To: The National Quality Forum (NQF)

From: The Centers for Medicare & Medicaid Services (CMS) and RTI International

Date: December 22, 2016

Subject: **Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678): Response to NQF Steering Committee Concerns Regarding Inpatient Rehabilitation Facility Measure**

Background and Context

On December 14, 2016, the Measure Application Partnership Post-Acute Care/Long Term Care Workgroup (MAP PAC/LTC or MAP) met, discussed, and voted on the measure under consideration (MUC16-143) Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) for Inpatient Rehabilitation Facilities (IRFs). This measure reports the percentage of IRF patient stays with Stage 2-4 or unstageable pressure ulcers that are new or worsened since admission. This measure is a modification of the measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). CMS submitted the measure to the Measures Under Consideration (MUC) List, along with analogous measures for Long Term Care Hospitals (LTCHs) (MUC16 – 144), Skilled Nursing Facilities (SNF) (MUC16 – 142) and Home Health Agencies (HHAs) (MUC16 – 145), as they were seeking to make the following substantive changes to the measure:

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), and
2. The use of M0300 (M1311 OASIS) items instead of M0800 (M1313 OASIS) items to calculate the quality measure. This modification is intended to:
    a. Facilitate cross-setting quality comparison as specified by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act),
    b. Allow alignment between payment and quality measures,
    c. Reduce redundancies in assessment items, and
    d. Counterbalance the possible incentives to over- or underreport pressure ulcers that exist in the SNF setting.
    e. Prevent inappropriate underestimation of pressure ulcers through the use of the M0800 items.

While the MAP provided a vote of "support" for the quality measures in the LTCH, SNF and HHA settings, questions were raised by members of the MAP and public commenters (Uniform Data System for Medical Rehabilitation (UDSMR)) regarding the reliability of the measure in the IRF setting. One provider-organization member of the MAP (HealthSouth) and same members of the public were specifically concerned with substitution of a calculation using M0300 data items in place of the current method of using M0800 data items to calculate the quality measure. The provider referenced analyses they had conducted on data obtained during the month of October 2016 in which their calculation of new or worsened pressure ulcers using M0300 data items did not correspond with results using M0800 data items. As a result, the IRF measure received a vote for "conditional support" contingent upon CMS and the measure

developer providing additional information regarding the measure reliability and addressing data concerns brought up by the IRF provider.

We have drafted this memo in order to meet contingencies imposed by the MAP and to address specific concerns identified by the MAP committee. We have summarized the MAP's major concerns regarding the measure, as well as our response to each concern below:

Concern 1: Data element reliability and validity. MAP Workgroup Members questioned whether data element reliability and validity were sufficiently demonstrated for the IRF setting, and if the data were publicly available.

Summary response: Data element reliability and validity for the M0800 and M0300 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. We also cite strong reliability results for items equivalent to M0300 counts and assessment items tested in all three PAC setting. Below, we provide evidence of publicly available testing results on the validity and reliability of the data elements.

Concern 2: Measure score reliability for IRF settings and reconciliation of data presented to the MAP. The MAP expressed concern regarding different findings on the impact of the use of M0300 items instead of M0800 items to calculate the pressure ulcer quality measure score in the IRF setting. While the measure developer, RTI, reported a decrease in the IRF pressure ulcer measure score using the M0300 item calculation with 2014-2015 data, an IRF provider, HealthSouth, reported an increase in the count of pressure ulcers using the M0300 item calculation versus the M0800 items using Q4 CY16 data. The MAP requested reconciliation of the data.

Summary response: We provide additional information regarding RTI's analyses of the impact of transition to the use of the M0300 Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) items to calculate the quality measure. We also provide potential reasons for variances between RTI testing and the results presented by HealthSouth. These potential reasons include differing calculation methods (counts vs. measure scores), time periods (2016 data vs. 2014-2015 data), length of time analyzed (one month vs. six months) and potentially differing treatment of missing data. While our recent analyses provide similar results to those presented to the MAP on December 14th, we conducted additional analyses to show why the M0300 calculation method is superior to the M0800 method of calculating the measure and is more accurate. The M0800 method is systematically undercounting new or worsened pressure ulcers in the IRF setting. We also provide results showing this finding is consistent with suspected undercounting of pressure ulcers in LTCH and SNF settings. Finally, we provide the results of a more recent (October 2016) analysis of IRF-PAI data, conducted by RTI, to explore potential variances between calculation of the quality measure using M0300 items and M0800 items.

To briefly summarize our findings, this memo provides the reader with detailed information that addresses the MAP's concerns showing the strength of our inter-rater agreement analyses for the MDS 3.0 and additional setting specific inter-rater reliability testing of pressure ulcer items similar to those used to calculate the quality measure in the IRF, LTCH and SNF settings. We provide further evidence that this testing information is publicly available through published studies and reports. With respect to the MAP's concern regarding reliability of the quality measure calculation using M0300 items, we offer solid evidence to show why the M0300 calculation method is more accurate compared to the M0800 method of calculation, as well as an

accounting of the potential reasons for variances between our testing and the results presented by HealthSouth.

