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**Technical Expert Panel Summary Report:
Refinement of the Changes in Skin Integrity Post-Acute Care:
Pressure Ulcer/Injury Quality Measure for Skilled Nursing
Facilities, Inpatient Rehabilitation Facilities, Long-Term Care
Hospitals, and Home Health Agencies**

Deliverable 14

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TECHNICAL EXPERT PANEL SUMMARY REPORT: REFINEMENT OF THE CHANGES
IN SKIN INTEGRITY POST-ACUTE CARE: PRESSURE ULCER/INJURY QUALITY
MEASURE FOR SKILLED NURSING FACILITIES (SNFs), INPATIENT
REHABILITATION FACILITIES (IRFs), LONG-TERM CARE HOSPITALS (LTCHs), AND
HOME HEALTH AGENCIES (HHAs)

DELIVERABLE 14

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LIST OF ACRONYMS AND SHORT FORMS

ACO	Accountable Care Organization
CMS	Centers for Medicare & Medicaid Services
DTI	deep tissue injury
HHA	Home Health Agency
IMPACT Act	Improving Medicare Post-Acute Care Transformation Act of 2014
IRF	Inpatient Rehabilitation Facility
IRF-PAI	Inpatient Rehabilitation Facility-Patient Assessment Instrument
LTCH	Long-Term Care Hospital
LTCH CARE Data Set	LTCH Continuity Assessment Record and Evaluation Data Set
MAP	Measure Application Partnership
MDS	Minimum Data Set
NDNQI	National Database of Nursing Quality Indicators
NF	Nursing Facility
NPUAP	National Pressure Ulcer Advisory Panel
NQF	National Quality Forum
OASIS	Outcome and Assessment Information Set
PAC	post-acute care
PPS	Prospective Payment System
PSHRH	Penn State Hershey Rehabilitation Hospital
QRP	Quality Reporting Program
QI	quality improvement
RAI	Resident Assessment Instrument
SNF	Skilled Nursing Facility
TEP	Technical Expert Panel
WCET	World Council of Enterostomal Therapists
WOCN	Wound, Ostomy, and Continence Nurses Society

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SECTION 1 INTRODUCTION AND OVERVIEW

1.1 Introduction

On behalf of the Centers for Medicare & Medicaid Services (CMS), RTI International and Abt Associates convened a Technical Expert Panel (TEP) to seek expert input on the refinement of the quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs). The TEP meeting consisted of a half-day webinar held January 30, 2018.

This report provides a summary of the TEP proceedings, detailing the key issues of measure development and TEP discussion around those issues. In this section, we provide a summary of the background, process for the TEP meetings, and organization of the TEP report.

1.2 Background

CMS has contracted with RTI and Abt Associates to develop quality measures reflective of quality of care, resource use, and other measures for post-acute care (PAC) settings to meet the mandate of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) and support CMS quality initiatives. The contract names are Development and Maintenance of Symptom Management Measures (HHSM-500-2013-13015I; Task Order HHSM-500-T0001) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance (HHSM-500-2013-13001I; Task Order HHSM-500-T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractor during measure development and maintenance.

As part of CMS' efforts to meet the requirements of the IMPACT Act and to support CMS quality initiatives, RTI and Abt Associates developed the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (National Quality Forum [NQF] #0678) quality measure that was originally implemented in the NH/SNF setting in 2010 and later expanded to LTCHs and IRFs in October 2012 and HHA in January 2017. As part of its measure development and refinement process, CMS convened a previous TEP on July 18, 2016, during which TEP members provided feedback on potential refinements to the pressure ulcer quality measure, including the inclusion of unstageable pressure ulcers/injuries due to slough/eschar, non-removable dressing/device, and deep tissue injuries (DTIs) in the quality measure numerator, potential updates to risk adjustment, and the use of M0300/M1311 patient assessment items to calculate the quality measure.

CMS used this feedback to guide the development of a refined, cross-setting pressure ulcer quality measure and as part of this process, sought public comment on the potential refinements. These potential refinements were then vetted through the Measure Application Partnership (MAP) Post-Acute Care/Long Term Care Workgroup in December 2016 and the MAP Coordinating Committee in January 2017. Based on feedback from the MAP Workgroup and MAP Coordinating Committee, as well as feedback from prior TEPs and public comments,

CMS further refined the pressure ulcer quality measure into the new cross-setting pressure ulcer quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. The replacement of the previously finalized Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) quality measure with the new Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure was finalized in the FY/CY 2018 Final Rules for FY/CY 2020 implementation. This cross-setting quality measure reports the percentage of patients/residents with Stages 2-4 pressure ulcers, or unstageable pressure ulcers/injuries due to slough/eschar, non-removable dressing/device, or DTI, 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. The measure is calculated using data from the MDS 3.0 assessment instrument for SNF residents, the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set for LTCH patients, the IRF-Patient Assessment Instrument (PAI) for IRF patients, and the OASIS data set for HHA residents.

The objective of the TEP meeting was to seek expert input on refinements of the cross-setting pressure ulcer measure for PAC settings, including input related to potential updates to manual definitions and guidance related to pressure ulcers/injuries and addition of clinical scenarios involving unstageable pressure ulcers/injuries.

1.3 Process of the TEP Meeting

1.3.1 TEP Members

On January 30, 2018, RTI reconvened our previous TEP members who last met on July 18, 2016, to provide feedback on potential refinements to the pressure ulcer quality measure, including unstageable pressure ulcers/injuries due to slough/eschar, non-removable dressing/device, and DTIs in the quality measure numerator, potential updates to risk adjustment, and the use of M0300/M1311 items to calculate the quality measure. The TEP members convened for a half-day webinar to provide input on guidance for the modified quality measure known as Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. The final TEP composition consisted of our previous 11 TEP members who offered a diverse range of clinical, research, and administrative expertise. The TEP composition was chosen to include one patient representative and others who offered expertise in the various PAC settings (SNF, IRF, LTCH, HHA) and knowledge of performance measurement about new or worsened pressure ulcers, nutrition, wound care, and physical therapy. In addition, TEP members offered a range of perspectives related to quality improvement, payer perspective, data collection and implementation, and health care disparities. *Appendix A* provides the TEP composition, with brief biographies of each member.

1.3.2 TEP Webinar

The half-day TEP webinar was held January 30, 2018. The agenda is provided as *Appendix B*. Each of the 11 TEP members attended the meeting virtually. Discussion was facilitated by the measure lead, Julie Seibert, RTI, with support from members of the RTI and Abt Associates measure development teams. Representatives from CMS were also in attendance. The following topics were discussed:

- (i) concept of “worsened” for numerically staged and unstageable pressure ulcers/injuries;
- (ii) potential updates to manual guidance and definitions for unstageable pressure ulcers/injuries; and
- (iii) guidance for providers regarding worsened unstageable pressure ulcers/injuries.

1.3.3 Pre-TEP Pressure Ulcer/Injury Scenario Exercise

Prior to the TEP webinar, RTI distributed a Pressure Ulcer Scenario Exercise Worksheet to TEP members (see ***Appendix C***). The worksheet collected input on clinical scenarios involving worsened, numerically stageable and unstageable pressure ulcers/injuries. RTI asked TEP members to indicate their interpretation of concepts related to “worsened” status for each scenario. The TEP feedback was summarized and incorporated into the pre-TEP materials and informed discussion during the TEP webinar.

1.4 Organization of the Report

The following sections of the report discuss the guidance updates explored by the TEP, and a summary of the feedback obtained from TEP members during the webinar. ***Section 2*** summarizes measure history and the transition process to the new pressure ulcer quality measure, and ***Section 3*** summarizes TEP feedback on proposed manual definitions and guidance. ***Section 4*** summarizes pre-TEP feedback on the clinical scenarios involving worsening, unstageable pressure ulcers/injuries and TEP discussion of the results.

