Public Comment Summary Report

Project Title:

Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury"

Dates:

- The Call for Public Comment ran from October 17, 2016 to November 17, 2016.
- The Public Comment Summary was finalized on (insert posting date).

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with RTI International and Abt Associates to further develop and refine a cross-setting post-acute care pressure ulcer measure in alignment with the Improving Medicare Post-Acute Care Transformation Act of 2014 (known as the IMPACT Act).

The contract names are Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I; Task Order HHSM-500-T0001) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (contract number HHSM -500-2013-13001I, Task Order HHSM-500T0002).

The purpose of this Call for Public Comment was to seek input on the further development of pressure ulcer measures for post-acute care (PAC) settings, including adaptations to measure specifications such as potential changes to the measure numerator, changes to assessment items used to calculate the quality measure and potential terminology changes.

Project Objectives:

- To obtain input on updates to the following cross-setting pressure ulcer measure in PAC settings:
  - Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678). (http://www.qualityforum.org/QPS/0678) (must accept copyright notice to access)
- To obtain feedback regarding potential updates to measure specifications and items used to calculate the quality measure.
- To further refine the cross-setting approach to data collection for pressure ulcers for SNFs, IRFs, LTCHs, and HHAs.

Information About the Comments Received:

- Web site used: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html
- Public comments were solicited by the following methods:
  - Posting on the CMS Public Comment website
  - Email notification to relevant stakeholders and stakeholder organizations
  - Email notification to the measure's Technical Expert Panel members.

Volume of responses received: CMS received a total of 79 submissions, 12 of which were duplicates of form letters, and three of which were received after the closing date. Many of the letters contained more than one comment; 30 of these included comments which were out of scope. The comment letters were submitted by a range of stakeholders, including providers, administrators and managers in PAC settings, academicians and researchers with technical expertise in quality measurement and pressure ulcer assessment and treatment, and advocacy associations representing a variety of PAC settings.

Stakeholder Comments—General and Measure-Specific

This report provides a summary of public comments received and CMS' responses to the public comments. CMS would like to thank all commenters for sharing their comments, concerns, and suggestions. In general, CMS received considerable support for the refinement of the pressure ulcer measure. We appreciate concerns shared by commenters, and have provided responses and clarifications regarding these concerns. At the end of the report, we provide a table containing the verbatim text of all public comments received.

1. General Support

Summary: A few commenters provided their support of all potential changes to the pressure ulcer measure under the project "Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term 'Pressure Injury'". One commenter mentioned the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings. One family member provided information regarding their experience as the caregiver to their parent, who had been a patient in multiple PAC facilities and had developed pressure ulcers, deep tissue injuries, and skin breakdown. The commenter expressed concern over quality of care and supported CMS' efforts to improve quality of care and address pressure ulcer issues. One commenter supported the revisions in the measure specifications and assessment items, contingent upon the updates being implemented uniformly across PAC settings.

Response: We thank commenters for their support of potential changes to the pressure ulcer measure under the project "Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term 'Pressure Injury'". In order to fulfill the

requirements of the IMPACT Act, CMS has engaged in multiple efforts to ensure standardization of assessment data and to align the pressure ulcer quality measure specifications across the PAC settings. We agree that skin integrity and changes in skin integrity are important issues for PAC settings and implementation of related quality measures should promote high-quality, person-centered care.

2. Inclusion of Unstageable Pressure Ulcers in the Quality Measure

Summary: Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and deep tissue injury (DTI)[9] (NPUAP, 2016) in the quality measure. A few commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar and due to non-removable dressing/device; however they did not support the inclusion of DTIs in the quality measure stating there was no universally accepted definition for this type of skin injury. A few commenters did not support the inclusion of any type of unstageable pressure ulcers in the quality measure, providing the reason that this would substantially change the measure and complicate the coding of new or worsened pressure ulcers.

Response: CMS appreciates comments regarding the inclusion of unstageable pressure ulcers, including DTIs in the quality measure. Unstageable pressure ulcers, including DTIs, are a debilitating, painful and potentially avoidable outcome of medical care, similar to Stage 2, Stage 3 and Stage 4 pressure ulcers.[1,2,3,4,5,6] Studies show that unstageable pressure ulcers can also be healed in acute, post-acute and long term care settings with appropriate medical care. Furthermore, some studies indicate that deep tissue injuries (DTIs), if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[7,8]

A cross-setting pressure ulcer Technical Expert Panel (TEP) convened by our measure development contractor in June and November 2013 strongly recommended that CMS hold providers accountable for the development of new unstageable pressure ulcers and DTIs by including them in the numerator of the quality measure. Although the TEP acknowledged that unstageable pressure ulcers and DTIs cannot and should not be assigned a numeric stage, panel members recommended that these be included in the numerator of NQF #0678 as new pressure ulcers if they develop in the facility. These

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[1] Casey, G. (2013). "Pressure ulcers reflect quality of nursing care." Nurs N Z 19(10): 20-24.
[2] Gorzoni, M. L. and S. L. Pires (2011). "Deaths in nursing homes." Rev Assoc Med Bras 57(3): 327-331.
[3] Thomas, J. M., et al. (2013). "Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality." J Am Geriatr Soc 61(6): 902-911.
[4] White-Chu, E. F., et al. (2011). "Pressure ulcers in long-term care." Clin Geriatr Med 27(2): 241-258.
[5] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744-51.
[6] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230-235.
[7] 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
[8] 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

recommendations were supported by advice provided by technical and clinical advisors and the National Pressure Ulcer Advisory Panel (NPUAP) in July 2014. An additional cross-setting TEP convened by our measure development contractor in July 2016 also supported the recommendation to include unstageable pressure ulcers in the numerator of the quality measure.

Analysis conducted by the measure development contractor indicated that adding unstageable pressure ulcers to the quality measure numerator resulted in a higher percentage of patients with new or worsened pressure ulcers in IRF, LTCH and NH/SNF settings and increased the variability of measure scores. A higher percentage indicates lower quality. This increased variability serves to improve the measure by improving the ability of the measure to distinguish between high and low quality facilities. Analyses showed the impact of adding unstageable pressure ulcers, including DTIs, varied by setting with the score increase ranging from 0.1% in IRF settings to 0.2% in LTCH settings to 1.7% in NH/SNF settings. In the IRF setting, using data collected from October 2014 through March 2015, adding the unstageable pressure ulcers increased the mean risk-adjusted pressure ulcer score from 0.9% to 1.0%. Using data collected from June 2013 through June 2014, the mean LTCH risk-adjusted score increased from 2.6% to 2.8% when adding unstageable pressure ulcer items. In NH/SNFs for the reporting period including data collected from October 2011 through March 2012, the mean risk-adjusted score increased from the original measure of 1.8% to 3.5% when we added unstageable pressure ulcer items.

3. Use of M0300 (M1311 OASIS) items instead of M0800 (M1313 OASIS) items to calculate the quality measure

Summary: Some commenters expressed general support for the use of M0300/M1311 items instead of M0800/M1313 items to calculate the quality measure. One commenter further encouraged alignment with other ongoing pressure ulcer and wound assessment projects in which pressure ulcer information and terminology standards were being harmonized. Several commenters representing the IRF and home health settings supported the transition to M0300/M1311 items, stating these items simplified the measure calculations and did not require the provider to perform the mental calculation and then enter it into the assessment item, which is the current practice.

Some commenters did not support the transition to M0300/M1311 items, stating that the current M1313 items are clearer. A few commenters expressed concern over the lack of reliability and validity testing for these items, particularly for the IRF setting where items for this measure have only been collected since October 2016. One commenter indicated concern for using an inferred, calculated numerator and believed the M0800 item to be more straightforward, while another commenter indicated that the currently implemented method using M0800 items requires the provider to determine if a pressure ulcer is new or worsened and then enter the data into an additional assessment item. One commenter provided analyses of IRF data showing differences between the two calculation methods and indicated that the transition to M0300 items could overestimate the number of new/worsened pressure ulcers. One commenter noted the lack of comparability between the two items in terms of how unstageable pressure ulcers will be counted as new or

worsened stating the use of M0300 items will be problematic since M0300 items do not distinguish whether a staged pressure ulcer that becomes unstageable is truly worsened. One commenter expressed concern over potential unintended consequences of this transition, including the potential for a provider to be penalized for a pressure ulcer acquired in a previous care setting.

Of the two commenters specifically representing the home health setting, one supported the transition to M1311 items as a means to simplify the measure calculations, while the other commenter did not support the transition to M1311 items, stating that the current M1313 items are clearer.

Response: Using M0300 items facilitates standardization of the measure across settings as required by the IMPACT Act. The M0800 item and the M0300 item represent two assessments that assess an equivalent concept. M0800 items provide a retrospective count of pressure ulcers that were not present on admission, but are present at the time of discharge, while M0300 items assess the total number of pressure ulcers present at the time of assessment (i.e. discharge) and of those, the total number present on admission. The value of the M0800 item is equivalent to the count of unhealed pressure ulcers reported in the relevant M0300 items and subtracting from this the number of ulcers present on admission (POA) for that stage.

Transitioning to M0300/M1311 items decreases provider burden by allowing the opportunity to reduce the number of pressure ulcer assessment items providers are required to complete, allows alignment between items used for payment and quality measures, counterbalances possible incentives to over- or underreport pressure ulcers in the NH/SNF and HH settings and prevents inappropriate underestimation of pressure ulcers through the use of the M0800 items.

Data element reliability and validity for the pressure ulcer items has been tested in several ways. Rigorous testing on the reliability and validity of the nursing home (NH) items in the MDS 3.0 provides evidence for the items used in the IRF setting, as well as LTCH and SNF settings.[9] 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. 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. Kappa statistics for IRF, LTCH, SNF and HHA ranged from .58 to 0.92 indicating "moderate" to "almost perfect" agreement. Also, a TEP meeting was held on July18, 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/M1311 items on the measure calculation. Overall, the TEP was supportive of the data element changes, indicating construct validity.

[9] 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.

As part of ongoing measure development of the cross-setting quality measure NQF #0678, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (short-stay), the measure development contractor tested alternative definitions to the numerator of the quality measure in three PAC settings (NH/SNF, IRF, and LTCH). One alternative explored the transitioning to the M0300 items to identify new or worsened pressure ulcers. Results showed that mean scores increased across the three PAC settings when using M0300 items for measure calculation. The mean risk adjusted score across all NH/SNFs increased by 1% by switching from M0800 items to M0300 items, while the mean score increased by .1% in the LTCH setting and .3% in the IRF setting. Additional analyses conducted using IRF data found that the M0300 items consistently report more pressure ulcers than the M0800 items for all types of pressure ulcers (i.e., stage 2, 3, 4, and unstageable ulcers).

Further analyses of these data conducted by CMS show the M0300 calculation method is superior to the M0800 method of calculating the measure and is more accurate. For example, in analyzing data from 82,038 IRF-PAIs from 10/1/2016 through 12/9/2016, CMS found 638 definite new or worsened Stage 2 pressure ulcers based on having a greater number of Stage 2 pressure ulcers on the discharge assessment (M0300B1) as compared to the admission assessment (M0300B). Out of this subgroup, use of the M0800 item to identify Stage 2 pressure ulcers found just 366 (57%) of these patients as having new or worsened Stage 2 pressure ulcers, thereby suggesting the M0800 method of identification is likely underestimating the pressure ulcer count and rate.

Since analyses show the rates are rising across the post-acute care settings, CMS believes this findings indicate that a transition to M0300/M1311 items is not adding bias to the pressure ulcer quality score. The potential implications of increased scores using the M0300 items was discussed with the July 18, 2016 TEP. TEP members advised that the change in measure specifications will likely affect rankings, however it should be made clear to providers and consumers that such shifts in quality measure scores may be due to changes in measure calculation, and are not reflective of a shift in quality of care.

CMS will engage in multiple educational efforts, including training events and updates to the manuals and training materials, and responses to Help Desk questions to ensure a smooth transition to the new items across all four PAC settings.

4. Consistency of measure specifications across PAC settings

Summary: A few commenters indicated support for standardization and consistency of pressure ulcer quality measure specifications across PAC settings, with one commenter specifically requesting that revisions made to pressure ulcer items and manuals in the IRF and LTCH settings be included in the MDS and RAI manual for the SNF setting.

Response: It is the goal of CMS to comply with the requirements of the IMPACT Act which requires CMS to implement specified clinical assessment domains using standardized (uniform) data elements to be nested within the assessment instruments currently required for submission by LTCH, IRF, SNF, and HHA providers. The Act further requires that CMS develop and implement quality measures from five quality

measure domains, including skin integrity and changes in skin integrity, using standardized assessment data. As a part of this requirement, CMS continuously strives to standardize data elements and quality measure specifications for the pressure ulcer quality measure through standardization of relevant pressure ulcer assessment items, quality measure specifications and Manual instructions.

5. Additional items to assess healed unstageable pressure ulcers

Summary: A few commenters requested CMS add three additional items including unstageable pressure ulcers due to slough/eschar, unstageable pressure ulcers due to non-removable dressing/device, and deep tissue injuries (DTI) to Section M 0900 Healed Pressure Ulcer(s) of the IRF-PAI v. 1.4, citing that in IRF settings, the number of pressure ulcers tends to be higher on admission than at discharge, indicating healing of pressure ulcers. Commenters further stated that in the IRF setting, unstageable pressure ulcers may be healed as often as Stage1 through 4 pressure ulcers, thus necessitating an item to account for this process.

Response: CMS understands the importance of treating and healing pressure ulcer wounds that are present on admission, including those that are unstageable. We also appreciate that unstageable pressure ulcers may be healed as often as pressure ulcers that are classified as Stage 1 through 4. CMS sought comments on the further development of pressure ulcer measures for post-acute care (PAC) settings, including adaptations to measure specifications such as potential changes to the measure numerator, changes to assessment items used to calculate the quality measure and potential terminology changes. While we received a few comments related to the inclusion of items related to healed unstageable pressure ulcers, they were outside of our scope and we will not be addressing those comments at this time.

6. Development of a healed pressure ulcer measure

Summary: A few commenters encouraged CMS to develop an additional measure that measures the rate of healed pressure ulcers, as this would provide a more complete picture of the quality of care in PAC settings. One commenter stated the national rate of new or worsened pressure ulcers is very low for IRFs, 0.8 %. The commenter cited provider data indicating that the rate of healed pressure ulcers to new or worsened is 15 to 1 suggesting that a measure designed to track healed pressure ulcers may be more meaningful for the IRF setting.

Response: We thank the commenters for their suggestions for additional quality of care measures. CMS is responsible for continuously evaluating existing quality reporting programs and identifying potential new measures. We will take this suggestion into consideration as we continue our evaluation and refinement of skin integrity quality measures for PAC settings.

7. Item Removal

Summary: A few commenters encouraged the removal of redundant items (M0800/M1313) in order to reduce provider data collection burden. In a similar vein, one

commenter commented on the lack of clarity as to whether the replaced items (M0800/M1313) would remain as assessment items.

Response: We appreciate stakeholders' suggestions to reduce redundancies and provider burden by removing the M0800/M1313 items from the PAC data assessment tools. CMS is cognizant of the importance of reducing item redundancies and the burden on providers where possible and will evaluate the possibility of removing the M0800 items from the LTCH CARE Data Set, the IRF-PAI, and the MDS. CMS will also evaluate the potential for removal of the M1313 item from the OASIS assessment instrument.

8. Adoption of NPUAP proposed terminology change to replace "pressure ulcer" with "pressure injury"

Summary: Many commenters commented on the changes in terminology for the pressure ulcer measure specifications and assessment items based on the changes presented by NPUAP at the April 2016 consensus conference. CMS sought comments on NPUAP proposed terminology changes to replace "pressure ulcer" with "pressure injury." While we received several comments related to other NPUAP proposed changes and processes, these were outside of our scope and we will not be addressing those comments at this time.

Many commenters were in support of adopting the NPUAP proposed terminology change to replace the term "pressure ulcer" with "pressure injury". Those who supported the change cited clarity of the new terminology and adoption of best practices as the reason. Some commenters pointed out that Stage 1 pressure wounds are not "open", so the term "injury" is more accurate. One stakeholder who supported the change indicated that insurers and other stakeholders should adopt this change in terminology as well. One commenter specifically supported the NPUAP proposed change to remove "suspected" from "sDTI". A few commenters supported the change, provided that there is adequate training and time for implementation of the change. One commenter requested that CMS publicly clarify that the term "pressure injury" should be considered equivalent to other terms and definitions used in the past to describe pressure or decubitus ulcers. One commenter requested a crosswalk of NPUAP terminology to current PAC data elements to assist in provider training, and requested that a minimum of 12 months be allowed between the change in instructions and implementation of the change, to allow for software updates and training.

Many commenters expressed opposition to the adoption of the new NPUAP terminology. Reasons for opposition were varied. Some commenters were concerned about the consistency of language used to describe these wounds across settings and systems. These commenters encouraged consistency with the language used in hospitals, and used in the current ICD-10 codes. A few commenters were concerned about the impact of the change on current ICD-10 codes. Some commenters indicated concern that the term injury is imprecise and not biologically accurate. Some of these commenters indicated that the term "injury" may imply intentionality, and expressed concern that this terminology change might lead to increased litigation or criminalization around pressure ulcers. Another commenter stated that "injury" may imply a faster healing and less serious wound than the

term "ulcer," which would be misleading. Other commenters noted that some pressure wounds are unavoidable, and that the term "injury" may inaccurately imply that the wound was avoidable. Some commenters expected that there would be a high burden associated with the adoption of new terminology, related to policy changes, changes to assessment instruments, and training. Some commenters indicated that the change is not expected to improve patient care, clinical care, or quality measurement, and therefore should not be implemented. Finally, one commenter indicated that the change should not be made because no new information warrants or demands a change.

Response: We thank the commenters for their feedback regarding the possible adoption of NPUAP terminology. CMS is evaluating the implications of the possibility of adopting NPUAP terminology and its impacts on data collection, patient/resident care and potential costs to PAC providers. This change is being considered because of a change in terminology used by the NPUAP, which was announced in April 2016.[10] A TEP held by our measure development contractor on July 15, 2016, was very supportive of adopting the NPUAP terminology of "pressure injury" instead of "pressure ulcer." Some members of the TEP stated that the term "injury" is not associated with blame or harm by an entity, that "injury" may be a more inclusive term than "ulcer", and that the term "pressure injury" may be more easily and positively understood by patients, residents, and family members than "pressure ulcer." The TEP recommended training for providers and consumers regarding any change in terminology.

Any change in terminology would be accompanied by additional training and guidance for providers and patients or residents to clarify the definition of "pressure injury".

Regarding concerns about changes to ICD codes, CMS would like to clarify that the changes under consideration in this call for public comments are limited to the terminology used in PAC assessment instruments.

Full consideration will be given to all aspects of the implications of adoption of NPUAP terminology. This possible change is still under consideration, and therefore there is no timeline for implementation.

9. Burden of Changes

Summary A few commenters expressed concerns about how the potential revisions to the quality measure would increase the cost of assessment. One commenter felt that the cost would exceed the benefits of the proposed changes. One commenter stated that implementing the proposals would be very expensive and would not improve patient care and safety.

Response: We thank the commenters for their feedback regarding perceived cost increases with the potential revisions in the quality measure. The revised measure calculation is

[10] National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury | The National Pressure Ulcer Advisory Panel - NPUAP. (2016, April 13), from http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/

based on assessment items that are currently included in IRF-PAI, LTCH CARE Data Set, MDS and OASIS assessment tools. Furthermore, all items to be used in the revised quality measure calculation are currently required items for the MDS and OASIS assessment tools. The discharge M0300 items for unstageable pressure ulcers are currently voluntary for the IRF-PAI and the LTCH CARE Data Set and are currently assessed and completed by many providers. We believe the potential revisions to the quality measure would result in no additional burden to providers, and may result in a decrease in provider burden if the M0800/M1313 items are eventually removed from the respective assessment instruments.

10. Exclusion Criteria

Summary: A few commenters requested that consideration be given to the exclusion criteria for the pressure ulcer quality measure. One commenter expressed concern that exclusion criteria differ between settings, and advised CMS to reexamine the exclusions to ensure consistency. Another commenter noted that in the SNF, LTCH, and HH settings, stays are excluded if there is insufficient assessment information to derive data for risk adjustment, but that this exclusion is not listed for the IRF setting. The commenter noted that exclusion criteria should be consistent across settings.