CMS' Detailed Responses to MAP Concerns

(1) *Data Element Reliability and Validity*

On December 14, 2016, the MAP met, discussed, and voted on the measure under consideration (MUC16-143) Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) for IRFs. The measure received a vote of "conditional support" as MAP Members questioned whether data element reliability and validity were sufficiently demonstrated for post-acute care settings, and if the data were publicly available. In this section, we present item-level testing results on the reliability and validity of the NH items in the MDS 3.0, as well as inter-rater reliability testing results from equivalent items done as part of the testing of the Continuity Assessment Record and Evaluation item set as part of the Post-Acute Care Payment Reform Demonstration (PAC PRD). These studies provide evidence for the items used in the IRF setting, as well as LTCH and SNF settings. Additionally, we provide clarification on the location of publicly available information on the validity and reliability of the data elements.

Construct Validity

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/M1313 items and inclusion of unstageable pressure ulcers in the measure calculation. Overall, the TEP was supportive of the data element changes as well as inclusion of unstageable pressure ulcers in the measure calculation, indicating construct validity.

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

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

None of the TEP members stated preference of the use of M0800 items instead of M0300 items in calculation of the quality measure and none of the members expressed objections to the modification. However, the TEP requested that consistent training across all post-acute care settings be made available to providers to support the change process if implemented. The TEP summary report is publicly available and is soon to be available on CMS' website.[1]

[1] Seibert, J., Frank, J., Free, L., Waldron, D. (2016, December). Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (IRFs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs). Contract No. HHSM-500-2013-13015I. Research Triangle Park, NC: RTI International.

Item-Level Reliability Testing (MDS 3.0)

Item reliability for data elements assessing pressure ulcers, including unstageable pressure ulcers, was tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[1] The project consisted of a representative sample of for-profit and not-for-profit facilities, and hospital-based and freestanding facilities, which included 71 community nursing facilities in 8 states and 19 Veterans Affairs (VA) nursing homes. The sample included 3,822 residents from community nursing homes and 764 residents from VA nursing homes. The RAND pilot test of the MDS 3.0 items showed good reliability and are applicable to the IRF-PAI as well as the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set because the items tested are the same as those used in the IRF-PAI and LTCH CARE Data Set. Across the pressure ulcer items, average gold-standard to gold standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate "almost perfect" agreement using the Landis and Koch standard for strength of agreement.[2] We believe that the kappa statistics comparing gold-standard nurse to facility nurse responses should be sufficient for evaluation of the validity of these items as well. The results of this study are publicly available on the CMS website.

More specifically, the RAND project found a high level of inter-rater reliability for assessment items used to calculate the pressure ulcer quality measure, including assessment items for unstageable pressure ulcers. The study included the following results[3]:

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

Item-Level Reliability Testing (CARE/PAC PRD)

Additional inter-rater reliability testing of pressure ulcer items similar to those used to calculate the quality measure in the IRF, LTCH and SNF settings was conducted as a part of the PAC PRD.[4] For the pressure ulcer item "Does this patient have one or more unhealed pressure ulcer(s) at stage 2 or higher or unstageable?" The kappa score across all settings (acute, IRF, LTCH, SNF and HHA) was 0.845, indicating almost perfect agreement. Setting specific scores are presented below. Kappa statistics for IRF, LTCH, SNF and HHA ranged from .58 to 0.92 indicating "moderate" to "almost perfect" agreement.

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

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[1] 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.

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

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

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

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

For the pressure ulcer item "Number of pressure ulcers present at admission by stage-Unstageable", the kappa score across settings was 0.652, indicating substantial agreement. A setting specific score was only provided for the LTCH setting (kappa= .417, moderate agreement) as the sample size for most individual settings was too small to report (< 15).

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

Additional Testing

RTI performed additional testing of the measure to compare the performance of the measure with proposed changes to the measure as currently specified.[1] Testing of the updated version of the measure, including adding unstageable pressure ulcers to the quality measure, increased performance scores in all settings (with scores increasing by 0.1% in IRF settings and 1.7% in NH/SNF settings) and increased the variability of measures scores. This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing facilities. RTI presented the results of their findings during the July 18, 2016 TEP. Information regarding this study are also included in the TEP Summary Report.