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SECTION 2

MEASURE HISTORY AND TRANSITION TO NEW MEASURE

2.1 Summary of Measure History

Measure development has continued since the previous TEP meeting, July 18, 2016. A public comment period was held in October and November 2016, which garnered general support for inclusion in the quality measure of unstageable pressure ulcers/injuries due to slough/eschar, due to non-removable dressing/device, and DTIs. The MAP Post-Acute Care/Long Term Care Workgroup met December 14, 2016, and the MAP Coordinating Committee met January 24-25, 2017, and recommended conditional support for rulemaking for the changes to the pressure ulcer measure. The changes to the measure resulted in a new measure, titled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which was proposed in the FY/CY 2018 Notice of Proposed Rulemaking for SNF, IRF, LTCH, and HHA settings. Public comments received through rulemaking were generally supportive of the inclusion of unstageable pressure ulcers/injuries and requested further training and guidance regarding worsening of unstageable pressure ulcers/injuries.

The new measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, was finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 37990 through 38589), the FY 2018 IRF PPS final rule (82 FR 36238 through 36305), and the FY 2018 SNF PPS final rule (82 FR 36530 through 36636) (CMS, 2017a, 2017b, 2017c) to replace the existing pressure ulcer quality measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678). The new measure includes unstageable pressure ulcers/injuries, including DTIs, in the numerator and is calculated using M0300 items for the SNF, IRF, and LTCH settings and M1311 items for HHA, which are aligned across item sets. A logistic regression model is used for risk adjustment, and the current covariates are assessed at admission or start of care. The risk adjusters are function/mobility (bed mobility), bowel incontinence, diabetes or peripheral vascular disease/peripheral arterial disease, and low body mass index.

2.2 TEP Discussion

2.2.1 Risk Adjustment

TEP members inquired whether additional risk adjusters would be considered for the measure, and RTI clarified that additional risk factors would be tested pending further data collection for measure refinement. TEP members recommended consideration of urinary incontinence and spinal cord injury as additional risk adjusters. Additional potential risk adjusters were discussed in greater detail during the July 2016 TEP meeting. CMS and the measure development contractors will take these recommendations into consideration for further risk adjustment testing.

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SECTION 3 REVIEW MANUAL DEFINITIONS AND GUIDANCE

3.1 Summary of Proposed Changes in Guidance

The following areas required clinical input to ensure that manual definitions and guidance are appropriate with respect to the new pressure ulcer measure:

- defining worsening in pressure ulcer/injury status,
- defining an unstageable pressure ulcer due to slough/eschar and providing staging guidance, and
- refining the definition and related guidance for coding Present on Admission.

The following definitions and guidance were provided to the TEP for consideration.

Definition: Worsening in Pressure Ulcer Status

Is when a numerically staged pressure ulcer/injury has progressed to a deeper level of tissue damage and is therefore staged as a higher number, using the staging assessment system classifications assigned to each stage (starting at stage 1 and increasing in severity to Stage 4) OR any pressure injury or numerically staged pressure ulcer/injury that becomes unstageable due to slough and/or eschar.

Definition/Guidance: Unstageable Pressure Ulcer Due to Slough/Eschar

Pressure ulcers that are covered with slough and/or eschar such that the tissues within the ulcer cannot be assessed should be coded as unstageable, because the extent of soft tissue damage (and therefore, the numerical stage) cannot be determined. Only when enough slough and/or eschar are removed to expose the extent of soft tissue damage involved can the numerical stage of the wound be determined.

If a pressure ulcer's tissues are obscured [by slough and/or eschar], such that the depth of soft tissue damage cannot be observed or palpated, it is considered to be unstageable [due to slough and/or eschar].

Definition/Guidance: Present on Admission

From LTCH QRP Manual Version 4.0 and IRF QRP Manual Version 2.0 (CMS, 2018a, 2018b)

Any pressure ulcer/injury identified and coded on the Admission assessment is assumed to be “present on admission,” per the definition of “on admission.”

For each pressure ulcer/injury identified and coded in items M0300B1-G1 on discharge (Planned or Unplanned), determine whether that pressure ulcer/injury was

present at the time of admission at that stage. Consider current and historical levels of tissue involvement to accurately code the present on admission items (M0300B2-G2) on discharge.

From the Minimum Data Set (MDS) 3.0 Resident Assessment Instrument (RAI) Manual Version 1.15 (CMS, 2017d)

For each pressure ulcer/injury, determine whether the pressure ulcer/injury was present at the time of admission/entry or reentry and not acquired while the resident was in the care of the nursing home. Consider current and historical levels of tissue involvement.

The designation of “present on admission” requires that the pressure ulcer/injury be at the same location and not have increased in numerical stage or become unstageable due to slough and/or eschar.

TEP members were then asked focal questions that prompted discussion around the clarity and accuracy of information presented, with special attention to whether there were any setting-specific concerns related to the proposed addition and changes and whether any special considerations needed to be made in conveying information about the changes to stakeholders.

3.2 TEP Discussion—Definition of Worsening

One of the major areas of concern for the TEP was around revising the definition of worsening so as to not suggest a linear progression in pressure ulcer/injury evolution. One TEP member pointed out that use of the word “progressing” might suggest a linear progression from one stage to a higher numerical stage, and this might result in unintended consequences in pressure ulcer/injury assessment. TEP members also stressed that the definition should not emphasize tissue depth in worsening; instead, TEP members stressed that the definition should reflect a change in tissue type rather than depth of tissue damage. The TEP clarified that this change in tissue type is because a wound can increase in numerical stage (“worsen”) with only a slight increase in depth, such as in an area of a superficial bony prominence.

Suggested language changes to address these two issues included:

1. change “tissue depth” to “additional tissue type damage,”
2. reference “underlying” damage, and
3. use the word “reveal,” referring to observed change in tissue damage.

These language changes were suggested so as to not imply linear progression. The TEP advised against the use of the word “evolve” in describing worsening of a pressure ulcer/injury, because it could imply linear progression and is a term of art used specifically to describe changes in DTIs.

The TEP also stressed the need to clearly define “worsened” in the context of a numerically staged pressure ulcer/injury becoming unstageable due to slough and/or eschar.

The TEP supported inclusion of both “injury” and “ulcer” in the definition of worsening.

3.3 TEP Discussion—Definition of Unstageable Pressure Ulcer/Injury Due to Slough and/or Eschar

TEP members were asked to consider the clarity of the definition provided for unstageable pressure ulcer/injury due to slough and/or eschar and provide recommendations for clarifications or modifications needed to improve the definition and make it more accurate.

One TEP member recommended removal of the word “extent” from the definition as it could imply depth. In discussing what would constitute worsening for a pressure ulcer that develops slough/eschar, another TEP member questioned whether the presence of any slough/eschar would make a pressure ulcer/injury worsened. After further discussion, the TEP determined that a Stage 2 pressure ulcer that develops any slough and/or eschar would be considered worsened, and any numerically staged pressure ulcer/injury that develops necrotic tissue, to the extent that the wound base is obscured by necrotic tissue and cannot be numerically staged, would be considered worsened. A final recommendation for this subject was that a scenario with a healing pressure ulcer/injury be provided for further guidance.

3.4 TEP Discussion—Guidance for Determining Present on Admission

TEP members stressed that the current guidance for present on admission (“the time of admission or as close to the time of admission as possible”) needs to be clarified. TEP members deliberated over which timespan made the most sense for each of the settings. Timeframes ranged from 24 to 48 hours, as recommended by National Database of Nursing Quality Indicators (NDNQI), to adhering to the 3-day rule currently understood by the TEP as the time-window for staging in IRFs. Another TEP member noted a new requirement in SNFs that required an evaluation be made within the first 48 hours; therefore, 3 days for evaluation would be unnecessarily long.

One TEP member presented a scenario in which a DTI evolves within 48 hours and explained that this type of wound would not be considered facility-acquired and would be considered present on admission with a 48-hour window. The TEP discussed another scenario from the IRF-PAI manual, which involved a patient leaving the IRF with a numerically staged wound and subsequently re-entering the IRF with a wound that had increased in numerical stage. For example, a patient has a Stage 2 pressure ulcer and then leaves for acute care for 12 hours. Because the patient was away from the IRF for less than 3 calendar days, this would be considered an interrupted stay, not a readmission. If the patient’s wound has worsened upon re-entry to the IRF, the IRF would still be held responsible for the worsened wound. CMS clarified that the payment policy is such that an interrupted stay is covered under the IRF Prospective Payment System (PPS) (and similar for LTCH). Because the stay is still under the IRF PPS, the IRF would be responsible.