One commenter recommended an exclusion from the quality measure calculation for patients or residents with pressure ulcers that develop within a specified time period prior to a patient's or resident's death. The commenter further suggested that admitting a hospice resident who expires during their stay can negatively impact a facility's quality score.

Response: CMS appreciates commenters' suggestions for additional exclusions for the pressure ulcer quality measure. The measure specifications currently exclude stays in which 1) there is no useable data by which to calculate the pressure ulcer items of interest; 2) there is no matching admission assessment by which to capture data for risk adjustment (covariates); and 3) the patient/resident died during the stay. CMS would like to clarify that although the language of the other exclusion criteria differs slightly by setting, the intent of these exclusions are consistent across settings. Reflecting differences in assessment forms, one commenter noted the specifications for the IRF setting do not explicitly state that stays lacking an admission assessment are excluded. This is because the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) is a single stay-level instrument that includes both admission and discharge data, unlike the other settings in which there are separate admission and discharge forms. For this reason, any submitted IRF-PAI record will include an admission assessment.

Current specifications for the measure exclude residents or patients who die at the end of their stay in all four care settings. In this manner, pressure ulcers that develop during a stay prior to death are excluded. Since residents or patients who die at the end of their stay are excluded from the measure, these stays do not have an effect on a facility's quality measure score. If the commenter is suggesting excluding residents or patients who die after discharge, it must be noted that the quality measure is currently based on data collected via an assessment tool at admission and discharge. As such, it would not always be feasible, and may be burdensome, for providers to obtain information on patient status

after discharge, since the discharging facility has no certainty of receiving the notification of patient death. CMS will consider additional exclusions as we continue to refine this measure.

11. Risk Covariates

Summary: A few commenters encouraged further consideration be given to the risk covariates for this measure. Two commenters requested further standardization of risk adjustment across the four PAC settings. One commenter specifically noted that the risk adjustment calculations use different mobility and bowel continence items across the four settings, and encouraged standardization using reliable and valid items. One commenter requested that the measure be risk adjusted for both low and high BMI. Another commenter requested that obesity and morbid obesity be considered for risk adjustment in all settings, and that poor psychosocial support and poor adherence to the plan of care be considered as risk adjusters in the HH setting. One commenter requested that severe protein or calorie malnutrition be considered as a risk adjuster, for example by looking at weight change. One commenter noted that studies indicate patients with multiple organ failure are at increased risk of skin failure, and requested that the measure consider this.

Response: We thank the commenters for their specific recommendations to inform and improve risk adjustment for this measure. It is expected that the measure will be risk adjusted for functional limitation, bowel incontinence, diabetes or peripheral vascular disease/peripheral arterial disease, and low body mass index in each of the four settings. We continue to analyze this measure as more data are collected and will consider changing the risk adjustment model, and testing the inclusion of other risk factors as additional risk adjustors for future iterations of the measure. The measure development contractor conducted an environmental scan in 2016 to identify additional pressure ulcer risk factors that could be considered for risk adjustment, and a TEP held July 15, 2016, provided guidance on the importance and relevance of these risk factors for testing. We will take into consideration the TEP discussion and the commenters' feedback regarding risk adjustment for obesity, high BMI, protein or calorie malnutrition, and multiple organ failure. As we transition to standardized data collection across PAC settings to meet the mandate of the IMPACT Act, we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of risk adjustment models and methodology. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of quality reporting programs. We remain committed to conducting ongoing testing and measure development activities in an effort to improve the risk adjustment of quality measures implemented through the quality reporting programs.

With regard to the suggestions pertaining to the incorporation of socioeconomic factors, such as psychosocial support as risk adjustors for the measures, NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk adjusting for sociodemographic factors is appropriate. This trial entails temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance

measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. CMS, in compliance with NQF's guidance, has tested sociodemographic factors in the measures' risk models and made recommendations about whether or not to include these factors in the endorsed measures. We intend to continue engaging in the NQF process as we consider the appropriateness of adjusting for sociodemographic factors in our outcome measures.

Furthermore, the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of social risk factors on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act.[11] We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available. We note that currently, there are no standardized data on variables such as living arrangements or family and caregiver supports across the four PAC settings.

12. Inclusion of Mucosal Membrane pressure ulcers

Summary: Several commenters requested that CMS consider including an additional category of unstageable pressure injury, mucosal membrane pressure injuries in future revisions of the pressure injury staging system. Commenters stated that due to the anatomy of the affected tissue, these injuries cannot be staged. One commenter also indicated the National Database for Nursing Quality Indicators (NDNQI®) is revising its database to incorporate the new NPUAP Pressure Injury Staging System, and that in future versions, mucosal membrane pressure injury will be a separate data element.

Response: We thank the commenters for their recommendations regarding mucosal membrane pressure injuries. CMS sought comments on the further development of pressure ulcer measures for post-acute care (PAC) settings, including adaptations to measure specifications such as potential changes to the measure numerator, changes to assessment items used to calculate the quality measure and potential terminology changes. While we received several comments related to mucosal membrane pressure ulcers, these were outside of our scope and we will not be addressing those comments at this time.

Preliminary Recommendations:

CMS and the measure development contractors appreciate the comments received for the pressure ulcer measure for PAC settings. The general comments about the potential changes to the measures, as well as specific input we received on the inclusion of unstageable pressure ulcers, including DTI in the measure numerator, potential changes in the calculation of the measure, inclusion of NPUAP terminology and other aspects of the measure specifications were informative to the measure's development. Comments suggesting additional covariates to consider for the measure will help inform the ongoing measure testing that will be conducted by measure development contractors. In addition,

[11] Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs

we plan to make necessary changes to the pressure ulcer quality measure over time based on our continued testing as required for maintenance of all quality measures, and as new evidence emerges. We will take other comments into consideration for future refinement of this measure, and development of other measures for our quality reporting programs.

We will take into consideration suggestions for further testing as we continue to refine this measure. To the extent possible, we will also incorporate suggestions received through public comment on the implementation of these measures. Specifically, we will plan *to:*

- Continue to ensure standardization of data items and measure specifications across PAC settings;
- Provide on-going instruction and training to providers regarding potential quality measure refinements;
- Test additional risk adjustors based on available data; and
- Submit the refined measures to NQF for review and endorsement.

Overall Analysis of the Comments and Recommendations

The comments and feedback received provided useful input for the refinement of the measure Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678).

The following table details the verbatim comments received.

Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/02/2016	I agree that CMS should change the terminology to the same as NPUAP.	Rona Schlau MS, RN Director of Nursing Long Island State Veterans Home	Rona.Schlau@lisvh.org	LTCH
11/04/2016	Please consider recent studies that indicate patients with MULTI ORGAN FAILURE are always going to have skin failure as well. This failure is the result of the disease processes and not due to poor care. Facilities should not be penalized for caring for end of life patients whose families refuse to comply with physician recommendations and insist on full care until there is nothing more to care for.	Mary Jane Stubbs, PT, MS, CWS Tenet Healthcare	MARY.STUBBS@tenethealth.com	
11/04/2016	When refining Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) it would be beneficial to exclude ulcers that develop within a specified identified time frame prior to death. Even with the best of pressure ulcer prevention programs, the skin, as an organ, declines and/or dies as other organs do prior to death. In addition the failure of body systems, cardiac, renal etc., place the skin organ at an even higher intrinsic risk of breakdown. As long term care facilities are admitting increasingly frail elderly, the factor of the skin as an organ declining/dying must be taken into consideration as an exclusion in order to serve this QM with greater accuracy. Facilities with comprehensive pressure ulcer prevention programs, can still be negatively impacted if admitting a hospice resident who expires within the 100 days or less.	Sandra Delgehausen RN, BSN Quality Assurance Specialist Elim Care	sandy.delgehausen@elimcare.org	
11/05/2016	Portions of comment content are redacted due to protected health information. Something needs to be done regarding these pressure ulcers and the lack of repositioning of bedridden residents at nursing homes and long term care facilities. It's wonderful the government is looking into this matter. I pray this information will provide insight into the pressure ulcers (bed sores) issue.	xxx xxx Patient family member	xxx@xxx.net	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/10/2016	I agree with all the proposed changes. Thank you for this.	Conchita Q. Rader, RN, MA, CFCN, CWCN, Wound Care Coordinator Select Medical Inpatient Rehabilitation Division	mailto:cqrader@selectmedicalcorp.com	IRF
11/11/2016	• An 'ulcer' is an erosive skin lesion. An 'injury' includes the concept of intentionality. According to the research, pressure damage of the skin begins at the level of the bone/muscle when perfusion to a muscle, which has high vascular requirements, is significantly diminished related to pressures exerted on it by squeezing it between a boney prominence and an external surface. This can lead to various levels of vascular damage and tissue death that can evolve to an erosive skin lesion. If there is approval to change the terminology to 'injury' then this will not only be a less accurate term, but the links with intentionality are likely to promote litigation which will financially challenge our already challenged post-acute settings. This challenge will come at our acute time of need, as our country struggle to deal with the needs of an aging population; hoping to keep these individuals out of hospital (acute care) and in the less costly post-acute setting. Further, the 'injury' connotation is *inconsistent* with the idea of 'unavoidable' which is a proven and recognized phenomenon related to skin organ failure. • A pressure 'ulcer' is an acute erosion and not an acute 'injury' like a laceration.	Jennifer Hurlow GNP-BC, CWOCN	jenny.hurlow@gmail.com	
	Same text as Jennifer Hurlow's comment above received from this commenter 11/13/2016.	Hollie Mangrum, PT, DPT, CWS, Healogics	Hollie.SmithMangrum@healogics.com	
	Same text as Jennifer Hurlow's comment above received from this commenter 11/14/2016.	Robert Durham Jr., CHT Hyperbaric Safety Director, George Washington University Hospital, Wound Healing and Limb Preservation Center	Robert.Durham@gwu-hospital.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	Same text as Jennifer Hurlow's comment above received from this commenter 11/16/2016.	Gerri Slowikowski RN BSN CWOCN Certified Wound, Ostomy, Continence Nurse, Yale-New Haven Hospital	Geraldine.Slowikowski@ynhh.org	
	Same text as Jennifer Hurlow's comment above received from this commenter 11/17/2016.	Susan Sousa, RN, BSN, CWOCN, Yale New Haven Hospital	Susan.Sousa@ynhh.org	
	Same text as Jennifer Hurlow's comment above received from this commenter 11/17/2016.	Maureen Maddern, RN, BSN, CWOCN, Yale New Haven Health System	Maureen.Maddern@ynhh.org	
11/12/2016	1. Remarkable work to achieve alignment across PAC sites. 2. Adoption of the new NPUAP definitions substituting pressure injury for pressure ulcer is appropriate and is a very welcome clarification. 3. The inclusion of DTIs in the numerator is appropriate. a. One concern about the NPUAP definitions is the lack of clarity between Stage 1 characterized by damaged but intact skin and DTI. They are both part of the same spectrum of injury. A more unifying term might be Pressure Injury with Intact Skin and then two sub classes, those that heal with intact skin and those that don't. We can only tell a Stage 1 pressure injury from a DTI after seeing whether the Stage 1 resolves or not, something that cannot be reliably predicted from the initial appearance. 4. Risk adjustment covariates #4 will miss individuals whose BMI is within normal range but who have severe protein/calorie malnutrition. This is frequently seen in individuals with end stage dementia who develop feeding difficulties, decreased mobility, incontinence, rapid weight loss and skin breakdown over a relatively short period of time. Consideration might be given to amending this covariate to something like "Low BMI based on height and weight OR wgt loss >10% over preceding 4 wks (or some other "weight change" co-factor.)	Terrence A. O'Malley, MD Spaulding Nursing and Therapy Center of the North End	TOMALLEY@mgh.harvard.edu	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/13/2016	Please do NOT adopt the NPUAP's proposed staging revisions. The change to "pressure injury" would be especially detrimental. As an AAWC (Association for the Advancement of Wound Care) member, I agree with the position statement by the AAWC Board of Directors as stated below: http://aawconline.org/wp-content/uploads/2016/10/AAWC-Position-Statement-on-the-Proposed-NPUAP-Pressure-Ulcer-Staging-System-Revised-10.14.16.pdf As the AAWC Board of Directors, our prime directive is the protection and evidence-based treatment of the patients we serve. 1. The evidence has long demonstrated that the pressure ulcer staging system is flawed. 2. The existing staging systems do not accommodate the current evidence of pressure ulcer formation. 3. Failure to correctly identify the extent of pressure related tissue damage has resulted in misdirected pressure ulcer prevention protocols and resources. 4. Implementing the modified NPUAP staging system is premature at this point. Implementing these changes on a national level will have significant implications and patient outcomes will be negatively affected. 5. The AAWC is an inter professional organization with 2400 members and would like to collaborate with stakeholders including the NPUAP to develop an evidence-based solution to the current PU staging system. The AAWC BOD recommends forestalling the implementation of the recently proposed NPUAP staging system. A new classification of identifying pressure related tissue damage must be developed based on current global evidence. I implore you NOT to adopt the NPUAP's staging revisions. Many in the wound care community disagree with the NPUAP's proposed changes. The revisions need to be placed on hold since there is so much controversy, especially with the term "pressure injury". Dr. Bohn, the AAWC President recently wrote an editorial about the	Joy E. Schank, RN, MSN, ANP, CWOCN,	joyschank@yahoo.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	objections to the NPUAP's staging revisions. The link below is to his editorial in OWM (Ostomy Wound Management Journal). http://www.o-wm.com/article/guest-editorial-maintaining-our-objections-npuap-changes			
	Same text as in Joy Schank comment (above) received from this commenter 11/15/2016.	Ginny Hanchett MS, FNP, APRN-BC, DCNP, COCN Senior Nurse Practitioner UR Medicine Ostomy Services	Ginny_Hanchett@URMC.Rochester.edu	
	Same text as in Joy Schank comment (above) received from this commenter 11/17/2016.	Tamera L. Brown	tammy.brown484@gmail.com	
	Same text as in Joy Schank comment (above) received from this commenter 11/17/2016.	Karen L Bauer, NP-C, CWS, CHRN Consumer Board Member, AAWC Director of Wound Services	Karen.Bauer@utoledo.edu	
	Same text as in Joy Schank comment (above) received from this commenter 11/17/2016.	Myra J. Maciag RN CWON	myra.maciag@gmail.com	
	Same text as in Joy Schank comment (above) received from this commenter 12/01/2016.	Emily Greenstein, RN, BSN, CWON	Emily.Greenstein@sanfordhealth.org	
	Same text as in Joy Schank comment (above) received from this commenter 12/01/2016, with the following additional paragraph: This is just a bad idea. As with many regulatory bodies, it is almost as if new rules are generated to justify NPUAP's existence. Please get more input/involvement/consensus of the care deliverers before taking this step.	John Dorsky, MD FACS CWSP WCC CPHIMS CHTS-CP	jdorsky@mdconsult.us	
	Same text as from Joy Schank (above) received from this commenter 12/01/2016.	Gerri Slowikowski RN BSN CWOCN Certified Wound, Ostomy, Continence Nurse, Yale-New Haven Hospital	Geraldine.Slowikowski@ynhh.org	
11/13/2016	This comment is largely the same but not identical to Jennifer Hurlow's comment above. I do not agree with a change in terminology from pressure ULCER to pressure INJURY.	Kara S. Couch, MS, CRNP, CWS, The George Washington University Hospital, Wound Healing and Limb Preservation Center	karacouch@gmail.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	An 'ulcer' is a gradual, erosive skin lesion. This is usually due to an underlying disease process (diabetic neuropathy, arterial insufficiency, venous insufficiency, pressure). An 'injury' is rapid and includes the concept of intentionality. Merriam-Webster defines “injury” as an act that damages or hurts. According to the research, pressure damage of the skin begins at the level of the bone/muscle when perfusion to a muscle, which has high vascular requirements, is significantly diminished related to pressures exerted on it by squeezing it between a boney prominence and an external surface. This can lead to various levels of vascular damage and tissue death that can evolve to a gradual, erosive skin lesion. The proposed NPUAP changes do not reflect current research on pathophysiology of tissue damage. If there is approval to change the terminology to 'injury' then this will not only be a less accurate term, but the links with intentionality are likely to promote litigation. Any resulting rise in litigation will further financially challenge our already challenged post-acute settings. Further, this challenge will come at our time of need. We are struggling to deal with the needs of an aging population; hoping to keep these individuals out of hospital (acute care) and in the less costly post-acute setting. In addition, the 'injury' connotation is inconsistent with the idea of 'unavoidable' which is a proven and recognized phenomenon related to skin organ failure. New ICD-10 codes that adopt the ‘injury’ term will not be able to remain in the skin chapter and would likely need to be moved to the trauma chapter. This again increases the medicolegal implications of these changes. Please consider the importance of not changing this terminology. The full negative impact has not been explored and will have grievous effects on the health care system. This is avoidable by not adopting the proposed changes at this time.			