Testing results by setting are as follows:

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

(2) *Measure score reliability for IRF Settings and reconciliation of data presented to the MAP*

Informed by pre-meeting Public and Member comments which suggested the proposed M0300 calculation to derive new or worsened pressure ulcers is not comparable to the existing M0800 pressure ulcer items, MAP Workgroup members voted for a rating of "conditional support" for the IRF pressure ulcer. The rating "conditional support" from the MAP Workgroup requires that additional information be provided to address differing results. In this section, we provide additional information regarding RTI's analyses of the impact of transition to the use of the M0300 IRF-PAI items to calculate the quality measure, potential reasons for variances between RTI testing; the results presented by HealthSouth, and the results of a more recent (October 2016) data analysis of IRF-PAI data to explore potential variances between calculation of the quality measure using M0300 items and M0800 items.

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

Testing results originally presented by RTI

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), RTI tested alternative definitions to the numerator of the quality measure in each of the three settings (i.e., NH/SNF, IRF, and LTCH). The alternatives explore the possibility of transitioning to the M0300 items to identify new or worsened pressure ulcers, as well as two alternative approaches to integrating unstageable pressure ulcers, including deep tissue injuries (DTI), into the numerator. We provide the results of the quality measure calculation using the M0800 data items and the M0300 data items in the IRF setting below. These results were also provided to the July 18, 2016 TEP.

For the IRF setting, the IRF-PAI items used in the analysis are from the October 2014 version of the IRF-PAI. In this version the items are numbered differently, but measure the same concepts as the equivalent MDS 3.0 and LTCH CARE Data Set items. Item numbers for all pressure ulcer items were harmonized with the other two data sets in the October 2016 IRF-PAI.

Current Measure Specifications Using M0800 Items

For the current measure specifications for the IRF setting, the numerator includes the number of IRF stays with new or worsened Stage 2, 3, or 4 or pressure ulcers. New or worsened pressure ulcers are identified using the M0800 (or equivalent for IRF) items for each stage:

- New or Worsened Pressure Ulcers: Stage 2 = M0800A
- New or Worsened Pressure Ulcers: Stage 3 = M0800B
- New or Worsened Pressure Ulcers: Stage 4 = M0800C

If any of the items listed above have a value equal to or greater than 1, then the numerator is triggered.

Table 1. Results for the QM Using Current Specifications and M0800 Equivalent Items
Distribution of Risk Adjusted NQF #0678 Facility Level Scores: IRFs
Current Measure Specifications: New or Worsened Stage 2, 3, or 4 Pressure Ulcers Using M0300B4, C4, D4+

Data Included	n	Mean	SD	Min	p10	p25	p50	p75	p90	Max	% Perfect†
Oct 2014 - Mar 2015	1,118	0.91%	1.26%	0	0	0	0.50%	1.37%	2.49%	9.85%	41.5% (n=464)

+Equivalent to the LTCH CARE Data Set and MDS 3.0. M0800A, B, and C items

†" A perfect score is defined as zero new or worsened pressure ulcers

SOURCE: Analysis of IRF-PAI data October 2014- March 2015 (Programing reference: RKO1), Analysis Date: 6/22/2015

Table 1 above presents the distribution of measure scores using the current measure specifications for NQF #0678, Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (short-stay) (New or worsened stage 2, 3, or 4 pressure ulcers using M0800 items) for IRFs. Facility-level distributions for the IRF setting using IRF-PAI assessments between October 2014 and March 2015 are presented. IRF analyses included in this memo were conducted on six months of data because the present on admission (POA) and unstageable pressure ulcer items were not added to the IRF-PAI until October 2014. IRF scores are updated quarterly using a rolling 12 months of data to allow for large enough numerator and denominator sizes to ensure validity, and reliability of the measure in IRFs. The mean and median IRF facility level scores using six months of data were 0.9% and 0.5% respectively.

Current Measure Specifications Using M0300 Items

In testing the potential use of M0300 items for calculation of the pressure ulcer quality measure, RTI also calculated the pressure ulcer quality measure using the M0300 alternative. This alternative was designed to provide a direct comparison between the M0800 and M0300 pressure ulcers items. We calculated new or worsened Stage 2, 3, or 4 pressure ulcers using the M0300 (or equivalent for IRF) items.

We calculated new or worsened Stage 2, 3, or 4, pressure ulcers using the count of unhealed pressure ulcers reported in the relevant M0300 (or equivalent for IRF) items and subtracting from this the number of ulcers present on admission (POA) for that stage.

The formulas by stage are listed below:

- Unhealed Pressure Ulcers Not Present on Admission: Stage 2 = M0300B1 *(unhealed Stage 2 pressure ulcers)* **minus** M0300B2 *(Stage 2 pressure ulcers, POA)*
- Unhealed Pressure Ulcers Not Present on Admission: Stage 3 = M0300C1 *(unhealed Stage 3 pressure ulcers)* **minus** M0300C2 *(Stage 3 pressure ulcers, POA)*
- Unhealed Pressure Ulcers Not Present on Admission: Stage 4 = M0300D1 *(unhealed Stage 4 pressure ulcers)* **minus** M0300D2 *(Stage 4 pressure ulcers, POA)*

If any of the items listed above have a value equal to or greater than 1, then the numerator would be triggered for this alternative.