3.5 TEP Discussion—Additional Considerations

With respect to additional considerations and concerns, one TEP member asked about wounds that have been surgically debrided and whether those would be considered in the same manner as non-surgically debrided wounds. The TEP member noted that there are clinicians who continue to stage these wounds as non-surgical wounds, which often reflect further tissue damage. TEP members agreed this wound would be considered a pressure ulcer/injury, with one TEP member clarifying that if the intention of debridement is to promote healing of the wound, then this type of wound still would be considered a pressure ulcer/injury. If the intention behind debridement is to close the wound with a flap or graft, then this type of wound would be considered a surgical wound. One TEP member suggested additional clarification be included in the manuals and others agreed.

3.6 Discussion Summary

In summary, TEP deliberations resulted in the following key recommendations:

- TEP members requested that language related to linear progression in worsening be avoided, that the definition of worsening emphasize a change in type of tissue damage as opposed to depth, and that the term “evolved” be used only in relation to DTIs.
- There was general support for Stages 3 and 4 pressure ulcers at admission that become unstageable due to slough and/or eschar at discharge to be considered “worsened.”
- Additional clarification was requested regarding the amount of slough/eschar that indicates unstageable due to slough/eschar and how this should be included in the definition of worsening.
- TEP members would like “present on admission” guidance to be clarified. For example, defining “present on admission” with a specific timeframe, such as within 24 or 48 hours.
- TEP members requested clear guidance in the manual on distinguishing between treatment of pressure ulcers/injuries and surgical wounds.

SECTION 4 REVIEW OF CODING FOR UNSTAGEABLE PRESSURE ULCER SCENARIOS

4.1 Pre-TEP Feedback on Unstageable Pressure Ulcer Scenarios

Prior to the TEP meeting, TEP members were emailed 14 scenarios depicting different configurations of unstageable pressure ulcers/injuries and DTIs assessed at admission and discharge in PAC settings. Scenarios also included information on whether the pressure ulcers/injuries were considered new, worsened, or not worsened at discharge, as well as a rationale for the decision (See Appendix C). The scenarios were sent to TEP members 1 week before the TEP meeting, and eight members provided feedback on the assessment of worsening and rationale. All eight responding TEP members agreed with five of the scenarios with no concerns. The majority of the members agreed with five additional scenarios, with a few members requesting additional clarification or discussion. TEP members provided mixed responses on the remaining four scenarios, indicating a need for further discussion. The main topics for discussion, as indicated by pre-TEP feedback, were:

1. clarification of the amount or location of slough and/or eschar needed to assess a pressure ulcer as unstageable due to slough/eschar;
2. the nuances of staging pressure ulcers/injuries known or discovered under a non-removable dressing or device; and
3. the appropriate assessment time window needed for DTIs.

4.2 Discussion Summary

4.2.1 *Unstageable Pressure Ulcers Due to Slough and/or Eschar*

TEP members were provided with six scenarios involving unstageable pressure ulcers with slough and/or eschar. The panel agreed with the staging determinations of the pressure ulcers described; however, additional clarification was requested regarding terminology and worsening status, in some cases. TEP members also discussed the need for clarification about the amount or location of slough and/or eschar needed to assess a pressure ulcer as unstageable due to slough/eschar.

Scenario 1: A patient is admitted to the LTCH with a Stage 2 pressure ulcer on her left heel. A week into the stay, the left heel ulcer begins to develop eschar and by discharge, the ulcer is covered with eschar, and the wound bed/extent of tissue damage cannot be visualized. The left heel wound is therefore unstageable due to slough/eschar at the time of discharge.

The majority of TEP members concurred with RTI's recommendation that the pressure ulcer/injury described in Scenario 1 should be considered worsened at discharge, because the numerically stageable pressure ulcer became unstageable due to slough or eschar. The panel discussed several aspects of presence of slough and eschar, including the amount of slough or eschar and the location. TEP members also discussed that a Stage 2 pressure ulcer that developed some slough and eschar would be assessed differently from a previous Stage 2 pressure ulcer that

was now completely covered by slough or eschar, or a Stage 3 or 4 pressure ulcer that developed some slough or eschar. RTI provided additional clarification that a pressure ulcer is considered unstageable only if the slough/eschar is such that the wound bed is obscured. Stage 3 and 4 pressure ulcers may contain slough or eschar; however, if they become completely covered such that the base of the wound cannot be assessed, these pressure ulcers are considered unstageable. Upon further discussion, TEP members concurred that a pressure ulcer that was a Stage 2 that develops slough/eschar would be considered worsened.

Scenario 2: A resident is admitted to the SNF with a Stage 3 pressure ulcer at his right hip. On day five, the hip ulcer is noted to have eschar at the center of the ulcer and at discharge, this ulcer is partially covered with eschar however, full thickness tissue loss is observed and subcutaneous fat is visible.

Scenario 4- A patient is admitted to the IRF with a Stage 4 pressure ulcer on her left hip. Upon reassessment at the time of discharge this ulcer is partially covered with eschar, but bone is visible.

TEP member discussion of Scenario 2 centered around the location of eschar in the wound bed and clarification regarding cleansing of the wound. The panel discussed that, in the case of Scenarios 2 and 4, a clean wound that develops slough/eschar would not be considered worsened, as the current definition does not address the amount of slough/eschar. Upon further discussion, some TEP members suggested that worsening occurs when there is any amount of slough/eschar that causes the wound bed to be obscured and the wound unable to be numerically staged. If such a definition were adopted, a facility would not be penalized as having a patient with a new or worsened pressure ulcer in every situation that slough/eschar develops, which is part of the natural progression of the wound and does not necessarily represent worsening of a wound. A TEP member clarified that this applies to Stages 3 and 4 pressure ulcers. Stage 2 pressure ulcers that develop any slough/eschar would have transitioned from a partial-thickness to a full-thickness pressure ulcer, and therefore would be considered worsened.

Scenario 3: A resident is admitted to the SNF with a Stage 3 pressure ulcer at his right hip. The ulcer is assessed on day five and slough is observed and noted. The resident is assessed at discharge and the ulcer is entirely covered with slough and the wound bed/extent of tissue damage cannot be visualized.

Scenario 5: A patient is admitted to the IRF with a Stage 4 pressure ulcer on her left hip. Upon reassessment at the time of discharge this ulcer is entirely covered with eschar and the wound bed cannot be assessed. The patient is discharged with an unstageable pressure ulcer/injury due to slough/eschar.

TEP member discussion of Scenarios 3 and 5 consisted of a review of the CMS guidance that a wound that develops slough or eschar to completely cover and obscure the wound bed is considered unstageable due to slough and/or eschar. Some TEP members concurred that pressure ulcers in Scenarios 3 and 5 would be considered worsened. One TEP member clarified that the intent is to reflect the quality of care provided in the facility; therefore, when a pressure ulcer/injury becomes entirely covered with slough and/or eschar, it should be considered to be worsened. The TEP member further noted that a wound completely covered by slough or eschar

would indicate that topical care was not appropriately provided, and so the wound is considered a worsened status. Another TEP member cautioned that there could be other physiological factors contributing to the wound deteriorating other than the quality of care in the facility. Other TEP members note that there should be a distinction between avoidable and unavoidable worsening in pressure ulcers/injuries.

Scenario 6: A patient is admitted to the LTCH with an unstageable pressure ulcer, due to the entire wound bed being covered with slough. Three days prior to discharge, the patient is seen at the wound clinic. Biological debridement is initiated and the patient returns with a dressing covering the wound and orders not to remove the dressing. The follow up wound clinic appointment is scheduled, but the patient is discharged to another facility before the scheduled appointment occurs. The patient is therefore discharged with an unstageable pressure ulcer/injury due to non-removable dressing/device.

There was consensus among TEP members with RTI's recommendations that the pressure ulcer in Scenario 6 should be considered to be not worsened at discharge. The ulcer was unstageable at the time of admission due to slough and did not increase in numerical stage or become unstageable due to slough or eschar at the time of discharge.