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11/13/2016	I am providing feedback regarding the refinement of the cross-setting post-acute care pressure ulcer measure in alignment with the 2014 IMPACT Act. As a clinician involved in wound care for over 30 years, I agree with the proposed update to the Home Health quality measures to include NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay). I further agree with the recommendation to add unstageable pressure ulcers (due to slough or eschar, or non-removable dressing or device, or presenting as deep tissue injuries) in the numerator to assessment items for the pressure ulcer quality measure. Utilizing the more detailed M1311 OASIS data in place of the M1313 OASIS data is appropriate and will provide more clarity for use of the measure. However, I urge the CMS not adopt any of the recent terminology changes to the NPUAP staging system for NQF #0678 quality measure or any other revisions to clinical assessment tools [OASIS, PAI, MDS, etc.). As the CMS noted, the NPUAP replaced the term 'pressure ulcer' with the term 'pressure injury' stating the "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin." Many wound care specialist disagree with the NPUAP. Multiple articles have been published since April 2016 addressing concerns and specific issues with the term 'injury' in place of 'ulcer' and the lack of evidence to support the NPUAP pressure ulcer staging system overall.[1-12] In addition, authors have voiced concerns with the methodology used by the NPUAP with the participants at the NPUAP Staging Consensus Conference in April 2016.[1,9] The CMS should be aware that less than 50% of the 400 wound care specialists attending the April NPUAP Consensus Conference meeting failed the visual testing of wound staging, using the 'new' NPUAP staging system, during the meeting. How can this possibly equate to a more accurate system?	Peggy Dotson, RN, BS Healthcare Reimbursement Strategy	Pdots.HRS@gmail.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	The term pressure 'Injury' implies an acute, deliberate (willful or negligent) process[13], such as with traumatic tissue loss. Whereas pressure 'ulcer' denotes tissue damage due to prolonged pressure that compresses vascular structures deeper in the tissues at the bone or muscle level causing gradual hypoxia and tissue necrosis or suspected deep tissue damage without an initial break in the skin. Pressure 'ulcer' also describes the prolonged stress or friction on the tissue layers that result in ulceration. The risk-adjustments to quality measures already incorporated in the assessment tools used in the PAC, identify multiple clinical conditions and factors that impact the development and risk for the development of pressure ulcers. These complicate the cause of tissue damage and can muddy the waters for health providers when documenting and /or defending the development of an unavoidable ulcer. Describing pressure-caused tissue damage as pressure 'injuries' will have far reaching implications for litigation, that can become crippling to our healthcare system. In support of these points, I have provided a list of the articles published since the NPUAP meeting that outline the weaknesses and inaccuracies in the new staging system and concerns with the process used by the NPUAP to revise the pressure ulcer staging (Table 1.) I encourage the CMS to review the clinical feedback from the wound care specialists' community and not embrace the NPUAP terminology at this time, until the wound care community can provide an alternative to the pressure ulcer staging system.			
11/14/2016	We wanted to ensure that you are aware of the standards work previously done to define wound assessments (including pressure ulcers). Attached is a manuscript describing the development of a skin and wound assessment model. The model was adopted by ONC for one of their challenge grants. A manuscript describing the work is attached. The current list of data elements (questions encoded with LOINC and answers encoded with SNOMED CT) can be found at www.fhims.org. There are also a couple of current initiatives occurring:	Susan A. Matney, PhD, RNC-OB, FAAN Medical Informaticist, Sr. , Intermountain Healthcare	susan.matney@imail.org	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	1) wound assessment is being used for an HL7 pilot project between HL7 CIMI and Patient care working groups for CIMI model development; and 2) the Health Services Platform Consortium (HSPC) has initiated a modeling project with the VA and Intermountain Healthcare to standardize skin and wound evaluation. A current draft of a scope statement for that project is attached. It is our hope that the data elements defined for the "Proposed NPUAP Terminology Changes for the Quality Measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)" will align with this work. We are willing to collaborate with you and assist with standardization as needed.			
11/14/2016	My name is Emily Greenstein and I am a certified wound and ostomy nurse in Fargo, ND. I am currently a member of the AAWC as well as the WOCN. Both organizations have different stances on the term "pressure injury". The WOCN supports the change in terminology where the AAWC does not support it. I personally do not support the change of the language at this time. And here is why: 1. The change was put forth by the NPUAP only, not all major organizations within wound care. This was not a true consensus conference. 2. Many of the new changes lack scientific integrity and rigor. 3. We need to create a system based on solid evidence with proven inter-rater reliability and validity first. 4. We also need to take a thoughtful look regarding the potential legal ramifications that these changes could have. Please consider these things before making any hesitant changes that could affect a large group of providers negatively.	Emily Greenstein, RN, BSN, CWON	Emily.Greenstein@sanfordhealth.org	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/14/2016	We welcome the chance to comment on the Pressure Ulcer Quality Measures Below are comments being sent on behalf of the Wound Ostomy and Continence Nurses Society (Mount Laurel N.J.) Proposed NPUAP Terminology Changes for the Quality Measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) The Wound Ostomy and Continence Nurses Society has endorsed the NPUAP terminology pressure injury, therefore supports the change to pressure injury in the Quality measures. Proposed Measure Specification for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) for the Skilled Nursing Facility Quality Reporting Program (SNF QRP), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), and the Home Health Quality Reporting Program (HH QRP) For the noted above Measure Specifications for Quality reporting additional risk adjustment should be considered which impacts Pressure Ulcer development. The co-morbidity of obesity is appropriate for all settings, especially morbid obesity as a contributing factor to pressure ulcer development. This is noted in the literature and at the bedside. Specific to home care, two other contributing issues that are very patient centric and lead to risk that needs to be considered for risk adjustment are Poor psychosocial support systems and Poor Adherence to developed plan of care for pressure ulcer prevention or treatment. Both of these items can have a great influence on success or failure of Pressure ulcer prevention or healing. We are happy to provide further information if needed	Kathleen G Lawrence MSN RN CWOCN Wound Ostomy and Continence Nurses Society Public Policy and Advocacy Coordinator	katedean@sover.net	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/14/2016	At the AAWC Board of Directors meeting held on October 6, 2016 in Las Vegas during the SAWC Fall conference, and in response to the concerns expressed about the proposed changes to the pressure ulcer staging system, it was decided to release a position statement addressing these proposed changes. Please reference this link http://aawconline.org/wp-content/uploads/2016/10/AAWC-Position-Statement-on-the-Proposed-NPUAP-Pressure-Ulcer-Staging-System-Revised-10.14.16.pdf to the AAWC Board of Director's position statement on the changes to the pressure ulcer staging system as proposed by the NPUAP. We ask that you share it with your colleagues and decision makers. Although the NPUAP is held in the highest esteem, the recent change in terminology from pressure "ulcer" to pressure "injury" poses numerous threats to our wounded patients and the clinicians who care for them. The discussion regarding this terminology actually perpetuates a staging system that is in great need of revision to reflect the current research describing the underlying mechanism of pressure induced tissue damage. In addition, the proposed changes introduce descriptors to the individual stages that are disputable. In the next few months, the AAWC will join with national and international colleagues who are wound healing and pressure ulcer experts and colleagues who represent the various interdisciplinary wound care professional organizations to take the appropriate steps to develop an accurate and reliable classification system for pressure induced tissue damage. During this time, we recommend that you NOT adopt the new terminology at your facility or in your organization. In the interim, it is advisable to continue using the well-known EXISTING system and ICD-10 coding to stage and classify pressure ulcers. If you have any questions about the AAWC Board of Director's position, please feel free to contact any of the AAWC Board Members.	Carl "CJ" Crane, BSN, RN, CWON, CFCN, AAWC, Board of Directors	cranec@empirehealth.org	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/14/2016	This email is in response to the April, 2016 NPUAP Consensus meeting to revise pressure ulcer terminology and definitions. I am a dual-certified RN, CWON and CWS. I have an MBA and am a Clinical Specialist for a company who makes products for pressure ulcer prevention and treatment. My job takes me to healthcare organizations across the nation. Many of my discussions over the past 7 months have been around these changes to pressure ulcer definition and classification. I was at the NPUAP Consensus meeting in April and spoke with many of the attendees about their opinions surrounding the changes. Here is a summary based on my numerous discussions and interviews since April: 1) The NPUAP Board knew what they wanted for Pressure Ulcer/Pressure Injury changes and "Stacked the deck" with the attendees. Most of the questions were phased in a way where there was no way to disagree. If you did disagree, the opportunity for discussion was minimal or non-existent. I feel this was not a "Shared Decision Making Process", it the changes were decisions made that they were sharing. 2) Ironically, many of the NPUAP Board Members are tied into the WOCN Society, who has endorsed the changes. However, AACW has come out and publicly rejected these changes. There are AAWC Board members also on the NPUAP Board. When NPUAP Board Members can't agree, how can this be consensus? 3) I believe there is a conflict of interest with a few figure heads on the NPUAP board of directors in regards to their private consulting businesses. Many of the directors are legal nurse consultants and expert witnesses in Pressure Ulcer lawsuits. Furthermore, by changing the terminology and definitions making things more confusing, they also benefit from Consulting with healthcare organizations and companies looking adopt the changes. Changing the definitions is job security for these consultants.	Andrew Marxen, BAN, RN, CWON, CWS, MBA Clinical Resource Specialist Crawford Healthcare	amarxen@yahoo.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	4) How does the switch from pressure ulcers to pressure injury improve patient care? It doesn't? There is so much variation in determining stages now, that changing it will just add to the confusion. I believe the conversion from "Ulcer" to "Injury" will just increase litigation opportunities with no benefit patient care. 5) The cost of change outweighs the potential benefits. Image the cost in hours of policy, protocol, and Clinical Practice Guideline changes in addition the waste of resources, paper, ink, revision of clinical tools and educational programs for nursing staff. Imagine the confusion and potential litigation for healthcare facilities when there is conflicting definitions and terminology from their regulatory bodies. 5) If this review is for Post-acute healthcare organizations, their info is different than hospitals adding to the confusion. Everyone has to have the same terminology in order for it to work. 6) NPUAP should have taken direction from CMS prior to moving forward, not after the fact. There is a lot of arrogance in assuming that they are the rule makers unless someone from CMS directed the board to move forward. 7) Mucosal Pressure Injury is ridiculous! It just adds to confusion. If a device caused a sore on the lip or tongue, it is a medical device event. Medical device events should be separate from the traditional staging system. If you have Medical Device Related Pressure Injury, all skin tears caused by adhesive removal should be included. Here are my recommendations for moving forward: 1) Do not adopt the NPUAP changes. 2) Develop an independent board to review terminology from academic organizations only 3) This Board should select a panel of experts with FULL disclosure of consulting honorarium and organization affiliations. 4) Require that Board Members and the Panel of Experts are only affiliated with one trade organization such as: a. AAWC b. WOCN c. APWH d. NPUAP			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	e. WCEI f. ABWM 4) This panel should be multi-disciplinary including: a. Governmental and private lawyers b. Physicians c. Advanced Practice Nurses or PA's with or without certification (WCC, CWOCN, CWS) d. Physical therapists/occupational therapists e. Researchers (Laura Bolton, Lia Van Rijswijk, or Janice Beitz) 5) Create a face validation survey and put it out to all trade organization's memberships 6) Plan an rollout if consensus is gained 7) If valid, move forward in ALL market units and not just post-acute 8) Wait for ICD-11 and implement across all markets at the same time. Oasis-C, MDS, Meaningful Use reporting, F-Tags....ALL implemented at the same time. 9) Enlist a new group to implement a Device Related Skin Injury separate from Pressure Ulcers and include: a) Any medical device that caused an injury b) Medical adhesive related skin injury c) Respiratory devices d) Orthotic/Prostetic/Cast/Splint devices I hope this information is helpful in your quest to find the truth			
11/14/2016	I like the proposed change to Pressure Injury- given that many Stage 1 injuries do not progress to open, ulcers. This terminology aligns with the DTI language, where we classify based on assessment of changes to the skin before knowing whether it will evolve to an open wound or resolve without compromised skin integrity.	Katherine Morris, Nurse Manager, Wound & Stomal Care Team, Cleveland Clinic Abu Dhabi	MorrisK@ClevelandClinicAbuDhabi.ae	
11/15/2016	The purpose of this email is to show my opposition to the new staging system proposed by NPUAP, including the term, "injury". Please note the editorial available at the following link. A list of articles concerning this topic are attached as well as 2 of the articles http://www.o-wm.com/article/guest-editorial-maintaining-our-objections-npuap-changes	Mike Schank	schankco@gmail.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/15/2016	I am the Clinical Editor of the Journal Ostomy Wound Management, a Certified Wound Care Nurse for > 30 years, and a doctoral student at West Chester University in PA. As an individual I am deeply concerned about the new Pressure Ulcer name and Staging changes because neither the level of evidence for such changes nor the process by which consensus was achieved appears to be solid and based on current standards in the scientific community. While changes to the system are needed, the process used should be scientifically rigorous, open and transparent. Please consider some of the excellent observations published by my colleagues (links below) as well as the standards promulgated by the Institute of Medicine for developing guidelines. Many of these recommendations should apply to such an important change in nomenclature and definitions (http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx). http://www.todayswoundclinic.com/articles/editor-pressure-ulcer-vs-injury http://www.o-wm.com/article/guest-editorial-changing-pressure-ulcer-terms-consensus-or-conspiracy http://woundcareadvisor.com/pressure-ulcer-name/ http://journals.lww.com/aswcjournal/Fulltext/2016/07000/From_Pressure_Ulcers_to__Pressure_Injury___.1.aspx	Lia van Rijswijk, MSN, RN, CWCN, Ostomy Wound Management, Clinical Editor	Lialine@comcast.net	
11/15/2016	CMS is also soliciting comments on changes in terminology for the pressure ulcer measure specifications and assessment items. NPUAP revised the Pressure Injury Staging System following a consensus conference in April 2016. The NPUAP replaced the term “pressure ulcer” with the term “pressure injury” stating the “change in terminology more accurately describes pressure injuries to both intact and ulcerated skin.” New NPUAP guidance further clarified that “in the previous staging system Stage 1 and Deep Tissue Injury described injured intact skin, while the other stages described open ulcers.	David Thomas, MD, FACP	thomasdrstl@gmail.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	This led to confusion because the definitions for each of the stages referred to the injuries as 'pressure ulcers'." CMS is soliciting comments regarding the adoption of new terminology as espoused by NPUAP. The term pressure "ulcer" and pressure "injury" are both imprecise terms. While "ulcer" is generally inaccurate, the terminology has widespread use among practitioners. However, the replacement of "injury" is equally imprecise and prejudicial. The term "injury" is variously defined as a "harm or hurt; usually applied to damage inflicted on the body by an external force. Source: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. © 2003 by Saunders, an imprint of Elsevier, Inc. or, "damage, harm, or loss, as from trauma, or a "particular form of hurt, damage, or loss. Source: The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company; or "damage, harm, or loss, to a person particularly as the result of external force" Source Medical Dictionary for the Health Professions and Nursing © Farlex 2012. There is considerable concern among wound healing specialists and wound care organizations (eg., American Association for the Advancement of Wound Care position statement, American College of Clinical Wound Specialists) that a change to the term "injury" will produce unintended consequences (Bolton 2016;62:Issue 6) First, the term is not consistent with current understanding of pressure ulcer etiology. Research suggests that development of a pressure ulcer is not due only to application of external force, but depends in large part on patient intrinsic factors unique to each individual. (DOI: http://dx.doi.org/10.12968/jowc.2016.25.Sup7.S3) Second, the term "injury" is widely used as a legal term. This is likely to have unintended consequences in malpractice suits. (Barios OWM 2016;62:Issue 7). Current understanding of pressure ulcer etiology is that pressure wounds are due to ischemic injury as a result of a myriad of issues, including but not limited to mechanical pressure, shear, friction positioning/re-positioning, the prodromal issues surrounding end-of-life, death and the dying process and/or skin failure.			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	Third, there is a clash between “injury” and “unavoidable” in the current dialog about etiology of pressure ulcers. Unavoidable, in terms of Federal guidelines, means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate." Labeling every pressure ulcer as an “injury” obscures this distinction. Current understanding of pressure ulcer etiology suggests that “most patients developing pressure ulcers were in the intensive care unit and had immobility resulting from a combination of factors including respiratory failure with endotracheal intubation, sedation, operative procedure, or multiple life support measures. Conditions such as life support modalities, pain, complex operative wounds, and chest tubes may interfere with or prohibit compliance with turning schedules. Other factors such as decreased sensorium, hypotension, and nutritional compromise may have played a part in ulcer genesis. We believe that the combination of immobility in the setting of multisystem organ disease and/or physiologic compromise led directly to pressure ulceration despite of recognition of risk and prevention measures. (Levine JCOM 2009:16:8, Thomas DR J Am Med Dir Assoc 2006;7:46–59). Finally, despite problems with the term “ulcer”, the substitution of the term “injury” is more problematic than useful. The entire approach to the staging system for pressure ulcers is currently experiencing a need for re-definition, which may help resolve some of the difficulties. Simply re-defining the ICD-10 codes will be problematic for the vast majority of providers. A major educational initiative will be required among practitioners nationwide and is likely to sow confusion. This proposed change in terminology is neither helpful or necessary, and is likely to make the situation worse.			

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11/15/2016	The consensus-based new Stage 2 pressure ulcer definition stating that partial-thickness Stage 2 dermal pressure ulcers do not have granulation tissue is inaccurate and inconsistent with recognized medical and surgical definitions of partial-thickness dermal wound healing. All dermal wounds replace lost dermal tissue with granulation tissue. This definition confuses professionals and reimbursement authorities across all health care settings and places institutions at risk of misdiagnosing Stage 2 pressure ulcers healing with normal granulation tissue as Stage 3 pressure ulcers. Please do not accept this erroneous definition of a Stage 2 pressure ulcer.	Laura Bolton, PhD Adjunct Assoc. Prof. Surgery Rutgers University Medical School	llbolton@gmail.com	
11/15/2016	This letter is written to express our strong opposition to the new proposed NPUAP staging system. In 2009 the NPUAP changed their staging system to the existing one because they realized how flawed and incomplete their old staging system was and how it didn't answer all of the questions posed by wound care providers. For your information the existing system is built from low evidence-based medicine, meaning it's based on the personal opinion of self-claimed experts. In modern academic medicine clinicians are obligated to demonstrate the highest level of evidence to get their point across and convince their fellow clinicians to follow their lead and trust their argument. Since the new staging system is also based on weak evidence based medicine we are really replacing a flawed system by another flawed one! In our opinion the new staging will cost millions of dollars to implement and will only create confusion and will not improve patients care and safety. For example heart attack is called myocardial infarction. It is an ischemic injury of the heart muscle but we don't call it an injury because it's understood and it won't change the management and outcome if we did call it injury. We believe that the only reason it's done here is to imply that it's an inflicted injury and to blame someone with the result which will increase the number of frivolous law suits against wound care clinicians and hospitals. This of course will increase the cost of healthcare. Another example on how weak the new system will be is the lack of clarity on Deep Tissue Injury (DTI) category. In our extensive	Richard Simman, MD, FACS, FACCWS Plastic and Reconstructive Surgery, Dermatology, Pharmacology and Toxicology Professor, Wright State University Boonshoft School of Medicine	Richard.simman@wright.edu	

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	clinical and research experience DTI can heal without any sequelae or it may evolve into a full stage IV pressure wound. This distinction for example is not clearly discussed in the new system due to lack of supportive research and evidence based medicine. Furthermore the references submitted to support their argument represent low level of evidence. Please notice that the majority of wound care professionals and medical organizations in the USA were not consulted on the proposed new system and most of them are opposed to the change. We propose to keep the existing staging system until new high evidence based research is out to support and justify the change. This can only be achieved by conducting large clinical trials, prospective randomized controlled trials and breakthrough in basic science research which is lacking at this time. Creating an independent committee to further study the issue will also be an excellent idea.			
11/16/2016	Strongly dissent re adopting the new “injury” wording re pressure wounds - main concern is use of the ‘loaded’ term, "injury”. The different implications of this word in medical vs legal circles will undoubtedly set the stage for a deluge of personal injury claims - for precisely the reason reflected in the that last term, “personal injury claim” - in legal usage “injury” implies causation, whether by ignorance, incompetence, neglect, or even willfully; where there is causation, someone is to blame and the stage is set for lawsuits. In medical usage “injury” often describes mechanism but does not at all necessarily imply causation and certainly regarding pressure wounds, there is not at all always a direct cause and effect situation. “Injury” is the wrong terminology to use in this circumstance; I understand the thinking that went into this proposed change but believe it needs a lot more thought before all stakeholders can agree regarding new terminology. The very fact that so many stakeholders - those who deal with pressure wounds on a daily basis - have such strongly held and divergent opinions re the proposed NPUAP changes signals that these changes are not all ready for adoption. Attached a letter to the editor I sent earlier to Ostomy/Wound Management regarding this issue. http://www.o-wm.com/article/letter-editor-pressure-terminology-sticks-and-stones-names-really-can-harm	Alistair Bairos, MD, CWS-P, FACCWS, North Hawaii Community Hospital Kamuela, Hawaii	alibaba@hawaii.rr.com	

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11/16/2016	The Academy of Physicians in Wound Healing (APWH) is an international organization consisting of wound care physicians in multiple specialties (MD/DO/DPM). The academy has had an opportunity to review the recent proposals and is herein responding to proposed changes regarding the skin lesion currently known as "pressure ulcer". These are changes terminology of the condition from "pressure ulcer" to "pressure injury". There's also a proposed change in the staging system pattern currently using Roman numerals to Arabic numerals. "Pressure ulcer" and the "Roman Numeral" staging system are used in ICD-10 coding system currently being introduced to the USA while it has been used in Europe and a number of other countries for several years. This is a global system and any attempt to change terminology for the USA will be inconsistent with these world-wide accepted descriptors and related communication. The same can be said for the changes in the staging number system. This has been accepted internationally and allows for international billing and identification of disease states. CMS changing of the term "pressure ulcer" to "pressure injury" would lead to extremely confusing international communication while virtually adding nothing to the understanding of the disease process involved. Additionally SAWC and a number of other wound care related organizations have raised concern regarding medical legal issues by changing "pressure ulcer" to "pressure injury". This does not clarify diagnostic criteria while it significantly broadens the language to potentially be inclusive of an extensive number of pathologies many of which would be unintended but could be useful to plaintiff attorneys. The APWH agrees with other organizations that broadening the language in this manner increases plaintiff viability, unnecessarily increasing the medical legal risk to all health care providers and institutions. The potential impact to physicians, hospitals and long-term care facilities could be significant to these providers who treat patients with pressure ulcers. APWH as other organizations is fully supportive of those identified measures which either reduces the incidence of new pressure ulcers and/or reduces the morbidity associated wound care for those with pre-existing pressure ulcers. However, this should be accomplished without increasing the medical/legal risks in already litigious climate for those health care providers already at risk.	Paul Kesselman, DPM, FAPWH, The Academy of Physicians in Wound Healing (APWH)	drkesselmandpm1@hotmail.com	

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	In conclusion the issues described herein provide cause for some restraint and therefore the APWH requests that CMS defer any further implementation. In addition, should there be a need to further pursue that proposed we would recommend that a consensus panel be brought together to thoroughly explore any and all potential medico-legal implications. The APWH would be pleased to meet with CMS, NPUAP and any other interested parties to further assess the proposed changes, the impact they have on patient care, the impact they have on documentation and medical legal aspects of practicing medicine.			
11/16/2016	I am writing to comment further on the New or Worsened SS PrU measure refinement. I recently participated on the TEP for this refinement on behalf of NASL. My feedback for the addition of unstageable pressure ulcers in the measure are well documented. I am commenting today on behalf of myself as a Physical Therapist and on behalf of my employer Nexion Health Management, Inc. In review, I agree unstageable pressure ulcers have a place in the measure calculation but I DON NOT agree with the addition of Deep Tissue Injuries at this time. There is far too little research on Deep Tissue Injuries and there is NOT a solid consensus on how long it may take for the body to actually reveal a Deep Tissue Injury-this matters because determining community acquired vs facility acquired is almost impossible on a consistent and reliable basis within a single setting much less consistently across all of PAC. There is also MUCH education needed in differentiating between a stage 2 blister and deep tissue injury which brings me to the proposal to change to pressure injury terminology and the changing of the RAI for coding blisters vs deep tissue injuries. 1. Terminology change- I think it is very controversial that the term pressure ulcer was changed to pressure injury. I believe this needs to be explored further before adoption in the RAI. Words matter. The term injury carries much more than just a description of an open area. It connotes trauma and all but says there is fault to be determined. 2. RAI manual stage 2 blister vs deep tissue injury. I absolutely disagree with the adoption of NPUAP definitions that differentiate stage 2 blister from deep tissue injury. The RAI takes assessment to a necessary level for differentiation. We have found that our	Tara Roberts, PT, Nexion Health Management, Inc.	TRoberts@nexion-health.com	

