient assessment 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, 3 self-care and 9 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 IPPS/LTCH PPS final rule (80 FR 49739 through 49747).

A table showing the functional status data elements for 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), included in the MDS 3.0, IRF-PAI 2.0 and LCDS 4.00 is provided in **Appendix 7**.

Section 3: Medical Conditions and Co-Morbidities

Standardized patient assessment 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 LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule, and for the other PAC quality reporting programs in the FY 2016 SNF PPS final rule, the FY 2014 IRF PPS final rule, and the CY 2016 HH PPS final rule. The standardized patient assessment 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 used to calculate the finalized 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.

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Appendix 1
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.[33] 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.[34] 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.

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[33] 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.

[34] 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 results[35]:

- 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.[36] 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 finalized changes to the measure as currently specified.[37] Testing of the finalized measure, including adding unstageable pressure ulcers to the quality measure, increased performance scores in all settings (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

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[35] 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

[36] 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

[37] 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.

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:

- 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.
- 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.
- 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.

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 finalized 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 measure. The TEP summary report is publicly available and is soon to be available on CMS' website.[38]

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

[38] 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),

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 finalized 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 analogously coded assessment items G0110A1 and GG0170C. Testing results indicate high concordance for those coded analogously as indicating 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.

Appendix 2
National Stay-Level Incidence of New or Worsened Pressure Ulcers by Stage and Post-Acute Care Setting

Table 1 lists the national stay-level incidence of new or worsened pressure ulcers at different stages. Data for IRFs come from IRF-PAI, data for LTCHs come from LTCH CARE Data Set, and data for SNFs come from MDS.

Table 1. National stay-level incidence of new or worsened pressure ulcers by stage and post-acute care setting

Pressure Ulcer Stage	IRF stays (%)	LTCH stays (%)	SNF stays (%)
Stage 2	0.56	0.95	1.28
Stage 3	0.09	0.65	0.26
Stage 4	0.01	0.48	0.05
Unstageable due to slough and/or eschar	0.14	1.15	0.40
Unstageable due to non-removable dressing/device	0.02	0.05	0.02
Deep tissue injury	0.26	1.01	0.57

SOURCE: RTI analysis of January 1, 2015 – December 31, 2015 IRF-PAI, LTCH CARE Data Set, and MDS

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Appendix 3
Distribution of Observed Scores for Quality Measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

Tables 1-3 below list the distributions of observed scores on the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) quality measure, and the pressure ulcer quality measure finalized for the IRF QRP, LTCH QRP, and SNF QRP beginning with FY 2020, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.

Table 1. IRF: Distribution of Observed Scores for Quality Measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

	n	Mean (%)	Sd (%)	P10 (%)	P25 (%)	P50 (%)	P75 (%)	P90 (%)	% Perfect Score[1]
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)	1,106	0.64	1.182	0.00	0.00	0.00	0.95	2.06	62.93
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	1,106	1.46	1.933	0.00	0.00	0.94	2.27	3.85	42.86

SOURCE: RTI analysis of October 1, 2016 – December 31, 2016 IRF-PAI

[1] The perfect score column refers to the proportion of facilities with scores of zero for this measure.

Table 2. LTCH: Distribution of Observed Scores for Quality Measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

	n	Mean (%)	Sd (%)	P10 (%)	P25 (%)	P50 (%)	P75 (%)	P90 (%)	% Perfect Score[1]
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)	421	1.95	2.481	0.00	0.53	1.29	2.49	4.17	12.11
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	421	3.73	3.216	0.45	1.53	2.97	4.89	8.11	5.46

SOURCE: RTI analysis of January 1, 2015 – December 31, 2015 LTCH CARE Dataset

[1] The perfect score column refers to the proportion of facilities with scores of zero for this measure.

Table 3. Distribution of Observed Scores for Quality Measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

	n	Mean (%)	Sd (%)	P10 (%)	P25 (%)	P50 (%)	P75 (%)	P90 (%)	% Perfect Score[1]
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)	14,153	1.75	2.121	0.00	0.00	1.19	2.53	4.32	29.11
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	14,153	2.58	2.655	0.00	0.65	2.00	3.70	5.83	20.32

SOURCE: RTI analysis of October 1, 2015 – September 30, 2016 MDS

[1] The perfect score column refers to the proportion of facilities with scores of zero for this measure.

Appendix 4
Data Elements Used in Calculation of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

IRF		LTCH		SNF	
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 ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3	Enter number ☐	1: Number of Stage 2 pressure ulcers. If 0 skip to M0300C, Stage 3
Enter number ☐	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 ☐	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 ☐	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.
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 ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4	Enter number ☐	1: Number of Stage 3 pressure ulcers. If 0 skip to M0300D, Stage 4
Enter number ☐	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 ☐	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 ☐	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
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 ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device	Enter number ☐	1: Number of Stage 4 pressure ulcers. If 0 skip to M0300E, Unstageable non-removable dressing/device

(continued)

IRF		LTCH		SNF	
Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission	Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> Stage 4 pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.
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 ☐	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 ☐	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 ☐	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 ☐	2: Number of <u>these</u> unstageable pressure ulcers/ injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/ injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers/ injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.
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 ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury	Enter number ☐	1: Number of unstageable pressure ulcers due to coverage of the wound bed by slough and/or eschar. If 0 skip to M0300G, Unstageable – Deep tissue injury
Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure ulcers that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.
G. Unstageable - Deep tissue injury		**G. Unstageable -** Deep tissue injury		**G. Unstageable -** Deep tissue injury	
Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention	Enter number ☐	1: Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to N2005, Medication Intervention	Enter number ☐	1. Number of unstageable pressure injuries presenting as deep tissue injury. If 0 skip to M1030, Number of Venous and Arterial Ulcers
Enter number ☐	2. Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2: Number of <u>these</u> unstageable pressure injuries that were present upon admission. Enter how many were noted at the time of admission.	Enter number ☐	2. Number of <u>these</u> unstageable pressure injuries that were present upon admission/ entry or reentry. Enter how many were noted at the time of admission / entry or reentry.