4.2.2 Unstageable Due to Non-Removable Dressing or Device

The TEP was provided with four scenarios involving pressure ulcers or injuries covered by a non-removable dressing or device. The TEP agreed with the status of the pressure ulcer and the rationale for most scenarios.

Scenario 7: A patient is admitted to the IRF with a Stage 3 pressure ulcer at the right buttocks. During the course of her stay she is seen at the wound clinic and returns to the IRF with a dressing and orders that the dressing is to remain intact until the next clinic visit. The patient is discharged to a SNF prior to the follow-up wound clinic visit. At the time of discharge this ulcer is covered with a non-removable dressing.

The TEP agreed with RTI's recommendations that the pressure ulcer in Scenario 7 is considered to be not worsened at discharge, because there is no evidence that the ulcer increased in numerical stage or became unstageable due to slough and/or eschar.

Scenario 8: A patient is admitted to the IRF with a Stage 3 pressure ulcer at her right buttocks. On day 5 of her stay the ulcer is assessed as a Stage 4 pressure ulcer. She is seen at the wound clinic and returns to the IRF with a dressing and orders that the dressing is to remain intact until the next clinic visit. The patient is discharged to a SNF prior to the follow-up wound clinic visit. At the time of discharge this ulcer is covered with a non-removable dressing.

TEP members concurred with RTI's recommendations that the pressure ulcer/injury in Scenario 8 should be considered worsened at discharge, because the ulcer increased in numerical stage during the patient's stay.

Scenario 11: A patient is admitted to the LTCH with documentation of an unstageable pressure ulcer on the left hip. There are physician orders that the dressing is to be

removed on day 4 of the LTCH stay. The dressing is subsequently removed as ordered on day 4, and the wound is assessed as an unstageable pressure ulcer entirely covered with eschar. This unstageable pressure ulcer/injury is unchanged at discharge.

The TEP members concurred with RTI's recommendations that in Scenario 11, the pressure ulcer would not be considered worsened at discharge, because the pressure ulcer did not increase in numerical stage and did not become unstageable due to slough and/or eschar, from the time the pressure ulcer/injury was first observed (i.e., the dressing was removed, and the ulcer assessed).

Some TEP members wished to pursue further discussion regarding a scenario in which a patient with a cast was admitted into a PAC facility with no documentation of a pressure ulcer/injury.

Scenario 12: A patient is admitted to the LTCH with a cast on his right lower extremity, and there is no documentation of a pressure ulcer/injury at the time the cast was applied. The cast is removed during the stay and the skin is assessed to identify a DTI on the heel and a Stage 3 pressure ulcer on the outer ankle which remain unchanged until the time of discharge.

A few TEP members did not agree with the recommendations that the pressure ulcer/injury in Scenario 12 would be considered new, stating that the sending facility should be responsible for the wound, and the PAC facility should not be responsible for a wound underneath a cast that was not applied by staff at the PAC facility. One TEP member commented that until a cast is removed, providers cannot assess whether a wound exists and cannot determine when a pressure ulcer/injury developed. Another TEP member agreed that the PAC facility should not be accountable; rather, the facility applying the cast should be accountable.

4.2.3 Deep Tissue Injury

The TEP was provided with four scenarios involving DTIs. The TEP agreed with rationale for worsening for most of these scenarios.

Scenario 9: A patient is admitted to an IRF with a maroon area of discolored intact skin that is painful and boggy on the sacrum. Based on assessment of the surrounding tissues, this area is determined to be a DTI. The sacral area develops a hard eschar on day 5 of the stay. The sacral area eschar remains dry and stable throughout the remainder of the IRF stay and at discharge.

The majority of TEP members agreed that this scenario depicted a DTI in evolution and not worsened at discharge, because the skin was intact, and the depth of tissue damage was unknown at the time of admission. One TEP member provided pre-TEP feedback indicating that based on recent studies, there is evidence that full thickness tissue damage has already occurred when a patient presents on admission with a DTI. Improved technology may clarify this clinical impression in the future; however, for now, the clinical appearance of DTI indicates that deep tissue damage has already occurred. Eschar would be considered part of the normal evolution, not a worsening.

Scenario 10: A patient is admitted to an IRF with a firm, butterfly-shaped purple and maroon area on the sacrum. Based on assessment of the surrounding tissues this area is determined to be a DTI. The DTI opened and was assessed as a Stage 3 pressure ulcer on day 5. The Stage 3 pressure ulcer remains at a Stage 3 until the time of discharge.

The majority of TEP members agreed that the pressure ulcer/injury in this scenario would be considered not worsened at discharge, because the DTI was present at the time of admission, and the depth of tissue damage was unknown at the time of admission because the skin was intact. Once the pressure ulcer/injury was numerically staged when the DTI opened, it did not increase in numerical stage or transition to an unstageable ulcer due to slough and/or eschar. One TEP member cautioned that using a butterfly-shaped description of the pressure ulcer/injury in training or guidance might be confusing, as this shape is typically associated with Kennedy ulcers.

TEP members discussed two scenarios that highlighted the timing of discovery of a DTI and how the timing of discovery impacts whether the DTI is considered new and is attributable to the PAC facility. The two scenarios are as follows.

Scenario 13: A resident is admitted to a SNF with Stage 1 pressure injury on the coccyx. The skin assessment of the tissues surrounding this injury on day 6 is consistent with DTI. This DTI remains intact at the time of discharge to home 3 days later.

Scenario 14: A patient is admitted to the LTCH and the admission skin assessment reveals no pressure ulcers/injuries. On day 2 of the stay, a DTI is observed at the sacrum and documented in the medical record. This DTI remains unchanged until the time of discharge.

The TEP discussed the importance of the timing of assessment of a DTI, noting that a DTI that should be considered present on admission may not be detected in the assessment time window dictated by PAC assessment and data collection tools. TEP members discussed the range of times in which it could take for a DTI to first be detected. One TEP member indicated that the median time for a DTI to appear is 48 hours. One TEP member cited literature that indicated it could take up to five days for a DTI to appear. A TEP member mentioned a survey conducted by a facility in which it was discovered that a 48–72-hour window was needed to determine whether a DTI was present on admission. Another TEP member shared clinical practice that conducts visual inspection with two staff on admission and then follows up with an additional skin check within 24 hours of the first assessment. Any pressure ulcer/injury within those time frames is counted as present on admission. TEP members stated a need for additional clinical guidance, as there are additional clinical factors that might affect DTI evolution. Additional clinical assessment is needed to differentiate between DTIs acquired at hospital and at PAC facilities.

TEP members noted the need for additional guidance for detecting DTIs. One TEP member indicated that stakeholders frequently request guidance from the National Pressure Ulcer Advisory Panel (NPUAP) regarding the time needed for a DTI to appear. One TEP member noted that stakeholders are looking to CMS or NDNQI to state a time frame for the development of a DTI to determine whether a DTI is present on admission. Due to the lack of existing, consistent guidance, one TEP member stated there was a need for a translational article

to describe DTIs that includes a survey of how providers are assessing and treating DTIs and recommendations, because there appears to be no consensus on this topic.

The majority of TEP members agreed that Scenario 13, which contained a 6-day timeframe, was a clear example of a new DTI. Several TEPs members expressed concern regarding interpretation of Scenario 14, which had a 2-day timeframe, for appearance of a DTI. Some TEP members agreed there is not sufficient provider education, assessment technology, or research to confidently state that a DTI that appears after 2 days is not present on admission. One TEP member also noted the difficulty in differentiating between a Stage 1 pressure injury and a Stage 2 pressure ulcer with a DTI.

SECTION 5 SUMMARY AND NEXT STEPS

5.1 TEP Meeting Summary

RTI and Abt Associates reconvened the pressure ulcer TEP in January 2018 to provide feedback on the concept of “worsened” for unstageable pressure ulcers/injuries, potential updates to manual guidance and definitions for unstageable pressure ulcers/injuries, and guidance for providers regarding worsened unstageable pressure ulcers/injuries.

Prior to the webinar, members were given a pre-TEP worksheet that included proposed definitions for worsening in pressure ulcer/injury status, guidance for determining present on admission status, guidance for classifying a pressure ulcer/injury as unstageable due to slough and/or eschar, and 14 scenarios depicting different configurations of unstageable pressure ulcers/injuries. Feedback from eight TEP members on the pre-TEP worksheet prompted discussion during the TEP meeting. A summary of TEP discussions on each topic follows.