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	clinicians are far more accurate in staging by using the steps to evaluate the surrounding skin vs solely relying on the contents of a blister. To adopt NPUAP definitions/assessment instructions would be a step backwards in my opinion.			
11/16/2016	I am writing to comment only on the language modification from "ulcer" to "injury". I would agree with the NPUAP stance related to intact skin injury that is not an ulcer. That being said – I am concerned about adopting new language since we still have "bed sores" and "decubitus ulcers" being identified by some providers. If there is a way to get insurance companies, medical providers, and educational programs all on board – I would like to see the language change.	Heather McCormack PT, DScPT, CWS Clinical Lead in Wound Management Assistant Professor in Physical Therapy	mccormack.heather@mayo.edu	
11/16/2016	The M1313 seems more crystal clear. The M1311 is the confusing part – M1308 had more clarity with the use of M1313. The providers need a tool and will need to keep the documentation up to date. Thanks for the opportunity to give input.	Shirley J. Wamsley OASIS Education Coordinator, R.N. COS-C	Shirley.Wamsley@odh.ohio.gov	

SOC Date	ROC Date	Follow-UP/Discharge Date	M1313 Response
M1306 present on admit stage: Location: Stage: Location: Stage: Location: (instructions here: Stage noted first day of admission etc.	M1306 present on admit stage: Location: Stage: Location: Instructions – if ROC and was present at SOC and now a higher stage Do not report etc.	What was the most recent stage of pressure ulcer(s)/injury at M1306 for the most recent SOC/ROC: List all Stage: Location: Stage: Location: Stage: Location	Current stage of pressure ulcer(s) List all. Stage: Location: Stage: Location: Stage: Location: Stage: Location:
		M1307 Oldest **Stage 2** response: Present at the most recent SOC/ROC:___ Developed after most recent SOC/ROC: _____ Date Developed: _____	M1307 Oldest **Stage 2** response: Present at the most recent SOC/ROC:___ Developed after most recent SOC/ROC: _____ Date Developed: _____
M1311 response: Current pressure ulcer stage: Location: Current pressure ulcer stage: Location:	M1311 response: Current pressure ulcer stage: Location: Current pressure ulcer stage: Location:		Use M1313 to determine Worsened or new pressure ulcers That will be reported at M1313 Form.

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11/16/2016	As an experienced certified would care specialist, I would support using pressure injury in place of pressure ulcer. Pressure injury would better define the condition since an ulcer is defined as an open sore and Stage 1 and deep tissue injury do not involve any opening in the skin. One thing to keep in mind, however is that even though pressure is the primary cause, there are many other contributing factors (shearing, moisture, nutrition, mobility and overall health status). Any quality program needs to assure that these issues are addressed. Another concern is that in many cases these factors cannot be controlled no matter how vigilant you are. Clients still have rights to refuse to move and turn, and in many cases once a pressure injury occurs, the client is already in a severely debilitated state that despite our many resources cannot be reversed. I would also support adding deep tissue injury. These injuries usually are progressive since damage has already occurred. This needs to be taken into account in looking at outcomes. This is a similar situation to unstageable pressure ulcers that when dead tissue is removed almost always reveal a Stage 3 or pressure ulcer. We appreciate the opportunity to allow our clinical expert to provide comment. Ms. Williams has years of acute care experience and is currently practicing in the long term acute care hospital setting. Thank you.	CHERYL BURZYNSKI, PRESIDENT McLaren Bay Special Care DEBORAH WILLIAMS, CWOCN McLaren Bay Special Care	Cheryl.burzynski@mclaren.org	
11/16/2016	AMRPA is the national trade association whose members provide rehabilitation services across the spectrum of health care settings including inpatient rehabilitation facilities (IRFs), hospital outpatient departments (HOPDs), and settings independent of the hospital, such as comprehensive outpatient rehabilitation facilities (CORFs), rehabilitation agencies, long-term care hospitals (LTCHs), and skilled nursing facilities (SNFs). AMRPA members help patients maximize their health, functional skills, independence, and participation in society so they can return to home, work, or an active retirement. We appreciate the opportunity to comment on the refinements proposed to NQF #0678 pursuant to how the measure is implemented in the IRF Quality Reporting Program (QRP). CMS seeks comment on the following proposed modifications to NQF #0678 for post-acute care providers: 1. Add “unstageable pressure ulcers due to slough or eschar, unstageable pressure ulcers due to non-removable dressing or	Mimi Zhang Government Relations and Policy Associate American Medical Rehabilitation Providers Association (AMRPA)	mzhang@amrpa.org	

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	device, and unstageable pressure ulcers presenting as deep tissue injuries" to the measure numerator. This was as recommended by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP). 2. Align the terminology for the pressure ulcer measure specifications and assessment items with terminology used by the NPUAP Pressure Injury Staging System released. In April 2016, the NPUAP replaced the term "pressure ulcer" with the term "pressure injury," stating the "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin." New NPUAP guidance further clarified that "in the previous staging system Stage 1 and Deep Tissue Injury described injured intact skin, while the other stages described open ulcers." According to NPUAP, this led to "confusion because the definitions for each of the stages referred to the injuries as 'pressure ulcers'." I. Numerator A. Pressure ulcers due to slough or eschar AMRPA supports the inclusion of unstageable pressure ulcers due to slough or eschar or due to non-removable dressing/device in the numerator, which we also supported when it was proposed in the FY 2016 IRF PPS proposed rule. Furthermore, we appreciate that CMS does not propose to include suspected injuries (sDTIs) in the numerator. We do not think it is appropriate to include sDTIs because much is still unknown about including whether there is an actual deep tissue injury. Many sDTIs heal without opening and it would be unfair to penalize a provider for these. B. Measure Specifications The proposed refinements would change how the IRF measure is calculated. It would use IRF PAI Item M0300, "Current Number of Unhealed Pressure Ulcers at Each Stage" to calculate new or worsened pressure ulcers by subtracting the number of pressure ulcers that were present on admission from the total number of pressure ulcers for each stage, all of which is contained in M0300 assessment data. Presently, the measure is calculated using IRF PAI Item M0800A-F, "Worsening in Pressure Ulcer Status Since Admission" which is assessed at discharge. This item requires providers to "indicate the number of current pressure ulcers that were not present at admission or were at a lesser stage at admission" for Stages 2-4 pressure ulcers and three types unstageable pressure ulcers. In other words, the present method requires providers to do			

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	the calculation for Item M0300 themselves and then enter the data into an additional assessment item. AMRPA supports modifying the measure calculation to using M0300 items directly. We commend CMS and its contractors on these efforts to simplify the measure calculation process. However, these simplification efforts should extend to the parallel assessment tools as well. Specifically, we request that CMS clarify whether M0800 would still be included on the IRF PAI if it no longer feeds into NQF #0678 calculations. If M0800 does not serve quality reporting purposes, AMRPA recommends that it be eliminated from the IRF PAI. This would reduce the number of items providers must report and thus decrease burden. II. Terminology: AMRPA supports revising the terminology for the NQF #0678 specifications and post-acute care assessment items in order to align it with terminology used by the NPUAP Pressure Injury Staging System. We believe that changing "pressure ulcers" to "pressure injuries" will help reduce confusion for IRFs in reporting NQF #0678. AMRPA commends CMS and its contractors for adopting guidance from national advisory organizations which are followed by practicing clinicians. III. Summary: AMRPA appreciates the opportunity to comment on the project Refinement of Percent of Residents/Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury." In summary: 1. We support modifying the measure numerator to include unstageable pressure ulcers slough, eschar, or non-removable dressing/device. A. We support using Item M0300 to calculate the measure instead of Item M0800. However, we request that CMS clarify whether Item M0800 would still be on the IRF PAI if it no longer feeds into NQF #0678 calculations. AMRPA recommends that this reporting burden be eliminated from the IRF PAI if it no longer serves quality reporting purposes. B. AMRPA supports revising the terminology for the NQF #0678 specifications and post-acute care assessment items in order to align it with terminology used by the NPUAP Pressure Injury Staging System. If you have any questions regarding our recommendations, please contact Carolyn Zollar, J.D., Executive Vice President for			

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	Government Relations and Policy Development, (czollar@amrpa.orgmzhang@amrpa.org) or Mimi Zhang, Policy and Research Associate () at 202-223-1920.			
11/16/2016	My responses to the new NPUAP verbiage- The new terms to be injury verses ulcers makes since as stage 1, DTI, and some stage 2 are NOT ulcers/open	Angel Sutton RN, MSN/Ed, CWCN, CCCN, CFCN. Life Care Centers of America	Angel_Sutton@lcca.com	
11/16/2016	I am board certified in general surgery, but also a certified wound specialist in Sacramento, CA. Traditionally the NPUAP has proposed new terminology or updates only after reviewing and researching new information as was done when Deep Tissue Injury and Unstageable became part of the staging system several years ago. In addition, these new categories were voted on at a Consensus Conference where everyone had input into the process. The recent terminology change and conversion to Arabic numerals from Roman numerals violates both of these tenants. First, there is no new information that warrants or demands a change in terminology. There is nothing the science has shown that such a change in terminology would improve patient care. Secondly, at the NPUAP Consensus conference this past April, only a few phrases were voted upon, but the change from Ulcer to Injury and the Numeral changes were already set in stone with no vote was obtained from the Consensus attendees. In addition, apparently over 40% of attendees of wound care clinicians failed to identify the proper stage of a wound during a photo exam session. This points to the fact that the staging system even as it exists today cannot be consistently used to identify wounds properly among wound care clinicians and certainly not among regular nurses and physicians. So this terminology change does nothing to solve this issue and serves no real purpose. The terminology change is not warranted, not needed and is not based on any new scientific or evidenced based information. Please do not institute the NPUAP terminology change. That is why almost every major multidisciplinary wound care organization such as the Association for the Advancement of Wound Care, ACCWS(The American College of Certified Wound Specialists) and the APWH (Academy of Physicians in Wound Healing) all oppose this terminology change and hope that governing bodies like CMS will not go forward with the changes. They serve no purpose clinically.	S. Kwon Lee, MD FACS CWSP	skwonlee11@gmail.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/16/2016	I am a Wound and Ostomy Nurse Practitioner in at Upstate Hospital in Syracuse, NY, and am certified in wound care. I am considered an expert in wound care, and have been an expert witness in many legal cases pertaining to pressure ulcer development and treatment. I would like to voice my displeasure with the new NPUAP pressure ulcer terminology. I attended the NPUAP conference in Chicago in April 2016, and am aware that CMS is considering adopting the proposed staging revisions. I am writing to strongly discourage this. This is based on the following statements: 1. The evidence has long demonstrated that the pressure ulcer staging system is severely flawed. There is strong evidence that pressure ulcers are mostly (if not exclusively) a bottom up phenomenon (meaning occurring from the deeper tissues up) and NOT a top down phenomenon as the current and proposed staging system suggests. This causes a lot of confusion among health care professionals and among those in the legal field. Sadly, this issue was not dealt with in the conference in April 2016. Our confusion and misinformation regarding this issue continues. 2. Changing the terminology from pressure "ulcer" to pressure "injury" strongly implies that an "injury" has necessarily occurred, giving ammunition to plaintiff attorneys, resulting in oft times unfounded and expensive lawsuits. This ignores the concept of natural "skin failure", a known phenomenon at end of life, resulting in unavoidable pressure ulcers and unnecessary lawsuits. 3. I am a member of the Association for the Advancement of Wound Care (AAWC), who has publicly come out against these revisions. With such disagreement among professional bodies, adopting these revisions are ill-advised without further consideration, debate, and analysis of the evidence. I implore you to NOT adopt the NPUAP's staging revisons at this time.	Heidi H. Cross, Upstate Hospital, Syracuse, NY	hcross914@gmail.com	
11/16/2016	I am writing to oppose the proposed changes for on changes in terminology for the pressure ulcer measure specifications and assessment items. The NPUAP revised the Pressure Injury Staging System following a consensus conference in April 2016. I have specialized in wound management and have particular expertise in pressure ulcer management since 1990.	Catherine Milne APRN, MSN, ANP/ACNS-BC, CWOCN-AP, Connecticut Clinical Nursing Associates, LLC	cmilneaprn@gmail.com	

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	• The proposed changes have only gone through a consensus validation with the NPUAP members and participants at the conference. Many of the participants at this conference are not experts and attended to learn the latest updates. Their expertise was not noted nor was there any demographic data collected on the participants. I have grave concerns about the methodology involved. • Histology suggests that granulation tissue presents in dermal wounds, contrary to the updated Stage 2 definition. Our burn colleagues recognize the difference between superficial papillary dermal and deep reticular dermal burns. Dermatological texts and our wound literature (Brown-Etris M. Measuring healing in wounds. Advances in Woundcare.1995;8(4):suppl 53-58.) has previously identified that granulation tissue can be generated from deep partial-thickness wounds. • The NPUAP has revised the staging system several times since their inception in 1989. While these changes have been accepted, and often embraced, by wound care organizations as well as geriatric societies and the general nursing profession. Unfortunately, there has NEVER been clinical reliability and validity performed on the pressure ulcer/injury Staging system. As we have incorporated and accepted evidence-based practice since 1989, I am disappointed that we accept a proposed update on a system that never has been validated to begin with. The literature has been ripe in the inaccuracies – including literature published by the AHRQ as early as 2008. Examples: Bruce TA, et al, Crit Care Nurs Q. 2012 Jan-Mar;35(1):85-101. doi: 10.1097/CNQ.0b013e31823b1f2; Alvy B., et al J Wound Ostomy Continence Nurs. 2012 Nov-Dec;39(6):607-12. doi: 10.1097/WON.0b013e31826a4b5c; Tschannan D., et al. Journal of Nursing Education. 2016;55(5):266-270.;Lyder C and Ayello E. Pressure Ulcers: A Patient Saftey Issue – chapter 12 in Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Hughes RG, editor. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr.) I often wonder why we insist that when we identify the Staging of pressure ulcers/injuries is inaccurate, we point to the providers, instead of looking at the method. I urge CMS to insist on a well-designed clinical reliability and validity study performed by an independent organization/institution other than the NPUAP and not to accept any changes until this is completed.			

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	• Additionally, while not related to pressure ulcer staging, is the reporting of the number percentage of new or worsened pressure ulcers in the Post-Acute Setting. I support this but would also like to measure improvement in pressure ulcers – this could be monitored by reporting percentage of residents with a decrease in wound surface area of the pressure ulcer. I find that this is a more reliable way to monitor quality of care and appears less punitive.			
11/17/2016	I am writing as an individual Clinical Nurse Specialist and WOC nurse who has system wide responsibilities for Skin and Wound Care in a 6-hospital enterprise in Central North Carolina. I have a 27 year history in this specialty area of Nursing and have worked in both acute care and home health care. I am in absolute favor of the change in terminology put forward by the NPUAP for it clarifies and illuminates the classification system currently in use. The refinements, while not sweeping, will allow for an increased accuracy and ease of use for the 2500 staff nurses in our enterprise-particularly in the area of Stage 2 pressure injuries. Here are my (and our hospitals') three points of support: • It has been extremely difficult to explain to physicians, other multidisciplinary colleagues, patients and families how the term "ulcer" was used to describe areas of injured, but not open, skin as was the case in Stage 1 and in sDTI. The term injury is universally easier to understand, teach and communicate and was immediately adopted in our facilities. • The change from Roman numerals to Arabic had already been made by our staff nurses-many were simply not familiar with Roman numerals. • The removal of "s" for suspected from deep tissue pressure injury is also applauded by the medical and nursing teams here at Cone Health. DTPI is intuitive and descriptive. Thank you for allowing us the opportunity to comment, compliment and publically support the NPUAP on this update to the Staging System. Finally and although you did not ask, I also wish to express appreciation and support of the new illustrations. They too, are clarifying and are a vast improvement over the previous illustrations.	Laurie McNichol, MSN, RN, CNS, GNP, CWOCN, WOC Nurse/Clinical Nurse Specialist	Laurie.McNichol@conehealth.com	

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11/17/2016	We would submit input to the proposed changes to the Changes in Terminology proposed by NPUAP. Our comments are outlined in the attached document. I would like to provide feedback regarding the refinement of the cross-setting post-acute care pressure ulcer measure in alignment with the 2014 IMPACT Act. Project Title: Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury" As President of the Association for the Advancement of Wound Care, I represent 2500 wound care providers across the country and internationally. I am writing in regards to the proposed changes in terminology submitted by the NPUAP. As a collaborating organization, we cannot support and do not support the implementation of these changes. We repeatedly have voiced objection to the process and the lack of scientific basis for these changes. There is no meaningful end to the adoption of these changes in terminology and adoption across our health care system will be costly. Adoption will add further ambiguity and mis-categorization to this difficult wound pathology. In terms of quality measures, a valuable quality measure must be founded in good clinical science and supported with evidence. The changes to terminology are not supported in current evidence. As a participant at the Consensus meeting, I can attest to the fact that there was very poor inter rater reliability in assessing the illustrations. In a hall with educated and experienced wound care providers, less than 50% could correctly identify the wound staging represented in the visuals. This poor inter rater reliability will result in misclassification of these pressure wounds and incorrect assessment for patients. Given poor and inaccurate input to the quality measures, the measure will not be truly reflective and of misdirected value to CMS and to improving patient care. Reference material included in Table 1.I would urge that CMS not adopt these proposed changes in terminology and look to the wound community at large for clarification where needed.	Gregory Bohn, MD FACS FACHM ABPM/UHM, President of the Association for the Advancement of Wound Care President American Board of Wound Healing	gregbohn2@aol.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/17/2016	I am commenting on behalf of myself – a Physical Therapist who performs wound care in multiple care settings. 1. Unstageable Pressure Ulcers (for the mentioned reasons in proposal) should be used in in numerator for calculating PrU measures. 2. Deep tissue injuries should not be used for the PrU measures. There is far too little research on etiology and evolution to definitely tie them to one care setting. For example, it is very difficult to determine community acquired vs. facility acquired when it is difficult to ascertain exactly when the initial injury occurred. 3. Many clinicians, including myself, are not comfortable with the NPUAP change in terminology from "ulcer" to "injury". The latter term connotes fault even in situations where the development of the insult was unavoidable. There is too little research to support such a language change beside the terminology reasons offered by the NPUAP.	Stanley McCallon, PT, DPT, CWS	smccal@lsuhsc.edu	
11/17/2016	Project Title: Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury": Would discourage adaptation of the April 2016 updated NPUAP Pressure Ulcer guidelines. Deep Tissue injury should remain suspected until declared and at that point be considered a full thickness injury and staged as III, IV, or Unstageable. The revised guidelines add confusion to an already poorly understood and applied staging process. Moves should be made to initiate identifying wounds as full and partial thickness, and identification of etiology should be proffered by the appropriately trained, qualified clinician.	Phill Botham BSN, RN, CWON Lead Coordinator for Wound, Ostomy and Continence Nursing and Vascular Access Insertion Nursing Programs Quality Management and Patient Safety Medical University of South Carolina	botham@musc.edu	
11/17/2016	I am writing in response to the call for public comments for Project: Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury". Thank you for bringing this topic forward for public comment. I have been conducting pressure injury research for over 20 years and am currently Director of the Center for Wound Healing Research at Daemen College and a member of the board of directors of the NPUAP. I co-chaired the NPUAP Staging Consensus	Laura Edsberg, PhD, Director of the Center for Wound Healing Research at Daemen College, Member, board of directors of the NPUAP	ledsberg@daemen.edu	

