EXHIBIT A

CMS Response to Public Comments Received for CMS-2011-0147

The Centers for Medicare and Medicaid Services (CMS) received comments from provider associations organization related to CMS-2011-0147. This is the reconciliation of the comments.

Comment:

One commenter expressed concern that the CMS-developed NQF-endorsed pressure ulcer measure (NQF #0678, "Percent of Residents with Pressure Ulcers that Are New or Have Worsened") was developed for short-stay nursing home patients and suggested that patients in LTCHs require hospital-level, physician-led, post acute care, while patients in nursing homes have far lower medical acuity and resource use. This commenter suggested that extending the use of a measure developed for a nursing home population to the LTCH population was clinically inappropriate and the measure "*needs to be modified for use in the LTCH setting."*

Response:

CMS appreciates the concern expressed by this commenter regarding the medical acuity differences between patients treated in LTCHs and nursing homes. Although we agree that LTCHs differ from nursing homes in terms of patient types, we do not agree that the issue of pressure ulcer treatment and prevention is substantially different in the two settings. The CMS measure development contractor convened a LTCH Technical Expert Panel (TEP) on January 31, 2011, which identified this topic as highly relevant and a high priority quality issue for the care of LTCH patients, and the application of this measure (NQF #0678) as appropriate for LTCHs. We recognized that NQF endorsement of this measure is currently limited to short-stay nursing home patients in the proposed rule, but we noted our belief that this measure is also highly relevant to patients in any setting who are at risk of pressure ulcer development and a high priority quality issue in the care of LTCH patients. Currently, there are no NQF-endorsed pressure ulcer measures that are applicable to LTCHs and we were unable to identify other measures for pressure ulcers that have been endorsed or adopted for the LTCH context by a consensus organization. We are also unaware of any other measures of pressure ulcers that had been approved by voluntary consensus standards bodies. For these reasons, we proposed to adopt an application of this NQF-endorsed measure under the Secretary's authority to select non-NQF endorsed measures where measures do not exist for a specified area or medical topic.

Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. Patients in the LTCH setting may have medically complex conditions, and are therefore at high risk for the development, or worsening, of pressure ulcers. Pressure ulcers are serious medical conditions and an important measure of quality. Pressure ulcers can lead to serious, life threatening infections, which substantially increase the total cost of care.

Comment:

One commenter recommends that CMS should work with stakeholders to develop a means of allowing the existing databases to report data on pressure ulcers to CMS for purposes of the LTCH quality measure. Further, the commenter notes that there are existing databases, such as the NALTH Health Information System (NHIS) and the National Healthcare Safety Network, that already receive the type of data requested on the proposed forms and report it to The Joint Commission on behalf of LTCHs as part of ORYX reporting. Additionally, the commenter suggest CMS convene a workgroup before finalizing the assessment forms to allow stakeholders to develop the means to allow reporting LTCH quality measures using existing databases.

Response:

CMS thanks the commenter for the suggestions. We note that the NHIS database referred to by the commenter is a proprietary database of NALTH which is in use by a very small number of LTCHs from among the LTCHs that are members of the NALTH. Not all NALTH member hospitals submit data into this database. Further, not all LTCHs in the United States are members of the NALTH. Since the NHIS is a proprietary database, the measure specifications and the data elements for measures included in this database are not in the public domain. Additionally, the small number of NALTH member LTCHs that submit data into the NHIS for the pressure ulcer measure report data on a pressure ulcer measure whose specifications are different than measure specifications for the Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) measure (NQF #0678) that was adopted in the FY 2012 IPPS/LTCH IPPS final rule for FY 2014 payment determination (76 FR 51752 through 51756). In order for CMS to collect data for this measure (NQF #0678), CMS has chosen to use standardized items in sync with the NPUAP Guidelines and measure specifications approved through the NQF endorsement review process. We have designed the LTCH CARE data set to collect data on Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) (NQF #0678) using standardized items. This allows LTCHs across the United States (irrespective of their membership status with NALTH and ALTHA) to submit data using standard data elements for NQF #0678. This also provides CMS with the capability to collect and analyze data as well as publicly report data on a NQF endorsed measure and allows comparison across LTCHs for this quality measure.

CMS takes under advisement comments from the public and other stakeholders to identify data collection and submission systems for the quality measures for its quality reporting programs. To this end, for the LTCH Quality Reporting Program, for CLABSI measure (NQF #0139) and CAUTI measure (NQF #0138), in the FY 2012 IPPS/LTCH IPPS final rule for FY 2014 payment determination (76 FR 51752 through 51756, CMS adopted the CDC/NHSN for data submission for these two measures to avoid duplication and reduce provider burden.

Comment:

One commenter expressed concern that the number of items in the LTCH CARE Data Set should be reduced, stating that some of the items were not relevant to the patient's medical condition or were duplicative. The commenter suggested that some of these items would be relevant if used for covariate risk adjustment as in the NQF-endorsed short-stay nursing home measure (NQF #0678, "Percent of Residents with Pressure Ulcers that Are New or Have Worsened"), but this was not announced in the Federal Register.

Response:

CMS appreciates the concern expressed by this commenter. The items referenced by the commenter are either part of the measure's risk adjustment calculation, hospital and patient identifiers or are voluntary items which need not be completed for successful LTCH CARE Data Set submission. The list of required items will be published on the CMS LTCH Quality Reporting Web site: *https://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/15_LTCHQualityReporting.asp* no later than January 31, 2012.

Comment

One commenter noted that it is unnecessary to require LTCHs to complete administrative information for a patient on multiple forms.

Response

CMS appreciates the concern expressed by this commenter. The required Administrative Information items are items that are used by the quality reporting system to match admission and discharge/expired assessments of a patient's stay.