In response to the proposed definitions for worsening in pressure ulcer/injury status, TEP members requested that language related to a linear progression in worsening be avoided. Therefore, TEP members cautioned against language such as “depth,” “progress,” and “evolve” (except for when referring to DTIs).

In response to the proposed guidance for determining present on admission status, TEP members requested a clearer definition for present on admission and that additional guidance be provided for determining present on admission. The majority of TEP members agreed on the need for a specific timeframe, such as 24 hours or 48 hours, for defining present on admission. However, most TEP members agreed that such a timeframe would be problematic for deep tissue injuries, because visualizing or determining the presence of a DTI is more difficult, given the unique etiology and evolution of DTIs.

In response to the proposed guidance for determining a pressure ulcer/injury to be unstageable due to slough and/or eschar, TEP members agreed that a Stage 3 or 4 pressure ulcer that develops slough and/or eschar and becomes unstageable due to slough and/or eschar would be considered worsened. The TEP noted that NPUAP guidance classifies a pressure ulcer with any amount of slough and/or eschar as at least a Stage 3 pressure ulcer (i.e., it would no longer be coded as Stage 2). TEP members requested additional clarification regarding the amount of slough/eschar that indicates unstageable due to slough/eschar and how this should be included in the definition of worsening. TEP members requested additional clarification regarding debridement and how this might impact determinations of worsening status.

In response to the 14 scenarios involving unstageable pressure ulcer/injury configurations, TEP members had high consensus on the status of worsening in scenarios involving an unstageable pressure ulcer/injury due to a nonremovable dressing or device. However, TEP members expressed concern with one scenario in which a patient/resident is admitted to a PAC facility with a non-removable dressing or device, and no documentation of known pressure ulcers/injuries, and is later discharged with pressure ulcers/injuries that were revealed underneath the cast. Most TEP members felt that the PAC facility should not be

responsible for a wound underneath a cast that was not applied by staff at the PAC facility, and the wound should not be considered new.

Lastly, a few TEP members had suggestions for additional risk adjustment including urinary incontinence and spinal cord injury as potential risk adjusters.

5.2 Next Steps

RTI and Abt Associates will consider TEP feedback and make recommendations to CMS for potential refinements to guidance for pressure ulcer coding for the quality measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. RTI and Abt Associates will use this TEP feedback to inform revisions and updates to future manuals and will make recommendations for additional guidance and coding scenarios to clarify and align training materials. Additionally, RTI and Abt Associates will continue to provide guidance through provider trainings and responses to help desk questions.

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APPENDIX A: TEP MEMBERS

❖ Elizabeth A. Ayello, Ph.D., RN, ACNS-BC, CWON, ETN, MAPWCA, FAAN

President; Clinical Editor for Advances in Skin and Wound Care

Ayello, Harris & Associates, Inc

Hillis Hills, NY

Senior Adviser

The John A. Hartford Foundation Institute for Geriatric Nursing

New York, NY

Dr. Elizabeth Ayello is a board certified wound and ostomy nurse recognized as an expert in pressure ulcers, wounds, skin, ostomy and continence practice, education and research. In addition to serving as the clinical editor for the journal *Advances in Skin and Wound Care*, she is a faculty member at Excelsior College School of Nursing, Vice President of World Council of Enterostomal Therapists (WCET), and executive editor emeritus for *WCET Journal*. Dr. Ayello served on the Board of Directors, was former president of the NPUAP, and holds several other leadership positions in a range of other wound care organizations. In addition to her clinical background, Dr. Ayello has experience working with quality improvement processes through her role as a consultant on several pressure ulcer quality initiatives, including consulting on the development of Minimum Data Set (MDS) 3.0 section M skin conditions for Long-Term Care, Long-Term Acute Care Hospital and Inpatient Rehabilitation Units. Furthermore, Dr. Ayello has published over 100 peer-reviewed journal articles and has co-authored various educational, wound care resources.

❖ Laurie Crookenden, BS, RN, CWOCN, CRRN

Wound, Ostomy, and Continence Nurse

Carolinas Rehabilitation

Charlotte, NC

Ms. Crookenden is recognized as an expert in rehabilitation and wound care as demonstrated by her certifications in these areas and her election by her peers to serve as President of the North Carolina Wound, Ostomy, and Continence Nurses (WOCN) Group. She is board certified in wound, ostomy, and continence care by the Wound, Ostomy, and Continence Nursing Certification Board. Ms. Crookenden possesses a firm foundation in quality improvement and performance measurement for pressure ulcers in post-acute care. She also served on several quality improvement teams during her career. Ms. Crookenden is a certified rehabilitation registered nurse and has been a WOCN for 10 years at Carolinas Rehabilitation, a large rehabilitation hospital in Charlotte, NC. Carolinas Rehabilitation participated in the Hospital Engagement Network, a CMS initiative supported by a grant, which advises and implements strategies to prevent hospital-acquired pressure ulcers and skin breakdown. Ms. Crookenden has served as a member of the grant's implementation team since it was awarded in 2012. In addition, Ms. Crookenden is Chair of Carolinas Rehabilitation's Skin Care Liaison Team, where she has helped maintain a hospital-acquired pressure ulcer rate of less than 2 percent.

❖ **Janet Cuddigan, PhD, RN, CWCN, FAAN**

Associate Professor

University of Nebraska Medical Center School of Nursing

Omaha, NE

Adjunct Professor

Kansas University Medical Center School of Nursing

Kansas City, KA

As a board-certified wound care nurse, Dr. Janet Cuddigan brings clinical knowledge of pressure ulcers/injuries and wound care in a range of settings, including acute care, long-term care, skilled nursing facilities, nursing homes, and home health care. During her career, she has served as an expert clinician, educator, and researcher across multiple settings. Since 1995, she has held multiple positions on the NPUAP Board of Directors. Given her commitment and contributions to the organization, Dr. Cuddigan received the NPUAP Kosiak Award in 2011. Additionally, in 2015, she received the NPUAP President's Award for Leadership in developing the international pressure ulcer guidelines. Dr. Cuddigan also has experience in quality improvement and performance measurement, development, and implementation through her role as the Pressure Injury Consultant to the NDNQI. At NDNQI, she contributed to the ongoing refinement of NDNQI pressure injury indicators, participated in data collection and analysis of measures, and reviewed and revised the pressure ulcer value sets. In her current role as an educator and researcher, Dr. Cuddigan continues to contribute to the ongoing refinement of pressure ulcer/injury guidelines as the Co-Chair of the 2019 NPUAP-European Pressure Ulcer Advisory Panel-Pan Pacific Pressure Injury Alliance International Guideline Governance Group.

❖ **Barbara A. Dale, RN, BSN, CWOCN, CHHN, COS-C**

Director of Wound Care

Quality Home Health

Livingston, TN

Ms. Barbara Dale serves as Director of Wound Care for Quality Home Health, a large proprietary home health agency in rural middle/east Tennessee, serving an average daily census of 1600 patients. In this role, she serves as a patient consultant, conducting comprehensive wound assessments and recommendations, ostomy care and teaching, continence assessments, and education. Ms. Dale has led and participated in numerous quality improvement (QI) projects in her current role, including surgical wound improvement initiatives, which eventually led to policy and practice change. Currently, Ms. Dale conducts monthly QI audits on the five potentially avoidable events that are wound or continence related, working closely with OASIS data items related to skin/wounds, diabetes, and Braden scale scoring. In addition to her clinical experience and quality improvement knowledge, Ms. Dale is board certified in the following: CWOCN—wound, ostomy, & continence nursing by the Wound Ostomy Continence Nurses Certifying Board; CHHN—home health nursing by the American Nurses Credentialing Center; and COS-C—Certificate OASIS Specialist-Clinical by the OASIS Certificate & Competency Board. Additionally, Ms. Dale has participated in various projects related to wound care and home health, published on the topics of wound care and pressure ulcers, and been invited to present on her work and expertise.