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	Conference in April and co-authored the manuscript based on the results of that conference (Edsberg LE, Black JM, Goldberg M, McNichol L, Moore L, Sieggreen M. National Pressure Ulcer Advisory Panel (NPUAP) Revised pressure injury staging system. Journal Wound Ostomy Continence Nursing 2016;43(6):1-13.). I have published on both the microstructure of tissue subjected to pressure, as well as the histology of pressure injuries. In preparing for the conference and drafting the definitions for consensus I reviewed the 3000 papers we identified in our literature searches and critically evaluated the 242 that directly addressed staging. Regarding the specific areas of Focus for Comments three CMS categories of unstageable in the numerator for this measure. The addition of unstageable pressure ulcers due to slough or eschar I strongly support the addition of unstageable pressure injuries due to slough and eschar. The NPUAP staging system is based on clinical visible tissue layers. In order to be obscured by slough or eschar these must be full thickness injuries and as such should be part of the tally of stage 2 and greater. Unstageable pressure ulcers due to non-removable dressing or device Unstageable pressure ulcers under a non-removable device is not a NPUAP designation, but is from the NDNQI and is a small percentage of NDNQI reported pressure injuries. Unstageable pressure ulcers presenting as deep tissue injuries in the numerator, as recommended by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP) I am in support of this with the assumption that the deep tissue pressure injury is accurately diagnosed. This is comparable to at least a stage 2 if it does not evolve into a full thickness injury. I have been recently working with Joyce Black and Evan Call to evaluate tissue samples of suspected deep tissue pressure injuries. It is important to note that this is unpublished data and the first study of human DTPI tissue that I am aware of at this time. These samples were collected from cadavers and were chosen based on location and the appearance of deep purple bruising. The histological examination of these samples has revealed an intact epidermis and			

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	dermis, with deeper layers of tissue damaged. In some samples there was evidence of tissue remodeling or healing and in other cases the damage to the deep layers of tissue was extensive. In response to CMS soliciting comments on changes in terminology for the pressure ulcer measure specifications and assessment items. Not all pressure injuries are ulcers in presentation and that has led to confusion in the past with utilization of the NPUAP Staging System. The NPUAP Staging System classifies pressure injuries based on the level of tissue loss that can be visualized or directly palpated. Based on what is currently known about pressure injuries and the extensive public comments we received we chose to revise the staging system based on the level of tissue loss. Based on the enthusiastic response and quick adoption by many organizations (list available at www.NPUAP.org) this decision was appropriate for the time. In the future, new evidence may support a different system of pressure injury classification, but there is insufficient published support for these changes. A major change in pressure injury classification as proposed by opponents will require in-depth planning in terms of intended and unintended consequences to patients, providers, education, research and public policy. The NPUAP has evaluate and revised the NPUAP staging system with comment and consensus as new evidence comes forth and we will continue to do so. The NPUAP replaced the term pressure ulcer with pressure injury after 18 months of discussion and consideration of what is currently known and the etiology and presentation of pressure injuries. Not all pressure injuries are ulcers, but they are all injuries. The diagnosis of a "pressure injury" does not mean that the health care provider(s) "caused" the injury. It is important that we consider the accuracy of the language in describing the injury to facilitate correct diagnosis and staging. Not all pressure injuries are full thickness tissue injuries and the dissemination of this heresy does not serve our patients well. Based on these baseless notions we may fail to prevent pressure injuries that are caused by superficial shear in combination with microclimate extremes. Additionally, this notion will also lead to wasteful "over treatment" of partial thickness pressure injuries, not to mention extension of financially punitive policies for a broader range of pressure injuries.			

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	All pressure injuries should be treated according to current standards of care and monitored closely for changes that require re-evaluation of treatment strategies. Please consider including Mucosal Membrane Pressure injuries. Although they are not staged due to unique anatomy, they are pressure injuries.			
11/17/2016	Nutrition and Dietetics The Academy of (Chicago, IL.) supports the CMS language modifications and adoption of new terminology as espoused by NPUAP. The Academy further supports the changes in terminology for the pressure ulcer measure specifications and assessment. The Academy agrees with replacing the term "pressure ulcer" with the term "pressure injury" since the "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin."[1] [1] NPUAP Press Release, April 13, 2016. http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/ .	Mujahed Khan Sr. Manager, Quality Improvement Academy of Nutrition and Dietetics	www.eatright.org	
11/17/2016	The National Association for Home Care & Hospice is the largest trade association in the country representing home health care agencies. NAHC members represent the entire spectrum of home care agencies, including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and free-standing, proprietary home health agencies. NAHC members serve over several million Medicare home health care beneficiaries each year. NAHC supports the refinement of the quality measure "Percent of Residents or Patients with Pressure Ulcers that are New or Worsened" to include in the numerator unstageable pressure ulcers due to slough or eschar, non-removable dressing or device, and pressure ulcers presenting as deep tissue injuries. NAHC also supports adopting the recommendations by the National Pressure Ulcer Advisory Panel (NPUAP) to replace the term "pressure ulcer" with the term "pressure injury in the measure specifications and assessment items. Lastly, NAHC supports using the Outcome and Assessment Information Set (OASIS) item M1311 instead of M1313 to calculate the quality measure in order to reduce redundancy. However, it is unclear whether OASIS item M1313 will remain as an OASIS assessment item.	Mary K. Carr Vice President for Regulatory Affairs, National Association for Home Care & Hospice (NAHC)	mkc@nahc.org	

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11/17/2016	1. The NPUAP "consensus conference of April 2016 changed pressure ulcer terminology inaccurately stating that no granulation tissue is formed when healing a partial-thickness Stage II pressure ulcer. There is ample evidence that this wording contradicts medical, dermatological and surgical textbook definitions of dermal wound healing confirmed by histology and biochemical evidence. (E.g. Witkowski J, Parish LC Histopathology of the decubitus ulcer. J Am Acad Dermatol., 1982;6:1014-1021; Bolton, L. and van Rijswijk, L., Wound dressings: Meeting clinical and biological needs. J. Dermatol. Nursing, 3(6), 146, 1991. Bolton L, Vasko A, Monte K. Quantification of wound healing. Chapter 17 in Doris Schwindt & Howard Maibach (Eds.) Cutaneous Biometrics, Kluwer Academic/Plenum Publishers, New York, 2000, pp. 205-219.) This change forces professionals to call a normally granulating Stage II pressure ulcer a Stage III pressure ulcer, placing institutions at risk of artificially inflated Stage III pressure ulcer prevalence. This causes legal and reimbursement confusion with adverse consequences to patients, professionals and payers. 2. To rename a pressure ulcer a "pressure injury" dismisses decades of meticulous research describing the histopathology, etiology and sequelae of these chronic ulcers (e.g. op cit) as well as text book definitions of "ulcers" and why they heal more slowly than acute injuries (e.g. Braun-Falco O, Plewig G, Wolff HH, Winkelmann RK. Dermatology. Springer-Verlag , New York, 1991, Page 7.) Renaming them simple "injuries" raises false expectations about their ease, speed and quality of healing or their importance as a public health care problem with a serious clinical and economic burden on health care systems. 3. To my knowledge, no attempt has been made to establish formal content validity of the new NPUAP nomenclature through active participation of informed stakeholders or professionals. Our field has moved past consensus to develop formally content validated evidence-based guidelines of venous and pressure ulcer care since 2000. (Bolton LL, Girolami S, CorbettL, van Rijswijk. The Association for the Advancement of Wound Care (AAWC) Venous and Pressure ulcer Guidelines. Ostomy/Wound Management 2014;60(11):42-81. Bolton LL, Girolami S, Hurlow J. Wound Wise:	Laura Bolton, PhD - Adjunct Assoc. Prof. Surgery Rutgers University Medical School	llbolton@gmail.com	

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	The AAWC Pressure Ulcer Guidelines. Amer. J. Nursing, 2013; 113(9):58-63.) No one should be forced to abide by opinion-based consensus statements or changes in definitions in managing these challenging wounds. Professionals serve patients more consistently and achieve better quality outcomes by doing what works, based on formally content validated recommendations supported by best available evidence and by using clear, operational definitions validated by research and shared across specialties in professional textbooks to foster interdisciplinary team wound care.			
11/17/2016	The US Wound Registry (USWR) has been a registry for patients with wounds and ulcers for more than a decade, starting in 2005. In 2008, the USWR was among the first registries recognized by CMS for reporting PQRI/PQRS data on behalf of eligible providers (EPs), and in 2014 we were among the first registries recognized by CMS as a Qualified Clinical Data Registry (QCDR). We develop quality measures relevant to wound care and currently have 21 measures approved by CMS including high value measures such as patient reported wound outcome and patient reported wound quality of life. Wound care practitioners can report relevant quality metrics for usual and customary care including diabetic foot ulcer off-loading, venous ulcer compression and vascular screening only through our QCDR since there are no wound related measures in PQRS. In conjunction with the Institute for Clinical Outcomes Research, we have developed the Wound Healing Index (WHI) which predicts the likelihood that patients suffering from various types of chronic wounds and ulcers will heal, including models that can predict the likelihood of healing pressure ulcers of the heel and other areas of the body. (Horn, S, Fife CE, Barret R, Thomson, B, "A Predictive Model for Pressure Ulcer Outcome: the Wound Healing Index. Advances in Skin & Wound Care: December 2015 - Volume 28 - Issue 12 - p 560–572. Available on line: http://journals.lww.com/aswcjournal/Fulltext/2015/12000/A_Predictive_Model_for_Pressure_Ulcer_Outcome__The.8.aspx We have an extensive repository of real world data that can provide insights into the risk factors for pressure ulcer formation, the comparative effectiveness of various treatments, and the way that the current staging system behaves with regard to ulcer treatment	Caroline E. Fife, MD Executive Director, US Wound Registry (USWR)	cfife@uswoundregistry.com	

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	over time. It is unfortunate that independent federal funding to properly understand this repository is not available, although it is it widely used by manufacturers to understand the value proposition for their products. It give the USWR insight into the weaknesses of the current staging system in ways that have not been properly addressed. Foundational Problems with the Staging System The NPUAP's reclassification of pressure "ulcer" to pressure "injury" does not correct the fundamental, serious problems with the pressure ulcer staging system. The NPUAP was correct in identifying that it was always inappropriate to call a "stage I" pressure ulcer an "ulcer" since there was no break in the skin. However, changing the name of all so-called pressure "ulcers" to "injuries" does not solve the numerous foundational problems with the staging system which was originally a descriptive system. The NPUAP "staging" system is inconsistent with what we now know about the pathophysiology of how pressure ulcers form. Using the current (admittedly flawed) system, we know that Deep Tissue Injuries (DTIs), Stage 3 and 4 ulcers all form from the inside OUT pathophysiologically speaking; whereas Stage 2 pressure ulcers occur from the outside IN via moisture, friction and sheer. A name change does not address the dichotomous nature of this process or the misconception created by giving this dichotomous problem SEQUENTIAL NUMBERS. Coding Implications of the Terminology Change Because ICD-10 terminology has not changed, using the new term "pressure injury" creates significant problems for hospital coders. However, this ill-considered proposed change on the part of the NPUAP has much bigger implications for coding under ICD-10 and ICD-11. The universe of non-healing cutaneous "problems" is divided by CMS and coding convention into "ulcers" which are due to an underlying medical problem, and "wounds" which are caused by surgical intervention or an accident. The decision by the NPUAP to redefine pressure ulcers as "injuries" will reclassify all of these ulcers as "wounds" due to an accident (which is where the "injury" codes reside). It is vital to understand that all of the "wound" codes MUST be linked to the surgery or accident which caused them. The extensive and detailed list of ICD-10 accident codes has been the cause of much levity when they were			

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	released as they encompass all of the injuries sustained by Looney Tunes cartoon characters including injury by an animal driven vehicle, being sucked into a jet engine, and being injured by a kite-carrying person. The injury codes are also quite specific and include injuries which detail almost every conceivable type of personal injury. We are concerned that that the door will be opened to a detailed list of codes to be used with "pressure injury" that will, in the absence of sufficient scientific evidence, link these skin lesions to specific medical devices, "inadequate turning by medical staff," "failure of adequate care," or other unsubstantiated claims which will imbue them with the force of law. Legal Implications of the Terminology Change Since the state of Texas passed tort reform in 2003, medical malpractice claims in the state have dropped 65%, and the average monetary award per case has dropped 22%. There is a cap on punitive damages of $250,000 in the state of Texas. However, if the plaintiff sues both the physician and the hospital, the award could be increased to $500,000, a situation which has increased the likelihood of both parties being sued in the case of a pressure ulcer. Furthermore, tort reform has had the perverse effect of INCREASING litigation regarding pressure ulcers, because there is no cap on punitive damages in the case of elder abuse. Plaintiff's attorneys link the development of pressure ulcers (including those occurring in the intensive care unit, and occurring in the dying process) with elder abuse in hopes of avoiding the cap on punitive damages. This is contributing to making pressure ulcers perhaps the most common reason for malpractice litigation nationwide. I regret to say that many of the experts working for the plaintiffs are current or former NPUAP board members, an activity which the NPUAP does not view as a conflict of interest. Whether that was a motivation for these changes I cannot say but when concern was raised at the NPUAP "Consensus" meeting that this terminology change had profound medicolegal implications, these concerns were summarily dismissed as being irrelevant. They are not. Of even greater concern is the trend toward criminalization of pressure ulcers. At least two family members and one nursing home operator that we know of have been tried in criminal court for cases related to pressure ulcers that formed on patients during the dying			

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	process. It was not necessary to demonstrate that death resulted from the pressure ulcer. The presence of the pressure ulcer was used as prima facie evidence of neglect, a dangerous standard not supported by scientific evidence. It should be remembered that CMS classifies pressure ulcers as “Reasonably Preventable HACs”, not as “Serious Preventable Events” (in other words, pressure ulcers are NOT “never events”). Calling pressure ulcers "injuries" will continue the trend towards criminalization of pressure ulcers, regardless of whether neglect or abuse has actually occurred or can be proven. In addition to the fact that this terminology change will certainly increase the success that plaintiffs have had in linking pressure ulcers to elder abuse in order to avoid the cap on punitive damages, saying that we "injured" a patient implies intentional harm. That makes pressure ulcers willful abuse and that makes them criminal conduct. Malpractice insurance does not cover a facility or a clinician for criminal charges of battery or manslaughter. The USWR fully supports comments you have already received from the Association for the Advancement of Wound Care (AAWC) which provide much greater detail as to the lack of scientific evidence for this change, the lack of consensus in the process by which it was put forth, and the generally premature nature of this terminology change. We strongly urge you NOT to make this terminology change until an actual consensus process has occurred.			
11/17/2016	Overall Comments on the Proposed IMPACT Measures Pressure Ulcers (Short Stay) for Home Health Care For the most part, VNAA agrees with the measures. VNAA believes that there are two areas we are commenting on specifically; risk adjustment for very low BMI as well as high BMI and the change from pressure ulcer to pressure injury. Risk Adjustment for Low BMI VNAA believes that you must risk adjust for both high BMI, as well as low BMI for large and small caustic pressure injuries. Patients with low BMI have boney prominence and thin adipose tissue and the skin is very thin. These factors combined increase the likelihood of pressure injuries and should be appropriately risk adjusted. Move from Pressure Ulcer to Pressure Injury	Joy M. Cameron Vice President, Policy and Innovation, Visiting Nurse Associations of America	JCameron@vnaa.org	

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	VNAA agrees with the move to pressure injury. VNAA believe that the move should lessen confusion amongst types of skin ulcers. VNAA appreciates the opportunity to comment on the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) proposed measures. Please contact Danielle Pierotti, Vice President of Quality and Performance Improvement ion at dpierotti@vnaa.org or 571-527-1529 with any questions or concerns.			
11/17/2016	These comments relate to the Home Health Care Setting In order for there to be accuracy CMS needs to revise the OASIS requirements to allow for multiple clinicians to provide input into/ revise scoring of the OASIS item within the 5 day window. Currently CMS requires that the OASIS have a sole author despite the fact that in all other settings the assessment tools are updated over a series of days by multiple clinicians. If, as often happens, a patient is admitted to home health care following an inpatient stay, a non-removable dressing may be in place at the time of admission with orders to remove or change it sometime within the 5 day window. This is more frequently the case with newer dressing supplies impregnated with antibiotics or other medications. Often the clinician conducting the initial assessment is unable to see the patient again within the remaining four days of the window and another clinician is scheduled to conduct the follow-up visit. CMS requirement of a single author as the only one to revise the scoring of that wound at such time that the dressing results in (1) inaccuracies in data when the single author cannot revisit and/or (2) imposition of additional cost and administrative burden to have the authoring clinician revisit in addition to another clinician. We strongly urge CMS to make this very simple, cost saving revision to regulation to allow subsequent clinician visits to conduct additional assessments and adjust the OASIS scoring remaining within the current 5 day window. This would result in greater accuracy as well as parity with other health care setting requirements.	Judith Flynn MBA BSN RN CHC Vice President Patient Care Quality, Compliance Officer. Partners HealthCare at Home	JBFLYNN@PARTNERS.ORG	HHA
11/17/2016	As an NPUAP board member and clinician practicing in the acute care setting, I wish to express my full support of the use of the newly revised NPUAP staging System definitions in all future CMS documentation.	Dr. Nancy Munoz, DCN, MHA, RDN, FAND, Assistant Chief, Nutrition and Food Services VA Southern Nevada Healthcare System	Nancy.Munoz3@va.gov	

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11/17/2016	I am a Wound and Ostomy Nurse Practitioner in at Upstate Hospital in Syracuse, NY, and am certified in wound care. I would like to voice my displeasure with the new NPUAP pressure ulcer terminology. This is based on the following statements: 1. The evidence has long demonstrated that the pressure ulcer staging system is severely flawed. There is strong evidence that pressure ulcers are mostly (if not exclusively) a bottom up phenomenon (meaning occurring from the deeper tissues up) and NOT a top down phenomenon as the current and proposed staging system suggests. This causes a lot of confusion among health care professionals and among those in the legal field. 2. Changing the terminology from pressure "ulcer" to pressure "injury" strongly implies that an "injury" has necessarily occurred, giving ammunition to plaintiff attorneys, resulting in oft times unfounded and expensive lawsuits. This ignores the concept of natural "skin failure", a known phenomenon at end of life, resulting in unavoidable pressure ulcers and unnecessary lawsuits. I implore you to NOT adopt the NPUAP's staging revisons at this time	Jessica Dow, MSN, RN, FNP, CWCN Wound & Ostomy Nurse Practitioner SUNY Upstate Medical University Hospital	DowJ@upstate.edu	
11/17/2016	The Federation of American Hospitals “FAH” appreciates the opportunity to comment on the proposed updates to the Post-Acute Care Pressure Ulcer measure. The FAH encourages CMS to consider developing a complimentary measure in addition to the measure that is proposed. Such a complementation measure would track the rate of healed pressure ulcers in addition to the proposed measure rate of new or worsened wounds. The current measure, as specified, does not provide a complete picture of the quality of care provided in these post-acute settings and it would be useful to understand and report the extent to which patients are discharged with healed pressure injuries. With regard to the proposed measure, the FAH offers below the following specific suggestions on the proposed data collection changes and updates to the measure specifications: • The FAH supports the proposal to align the pressure injury terminology with the terminology adopted by the National Pressure Ulcer Advisory Panel (NPUAP). The FAH also encourages CMS to “adopt” instead of “adapt” the pressure injury definitions from NPUAP so that they remain consistent with clinical practice standards for wound care clinicians, regardless of setting.	Jayne Hart Chambers Senior Vice President Quality, Federation of American Hospitals	JChambers@FAH.org	

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	• The FAH encourages CMS to consider adding to Section M0900 of the IRF-PAI unstageable pressure injuries due to slough or eschar, unstageable pressure injuries due to non-removable dressing or device, and unstageable pressure injuries . Wound clinicians heal these unstageable pressure injuries as often as Stage 1-4 pressure injuries; yet, these items are noticeably absent from the existing IRF PAI. • Regarding the proposed updates to the measure specifications, the FAH supports the addition of the unstageable pressure injuries to the numerator and the consistent specifications across the post-acute settings and data collection tools. • The FAH is concerned about the proposal to replace a question that directly collects the intended numerator (number of new or worsened pressures injuries as currently exists with M0800) with a calculated, inferred numerator based on the items collected in M0300. These items for this measure have only been collected in inpatient rehabilitation facilities (IRFs) since October 1, 2016. The data that is available for analysis and testing of this measure is extremely limited and there is insufficient information to enable sufficient testing on reliability and validity. • In addition, the FAH does not believe that the distinctions between "present on admission" and "new/worsened" are clearly defined. Therefore, the FAH is concerned that this lack of clarity could directly impact the reliability and validity of the measure and limit comparability of the results across providers. Given the concerns outlined above, the FAH strongly encourages CMS to submit the modifications of the measure along with testing results of the modified measure to the National Quality Forum for review and potential endorsement prior to implementation in any federal payment program.			
11/17/2016	I am exceedingly opposed to the implementation of the NPUAP revised/renamed pressure ulcer staging system. I am a board certified Wound Care Nurse with more than 20 years of hands on wound care experience in the post-acute and outpatient settings. I am currently working in a primary care medical practice. I am also a proud member of both the AAWC and WOCN. The staging system currently in use is flawed. Many bedside clinicians are known to be unable to interpret and utilize the current system to accurately assess and stage the extent of visible pressure	Mary B. Haddow, RN, CWCN	mbhaddow@yahoo.com	

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	induced tissue damage. Neither the current nor the newly proposed staging system is evidence based. Nor was the approval process used by the NPUAP with the participants at the NPUAP Staging Consensus Conference in April 2016 a 'consensus' by ANY definition. Brilliant researchers are unable to definitively discern and validate which theory or mechanisms trigger the tissue damage. Does it occur top down or bottom up? And what is the impact of other factors that compromise tissue integrity: shear, perfusion, circulation and moisture to name but a few. Adding new categories of tissue damage that do not impact accurate identification of the level of visible tissue damage merely muddies the water. Implementation of and assigning ICD codes to NPUAP's proposed revised staging system will miss-direct already limited resources for pressure induced tissue damage prevention which will have financial as well as legal repercussions in addition to negative patient outcomes. I do agree with the proposed update to the Home Health quality measures to include NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay). However, I strongly oppose the adoption of NPUAP's language. On learning of the proposed change in terminology from 'ulcer' to 'injury', my colleague, a well-respected, talented Internal Medicine Physician in primary care replied in utter disbelief "What are they thinking? 'Injury' implies intent". Implementation of the proposed terminology will open the door to litigation against any clinician or caregiver involved in the care of a patient with a pressure ulcer regardless of whether the ulcer was avoidable or unavoidable. Surely implementation of the revised NPUAP system is premature at best. As a clinician, I urge CMS to pause and consider the next step well. NPUAP's new classifications lack sufficient evidence to support a significant change in policy and practice. Best practice dictates that we all step back and analyze the process thoroughly to ensure that policy and practice are evidence based. I urge you NOT to implement any of the recent terminology changes to the NPUAP staging system for NQF #0678 quality measure or any other revisions to clinical assessment tools [OASIS, PAI, MDS, etc.). The current system, although flawed, should remain in use while the wound care community develops an evidence based, validated system for assessment and defining levels of pressure induced tissue damage.			