Table 2. Results for the QM Using Current Specifications and M0300 Equivalent Items
Distribution of Risk Adjusted NQF #0678 Facility Level Scores: IRFs
Numerator Alternative 1: New or Worsened Stage 2, 3, or 4 Pressure Ulcers Using M0300 B-D minus Pressure Ulcer POA+

Data Included	n	Mean	SD	Min	p10	p25	p50	p75	p90	Max	% Perfect†
Oct 2014 - Mar 2015	0.73%	0.73%	1.13%	0.00%	0.00%	0	0.21%	1.14%	2.14%	0.00%	48.3% (n=54)

+ New or worsened pressure ulcers are identified by obtaining the count of pressure ulcers (M0300B, C, D) and subtracting the pressure ulcers present on admission by stage. This is equivalent to the calculations used for the MDS 3.0 and LTCH CARE Data Set analysis.

†" A perfect score is defined as zero new or worsened pressure ulcers

SOURCE: Analysis of IRF-PAI data October 2014- March 2015 (Programing reference: RKO1), Analysis Date: 6/22/2015

For the IRF setting (**Table 2**), the mean and median scores for this measure decreased when we transition to using the M0300 equivalent IRF-PAI items. The mean risk adjusted score across IRFs decreased from 0.91% to 0.73% and the proportion of IRFs with "perfect-score" increased from approximately 42% to 48% as we switch from M0800 items to M0300 items. RTI noted that this result for IRFs was not consistent with results from the LTCH and SNF settings. In other testing (not shown) the mean risk adjusted score across all NH/SNFs increased from 1.8% to 2.8% by switching from M0800 items to M0300 items. In the LTCH setting, the direction of change varied over time. For the first two reporting periods, mean scores decreased when we switched to the M0300 items, while in the second two reporting periods mean scores increased. For example, in Q3 2013 the mean decreased from 2.9% to 2.8% when we switched to the M0300 items, while in Q2 2014 the mean score increased from 2.6% to 2.7%. It is unclear why in the IRF setting scores changed in the opposite direction, compared to NH/SNFs and LTCHs. One possibility is that this is the only setting where the M0300 equivalent items were voluntary and IRFs could submit the IRF-PAI without completing these items. The way the alternative was calculated, IRFs only needed to have usable data for one item to remain in the denominator and all other missing data would be counted as a 0 (or no new/worsened pressure ulcer in the numerator), potentially resulting in patients that were included in the denominator with mostly missing data. In all settings, coding errors are suspected to be contributing to the differences and ongoing training is encouraged. For the IRF setting, exploration of the raw numerator proportions were consistent with the decrease in measure scores.

a. Potential reasons for variances from results presented by HealthSouth

Pre-meeting Public and Member comments indicate that an IRF provider, HealthSouth, conducted analyses showing that the proposed M0300 calculation to derive new or worsened pressure ulcers is not comparable to the existing M0800 pressure ulcer items. The comments indicated the proposed M0300 calculation increases the number of new or worsened pressure ulcers by 33 to 233 percent[7] depending upon the item. While it would be difficult to ascertain the specific reasons for differences, as we do not have access to their data set and the analytic methods of the provider are unknown, we offer several potential reasons for differences in analytic results. We rely on a letter received by RTI from HealthSouth as a part of a Call for Public Comment which ran from October 17, 2016 to November 17, 2016 to speculate upon the differences. A copy of this letter is included for your review.

Potential reasons for differences in RTI and HealthSouth analytic results include the following:

i. HealthSouth analyses results only included a count of new or worsened pressure ulcers and did not include calculation of the quality measure. As such, HealthSouth results did not include a calculation of the quality measure including a numerator and denominator. The HealthSouth analysis appears to provide counts of new or worsened pressure ulcers stages 2 through 4, unstageable pressure ulcers due to non-removable

[7] Percent increases in the HealthSouth analyses were based on ratio increases of pressure ulcer frequencies. As we note in our results section, we believe it is more appropriate to look at interval increases rather than ratio increases. For example, the figure of a 233 percent ratio increase cited here is better understood when presented as an interval increase from 3 to 7 out of a possible 18,000; an increase on the order of four hundredths of a percentage point.