❖ **Jean M. deLeon, MD, FAPWCA**

Professor; Physical Medicine & Rehabilitation; Medical Director of Wound Care
University of Texas (UT) Southwestern Medical Center
Dallas, TX

Dr. Jean deLeon, board certified in Physical Medicine and Rehabilitation, received her degree from the University of Oklahoma. Dr. deLeon has focused her career on wound care, with clinical experience in LTCHs and IRFs. She was responsible for developing the first wound care program and outpatient wound care center at Baylor Specialty Hospital in Dallas, TX, and the first inpatient wound care unit in the Baylor Health Care system. She left the Baylor Healthy Care System in 2012 and took a position of Professor in the Department of Physical Medicine and Rehabilitation at UT Southwestern Medical Center in Dallas, TX. She helped open the first outpatient wound care clinic for the University. She currently serves as Medical Director of the UT Southwestern University Wound Care and Hyperbaric Clinic and as Medical Director of Wound Care at Lifecare Dallas Long Term Acute Care Hospital. Her area of interest is improving clinical outcomes and developing process improvement initiatives. She also serves as the wound care quality consultant for the Parkland Healthcare System. UT Southwestern and Texas Health Resources have recently formed an Accountable Care Organization (ACO), and Dr. deLeon is helping to lead the Post-Acute Care strategy for the ACO. She has also provided expertise on a range of national wound and post-acute care quality measurements.

❖ **Aimee Garcia, MD, CWS, FACCWS**

Director, Clinical Wound Care Fellowship; Associate Professor of Medicine and Geriatrics
Baylor College of Medicine
Houston, TX
Medical Director, Wound Care Clinic and Consult Service
Michael E. DeBakey VA Medical Center
Houston, TX

Dr. Aimee Garcia has spent her entire career serving the geriatric population, focusing her career on Geriatric Medicine and wound care. In her current role as Medical Director at the Michael E. DeBakey VA Medical Center in Houston Center, she serves an elderly veteran population in acute care, long-term care, skilled nursing, and hospice settings. She has clinical expertise on wound care in all care settings, including outpatient care. Dr. Garcia has published on the topics of wound care and pressure ulcers and has presented nationally and internationally on the prevention and treatment of pressure ulcers. Additionally, Dr. Garcia was President of the NPUAP from 2012-2013 and has served as the Chair of the Public Policy Committee for the NPUAP since 2008, where she has contributed to the ongoing prevention and treatment of pressure ulcers, working with CMS to develop a standardized, cross-setting tool to track pressure ulcers across the care continuum.

❖ **Brenda Mallory, MD**

Professor of Physical Medicine and Rehabilitation

Penn State College of Medicine

Hummelstown, PA

Dr. Mallory serves as the Chief Medical Officer of the Penn State Hershey Rehabilitation Hospital (PSHRH), where she is tasked with overseeing the medical care of persons receiving treatment in: PSHRH's 98 bed Inpatient Rehabilitation Facility and Transitional Care (which provides SNF level of care), Outpatient Rehabilitation Therapy Department and Wound Care Center. At the PSHRH, the integration of wound care specialists, inpatient teams and outpatient teams in both the IRF and SNF settings, has resulted in a standardized, evidence driven approach to quality care for persons at risk for pressure injury. She has worked to facilitate best practices to improve patient outcomes for pressure ulcers in multiple settings and levels of care. Her professional experience includes consulting in an acute care hospital, where strategies to prevent pressure injury are at the forefront. Additionally, she is familiar with outpatients with spinal cord injury and extensive pressure ulcers. Dr. Mallory has coordinated care with Home Services and Plastic Surgeons, as well as physical and occupational therapists and certified rehabilitation technology specialists. She also holds a firm grounding in quality improvement and performance measurement. She implements the PSHRH's quality assessment and performance improvement and served as the Director of Quality Assurance for the Department of Physical Medicine and Rehabilitation from 2010 to 2015. Among her numerous professional memberships, Dr. Mallory is a Fellow of the American Academy of Physical Medicine and Rehabilitation, a member of the American Association of Academic Physiatrists, and a member of the American Spinal Injury Association.

❖ **Benjamin Peirce, BA, RN, CWOCN**

VP of Utilization and Quality Management

Wound Technology Network

Plantation, FL

Mr. Benjamin Peirce serves as Vice President of Utilization and Quality Management for a physician-based provider of wound management services in the home for health plan and medical group patients in Florida, California, Nevada and Texas. In addition to his clinical experience, Mr. Peirce has worked in QI for the past 4 years and has led and participated in numerous QI projects, including the Post-Acute Care Payment Reform Demonstration project in 2008 while employed by Gentiva Home Health and Hospice. Currently, Mr. Peirce serves as Chair of the OASIS Task Force of the Wound Ostomy Continence Nursing Society (WOCN). This task force is responsible for maintaining the WOCN OASIS Guidance document to facilitate accurate classification of wounds by home health clinicians when answering integumentary items in OASIS. He also served as Co-Chair of the Pressure Ulcer Framework Steering Committee for the NQF in 2009.

❖ **Tara Roberts, PT**

VP of Rehabilitation and Wound Care Services

Nexion Health Management, Inc.

Sykesville, MD

Ms. Tara Roberts has 21 years of experience as a Physical Therapist, where she has practiced in acute, subacute, and post-acute care settings, serving the inpatient, outpatient, IRF, LTCH, SNF, and home health patient populations. In her most recent role serving the SNF and LTCH settings, Ms. Roberts authored the SUCCESS (Securing Unmatched Clinical Competence in an Evolving Skin System) skin and wound care platform, as well as the iCARE approach to effective clinical management for skin and wound care. In addition, Ms. Roberts developed the 3 Cs of Skin and Wound Care training module, a skin and wound care program that emphasizes Competence, Confidence, and Continuous quality assurance. In her current role as Vice President of Rehabilitation and Wound Care Services with Nexion Health, Ms. Roberts educates nursing and physical therapy staff on skin and wound care management. Additionally, Ms. Roberts serves on the Board of Governors for the National Association for the Support of Long-Term Care, serving on the IMPACT Act and Medical Services committees. She is also a member of the American Health Care Association, serving on the Quality Improvement and Political Involvement committees, and participating in the development of a Short and Long Stay Quality Measure for Unintended Healthcare Outcomes and development of an Infection Prevention Control Officer Tract and Certification; American Physical Therapy Association member of Geriatrics, Clinical Electrophysiology and Wound Management, Cardiovascular and Pulmonary section, and Regulatory section sub-committees. Ms. Roberts currently co-chairs the Licensed Nursing Home Administrators Quality Improvement Initiative Committee for Pressure Ulcers. Given her extensive wound care clinical experience and knowledge, Ms. Roberts is frequently a guest columnist for McKnight's Long-Term Care News and has provided continuing education on the topic of wound care and pressure ulcers, with emphasis on MDS Coding and Quality of Care and Quality Improvement Strategies for pressure ulcers.

❖ **Aamir Siddiqui, MD**

Division Head of Plastic Surgery

Henry Ford Hospital

Detroit, MI

Dr. Aamir Siddiqui serves as the Division Head of Plastic Surgery at Henry Ford Hospital and the Medical Director of Wound Care Service, where he has focused his career on wound care and reconstructive surgery. In his current role, Dr. Siddiqui treats pressure ulcer patients in both inpatient and outpatient settings and contributes to clinical and benchtop research. Dr. Siddiqui has also worked on quality improvement initiatives and currently serves on the Board of Directors of the NPUAP. Dr. Siddiqui was named the American Society of Plastic Surgeons representative to the American Medical Association Physician Consortium for Performance Improvement and served on the work group that developed the Medicare Physician Quality Reporting Initiative chronic wound measures approved by the National Quality Forum. Dr. Siddiqui is also active in the Wound Healing Society and serves as the co-program chairperson for the 2013 annual meeting. As an educator, he is involved in the training of surgery

residents and plastic surgery fellows and travels internationally as part of medical missions for the correction of acquired and congenital deformities.