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11/17/2016	On behalf of National Pressure Ulcer Advisory Panel I would like to thank you for bringing the topic of pressure injuries/ulcers forward for comment. This is a topic of great importance to the NPUAP as we serve our patients and clinical peers. We are particularly pleased to see the inclusion of the new NPUAP Pressure Injury Classification System in your call for public comment. The NPUAP fully supports the recommended changes to NQF 0678. The changes will harmonize implementation of this quality indicator across post-acute care settings, facilitate more accurate monitoring of pressure injuries and heighten clinician awareness of pressure ulcer prevention, detection and treatment. Under your Project Objectives Re: Refinement of Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short Stay) (NQF #0678) The National Pressure Ulcer Advisory Panel (NPUAP) supports adding to the numerator residents/patients with: 1. Unstageable pressure ulcers due to slough or eschar are considered full-thickness pressure injuries. “If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed.”[1, 2] 2. Unstageable pressure ulcers due to non-removable dressing or device is not a NPUAP category but rather is classified "indeterminable” by National Database for Nursing Quality Indicators (NDNQI). The NPUAP supports the use of this data element in this quality measure. 3. Unstageable pressure ulcers presenting as deep tissue pressure injury should be included in a quality indicator measuring Stage 2, 3, or 4 pressure injuries. NPUAP has received positive feedback from clinicians and wound care organizations that the new NPUAP staging definitions[1, 2] are much clearer, supporting more accurate classification of pressure injuries. The NPUAP supports the inclusion of “worsened” pressure ulcers in this quality indicator. The NPUAP Pressure Ulcer Scale for Healing (PUSH Tool) is a tool that might be considered to measure this quality indicator. The NPUAP has revised this tool and will undertake testing of the revised tool in 2017.	Mary Sieggreen, MSN, CNS, NP, CVN President Jen Bank Director of Meetings & Operations NPUAP	JBank@hauck.com	

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	The NPUAP encourages CMS to also consider the inclusion of Mucosal Membrane Pressure Injuries in the future. This is a category endorsed by NPUAP after the 2016 Consensus Conference. The anatomy of the tissue makes these injuries impossible to stage with the staging system we have in place now. They are preventable pressure induced injuries which should be recognized as such and they reflect the quality of care. The National Pressure Ulcer Advisory Panel (NPUAP) revised the NPUAP staging system definitions and changed the name of this condition from "pressure ulcer" to "pressure injury" following an extensive review of the research literature by the NPUAP Staging Task Force. Our process included distributing initial drafts to national and international stakeholders. All stakeholder comments were reviewed and discussed rigorously. Statements that were supported by science were not presented for discussion at the Consensus Conference, which was convened in April 2016.[1,2] An open-invitation Consensus Conference was convened in April 2016. The NPUAP has worked actively with a number of entities to ensure the smooth implementation of the new NPUAP Staging System. We have received strong support from other organizations. The Wound Ostomy and Continence Nursing Society (WOCN) and the Academy of Nutrition and Dietetics have endorsed the new staging system. The National Database for Nursing Quality Indicators (NDNQI) is revising its database and data collection guidelines to conform to this change. Coding systems such as LOINC and SNOWMED CT are being analyzed for congruence with the new staging. The Veterans Affairs is revising teaching materials to align with these changes. The Joint Commission has included a copy of the new staging system on its website. The rationale for the changes made by the NPUAP after the 2016 Consensus Conference is clearly stated in the announcement on the NPUAP website (www.npuap.org) and is detailed in the publication: Revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System Revised Pressure Injury Staging System L E. Edsberg J M. Black Mt Goldberg L McNichol L Moore M Sieggreen J Wound Ostomy Continence Nurs. 2016;43(6):1-13. Lippincott Williams & Wilkins			

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	As noted on the NPUAP website, (www.npuap.org) many professional organizations have publically endorsed the changes. The few concerns that have been raised against the changes are not well supported by experience or research. Some of those concerns are: a. New found opposition to use of the term injury. Even though this has been used in the category "Deep Tissue Injury" for some time, it has been expressed by some as a concern. We have found no evidence that this will increase the risk for the caregivers or the facilities. The diagnosis of a “pressure injury” does not mean that the health care provider(s) “caused” the injury. b. The NPUAP Staging System classifies pressure injuries based on the level of tissue loss that can be visualized or directly palpated. Yes, there are limitations to a staging system based on identification of visible tissue loss. Following a comprehensive literature review and careful consideration of stakeholder comments, NPUAP decided that there was insufficient evidence to “abandon staging based on visible tissue loss”. Therefore our efforts were focused on clarifying the staging system based on recent evidence. In the future, new evidence may support a different system of pressure injury classification. However, we are not there yet. NPUAP in collaboration with its international guideline partners (EPUAP and PPPIA) are conducting ongoing systematic reviews of the research literature to answer these and other questions regarding the prevention, diagnosis and treatment of pressure injuries. A major change in pressure injury classification as proposed by opponents will require in-depth planning in terms a intended and unintended consequences to patients, providers, education, research and public policy. We are not afraid of a major over haul. It is our considered opinion that there is currently insufficient evidence to do this well. c. We reject the hypothesis that all pressure injuries are full thickness. Furthermore, we believe that promulgation of this misconception does not serve our patients well. We may fail to prevent pressure injuries that are caused by superficial shear in combination with microclimate extremes. This philosophy will also lead to wasteful “over treatment” of partial thickness pressure injuries, not to mention extension of financially punitive policies for a broader range of pressure injuries.			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	We look forward to an ongoing dialogue with all our colleagues and organizations striving to move the science forward on this most important patient issue. 1. Edsberg LE, Black, J. M., Goldberg M, McNichol L, Moore L, Sieggreen M. Revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System. Journal of wound, ostomy, and continence nursing: official publication of The Wound, Ostomy and Continence Nurses Society / WOCN. 2016;43(6):1-13. 2. National Pressure Ulcer Advisory Panel. National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury. Available at: http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/ . Accessed June 14, 2016.			
11/17/2016	I would like to thank you for bringing the topic of pressure injuries/ulcers forward for comment. This is a topic of great importance and I am particularly pleased to see the inclusion of the new NPUAP Pressure Injury Classification System in your call for public comment. I fully support the recommended changes to NQF 0678. The changes will harmonize implementation of this quality indicator across post-acute care settings, facilitate more accurate monitoring of pressure injuries and heighten clinician awareness of pressure ulcer prevention, detection and treatment. Under your Project Objectives Re: Refinement of Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short Stay) (NQF #0678) I support adding to the numerator residents/patients with: 1. Unstageable pressure ulcers due to slough or eschar are considered full-thickness pressure injuries. “If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed.”1, 2 2. Unstageable pressure ulcers due to non-removable dressing or device is not a NPUAP category but rather is classified "indeterminable " by National Database for Nursing Quality Indicators (NDNQI). I support the use of this data element in this quality measure. 3. Unstageable pressure ulcers presenting as deep tissue pressure injury should be included in a quality indicator measuring Stage 2,	Margaret Goldberg, RN, MSN, CWOCN, Past President Wound Ostomy and Continence Nurses Society Past President NPUAP	margoldb@comcast.net	

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	3, or 4 pressure injuries. I think that the new NPUAP staging definitions are much clearer, supporting more accurate classification of pressure injuries. I support the inclusion of "worsened" pressure ulcers in this quality indicator. The NPUAP Pressure Ulcer Scale for Healing (PUSH Tool) is a tool that might be considered to measure this quality indicator. The NPUAP has revised this tool and will undertake testing of the revised tool in 2017. CMS might also consider the inclusion of Mucosal Membrane Pressure Injuries in the future. The anatomy of the tissue makes these injuries impossible to stage with the staging system that is in place now. They are preventable pressure induced injuries which should be recognized as such and they reflect the quality of care. There appears to be some limited opposition to use of the term injury. Even though this has been used in the category "Deep Tissue Injury" for some time, it has been expressed by some as a concern. I have not seen any evidence that this will increase the risk for the caregivers or their facilities. The diagnosis of a "pressure injury" does not mean that the health care provider(s) "caused" the injury. The NPUAP Staging System classifies pressure injuries based on the level of tissue loss that can be visualized or directly palpated. I agree there are limitations to a staging system based on identification of visible tissue loss. However I don't believe there is insufficient evidence to abandon staging based on visible tissue loss. NPUAP in collaboration with its international guideline partners (EPUAP and PPPIA) are conducting ongoing systematic reviews of the research literature to answer these and other questions regarding the prevention, diagnosis and treatment of pressure injuries. A major change in pressure injury classification as proposed by opponents will require in-depth planning in terms of intended and unintended consequences to patients, providers, education, research and public policy I do not see evidence that all pressure injuries are full thickness. Promulgation of this misconception does not serve our patients well. We may fail to prevent pressure injuries that are caused by superficial shear in combination with microclimate extremes. This philosophy will also lead to wasteful "over treatment" of partial thickness pressure injuries, not to mention extension of financially punitive policies for a broader range of pressure injuries.			

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11/17/2016	I am writing to express my concern over a controversial decision made at an NPUAP conference. The term pressure ulcer has been changed to pressure injury. This is of concern for both physiologic reasons, as well as, legal reasons. I do believe that the new terminology is incorrect. I will identify a few key, but basic issues that should at a minimum, delay the terminology change. 1. Pressure ulcers occur over time from within deep tissue and then appear visible to the eye. 2. Pressure ulcers are not acute injuries- they are chronic wounds. 3. An acute injury leading to a wound would be considered traumatic.	Diane Merkle APRN, CWOCN, PhD Center for Wound Healing and Hyperbaric Medicine Bridgeport Hospital	Diane.Merkle@bpthosp.org	
11/17/2016	Public comment for response to: Project Title: Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury" I am writing to respond during the open public comment period on the above listed Project. As a NPUAP Board member as well a physical therapist and certified wound care specialist in the post-acute community I fully endorse and support the changes that have been made. I believe these changes are a step toward the progression of accurately identifying a pressure injury and describing the various levels of destruction. I believe that science of skin is evolving and is a step in the right direction. Our skin is the largest organ of our body, it will have injuries for many different reasons; these definitions help better understand the nature of a skin injury as a result of pressure. Again, I fully endorse and support these changes. I would be happy to discuss further should that be of interest. Thank you for taking the time to review my comment.	SARAH HOLDEN-MOUNT, PT, CWS, FACCWS, Senior Vice President-Sales AMERICAN MEDICAL TECHNOLOGIES	Sarah.Holden-Mount@amtwoundcare.com	
11/17/2016	I fully support the changes to the NPUAP Staging System. I also support the changing of ULCER TO INJURY.	Dr. Arthur Stone President, MedNexus,Inc.	drartstone@bellsouth.net	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/17/2016	The National Association of Long Term Hospitals (NALTH) is pleased to submit comments on the Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF#0678) and Language Modifications Being Explored with the Term "Pressure Injury" for the Post-Acute Care (PAC) Long Term Care Hospital Quality Reporting Program (Required under the IMPACT Act). NALTH is the only hospital trade association in the nation that is devoted exclusively to the needs of patients who require services provided by long term care hospitals (LTCHs). NALTH is committed to research, education and public policy development that further the interests of the very ill and often debilitated patient populations who receive services in LTCHs throughout the nation. NALTH's membership is composed of the nation's leading LTCHs, including free-standing, hospital-within-hospital, for-profit, and non-profit LTCHs. On behalf of our member hospitals, we wish to express our gratitude for the opportunity to share our comments on the draft specifications for the pressure ulcers that are new or worsened (short-stay) measure. We have carefully reviewed the draft data element specifications for the pressure ulcers that are new or worsened (short-stay) measure and have concerns regarding the ability of the measure to estimate quality care for patients with pressure ulcers. We discuss these concerns below. Inclusion of unstageable pressure ulcers in the numerator and the use of M0300 items instead of M0800 items to calculate the measure. Under the proposed measure specifications, CMS would modify the numerator of NQF#0678 to include unstageable pressure ulcers, including 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. While NALTH does not disagree with this change by itself, we believe that it is problematic when combined with the recommendation to use the M0300 items instead of the M0800 items to score the measure. Under the proposal, PAC providers could be unfairly identified as having a patient with a new or worsen pressure ulcer, because the design of the M0300 items does not allow CMS to	Jennifer Nguyen NALTH	jennifer.nguyen@kngheal th.com	

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	distinguish whether a pressure ulcer that becomes unstageable is truly a worsening of a pressure ulcer. For example, NALTH does not consider a stage 4 ulcer that becomes unstageable as a worsening of an ulcer because it is covered with slough or eschar. However, the measure specification document from RTI indicates the numerator would flag a new or worsening pressure ulcer if the following occurs: • Stage 2 (M0300B1) - (M0300B2) > 0, OR • Stage 3 (M0300C1) - (M0300C2) > 0, OR • Stage 4 (M0300D1) - (M0300D2) > 0, OR • Unstageable – Non-removable dressing/device (M0300E1) - (M0300E2) > 0, OR • Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0, OR • Unstageable – Deep tissue (M0300G1) - (M0300G2) > 0 Thus, it would appear (assuming no other changes to any of the pressure ulcers and no new pressure ulcers) that in our example, the case would have Unstageable – Slough and/or eschar (M0300F1) - (M0300F2) > 0. Another example is when a patient comes into the PAC provider with an unstageable pressure ulcer that is then a stage 2 upon discharge. Without consideration of the M0800 items, this patient would again be flagged as having a worsen pressure ulcer because it has a Stage 2 (M0300B1) - (M0300B2) > 0. We strongly urge the measure development team to either continue to use the M0800 items or develop other mechanisms to ensure that patients are not incorrectly flagged as having new or worsening pressure ulcers. Language modifications being explored with the term “pressure injury.” In the proposed measure specification, all instances of the term “pressure ulcer” have been replaced with the term “pressure injury.” During the 2016 National Pressure Ulcer Advisory Panel Staging Consensus Conference, a pressure injury was defined as[1]: [1] National Pressure Ulcer Advisory Panel. “NPUAP Pressure Injury Stages.” Available at: http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/ Localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open 3 ulcer and may be			

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	painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue. This change in terminology creates a problem for medical coders as the current version of the ICD-10-CM does not include "pressure injury". Instead, it has two terms used to describe pressure injury: decubitus ulcer and pressure ulcer. To avoid confusion until ICD-10-CM is appropriately modified, CMS should clarify through release of a public statement that all previous definitions in physician documentation indicating a pressure or decubitus ulcer should be considered a pressure injury and vice versa for coding purposes. If you have any questions about these comments, please contact Lane Koenig, PhD, NALTH Director of Research and Quality, at lane.koenig@knghealth.com			
11/17/2016	The American Health Care Association (AHCA) represents more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with intellectual and developmental disabilities. By delivering solutions for quality care, AHCA aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member centers each day. AHCA appreciates the opportunity to submit comments on Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury". In the enclosed comments, we address the requested focus areas with recommendations and rationale for those recommendations. Thank you for inviting our feedback and considering these recommendations. Please feel free to contact me with any questions or for further information at hharmon@ahca.org As requested in the call for comments, we have commented on the specified areas of focus below.	Holly Harmon, RN, MBA, LNHA Senior Director of Clinical Services The American Health Care Association (AHCA)	hharmon@ahca.org	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	1. 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, as recommended by a cross-setting pressure ulcer Technical Expert Panel (TEP) and supported by the National Pressure Ulcer Advisory Panel (NPUAP) AHCA recommends: • Do not add unstageable pressure ulcers due to slough or eschar, unstageable pressure ulcers due to non-removable dressing or device or unstageable pressure ulcers presenting as deep tissue injury to the measure. These MDS items do not indicate a worsened pressure ulcer nor clearly represent a new pressure ulcer acquired in the SNF, which are what the measure is intended to capture. Rationale: We do not support the addition of unstageable pressure ulcers because these types of pressure ulcer coding of unstageable by nature do not indicate worsening of the pressure ulcer. Another example of a reason to oppose including unstageable pressure ulcers, such as "Unstageable –Non-removable dressing/device (M0300E1) - (M0300E2) > 0" because the presence of a non-removable dressing/device does not necessarily indicate a worsened pressure ulcer. There are times when a person has a pressure ulcer with non-removable dressing/device during the MDS assessment window, thus this item would be coded. The measure specifications as proposed, would indicate this pressure ulcer as new or worsened, which is not necessarily accurate. In addition, deep tissue injuries take time to appear and in some cases may have occurred before admission to the SNF due to the time it takes to be present to the naked eye. Please see attached reference from A. Gefen, PHD; K. Farid, DNP, MA, CWON; and I. Shaywitz, MD – in Ostomy Wound Management February 2013 "by the time dead skin becomes a more detectable black eschar, the original DTI at the level of bone (the death of the underlying tissues) is approximately 2 weeks old. Regardless of whether the patient has been in the facility 2 weeks or less, the pressure ulcer then is classified facility-acquired "unstageable," even though it most likely was present underneath on admission."			

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	2. The use of M0300 (M1311 OASIS) items instead of M0800 (M1313 OASIS) items to calculate the quality measure. This modification is intended to reduce redundancies in assessment items and facilitate cross-setting quality comparison as specified by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act). HCA Recommends: o Do not use M0300 items instead of M0800 items to calculate the quality measure. M0800 provides the most accurate reconciliation of pressure ulcers for the purposes of what this measure is intended to capture. Rationale: M0800 provides an opportunity to reconcile pressure ulcers to verify which of current pressure ulcers were not present or were at a lesser stage on prior assessment or last entry. The CMS RAI Version 3.0 Manual also states on page M-26 under Coding tips: "Coding this item will be easier for nursing homes that document and follow pressure ulcer status on a routine basis." 3. CMS is also soliciting comments on changes in terminology for the pressure ulcer measure specifications and assessment items. NPUAP revised the Pressure Injury Staging System following a consensus conference in April 2016. The NPUAP replaced the term "pressure ulcer" with the term "pressure injury" stating the "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin."1 New NPUAP guidance further clarified that "in the previous staging system Stage 1 and Deep Tissue Injury described injured intact skin, while the other stages described open ulcers. This led to confusion because the definitions for each of the stages referred to the injuries as 'pressure ulcers'." CMS is soliciting comments regarding the adoption of new terminology as espoused by NPUAP. AHCA recommends: • Adopt the revised staging definitions in the pressure ulcer measure specifications and assessment items as long as the same updates occur in the MDS/RAI manual. It is critical to have consistency across these two key areas. • Continue with the term pressure ulcer versus pressure injury. Changing it does not bring value to clinical care or quality measurement.			