Appendix 5
Pressure Ulcer Quality Measure Item Standardization: Data Elements Collected for Calculation of Quality Measures used in IRF, LTCH, and SNF Quality Reporting Programs

IRF, LTCH, and SNF PAC Settings: Items Collected at Discharge				
Item	**Item Description**	**IRF-PAI v2.0 (effective 10/1/2018)**	**LTCH CARE Data Set v4.00 (effective 7/1/2018)**	**MDS 3.0 (effective 10/1/2018)**
M0300	**Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage**			
A	Number of Stage 1 pressure injuries	X	X	X
B1	Number of Stage 2 pressure ulcers	X	X	X
B2	Number of these Stage 2 pressure ulcers that were present upon admission	X	X	X
C1	Number of Stage 3 pressure ulcers	X	X	X
C2	Number of these Stage 3 pressure ulcers that were present upon admission	X	X	X
D1	Number of Stage 4 pressure ulcers	X	X	X
D2	Number of these Stage 4 pressure ulcers that were present upon admission	X	X	X
E1	Number of unstageable pressure ulcers/injuries due to non-removable dressing/device	X	X	X
E2	Number of these unstageable pressure ulcers/injuries that were present upon admission	X	X	X
F1	Number of unstageable pressure ulcers due to coverage of wound bed by slough and/or eschar	X	X	X
F2	Number of these unstageable pressure ulcers that were present upon admission	X	X	X
G1	Number of unstageable pressure injuries presenting as deep tissue injury	X	X	X
G2	Number of these unstageable pressure injuries that were present upon admission	X	X	X

X = Item is present

Appendix 6
Data Elements Used in Risk Adjustment of Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

IRF Risk Adjustment Covariates	LTCH Risk Adjustment Covariates	SNF Risk Adjustment Covariates
Functional Mobility Admission Performance		
GG0170C. Mobility: Lying to Sitting on Side of Bed: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed**: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Patient refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns	**GG0170C. Mobility: Lying to Sitting on Side of Bed**: The ability to move from lying on the back to sitting on the side of the bed with feet flat on the floor, and with no back support. 06. Independent 05. Setup or clean-up assistance 04. Supervision or touching assistance 03. Partial/moderate assistance 02. Substantial/maximal assistance 01. Dependent If activity was not attempted, code reason: 07. Resident refused 09. Not applicable 10. Not attempted due to environmental limitations 88. Not attempted due to medical condition or safety concerns
Bowel Continence		
H0400. Bowel Continence 0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated	**H0400. Bowel Continence** 0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated	**H0400. Bowel Continence** 0. Always continent 1. Occasionally incontinent 2. Frequently incontinent 3. Always incontinent 9. Not rated
Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) or Diabetes		
I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD) 0. Does not have PVD or PAD 1. Have PVD or PAD **I2900 Diabetes Mellitus (DM)** 0. Does not have DM 1. Has DM	**I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)** 0. Does not have PVD or PAD 1. Have PVD or PAD **I2900 Diabetes Mellitus (DM)** 0. Does not have DM 1. Has DM	**I0900. Peripheral Vascular Disease (PVD) / Peripheral Arterial Disease (PAD)** 0. Did not have PVD or PAD in the last 7 days 1. Had PVD or PAD in the last 7 days **I2900 Diabetes Mellitus (DM)** 0. Did not have DM in the last 7 days 1. Had DM in the last 7 days
Height and Weight (Low Body Mass Index)		
25A (Height); and 26A (Weight).	**K0200A (Height); and K0200B (Weight).**	**K0200A (Height); and K0200B (Weight).**

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Appendix 7
Self-Care and Mobility Items Included in Section GG of the IRF-PAI, MDS, and LTCH CARE Data Set to Assess Functional Status – Effective on or before October 1, 2018

Table 1 lists the function items included in Section GG of the IRF-PAI, MDS, and LTCH CARE Data Set that are adopted as standardized data elements in FY 2018 IRF PPS, LTCH PPS and SNF PPS to satisfy the requirement to report standardized patient assessment data under section 1899B(b)(1)(B)(i) of the Act addressing functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.

Table 1. Self-Care and Mobility Items Included in Section GG of the IRF-PAI, LTCH CARE Data Set, and MDS That are Adopted as Standardized Data Elements – Effective October 1, 2018

Item	Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) Version 2.0	Long-Term Care Hospital CARE Data Set Version 4.00	Minimum Data Set (MDS) 3.0 Version 1.16.0
Self-Care			
GG0130A Eating*	✓	✓	✓
GG0130B Oral hygiene*	✓	✓	✓
GG0130C Toileting hygiene*	✓	✓	✓
Mobility			
GG0170B Sit to lying*	✓	✓	✓
GG0170C Lying to sitting on side of bed*	✓	✓	✓
GG0170D Sit to stand*	✓	✓	✓
GG0170E Chair/bed-to-chair transfer*	✓	✓	✓
GG0170F Toilet transfer*	✓	✓	✓
GG0170J Walk 50 feet with two turns*	✓	✓	✓
GG0170K Walk 150 feet*	✓	✓	✓
GG0170R Wheel 50 feet with two turns*	✓	✓	✓
GG0170S Wheel 150 feet*	✓	✓	✓

NOTES:

* Items included in cross-setting quality 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) and finalized as standardized data elements in FY 2018 IRF PPS, SNF PPS and LTCH PPS.