❖ **Sheri Slater, M.S.**

Patient Representative

Forest Hills, MD

Ms. Sheri Slater received her Master of Science in Child Life from the University of La Verne in La Verne, CA, and brings a valuable patient perspective to the TEP. Ms. Slater has volunteered and worked as a Child Life Specialist and has studied the effectiveness of various therapies for children, focusing on helping children cope with being in the hospital by providing therapeutic interventions to relieve anxiety through play, preparing children for procedures, and helping children and families have the best experience they can while in the hospital. Ms. Slater also served as the patient representative on the 2013 cross-setting pressure ulcer TEP.

**APPENDIX B:
TEP WEBINAR AGENDA**

**Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Technical Expert Panel (TEP) Meeting**

Agenda

Technical Expert Panel (TEP) Meeting
Development of Pressure Ulcer (PU) Measures for Post-Acute Care

11:00am-4:00pm EST, Tuesday, January 30th, 2018
Dial-in Number: (see attachment for instructions to join the webinar)

—TEP Schedule—

<i>Time</i>	<i>Agenda Item</i>	<i>Lead</i>
1:00–1:15 pm	Welcome and Introductions	RTI
1:15–1:30 pm	Background and Overview of Issues Needing TEP Input	RTI
	<ul style="list-style-type: none"> • Background and summary of feedback from previous TEP (July 2016) • Update on measure in FY2018 rule 	
1:30–2:15 pm	Review of Manual Definitions and Guidance	RTI
	<ul style="list-style-type: none"> • Definition of Worsening • Definition of Unstageable Pressure Ulcer/Injury Due to Slough and/or eschar • Guidance for Determining Present on Admission • Topics for Discussion: <ul style="list-style-type: none"> – <i>Are the proposed definitions of worsening clear and understandable to providers? If not, which elements would you recommend be clarified or modified?</i> – <i>Are the proposed definitions of unstageable pressure ulcers clear and understandable to providers? If not, which elements would you recommend be clarified or modified?</i> – <i>Is the proposed guidance for present on admission clear and understandable to providers? If not, which elements would you recommend be clarified or modified?</i> – <i>Are there any setting-specific concerns regarding this proposed addition?</i> – <i>Are there any special considerations that need to be taken into account in conveying information about the changes to stakeholders?</i> 	
2:15–2:30 pm	Break	

2:30–3:45 pm

Review of Unstageable Scenarios

RTI

- Prioritize Scenarios for discussion based on CMS guidance

3:45–4:00 pm

Wrap-Up and Next Steps

RTI

- Review consensus decisions and areas for further exploration
- Review next steps

**APPENDIX C:
PRESSURE ULCER SCENARIO EXERCISE WORKSHEET AND SUMMARIZED TEP
MEMBER RESPONSES**

Unstageable Pressure Ulcer/Injury Scenarios

Background: CMS's measure development contractor has developed a new pressure ulcer/injury measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will be effective July 2018 for Long Term Care Hospitals (LTCHs) and October 2018 for Inpatient Rehabilitation Facilities (IRFs) and Skilled Nursing Facilities (SNFs). This new measure includes new and worsened unstageable pressure ulcers. We recognize the prior definition of worsening (increasing in numerical stage) is no longer adequate for the new measure. We seek to update the definition of worsening and obtain feedback on scenarios in order to ensure clinical accuracy.

Definition: WORSENING IN PRESSURE ULCER STATUS

Is when a numerically staged pressure ulcer/injury has progressed to a deeper level of tissue damage and is therefore staged as a higher number using the staging assessment system classifications assigned to each stage (starting at Stage 1 and increasing in severity to Stage 4) **OR** Any pressure injury or numerically staged pressure ulcer/injury that becomes unstageable due to slough and/or eschar.

Scenario 1. Stage 2 pressure ulcer transitions to Unstageable due to slough/eschar

A patient is admitted to the LTCH with a Stage 2 pressure ulcer on her left heel. A week into the stay the left heel ulcer begins to develop eschar and by discharge the ulcer is covered with eschar and the wound bed/extent of tissue damage cannot be visualized. The left heel wound is therefore unstageable due to slough/eschar at the time of discharge.

We consider this pressure ulcer/injury to be worsened at discharge because the numerically stageable pressure ulcer became unstageable due to slough and/or eschar. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Six TEP members agreed with the presented scenario and interpretation. Two TEP members expressed concern with the interpretation of this scenario. One TEP member clarified that scenarios involving heels are especially tricky and if this wound is due to lack of blood flow to the patient's heel then the wound evolution would not necessarily be considered worsened. One TEP member expressed concern about the scenario, stating that even after debridement, the wound can appear to be covered with eschar for a few days.

Scenario 2. Stage 3 pressure ulcer transitions to partially covered with slough/eschar

A resident is admitted to the SNF with a Stage 3 pressure ulcer at his right hip. On day five, the hip ulcer is noted to have eschar at the center of the ulcer and at discharge, this ulcer is partially covered with eschar however, full thickness tissue loss is observed and subcutaneous fat is visible.

We consider this pressure ulcer not to be worsened at discharge, because the ulcer is still numerically stageable and did not increase in numerical stage or become unstageable due to slough and/or eschar. Do you see any major issues or concerns with this interpretation? If so, please describe.

***Summarized TEP Member Response:** Four TEP members agreed with the presented scenario and interpretation of the scenario to be considered not worsened. Four TEP members disagreed with the interpretation of this scenario, stating that the wound could not be determined as worsening since we cannot determine what is under the eschar. Some TEP members would require additional information such as placement and percentage of the eschar covering the wound in order to determine worsening status. One TEP member clarified that since the wound was covered at its center by eschar, the worsening status could not be determined until enough eschar was removed to reveal the center of the wound bed. Since the scenario describes eschar on the center of the wound rather than the wound perimeter to ensure the wound was still a Stage 3 at discharge and therefore not worsened.*

Scenario 3. Stage 3 pressure ulcer transitions to unstageable due to slough/eschar

A resident is admitted to the SNF with a Stage 3 pressure ulcer at his right hip. The ulcer is assessed on day five and slough is observed and noted. The resident is assessed at discharge and the ulcer is entirely covered with slough and the wound bed/extent of tissue damage cannot be visualized.

We consider this pressure ulcer/injury to be worsened at discharge.^a Do you see any major issues or concerns with this interpretation? If so, please describe.

***Summarized TEP Member Response:** Three TEP members agreed with the presented scenario and interpretation. Five TEP members expressed concern with the interpretation of the scenario. One of these TEP members would need more information about the change in size of the wound and percentage of necrotic tissue to determine worsening status. Two TEP members noted that because the wound is completely covered by slough, the extent of tissue damage is unable to be assessed. Therefore, worsening status cannot be assessed. Some TEP members stated it helpful to define the criteria for the necessary amount of eschar required for an injury to be unstageable. Additionally, one TEP member expressed concern with the definition of worsening and indicated that worsening status could be defined as increasing in numerical stage and a Stage 3 becoming unstageable due to slough/eschar can be cleaned to reveal no worsening in numbered stage.*

Scenario 4. Stage 4 pressure ulcer transitions to partially covered with slough/eschar

A patient is admitted to the IRF with a Stage 4 pressure ulcer on her left hip. Upon reassessment at the time of discharge this ulcer is partially covered with eschar, but bone is visible.

We consider this pressure ulcer not to be worsened at discharge, because the ulcer is still numerically stageable and did not increase in numerical stage or become unstageable due to slough and/or eschar. Do you see any major issues or concerns with this interpretation? If so, please describe.

^a. Please note this interpretation represents a change from current guidance and will be implemented with implementation of the new pressure ulcer/injury measure in 2018.

Summarized TEP Member Response: Six TEP members agreed with the presented scenario and interpretation. Two additional TEP members agreed with the interpretation of this scenario as not worsened but had additional comments. One of the TEP members clarified that a Stage 4 without eschar that subsequently develops eschar would be worsened, not necessarily in numerical stage, but overall it has worsened. In response to this scenario, one of the TEP members also encouraged use the collection of additional data including a standardized healing score.

Scenario 5. Stage 4 pressure ulcer transitions to unstageable due to slough/eschar

A patient is admitted to the IRF with a Stage 4 pressure ulcer on her left hip. Upon reassessment at the time of discharge this ulcer is entirely covered with eschar and the wound bed cannot be assessed. The patient is discharged with an unstageable pressure ulcer/injury due to slough/eschar.