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	Rationale: First, the staging definition changes will serve to improve accuracy of both clinical recognition and staging of pressure ulcers/injuries. We recognize that the revised and added wording to the definitions do not change anything in regards to the depth of injury. For example, an accurately identified stage 'III' using the old definitions will still be the same stage '3' with the new definitions. However, the added descriptors may improve the clinician's ability to better recognize and document the findings that render it to be a stage 3. We look forward to NPUAP's future release of teaching slides and other materials. Second, the staging definition changes are being widely accepted at a national and international level. WOCN has fully supported the updated staging definitions, along with the Joint Commission, and the Academy of Nutrition and Dietetics. NDNQI is updating their reporting systems in 2017 to reflect the revisions. In terms of ICD-10; today, all coders are supplied a list of synonyms for pressure ulcers that include bed sores, decubitus, plaster ulcer, pressure area, and pressure sore. Third, the term pressure injury has significant opposition and reported legal ramifications that only detracts from the meaningful staging definition changes. The term injury has caused fear that has been escalated by editorials advising that this could increase litigation as attorney's may use the term 'injury' to equal 'abuse' (Joy Schank, Catherine Miline). Further, the term 'injury' is being refuted by the Association for the Advancement of Wound Care (AAWC), an inter-professional organization of 2,400 wound care members (please see attachments). In addition, legal counsel for various nursing centers have shared similar concern and opposition to using the term injury. Use of the term pressure injury vs. pressure ulcer does not add any value to the clinical care or approach for the patient or resident. Thus, we recommend continuing with the term pressure ulcer. To summarize, the upgraded definitions offer clinicians clarity on both the recognition of pressure ulcers and added descriptors to improve accuracy of staging. In our opinion, supporting these changes and adoption of these changes to the RAI will serve to improve accuracy of section M. It will take time for nursing centers to transition forms and other materials, thus we suggest CMS make an advance statement as to whether an update will occur to the next MDS/RAI version.			

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11/17/2016	UDSMR has the following overall comments and concerns related to the proposed changes for the Quality Measure Percent of Residents of Patients with Pressure Ulcers That Are New or Worsened: 1. UDSMR agrees with aligning the quality measures relating to skin conditions with the terminology adopted by the National Pressure Ulcer Advisory Panel in April of 2016. Utilizing one consistent, updated and endorsed staging system in both clinical and quality documentation will lessen confusion and thus error in accurately reporting different types of pressure injuries. However, there are inconsistencies with the 2016 NPUAP language and the RTI proposed example items for the PAC quality reporting. For section M0300A in describing a stage 1 pressure injury it states "in dark skin tones only it may appear with persistent blue or purple hues." In NPUAP's description of a stage one pressure injury it states "Color changes do not include purple or maroon discoloration." In section M0300G the description for unstageable deep tissue injury states "Deep tissue injury in evolution." NPUAP defines this type of pressure injury as "persistent non-blanchable deep red, maroon or purple discoloration". The term "in evolution" is inconsistent with NPUAP's statement that this type of pressure injury "may resolve without tissue loss". 2. While stage 1 pressure injuries are included in the example quality reporting items for SNF QRP, LTCH QRP and IRF QRP this is not a proposed item for HH QRP. The items used for PAC QRP need to be standardized and consistent across provider types and not unnecessarily burdensome for the providers. The stage 1 pressure ulcer count is not used in the calculation of this quality measure therefore it is unnecessary to include for any of the PAC providers. 3. Inclusion of unstageable pressure injuries in the numerator of the calculation for quality measure NQF #0678 substantially changes this measure. For example, currently for IRF-PAI version 1.4 reporting unstageable pressure ulcers is voluntary at discharge and not included in the calculation of this measure. Inclusion of unstageable pressure injury data will increase the overall IRF cases with new or worsening pressure injuries by .4 to .6% according to an analysis of the first month of data from IRF-PAI version 1.4. This	Brigid Greenberg PT, MHS Business Development Advisor & Appeals Specialist Uniform Data System for Medical Rehabilitation	bgreenberg@udsmr.org	

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	increase is not reflective of a drop in quality performance but rather a change in the quality measure itself. UDSMR strongly believes that measures selected for including in PAC QRP should undergo review and be endorsed for reliability and validity. The substantial changes to the measure and resulting from this measure as proposed warrant complete review by NQF for continued endorsement. Data derived from this new measure should not be compared to data currently collected as portions are voluntary, represent an incomplete number of cases and therefore render the current data unreliable and valid for comparison. 4. RTI International and CMS continue to propose quality measures to support the IMPACT Act that are not standardized and cannot be considered as cross-cutting due to setting specific inclusion/exclusion criteria. The target populations for this quality measure are defined differently for each of the four PAC provider types. SNF includes Medicare part A stays only, IRF includes Medicare part A and C stays and both LTACH and HH have undefined patient stay types. In order to provide the ability to measure quality within the population of Medicare cases that are growing under part C UDSMR recommends including all Medicare Part A and Part C patients for each PAC provider type, except those as defined by specific cross cutting exclusion criteria. Additionally, in the specific exclusion criteria, SNF, LTACH and HH stays are excluded if there is insufficient assessment information to derive data for risk adjustment. There is no such exclusion proposed for IRF. Again, data needs to be standardized with inclusion and exclusion criteria that are the same across all PAC settings in order for the measure to meet IMPACT act specifications and purpose. 5. The risk adjustment for this measure utilizes different mobility and bowel incontinence items across the PAC settings as functional measures continue to be defined, measured and reported differently depending on the PAC provider type. UDS encourages CMS and its contractors to identify any measure used in the PAC QRP including items utilized for risk adjustment to have evidence of being reliable, valid, meaningful and useful in a quality reporting program, have been used by providers in all PAC venues, are predictors of quality, cost, and payment, and have been endorsed, approved, and/or found to be “best in class” by industry stakeholders. As function has			

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	proved to be such a strong indicator of patient outcomes we encourage high focus and careful analysis of PAC functional measures in order to truly standardize these across settings utilizing proven, reliable and valid tools. 6. CMS has stated in the Call for Public Comment for this measure that the use of M0300 instead of M0800 items to calculate the measure is "intended to reduce redundancies in assessment items…" As noted below in section 7, the PAC providers have a tremendous increasing data collection burden which is proving to be costly. UDSMR supports efforts to reduce this burden including reducing redundancy in reporting. We recommend that if the current proposed items in M0300 are used to calculate this measure that it is explicitly stated that section M0800 will be removed. 7. IRF's have been reporting information on new and worsening pressure ulcers using measure NQF #0678 on the IRF PAI since October 2014. UDSMR's data indicates this measure is only applicable to less than 1% of IRF patients. UDSMR encourages CMS and its contractors to evaluate the QRP items as data is available for meaningfulness and usefulness in a Quality Reporting Program. In IRF's the burden of data collection has increased exponentially in the current fiscal year, with the IRF PAI going from 8 pages to 18. This increased data collection burden is costly which shows in the form of additional staff education and training, additional administrative burdens to document and report on new items, and updates to existing forms or systems and ultimately will be passed along to the Medicare program. If quality indicators have demonstrated little usefulness in measuring or improving quality of care consideration needs to be given to discontinuing the measure altogether. We appreciate both the opportunity to provide public comment and the careful consideration of the comments we have provided. We welcome the opportunity to work with you to provide ongoing research regarding the selection and implementation of standardized and interoperable quality indicators. If you have any questions about these comments or require additional information, please contact us at 716-817-7800.			

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11/17/2016	As the largest provider of inpatient rehabilitation facility ("IRF") services in the nation, and in partnership with Encompass Home Health, the fourth largest Medicare home health ("HH") provider, we appreciate the opportunity to submit comments on your work for of the Centers for Medicare and Medicaid Services ("CMS") regarding the refinement of percent of residents or patients with pressure ulcers that are new or worsened. I. PROPOSED ITEM SPECIFICATIONS A. Support for Alignment with Existing Standards We support CMS' proposal to align the pressure injury terminology with the terminology adopted by the National Pressure Ulcer Advisory Panel (NPUAP). We would also encourage CMS to "adopt" instead of "adapt" the pressure injury definitions from NPUAP to remain consistent with clinical practice standards for wound care clinicians, regardless of setting. B. Consideration for Additional Items We would also encourage CMS to include unstageable pressure injuries due to slough or eschar, unstageable pressure injuries due to non-removable dressing or device, and unstageable pressure injuries presenting as deep tissue injury to Section M0900 (see below, Section M "Healed Pressure Ulcer(s)" – IRF PAI v1.4). Generally, we've observed the rate of pressure injuries present on admission to IRFs is significantly higher than those new or worsened. Meaning that successful IRF wound clinicians are not only preventing pressure injuries from forming or worsening, but more often healing wounds that present with the patient. Wound clinicians heal unstageable pressure injuries due to slough or eschar, unstageable pressure injuries due to non-removable dressing or device, and unstageable pressure injuries presenting as deep tissue injury as often as Stage 1-4 pressure injuries. These items are noticeably absent from the existing IRF PAI Section M (particularly when they were added to M0800 "Worsening in Pressure Ulcer Status Since Admission" in IRF PAI v1.4) and we would encourage CMS to include these additional three items to M0900 "Healed Pressure Ulcer(s)."	Andrew C. Baird, Director, Government Relations Mary Ellen Debardeleben, Associate Director, Quality HealthSouth	Andrew.Baird@HealthSouth.com Mary.Debardeleben@HealthSouth.com	IRF

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	PROPOSED MEASURE SPECIFICATION A. Additions to Numerator We support CMS' proposal to modify the quality measure with the addition of unstageable pressure injuries due to slough or eschar, unstageable pressure injuries due to non-removable dressing or device, and unstageable pressure injuries presenting as deep tissue injuries in the numerator. We also support the consistency of measure specifications across post-acute care settings and across tools. B. Item Replacement We support CMS' intention to facilitate cross-setting quality comparison and reduce redundancies in assessment items, but are cautious of replacing a question that directly collects the intended numerator (number of new or worsened pressures injuries as currently exists with M0800) with a calculated, inferred numerator. The proposed M0300 items have only been collected in IRFs since IRF PAI v1.4 went into effect October 1, 2016, so the data available for analysis is limited to patients discharged in October, 2016. Based on the preliminary data presented in Figure 1 the proposed M0300 calculation to derive new/worsened pressure injuries is not comparable to the existing M0800; these items should not be considered interchangeable. The proposed M0300 calculation increases the number of new/worsened pressure ulcers by 33-233% depending on the item. This discrepancy is likely caused on the distinct coding criteria in the IRF PAI training manual regarding how to determine present on admission and new/worsened, which are assessed and coded separately based on their respective IRF PAI manual instructions. Given the straightforwardness of item M0800, which directly asks how many pressure injuries are new or worsened, we predict this item more accurately captures the number of new/worsened pressure injuries			

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	Number of New/Worsened Pressure Injuries (Item Level) Existing M0800 Item Proposed M0300 Calculation % Increase from Existing to Proposed Stage 2 86 137 +59% Stage 3 29 40 +38% Stage 4 2 4 +100% Unstage – Dressing 3 10 +233% Unstage – Slough 34 49 +44% Unstage – DTI 51 68 +33% Figures 1. IRF PAI items from over 18,000 UDS IRF Medicare 02 and 51 primary payor cases discharged in October, 2016 as of November 1, 2016. While Figure 1 displays the variation among the existing and proposed new/worsened pressure injuries at the item level, the measure level (patients with new/worsened pressure injuries) would also be significantly affected. Based on the same data as Figure 1, number of patients with new/worsened pressure ulcers would increase an estimated 0.3 to 0.5 percentage points. This may seem insignificant, but the current national average for Percent of Patients with New or Worsened Pressure Ulcers is 0.8% (according to the IRF PAI Provider Preview Report, released in September 2016) and an increase of 0.3 to 0.5 percentage points would represent at 38-63% increase in the national rate simply by switching items. Replacing M0800 with a calculation derived from M0300 would overestimate the number of new/worsened pressure ulcers (and subsequently the number of patients with new/worsened pressure ulcers) and should not be considered for IRFs until the data can be considered consistent and reliable. This may also call into question the validity and reliability of the derived M0300 calculation as currently used in other settings to indicate new/worsened pressure ulcers. Given the discrepancy between the items, we believe this type of change would need to be reviewed through the National Quality Forum (NQF) measure endorsement process. C. Item Removal: We would encourage removal of any item on the IRF PAI that is redundant. D. Consideration for Quality Measure Related to Healed Pressure Injuries: We would encourage CMS to considered developing a pressure injury quality measure that tracks the rate of healed pressure ulcers in addition to the rate of new or worsened wounds.			

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	As mentioned about in section I.B. HealthSouth has generally noticed that the vast majority of pressure injuries cared for in the IRF setting are present on admission and only a fraction of patients experience new or worsened pressure injuries; according to the IRF PAI Provider Preview report, released in September 2016, the IRF national rate for percent of patients with new or worsened pressure injuries was 0.8%. Our data demonstrates that the ratio of healed pressure injuries to new or worsened pressure injuries is around 15:1, suggesting a measure designed to track the healing of existing pressure ulcers may be more meaningful than the existing new or worsened measure in post-acute settings.[1] [1] Data from over 120,000 HealthSouth IRF cases discharged January, 2016 to September, 2016 Thank you for your attention to these comments. We hope our views and insights will prove constructive in the refinement of the quality reporting pressure ulcer, especially at this stage in the development process. Should you wish to discuss any content contained in this letter, please contact us at the information below.			
11/17/2016	The American Academy of Physical Medicine and Rehabilitation (AAMP&R), the society that represents more than 9,000 physiatrists, appreciates the opportunity to submit comments on the draft specifications for the functional status quality measures for skilled nursing facilities. Physical medicine and rehabilitation (PM&R) physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize function and quality of life. Physiatrists coordinate, supervise and provide medical rehabilitation services in a wide variety of settings including all of the post-acute care (PAC). Physical medicine and rehabilitation (PM&R) physicians are increasingly present across the post-acute care continuum and are not aligned with any one PAC setting and, as a result, can act as an impartial medical decision-maker to help direct patients to the most appropriate setting and intensity of rehabilitative care to meet the individual medical and functional needs of patients.	Beth Radke Manager, Quality and Research Initiatives, American Academy of Physical Medicine and Rehabilitation (AAMP&R)	bradtke@aapmr.org	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	Standardizing quality measurement amongst Post-Acute Care (PAC) settings is important work that greatly impacts AAPM&R's members. In an effort to comprehensively state AAPM&R's support for standardization, we developed Recommendations on Post-Acute Care Data Standardization and Quality Measurement that was approved by AAPM&R's Board of Directors in June 2016. This document is intended to show our support for moving towards standardizing data elements across PAC settings as long as reliable, feasible and risk adjusted methods are at the forefront of doing so. Attached at the end of this comment letter is AAPM&R's official stance on data standardization across PAC settings. In response to your specific comment request, AAPM&R appreciates the opportunity to comment and ask that you take into consideration our comments below. Proposed National Pressure Ulcer Advisory Panel (NPUAP) Terminology Changes • AAPM&R agrees with the NPUAP terminology changes reflected in the example provided, however we urge CMS to ensure that standard terminology is used across all PAC settings. The only way that data and measures can be compared across settings is by using a common vocabulary. Quality benchmarking will not be meaningful if these terminology changes are not widely adopted. Proposed Measure Specification for the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) for the Skilled Nursing Facility Quality Reporting Program (SNF QRP), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), and the Home Health Quality Reporting Program (HH QRP) • While AAPM&R believes in the importance of standardizing measurement amongst PAC settings, we are very concerned at the lack of consistency in the measure specifications. As is, there are differences among settings in the exclusions and risk adjustment covariates. Therefore, we advise CMS to reexamine both the exclusions and risk adjustment to ensure they are consistent among settings. We believe that if all settings are to be held to the same standards, then these areas should not differ with the measure specification.			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	AAPM&R would also like to highlight the effect physiatrist leadership of the skilled nursing facility has on patient outcomes. American Academy of Physical Medicine and Rehabilitation Position Statement: Physiatrists Role in Skilled Nursing Facilities details the expertise physiatrists have to lead patient care across post-acute care settings. This position was approved by AAPM&R's Board of Governors in June 2016. It is intended to explain how and why physiatrists are optimally suited by way of the unique combination of medical and functional knowledge and expertise to achieve the highest functional outcome for patients at the least financial cost to our society across post-acute care settings. We appreciate the opportunity to comment on the IMPACT Act Cross-Setting Quality Measure on Pressure Ulcers The AAPM&R looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Beth Radtke, Manager, Quality and Research Initiatives at bradtke@aapmr.org or at (847) 737-6088.			
11/17/2016	Thank you for requesting comments of the new NPUAP Staging terminology as well as other changes in "Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury" I have worked in long term care for over 25 years. During that time, the care of individuals with pressure related skin injuries has changed dramatically. I attended the 2016 NPUAP Consensus Conference and was impressed with the scholarly work the Task Force presented. I am pleased to see that CMS has incorporated the new staging terminology and definitions into the pressure ulcer/injury assessment items as part of the quality reporting program for post-acute care. Changing the terminology from ulcer to injury was of particular interest to me. I support the use of the term injury instead of ulcer because the Stage 1 and deep tissue injuries are not ulcers- they are injuries below intact skin. I think that the diagnosis of a "pressure injury" does not imply that the health care professional or family member "caused" the injury. It simply describes the some of the etiology contributing to changes in the condition of the skin.	Mary Litchford	mdlphd@yahoo.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/17/2016	I agree with and support the pressure injury staging terminology and definitions which resulted from the NPUAP Consensus Conference in April, 2016.	Terry Coggins	Terry.Coggins@smith-nephew.com	
11/17/2016	1. I fully support numerator revisions that include residents/patients with (1) unstageable pressure ulcers due to slough or eschar, (2) unstageable pressure ulcers due to non-removable dressing or device and (3) unstageable pressure ulcers presenting as deep tissue pressure injury. Rationale: • Unstageable pressure ulcers due to slough or eschar are considered full-thickness pressure injuries. "If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed."[1, 2] It is reasonable to include this category of unstageable pressure injuries in an indicator measuring Stage 2, 3 and 4 pressure injuries; in fact these injuries are probably Stage 3 or 4. This change will increase the reported number pressure injuries and persons with pressure injuries. However, it will provide a better measure of the true nature and extent of pressure injuries. • Unstageable pressure ulcers due to non-removable dressing or device is not an NPUAP designation. However, it is a data element in the National Database for Nursing Quality Indicators (NDNQI®). The CMS definition for this data element ("known but not stageable due to non-removable dressing/device") is roughly comparable to the NDNQI data element ("for a known pressure injury located under a non-removal dressing or device that cannot be visualized at the time of the skin inspection and the ulcer stage is not documented in the patient's record".) This NDNQI-specific category is used only when a stage is not documented in the patient record. This phenomena is currently recorded as "Indeterminable" which is a mixed NDNQI category that also includes Mucosal Membrane Pressure Ulcers. NDNQI is revising its database and training materials to incorporate the new NPUAP Pressure Injury Staging System. In future versions, Mucosal Membrane Pressure Injury will be a new separate data element and pressure injuries under non-removable medical devices will be classified using a new data element, "Non-visible". In past NDNQI surveys, "Indeterminable" represented a relatively small number of pressure injuries (1.6%).[3]	Janet Cuddigan PhD, RN, CWCN, FAAN NPUAP BOD; NDNQI	jcuddiga@unmc.edu	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	• Unstageable pressure ulcers presenting as deep tissue pressure injury should reasonably be included in a quality indicator measuring Stage 2, 3 and 4 pressure injuries. This is said with the caveat that DTPIs are being accurately diagnosed. The NPUAP has received a great deal of positive feedback from clinicians and other wound care organizations that the new NPUAP staging definitions[1, 2] are much clearer, supporting more accurate classification of pressure injuries. This is particularly true of the clarifications to the DTPI definitions based on recent research. Historically, there has been some hesitation about including DTPI in this quality indicator. This was based on studies of the natural history of DTPI indicating fairly wide variation in the final evolution of DTPIs.[4-10]. Although between 10%[8] and 71%[4] of the DTPIs in these studies evolved into full-thickness wounds, others resolved or improved without visible full-thickness tissue loss. This led some to conclude that deeper tissues were never damaged. Bioengineering studies indicating that significant shear strains at the bone-muscle interface do indeed create tissue deformation and ischemic damage in deeper tissues such as muscle and fat.[11-13] Just because there isn't a break in the epithelium or just because the deeper damage heals with epithelial breakdown, doesn't mean that the deeper damage did not occur. The science has advanced to the point where DTPI can be accurately assessed and clinicians are focusing on the interventions necessary to ensure injured tissues heal without evolution to visible full-thickness injury. DTPI should be included as an element in this quality indicator. 2. I would encourage CMS to also consider the inclusion of Mucosal Membrane Pressure Injuries in the future. Due to the anatomy of the tissue these injuries cannot be staged.[1, 2, 14] However, they are preventable pressure induced injuries that reflect the quality of care. 3. I fully support the inclusion of "worsened" pressure ulcers in this quality indicator. Facilitating healing of existing pressure injuries is as important to quality care as prevention of new pressure injuries. There are some remaining challenges to reliable and valid data collection on this aspect of the indicator. Currently, "worsening stage" between admission and discharge is being evaluated. This may be complicated by the inclusion of DTPI as an element in the measure. In the future, there may be better ways to evaluate "progress toward healing". The NPUAP Pressure Ulcer Scale for			