dressing or device, unstageable pressure ulcers due to slough or eschar and deep tissue injuries. Counts are provided for the number of pressure ulcers in each category. Since the pressure ulcer measure is stay- based, as opposed to patient or ulcer based, and the numerator of the quality measure is triggered by one or more new or worsened pressure ulcers, RTI testing included an analysis of how the use of the M0300 items would impact calculation of the quality measure. RTI found that for the IRF setting, the mean and median scores for the pressure ulcer quality measure decreased when we transitioned to using the M0300 equivalent IRF-PAI items. The mean risk adjusted score across IRFs decreased from 0.9% to 0.7% and the proportion of IRFs with "perfect-score" increased from approximately 42% to 48% as we switch from M0800 items to M0300 items. HealthSouth's analysis does not include the quality measure calculation.

ii. **The data for the HealthSouth analysis were derived from a different time period.** The HealthSouth analysis was limited to analysis of IRF-PAI items from over 18,000 Medicare cases discharged in October 2016 as of November 1, 2016. The RTI testing analyses was performed using IRF-PAI assessments conducted between October 2014 and March 2015. The analysis conducted by RTI was based on data provided by 1,118 IRF facilities. It should be noted that RTI testing analyses were only conducted on six months of IRF data because the present on admission and unstageable pressure ulcer items were not added to the IRF-PAI until October 2014. Differences in HealthSouth and RTI analytic results could be attributed to data analyzed from different time periods.

iii. **The pressure ulcer count provided by HealthSouth is calculated from one month of data**. The quality measure specifications for the new or worsened pressure ulcer quality measure require that pressure ulcer quality measure scores be calculated quarterly using a rolling 12 months of data to allow for large enough numerator and denominator sizes to ensure validity, and reliability of the measure in the IRF, LTCH and SNF settings. We believe that one month of data is insufficient to ensure validity and reliability, and should not be used to compare count differences between the proposed M0300 calculation and the existing M0800 pressure ulcer items.

iv. **The unstageable present on admission items are voluntary for the IRF setting.** In the IRF setting, all of the pressure ulcer items that were not required for calculation of the quality measure are considered "voluntary" on the IRF-PAI, meaning that IRFs can chose not to submit data for these items and code an equal sign "=," in addition to the option to code a dash for not assessed or unavailable. For all analyses conducted by RTI and HealthSouth, the M0800 items are mandatory. Due to changes in policies, for the time period analyzed by RTI, all of the M0300 items were voluntary. For the time period analyzed HealthSouth, only the unstageable M0300 items were voluntary.

In order to assess the impact of voluntary data, RTI assessed the combined missing rates, as indicated by responses entered as dashes or equal signs, which ranged from 1.3% to 1.7% on the voluntary pressure ulcer items (used in each of the alternative numerator definitions). Because it is not possible to know how these voluntary items

would have been completed had they been required, we completed an additional analysis using the IRF-PAI data which included only patients with complete data for the voluntary items. For the purpose of this analysis we calculated facility-level risk adjusted scores by excluding from our analysis patient stays with any missing data on the voluntary M0300 items. In RTI's earlier testing a patient needed to be missing data for all M0300 items to be excluded. The results of this new analysis, restricted to only stays with complete data, are consistent with the results of the previous analyses. The average unadjusted measure score decreased as we switched from the use of the M0800 equivalent to M0300 equivalent items and the inclusion of unstageable pressure ulcers increased measure scores, as well as the variability in scores across facilities. Despite the inclusion of involuntary items in their assessment, HealthSouth did not provide any evidence of testing potentially missing data.

b. Additional testing conducted by RTI

In order to gain a better understanding of the IRF data presented by HealthSouth during the MAP meeting, we directed RTI to conduct analyses of IRF data using data from IRF patients discharged between October 1 and November 15, 2016. The analyses were simplified to counts of instances of new or worsened pressure ulcers and observed rates, and compared the M0800 items to the M0300 items without risk adjustment. The values were first calculated across all IRF facilities for each pressure ulcer stage, each category of unstageable pressure ulcer, and across all numeric stages. To better understand concerns identified by HealthSouth representatives during the MAP meeting, we examined data relevant to their facilities and compared it to data provided from all other facilities.

The items used in this analysis are from the October 2016 version of the IRF-PAI (IRF-PAI v. 1.4 current and in use as of October 1, 2016). Additionally, information relevant to the revised M0300 and new M0800 stage pressure ulcer items are both mandatory in IRF-PAI v.1.4, whereas the information relevant to the revised M0300 and new M0800 items for unstageable pressure ulcers is still voluntary.

Pressure Ulcer Calculations Using M0300 Items vs. M0800 Items

We calculated new or worsened Stage 2, 3, 4, or unstageable pressure ulcers using the count of unhealed pressure ulcers reported in the relevant M0300(x)1 items and subtracting from this the number of pressure ulcers present on admission (POA) reported in the relevant M0300(x)2 items on the discharge section of the IRF-PAI. The formulas used are consistent with those described in the analysis above (Section 2.a.).