We consider this pressure ulcer/injury to be worsened at discharge. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Two TEP members agreed with the presented scenario and interpretation. Two TEP members agreed with the scenario but expressed concern. One TEP member stated it would be helpful to define the criteria for the necessary amount of eschar required for an injury to be unstageable. Another TEP member expressed concern, stating that even after debridement, the wound can appear to be covered with eschar for a few days and should not necessarily be considered worsened. Four TEP members disagreed with the interpretation of this scenario and emphasized there is nothing worse than a Stage 4 pressure ulcer; therefore, the pressure ulcer cannot worsen and the presence of slough/eschar would not make a Stage 4 worsened.

Scenario 6. Unstageable pressure ulcer due to slough/eschar transitions to unstageable due to non-removable dressing

A patient is admitted to the LTCH with an unstageable pressure ulcer due to the entire wound bed being covered with slough. Three days prior to discharge, the patient is seen at the wound clinic. Biological debridement is initiated and the patient returns with a dressing covering the wound and orders not to remove the dressing. The follow up wound clinic appointment is scheduled, but the patient is discharged to another facility before the scheduled appointment occurs. The patient is therefore discharged with an unstageable pressure ulcer/injury due to non-removable dressing/device.

We consider this pressure ulcer not to be worsened at discharge because the ulcer was unstageable at the time of admission due to slough and did not increase in numerical stage or become unstageable due to slough or eschar at the time of discharge. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: All eight responding TEP members agreed with the scenario and interpretation as presented.

Scenario 7. Stage 3 pressure ulcer transitions to unstageable due to non-removable dressing/device

A patient is admitted to the IRF with a Stage 3 pressure ulcer at the right buttocks. During the course of her stay she is seen at the wound clinic and returns to the IRF with a dressing and orders that the

dressing is to remain intact until the next clinic visit. The patient is discharged to a SNF prior to the follow-up wound clinic visit. At the time of discharge this ulcer is covered with a non-removable dressing.

We consider this pressure ulcer/injury not to be worsened at discharge because there is no evidence that the ulcer increased in numerical stage or became unstageable due to slough or eschar. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: All eight responding TEP members agreed with the scenario and interpretation as presented.

Scenario 8. Stage 3 pressure ulcer that transitions to a Stage 4 pressure ulcer then is covered with a non-removable dressing

A patient is admitted to the IRF with a Stage 3 pressure ulcer at her right buttocks. On day 5 of her stay the ulcer is assessed as a Stage 4 pressure ulcer. She is seen at the wound clinic and returns to the IRF with a dressing and orders that the dressing is to remain intact until the next clinic visit. The patient is discharged to a SNF prior to the follow-up wound clinic visit. At the time of discharge this ulcer is covered with a non-removable dressing.

We consider this pressure ulcer/injury to be worsened at discharge because the ulcer increased in numerical stage during the patient's stay. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: All eight responding TEP members agreed with the scenario and interpretation as presented.

Scenario 9. Deep Tissue Injury (DTI) that transitions to an ulcer entirely covered with eschar

A patient is admitted to an IRF with a maroon area of discolored intact skin that is painful and boggy on the sacrum. Based on assessment of the surrounding tissues this area is determined to be a DTI. The sacral area develops a hard eschar on day 5 of the stay. The sacral area eschar remains dry and stable throughout the remainder of the IRF stay and at discharge.

We consider this pressure ulcer/injury to be a DTI in evolution and not worsened at discharge because the skin was intact and the depth of tissue damage was unknown at the time of admission. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Seven TEP members agreed with the scenario and interpretation as presented. One TEP member agreed with the interpretation, but provided additional feedback. The TEP member clarified that the clinical appearance of DTI indicates that deep tissue damage has already occurred. Eschar would be part of the normal evolution of a DTI and would not necessarily indicate worsening.

Scenario 10. DTI that reveals itself as a Stage 3

A patient is admitted to an IRF with a firm, butterfly-shaped purple and maroon area on the sacrum. Based on assessment of the surrounding tissues this area is determined to be a DTI. The DTI opened and

assessed as a Stage 3 pressure ulcer on day 5. The Stage 3 pressure ulcer is remains at a Stage 3 until the time of discharge.

We consider this pressure ulcer/injury not to be worsened at discharge because the DTI was present at the time of admission, the depth of tissue was unknown at the time of admission because the skin was intact, and once the ulcer was numerically staged when the DTI opened, it did not increase in numerical stage or transition to an unstageable ulcer due to slough or eschar. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Six TEP members agreed with the scenario and interpretation as presented. One TEP member agreed with the interpretation of this scenario however the TEP member cautioned against using the term “butterfly-shaped”, which is typically associated with Kennedy Ulcers. Another TEP member felt unsure about this coding scenario, questioning whether a DTI that has evolved could be staged or classified as worsened.

Scenario 11. Unstageable due to non-removable dressing transitions to unstageable due to slough/eschar

A patient is admitted to the LTCH with documentation of an unstageable pressure ulcer on the left hip. There are physician orders that the dressing is to be removed on day 4 of the LTCH stay. The dressing is subsequently removed as ordered on day 4 and the wound is assessed as an unstageable pressure ulcer entirely covered with eschar. This unstageable pressure ulcer/injury is unchanged at discharge.

We consider this pressure ulcer/injury not to be worsened at discharge because the pressure ulcer did not increase in numerical stage or become unstageable due to slough or eschar, from the time the ulcer was first observed (i.e. the dressing was removed and the ulcer assessed). Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: All eight responding TEP members agreed with the scenario and interpretation as presented

Scenario 12. No documented pressure ulcer/injury at admission, upon removal of cast a DTI and a Stage 3 pressure ulcer are assessed

A patient is admitted to the LTCH with a cast on his right lower extremity and there is no documentation of a pressure ulcer/injury at the time the cast was applied. The cast is removed during the stay and the skin is assessed to identify a DTI on the heel and a Stage 3 pressure ulcer on the outer ankle which remain unchanged until the time of discharge.

We consider this pressure ulcer/injury to be new and not to be worsened at discharge. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Six TEP members agreed with the scenario and interpretation as presented. Two TEP members expressed concern, saying this would not be attributable to the wound care of the facility but rather to the person applying the cast and the accepting facility should not be responsible for a cast they did not apply. This wound should be counted as present on admission rather than new.

Scenario 13. Stage 1 pressure injury that later presents as a DTI

A resident is admitted to a SNF with Stage 1 pressure injury on the coccyx. The skin assessment of the tissues surrounding this injury on day 6 is consistent with a DTI. This DTI remains intact at the time of discharge to home 3 days later.

We consider this pressure ulcer/injury to be worsened at discharge because assessment of the pressure injury and surrounding tissue indicates an increase in tissue damage not previously present. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Three TEP members agreed with the scenario and interpretation as presented. Five TEP members expressed concern with this scenario, specifically surrounding factors affecting the DTI evolution. One TEP member expressed concern and requested additional details to explain what classified the pressure injury as a Stage 1 on admission and what classified it as a DTI on Day 6. Two TEP members expressed concerned with properly differentiating a Stage 1 from a DTI and stated that a DTI can often be present on admission but go undetected on admission due to delayed evolution. One TEP member agreed with the scenario but expressed concern that a DTI evolution is dependent on many outlier factors is not reflective of the quality of care in the facility.

Scenario 14. DTI revealed on day 2, not assessed on admission assessment

A patient is admitted to the LTCH and the admission skin assessment reveals no pressure ulcers/injuries. On day 2 of the stay, a DTI is observed at the sacrum and documented in the medical record. This DTI remains unchanged until the time of discharge.

We consider this pressure injury to be new because the resident did not have a pressure ulcer or injury on the sacrum at the time of admission. Do you see any major issues or concerns with this interpretation? If so, please describe.

Summarized TEP Member Response: Five TEP members agreed with the scenario and interpretation as presented. However, two TEP members acknowledged there are many outlying factors affecting DTI evolution which may not be reflective of the quality of care in the facility. Three TEP members had concerns with this scenario, stating that a DTI could have been present but gone undetected on admission since oftentimes it takes 48 to 72 hours before the DTI manifests. Therefore, one of the TEP members felt that this should not be counted as present on admission or worsened.