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	Healing (PUSH Tool) is one of two such tools mentioned in previous CMS TEP reports on this subject. The NPUAP has revised this tool and will undertake testing of the revised tool in 2017. 4. As an NPUAP Board member, I fully support use of the new NPUAP Staging System definitions in all future CMS documentation. The NPUAP developed the definitions after an exhaustive search of the literature. Individual and organizational stakeholder comments to early drafts were widely solicited and carefully reviewed. A consensus conference with 400 participants was held to deliberate and reach consensus on questions that were not answered by current research evidence and/or stakeholder comments. The definitions have been adopted and endorsed by professional organizations such as the Wound Ostomy and Continence Nurses Association. The VA is incorporating the terms in its teaching materials. NDNQI is revising its pressure injury indicator and teaching materials to incorporate the new definitions. Facilities throughout the country are adopting the new system.[15] The term, pressure injury, is already listed in the beta version of ICD-11 http://apps.who.int/classifications/icd11/browse/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f455330172 . NPUAP is engaging in efforts to harmonize terms and definitions in LOINC and SNOWMED CT. The new NPUAP staging system clarifies definitions, but does not make substantive changes in our understanding or operationalization of pressure injury stages. These changes should not have a significant impact in longitudinal trend lines, but should improve staging accuracy. References 1. Edsberg LE, Black, J. M., Goldberg M, McNichol L, Moore L, Sieggreen M. Revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System. Journal of wound, ostomy, and continence nursing: official publication of The Wound, Ostomy and Continence Nurses Society / WOCN. 2016; 43(6):1-13. 2. National Pressure Ulcer Advisory Panel. National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury. Available at: http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/ . Accessed June 14, 2016.			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	3.Bergquist-Beringer S, Dong L, He J, Dunton N. Pressure ulcers and prevention among acute care hospitals in the United States. Joint Commission Journal on Quality and Patient Safety. // 2013; 39(9):404-414. 4. Baharestani MM. Natural history of suspected deep tissue injuries from clinical manifestation to outcome. 2013 NPUAP Biennial Conference. DTI: The State of the Science. Houston, TX; 2013. 5 .Black JM, Brindle CT, Honaker JS. Differential diagnosis of suspected deep tissue injury. International wound journal. Jun 30 2015. 6. deep tissue injury profile: a pilot study. Advances in skin & wound care. Mar 2014; 27(3):133-140; quiz 141-132. 7 Farid KJ, Winkelman C, Rizkala A, Jones K. Using temperature of pressure-related intact discolored areas of skin to detect deep tissue injury: an observational, retrospective, correlational study. Ostomy/wound management. Aug 2012; 58(8):20-31. 8. Sullivan R. A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy/wound management. Sep 2013; 59(9):30-39. 9. Sullivan R. A 5-year retrospective study of descriptors associated with identification of stage I and suspected deep tissue pressure ulcers in persons with darkly pigmented skin. Wounds: a compendium of clinical research and practice. Dec 2014; 26(12):351-359. 10 .Sullivan R. Use of a Soft Silicone Foam Dressing to Change the Trajectory of Destruction Associated with Suspected Deep Tissue Pressure Ulcers. Medsurg nursing: official journal of the Academy of Medical-Surgical Nurses. Jul-Aug 2015; 24(4):237-242, 267. 11. of deep tissue injury development, detection, and prevention: shear savvy. Ostomy Wound Management. 2013; 59(2):26-35. 12. Gefen A, Weihs D. Cytoskeleton and plasma-membrane damage resulting from exposure to sustained deformations: A review of the mechanobiology of chronic wounds. Med Eng Phys. Jun 13 2016. 13. Oomens CW, Bader DL, Loerakker S, Baaijens F. Pressure induced deep tissue injury explained. Annals of biomedical engineering. Feb 2015; 43(2):297-305.			

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	14. National Pressure Ulcer Advisory Panel. Mucosal Pressure Ulcers: An NPUAP Position Statement. National Pressure Ulcer Advisory Panel. Available at: http://www.npuap.org/wp-content/uploads/2012/01/Mucosal_Pressure_Ulcer_Position_Statement_final.pdf . Accessed August 1, 2016. 15. McInerney J, Morrison T. Implementing the NPUAP pressure injury changes. Ostomy/wound management. 2016; 62(10):62, 64.			
11/17/2016	I fully support numerator revisions that include residents/patients with (1) unstageable pressure ulcers due to slough or eschar, (2) unstageable pressure ulcers due to non-removable dressing or device and (3) unstageable pressure ulcers presenting as deep tissue pressure injury. Rationale: • Unstageable pressure ulcers due to slough or eschar are considered full-thickness pressure injuries. "If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed."[1, 2] It is reasonable to include this category of unstageable pressure injuries in an indicator measuring Stage 2, 3 and 4 pressure injuries; in fact these injuries are probably Stage 3 or 4. It will provide a better measure of the true nature and extent of pressure injuries. • Unstageable pressure ulcers due to non-removable dressing or device is not an NPUAP designation. However, it is a data element in the National Database for Nursing Quality Indicators (NDNQI) • Unstageable pressure ulcers presenting as deep tissue pressure injury should be included in a quality indicator measuring Stage 2, 3 and 4 pressure injuries. The NPUAP has received a great deal of positive feedback from clinicians and other wound care organizations that the new NPUAP staging definitions[1, 2] are much clearer, supporting more accurate classification of pressure injuries, and easier to teach new staff. Documentation will be more accurate. • Recent studies are showing that significant shear strains at the bone-muscle interface do indeed create tissue deformation and ischemic damage in deeper tissues such as muscle and fat.[11-13] An intact epithelium doesn't always mean that deeper damage did not occur. The science is supporting that DTPI can be accurately	Sharon Baranoski, MSN, RN, CWCN, APN-CCNS, FAAN Wound Care Dynamics, Inc. Nurse Consultant Services	nrsebear@aol.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	assessed and clinicians can are focus on the interventions necessary to prevent further tissue injury. DTPI should be included as an element in this quality indicator. I would encourage CMS to also consider the inclusion of Mucosal Membrane Pressure Injuries in the future. Due to the anatomy of the tissue these injuries cannot be staged.[1, 2, 14] I fully support the inclusion of "worsened" pressure ulcers in this quality indicator. The NPUAP Pressure Ulcer Scale for Healing (PUSH Tool) is one of two such tools mentioned in previous CMS TEP reports on this subject. The NPUAP has revised this tool and will undertake testing of the revised tool in 2017. As an NPUAP Board member, I fully support use of the new NPUAP Staging System definitions in all future CMS documentation. I believe the changes in terminology represent the best attempt at an up-to-date staging system based on current understanding of clinical and research findings. An extensive literature search was conducted by NPUAP task force. Individuals and organizations has input into the drafts presented. 87% of attendees at the April NPUAP consensus meeting agreed with the changes. The impetus for these revisions was an attempt to close the gap between what we see clinically and what the research tells us. It is interesting to note that many people complained prior to the terminology and staging change that the staging system was not an accurate description of the clinical phenomenon. The focus throughout this endeavor has been patient-centered. The term, pressure injury, is already listed in the beta version of ICD-11 http://apps.who.int/classifications/icd11/browse/l-m/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f455330172 . Dr. Janet Cuddigan, BOD of NPUAP colleague, states "NPUAP is engaging in efforts to harmonize terms and definitions in LOINC and SNOWMED CT. The new NPUAP staging system clarifies definitions, but does not make substantive changes in our understanding or operationalization of pressure injury stages. These changes should not have a significant impact in longitudinal trend lines, but should improve staging accuracy."			

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11/17/2016	Advocate Health Care (Advocate) appreciates the opportunity to provide comments on the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Cross-Setting Quality Measure to further develop and refine the percent of residents or patients with pressure ulcers that are new or worsened (short-stay) and language modifications being explored with the term "Pressure Injury". Background Advocate, a not-for-profit, mission-based health system, is the largest health system in Illinois and one of the largest health care providers in the Midwest. Advocate operates more than 450 sites of care, including 12 hospitals that encompass 11 acute care hospitals, one of the area's largest home health care companies, and one of the region's largest medical groups. We are proud to contribute to the development of the health care workforces of Illinois and the nation by training more primary care physicians and residents at our four teaching hospitals than any other health system in the state. Advocate at Home, part of Advocate Health Care, is one of the largest privately-held home care organizations in Illinois and provides care to more than 25,000 patients annually. Advocate at Home provides a comprehensive, cost-effective, quality-oriented approach to home care, ensuring patients and their families have a seamless transition from inpatient care to their home while decreasing hospital readmissions, and providing a continuum of care for all of our patients. Our services are provided throughout the Chicagoland area, from Wisconsin to Indiana, west to DeKalb, and also in Central Illinois. We appreciate your consideration of our recommendations and comments below. Unstageable Pressure Ulcers As recommended by the cross-setting pressure ulcer Technical Expert Panel and supported by the National Pressure Ulcer Advisory Panel (NPUAP), Advocate recommends the addition of unstageable pressure ulcers to the numerator in the pressure ulcer cross-setting measure. This will allow home health agencies the opportunity to document unstageable pressure ulcers; for example, those that were present on admission. Such detailed documentation is imperative, as	Shauna McCarthy on behalf of Denise Keefe Advocate Home Health	Shauna.Mccarthy@advocatehealth.com	

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	these ulcers are often advanced when eventually staged. Moreover, including all types of pressure ulcers will allow for more accurate calculations of improvement measures. Calculation of Quality Measure Advocate recommends the use of M0300 (M1311 Outcome Assessment and Information Set (OASIS)) items as opposed to M0800 (M1313 OASIS) items to calculate the quality measure. Such a modification will reduce redundancies in assessment items and facilitate cross-setting quality comparison as specified by the IMPACT Act. We support the utilization of M1311 to reduce redundancy in the measure calculation and endorse it for the cross-setting quality comparison. Pressure Ulcer Measure Specifications and Assessment Items Following a consensus conference in April 2016, NPUAP revised the Pressure Injury Staging System, replacing the term "pressure ulcer" with the term "pressure injury," stating the "change in terminology more accurately describes pressure injuries to both intact and ulcerated skin." New NPUAP guidance further clarified that "in the previous staging system Stage 1 and Deep Tissue Injury described injured intact skin, while the other stages described open ulcers. This led to confusion because the definitions for each of the stages referred to the injuries as 'pressure ulcers'." Advocate strongly supports and endorses the new terminology of pressure injury replacing the term pressure ulcer, as we believe this revision offers much-needed clarity for providers. We also recommend changing it in the OASIS data set as soon as possible. Conclusion: Again, we thank you for the opportunity to provide our feedback on the IMPACT Act's pressure ulcer cross-setting quality measure. Advocate is dedicated to working with policymakers at all levels of government to promote and preserve the health of the individuals, families, and communities of Illinois, and to advance innovation in health care delivery to ensure quality and improve outcomes for all who are served by the nation's health care system. Please do not hesitate to contact me or Meghan Woltman, Advocate Vice President, Government and Community Relations, (630/929-6614, Meghan.Woltman@AdvocateHealth.com) should you have any questions or if we can be of any assistance.			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/17/2016	On behalf of Allina Health (Allina), I appreciate the opportunity to comment on the Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury". Allina Health is dedicated to the prevention and treatment of illness and enhancing the greater health of individuals, families and communities throughout Minnesota and western Wisconsin. A not-for-profit health care system, Allina Health cares for patients from beginning to end-of-life through its 90+ clinics, 13 hospitals, 15 pharmacies, specialty care centers and specialty medical services that provide home care, senior transitions, hospice care, home oxygen and medical equipment, and emergency medical transportation services. Allina Health has concerns with CMS' proposal to use M0300 in place of M0800. While we understand the intent of this proposal is to reduce redundancies in assessment items, and facilitate cross-setting quality comparison as required by the IMPACT Act, we are concerned that changing this measure could have unintended consequences. Specifically, Allina Health is concerned that one care provider may potentially be judged on a pressure ulcer a patient acquired in a previous care setting. We encourage CMS to reconsider replacing M0300 with M0800. We thank CMS for the opportunity to provide comment on proposed quality measures. We hope to see a revised quality measure for Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury" that is inclusive of the change we've recommended in this comment letter. If you have any questions regarding these remarks, please feel free to contact me at 612-262-4908.	Allyson Hammer, MPH Manager Organizational Integrity • Compliance & Regulatory Affairs Allina Health	Allyson.Hammer@allina.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/17/2016	AAWC strongly disagrees with the proposed changes from the NPUAP. Changing the word "ulcer" to "injury" was premature, not evidence based and not widely supported by consensus. Please see attached notification to AAWC members about this change, the AAWC Board of Directors Position Statement and a document that lists multiple articles on this subject. http://aawconline.org/wp-content/uploads/2016/10/AAWC-Position-Statement-on-the-Proposed-NPUAP-Pressure-Ulcer-Staging-System-Revised-10.14.16.pdf	Tina Thomas, Executive Director AAWC	tthomas@aawconline.org	
11/18/2016	Cerner Corporation, a leading supplier of electronic health record, clinical and revenue cycle information systems, and EHR vendor for a large contingent of US based hospitals, critical access hospitals, eligible professionals and Post Acute Care (PAC) providers appreciates the opportunity to submit comments on the IMPACT Act measures as CMS seeks to standardize patient assessment data across settings to improve the patient quality of care and quality of life. As a vendor who supplies solutions across the longitudinal patient care, we find there are many challenges in providing the transitional care data from one provider of care to another, because there is a lack of standardization not just between the PAC venues but also from the acute care to the PAC. We recognize and appreciate the work CMS has invested to mitigate these challenges and we continue to support this work. We are submitting comments to the project titled Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury". The project request for public comment asked for commenters to review the proposed update to the cross-setting pressure ulcer measure in post-acute settings. Cerner provides solutions for home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long-term acute care hospitals (LTCH) and skilled nursing facilities (SNFs). We gathered multiple representatives from each of these venues to discuss these data elements and their impact. Our comments are reflective of all four post-acute care settings.	John Travis, Vice President and Compliance Strategist Cheri Whalen, CHTS-IM, CHC Regulatory Strategy Cerner Corporation	Cheri.Whalen@Cerner.com	

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
	RE: Refinement of Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) and Language Modifications Being Explored with the Term "Pressure Injury" Overall, we feel this change is beneficial to align the measurement of pressure ulcers across the post-acute care continuum and are supportive of changes to terminology and measure specifications. However, there are a few items we ask to be further clarified as outlined below. Numerator Clarification Within the Proposed Measure Specification, the Home Health Numerator was defined as (emphasis added): The numerator is the number of patients with a complete quality episode for which the assessment completed at the end of care indicates one or more new or worsened stage 2-4 or unstageable pressure injuries compared to the most recent SOC/ROC assessment. Given the meaning that the term "episode" already has for post-acute care, we feel the wording of "complete quality episode" should be further clarified. Does CMS mean to include each patient 60-day episode of care, or only the patient admission regardless of the number of episodes? The first would mean the individual patient could have many assessments. The latter would mean the individual patient would only include the discharge assessment. And the wording "assessment completed at the end of care", should be further clarified to mean when a Discharge Assessment or Transfer Assessment (where there was no Resumption of Care Assessment present and a patient discharge date has been entered) exists. Risk Adjustment Covariates Within the Proposed Measure Specification for each PAC venue we request a clarification of "or more" within the indicator of need for assistance (emphasis added). Indicator of requiring limited or more assistance in bed mobility self-performance on the PPS 5-Day assessment We feel this wording is subjective and request further clarification on the measurement of "or more". PAC Assessment Wording			

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	Within the Example Items with Proposed NPUAP Terminology document, we find there is some confusion regarding the National Pressure Ulcer Advisory Panel (NPUAP) terminology adopted in April 2016 and the proposed PAC assessment data elements. We found a clear mapping between the Stage 1, Stage 2, Stage 3, and Stage 4 elements; however, for the Unstageable Pressure Injuries, Deep Tissue Pressure Injuries, Medical Device Related Pressure Injury and Mucosal Membrane Pressure Injury definitions from NPUAP, we found it was difficult to determine which selection was relative to the new PAC data element options. We recommend providing a cross-mapping of the NPUAP terminology to the PAC data elements. This will greatly assist in the provider training. Additional PAC Assessment Elements not noted in Request We found there are additional elements within the PAC assessments which need wording changes from “ulcer” to “injury” in order to avoid confusion. Skilled Nursing, Long-Term Care Hospital, and Inpatient Rehabilitation Facility Item: Section M – M0210 Unhealed Pressure Ulcer(s) Home Health Items: M1300 Pressure Ulcer Assessment M1302 Does this patient have a Risk of Developing Pressure Ulcers? Finally, we are concerned with the amount of time it will take to train on the new language and cross-reference between the NPUAP. We encourage CMS to provide >12 months from the time the wording is changed in the official instructions to the implementation date. We feel this is the minimum acceptable time to provide software updates and clinician training prior to the implementation in order to achieve a successful result. In conclusion, we appreciate the efforts CMS is spending to more closely align the assessment process in the post-acute venues of care. Cerner Corporation hopes these comments will be of value in considering possible update to the cross setting standardization of post-acute care assessment data. We are happy to help clarify any of the comments should you wish to pursue any such conversations with us. Sincerely. John Travis			

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Date Posted	Verbatim Comments	Name, Credentials, and Organization of Commenter	Email Address	Type of Organization
11/18/2016	I support the changes in terminology developed by the NPUAP. As a board member of NPUAP I can assure you that the process was thorough and measured. The goal was to better align the terminology and definitions with the scientific research. The noise coming from distractors was expected and inevitable. The claims by those groups is baseless. The changes are already in place overseas in Europe and Australia. Our preliminary discussion with CMS confirms that they are interested in the changes and are receptive. One contention of the opposing side is that using the term injury will imply guilt on the part of caregivers. There is no evidence to support this claim. Cerebral vascular accident and reperfusion injury are medical terms that already exists and have not resulted in any spike in litigation.	Aamir Siddiqui, MD Division Head, Plastic Surgery, K-16 Henry Ford Hospital	ASIDDIQ1@hfhs.org	
11/20/2016	The wording of "pressure injury" opens the door more readily for litigation. Four elements of a negligence (medical malpractice case), are: 1. Duty (did the healthcare provider owe a duty of care to the patient? The answer here is almost always yes, since the person is a patient) 2. Breach (did the healthcare provider breach that duty by not meeting the applicable standard of care?) 3. Injury (did the patient suffer an injury?) 4. Causation (was the breach by the provider the proximate cause of the injury?). If the term "injury" is used it then opens the door that someone caused the injury while the patient was under someone's care. I think that in healthcare we need to do all we can to minimize the risk of litigation by quality care but also by appropriated documentation and descriptions. Leave the term ulcer and not injury!	Cordell Atkins	Cordell.Atkins@imail.org	