Summary of Findings

The differences between observed incidence rates of each type of pressure ulcer are presented in ***Tables 3 -5*** in terms of interval (subtractive) differences rather than ratio differences in order to preserve perspective. The frequencies of different types of pressure ulcers are small relative to the number of IRF patient stays. It is therefore important to judge the differences in counts of ulcers that would be eligible for inclusion in the numerator of the measure in the context of the larger sample. A difference of one or two ulcers may represent a large percentage increase in the

count of ulcers, especially when counts are generally low using the M0800 method, but would result in only a very small percentage point change in the rate of detected ulcers in the sample of eligible stays. For example, in the data studied for this analysis, there are 5 residents with new or worsened stage 4 pressure ulcers as measured using M0800 items and 8 residents with new or worsened stage 4 pressure ulcers as measured using M0300 items. This represents a 60% increase using M0300 items over M0800 items, but only means a real contribution of less than one-hundredth of a percentage point to the national incident rate of new or worsened stage 4 pressure ulcers[8].

Facility-level numerators and observed scores increased across all facilities when the M0300 items were used instead of M0800 items to conduct calculations (Table 3). The cumulative observed score for stages 2-4 increased 0.33 percentage points, from 0.65% to 0.98%. The noted increases are aligned with expectations of this item transition, and align with observed item behavior when the analyses were previously conducted for SNF and LTCH settings.

Table 3. Observed Pressure Ulcer Rates Using M0300 Items vs. M0800 Items – all facilities

M0300				M0800			
Pressure Ulcer Item Inclusion Level (Numerator name)	Nume-rator	Denomi-nator	National rate (%)	Nume-rator	Denomi-nator	National rate (%)	Percentage Point Difference between observed rates
Stage 2	466	59,223	0.79%	306	59,239	0.52%	0.27%
Stage 3	117	59,234	0.20%	83	59,239	0.14%	0.06%
Stage 4	8	59,238	0.01%	5	59,239	0.01%	< 0.01%
Dressing only	17	59,233	0.03%	3	59,234	0.01%	0.02%
Slough or eschar only	140	59,228	0.24%	97	59,234	0.16%	0.08%
DTI only	225	59,224	0.38%	177	59,234	0.30%	0.08%
Stages 2-4	582	59,218	0.98%	387	59,239	0.65%	0.33%

The increases observed across the identified HealthSouth facilities (Table 4), are similar to the changes seen at the national level, with an increase of 0.37 percentage points in their observed score for all numeric stages (from 0.57% to 0.94%). The increases were also comparable across

[8] Note that in the case where there are zero ulcers indicated by M0800 items, the calculation of a ratio increase would be impossible

non-HealthSouth facilities (Table 5), where an increase of 0.31 percentage points was observed in the cumulative score for stages 2-4 (from 0.69% to 1.00%).

The M0300 items provide a methodology that is not reliant on self-reporting as the M0800 items, making it more likely to accurately identify new/worsened pressure ulcers that may be difficult to accurately identify using the M0800 items and would otherwise go unreported. As such, we suspect that part of the differences observed are due to potential discrepancies in coding that could be resolved with ongoing training.

Table 4. Observed Pressure Ulcer Rates Using M0300 Items vs. M0800 Items – HealthSouth facilities

M0300				M0800			
Pressure Ulcer Item Inclusion Level (Numerator name)	Nume-rator	Denomi-nator	National rate (%)	Nume-rator	Denomi-nator	National rate (%)	Percentage Point Difference between observed rates
Stage 2	111	16,995	0.65%	67	16,995	0.39%	0.26%
Stage 3	46	16,995	0.27%	30	16,995	0.18%	0.09%
Stage 4	5	16,995	0.03%	0	16,995	0.00%	0.03%
Dressing only	7	16,995	0.04%	1	16,995	0.01%	0.03%
Slough or eschar only	57	16,995	0.34%	38	16,995	0.22%	0.12%
sDTI only	74	16,995	0.44%	61	16,995	0.36%	0.08%
Stages 2-4	160	16,995	0.94%	97	16,995	0.57%	0.37%

Table 5. Observed Pressure Ulcer Rates Using M0300 Items vs. M0800 Items – nonHealthSouth facilities

M0300				M0800			
Pressure Ulcer Item Inclusion Level (Numerator name)	Nume-rator	Denomi-nator	National rate (%)	Nume-rator	Denomi-nator	National rate (%)	Percentage Point Difference between observed rates
Stage 2	355	42,228	0.84%	239	42,244	0.57%	0.27%
Stage 3	71	42,239	0.17%	53	42,244	0.13%	0.04%
Stage 4	3	42,243	0.01%	5	42,244	0.01%	< 0.01%
Dressing only	10	42,238	0.02%	2	42,239	0.01%	0.01%
Slough or eschar only	83	42,233	0.20%	59	42,239	0.14%	0.06%
sDTI only	151	42,229	0.36%	116	42,239	0.28%	0.08%
Stages 2-4	422	42,223	1.00%	290	42,244	0.69%	0.31%

Additional Analyses

In order to gain a better understanding of coding differences between the M0300 and M0800 items, we directed RTI to conduct an analysis of the basic count and frequencies of each type of pressure ulcer using both M0800 and M0300 items. The results are presented in **Table 6.**

RTI found that the M0300 items report more pressure ulcers than the M0800 items for all types of pressure ulcers (i.e., stage 2, 3, 4, and unstageable ulcers). Depending upon pressure ulcer type, the M0800 items capture between 55.6 and 76.6 percent of the pressure ulcers identified through the M0300 items.

For the pressure ulcers captured by the M0800 item, but not captured by the M0300 items, we also see the following pattern: the number of pressure ulcers coded as present on discharge (M0300x1), and the number of pressure ulcers recorded in M0800 are the same; however, the number of these coded as present on admission (M0300x2) results in the actual number of *new or worsened* pressure ulcers (M0300x1-M0300x2) equaling zero, no longer matching the numeric value reported in M0800. This indicates a TEP member concern previously outlined may be occurring: the M0800 items are requiring the data abstractor to perform a mental calculations and opening up opportunity for error. It also illustrates conceptual confusion between the items. We believe this is an indication that additional provider training is needed to ensure coders are accurately coding pressure ulcer items.

Table 6: Count of Pressure Ulcers that are New or Worsened Using M0300 Items and M0800 Items – all facilities

Pressure Ulcer Stage	M03001-M03002	M0800	Percentage difference
Stage 2	526	336	63.88%
Stage 3	131	97	74.05%
Stage 4	9	5	55.56%
Unstageable NRD	19	4	21.05%
Unstageable ESC	155	106	68.39%
Unstageable DTI	270	207	76.67%
	1110	755	68.02%

CMS also conducted a separate analysis using IRF-PAI data to analyze the effect of only using the retrospective M0800 items to identify new or worsened pressure ulcers. The CMS analysis uses data from 82,038 IRF-PAIs from 10/1/2016 through 12/9/2016. In this data, 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.

These new IRF-PAI analyses conducted by RTI and CMS mirror previous analyses conducted by RTI for the SNF and LTCH settings in which the rate of pressure ulcer scores increased using M0300 items. Since new data and new analyses show the rates are rising across the post-acute care settings, we believe this finding indicates that a transition to M0300 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.

Summary and Conclusion

RTI and CMS have addressed each of the MAP's concerns as follows:

Concern that the data element reliability and validity was not sufficiently demonstrated and publicly available.

> *We have provided information on the results of the inter-rater agreement analyses for the MDS 3.0 pressure ulcer items for which the kappa statistics indicated almost perfect agreement and restates the argument with additional support that these testing results are appropriate to apply to the evaluation of the LTCH and IRF items because the items are identical across assessments, and there is significant overlap in the populations cared for by these providers. We have also provided additional setting specific inter-rater reliability testing of pressure ulcer items similar to those used to calculate the quality measure in the IRF, LTCH and SNF settings from the PAC PRD study. We have further provided evidence that testing information is publicly available through published studies. RTI has presented analyses to show the impact of a transition to the calculation of the measure using M0300/M1313 items and inclusion of unstageable pressure ulcers in the measure calculation to a TEP on July 18, 2016 and the information is available to the public in a TEP Summary report.*

Concern regarding reliability of quality measure calculation using M0300 items due to differing testing results provided by CMS and RTI and a provider.

> *We have provided additional information regarding RTI's analysis of the impact of the transition to the use of the M0300 IRF-PAI items to calculate the quality measure. We also provided potential reasons for variances between RTI testing and the results presented by HealthSouth. Finally, we provided additional analyses using IRF PAI data from October 2016, similar to the timeframe for the data used by HealthSouth. While our analyses provides similar results to those presented to the MAP on December 14th, we conducted additional analyses to show why the M0300 calculation method is superior to the M0800 method of calculating the measure and is more accurate.*

In summary, we believe the M0300 method should be used to calculate the pressure ulcer quality measure for the following reasons:

a. *To facilitate cross-setting quality comparison as specified by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act),*

b. *To allow alignment between payment and quality measures,*

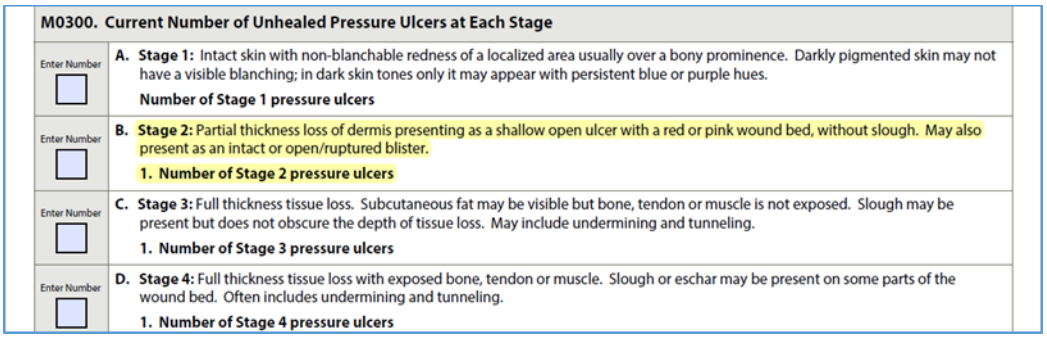
c. *To reduce redundancies in assessment items,*

d. *To counterbalance the possible incentives to over- or underreport pressure ulcers that exist in the SNF setting, and*

e. *To prevent inappropriate underestimation of pressure ulcers through the use of the M0800 items.*

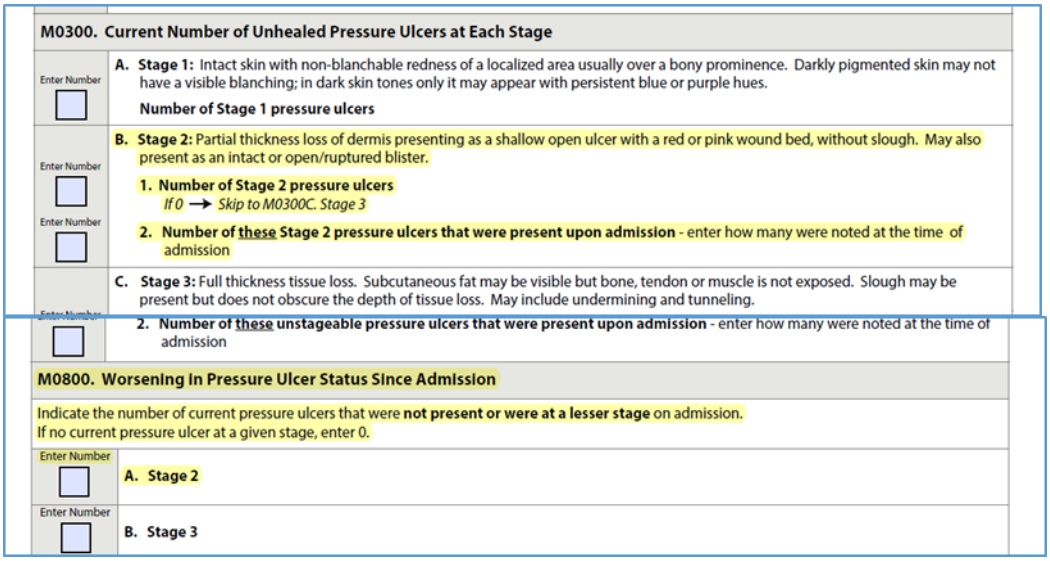
ADDENDUM: IRF-PAI ITEMS USED FOR DIAGNOSIS OF NEW OR WORSENEING STAGE II PRESSURE ULCERS

ADMISSION IRF PAI:



M0300. Current Number of Unhealed Pressure Ulcers at Each Stage	
Enter Number ☐	**A. Stage 1:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only it may appear with persistent blue or purple hues. **Number of Stage 1 pressure ulcers**
Enter Number ☐	**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. **1. Number of Stage 2 pressure ulcers**
Enter Number ☐	**C. Stage 3:** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. **1. Number of Stage 3 pressure ulcers**
Enter Number ☐	**D. Stage 4:** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling. **1. Number of Stage 4 pressure ulcers**

DISCHARGE IRF PAI:



M0300. Current Number of Unhealed Pressure Ulcers at Each Stage	
Enter Number ☐	**A. Stage 1:** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only it may appear with persistent blue or purple hues. **Number of Stage 1 pressure ulcers**
Enter Number ☐	**B. Stage 2:** Partial thickness loss of dermis presenting as a shallow open ulcer with a red or pink wound bed, without slough. May also present as an intact or open/ruptured blister. **1. Number of Stage 2 pressure ulcers** *If 0 → Skip to M0300C. Stage 3*
Enter Number ☐	**2. Number of <u>these</u> Stage 2 pressure ulcers that were present upon admission** - enter how many were noted at the time of admission
	C. Stage 3: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
☐	**2. Number of <u>these</u> unstageable pressure ulcers that were present upon admission** - enter how many were noted at the time of admission
M0800. Worsening in Pressure Ulcer Status Since Admission	
Indicate the number of current pressure ulcers that were **not present or were at a lesser stage** on admission. If no current pressure ulcer at a given stage, enter 0.	
Enter Number ☐	**A. Stage 2**
Enter Number ☐	**B. Stage 3**