Comment:

Several commenters believed that the burden calculation was underestimated.

Response:

CMS appreciates these concerns regarding the burden estimate for the LTCH CARE Data Set PRA. The items in the LTCH CARE Data Set are data that LTCHs are already collecting on patient's pressure ulcers as part of delivery of clinical care. The burden estimate provided in the PRA is the additional time that will be required to enter the data onto the form and is in no way reflective of the assessment time performed by clinicians.

Comment:

One commenter noted that measuring pressure ulcers the same way as the LTCH CARE Data Set requires would necessitate additional staff training, which was not accounted for in the PRA burden estimate calculation.

Response:

CMS appreciates the commenter's concern and will provide training to support providers in this requirement.

Comment:

Two commenters believed that the term "worsening" *"is ambiguous and only new pressure ulcers should be tracked"* and that *"an appropriate definition of the term 'worsening' needs to be developed."* One commenter suggested that pressure ulcer worsening in the LTCH setting can be unavoidable due to circumstances specific to particular patients.

Response:

This proposed measure is an application of a measure that NQF-endorsed in the SNF setting. We do not agree that the measure is ambiguous or that it should be based solely on the development of new pressure ulcers. As specified for the LTCH setting, the measure is based on changes in skin integrity between the admission and discharge assessments. Pressure ulcer ''worsening'' is defined in the measure specifications as a pressure ulcer that has progressed to a deeper level of tissue damage and is therefore staged at a higher number using a numerical scale of 1 through 4 (using the staging assessment determinations assigned to each stage; starting at the stage 1, and increasing in severity to stage 4) on the discharge assessment as compared to the admission assessment. The National Pressure Ulcer Advisory Panel (NPUAP) has specific, well established clinical criteria for determining the current stage of a wound (stages I through IV). These criteria, which are incorporated into the measure specifications, are used by clinicians in determining whether or not a wound has changed stages, and thereby worsened or improved. The LTCH CARE Data Set includes an item related to Stage I pressure ulcers, but the pressure ulcer measure does not use this item as part of the calculation.

For additional information related to this measure, including definitions related to worsening, the staging of the pressure ulcers, we refer readers to the Minimum Data Set 3.0 (MDS 3.0) Resident Assessment Instrument Manual, page 24 of Section M, Skin Conditions, which describes the NPUAP approach. This information can be found on the CMS Web site for the MDS 3.0: *http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage*. **CMS welcomes further input on the issues of defining "worsening." CMS will post further details, including specifications, for this measure no later than January 31, 2012 on the CMS LTCH Quality Reporting Web site:** *https://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/15_LTCHQualityReporting.asp*

Comment

Two commenters suggested not reporting Stage I or Stage II pressure ulcers for reasons including that it is difficult to measure them across different populations and that they can present *"temporary conditions that typically resolve with the use of minimal resources."*

Response:

CMS thanks the commenters for their suggestions in not reporting Stage I and Stage II pressure ulcers. We are using the complete nationally-standardized pressure ulcer assessment items on the Medicare population. The Stage I item is not considered a new pressure ulcer for the quality measure, but is reported for consistency with the nationally accepted pressure ulcer measurement. For additional information related to this measure, including definitions related to the staging of the pressure ulcers, we refer readers to the Minimum Data Set 3.0 (MDS 3.0) Resident Assessment Instrument Manual, page 24 of Section M, Skin Conditions, which describes the NPUAP approach. This information can be found on the CMS Web site for the MDS 3.0:
http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage.
The LTCH CARE Data Set Manual will include this information and will be posted on the CMS LTCH Quality Reporting Web site no later than January 31, 2012:
https://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/15_LTCHQualityReporting.asp

Comment:

One commenter expressed concern that there was inconsistency in definitions in measuring dimensions of Stage III and Stage IV pressure ulcers based on the differences in current pressure ulcer dimension measurement.

Response:

CMS thanks the commenter for expressing this concern. We are using the complete nationally-prescribed pressure ulcer item set. Unstageable wounds include deep tissue injuries and pressure ulcers covered by nonremovable dressings, slough or eschar. These are not currently included in this measure since unstageable wounds cannot be measured, and therefore the presence of worsening cannot be determined. For example, a pressure ulcer that presents with slough or eschar cannot be staged, and is not considered worsened. Only after, and if, debridement occurs, and the dead issue is removed, can such a wound be properly staged. If after wound debridement, the wound is staged and subsequently evaluated to have increased in the stage, the wound is considered worsened. However, such a wound may not be considered worsened if the stage remains unchanged after debridement and staging.

For additional information related to this measure, including definitions related to worsening, the staging of the pressure ulcers, we refer readers to the Minimum Data Set 3.0 (MDS 3.0) Resident Assessment Instrument Manual, page 24 of Section M, Skin Conditions, which describes the NPUAP approach. This information can be found on the CMS Web site for the MDS 3.0:
http://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp#TopOfPage. **CMS will post further details regarding reporting requirements for this measure on**

the CMS LTCH Quality Reporting Web site no later than January 31, 2012:
https://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/15_LTCHQualityReporting.asp

Comment:

One commenter indicated that there was a need for consistent, standardized definitions of "Planned Discharge" and "Unplanned Discharge." With respect to "Unplanned Discharge," the commenter suggested that the definition clearly delineate the difference between an "Unplanned Discharge" and an "Interruption of Stay." One commenter expressed concern that the LTCH CARE Data Set does not account for interrupted stays, stating that if patients were to develop a pressure ulcer during an interrupted stay, *"the pressure ulcer should not be counted against the LTCH."*

Response:

CMS thanks the commenters for these suggestions on the need to define a planned discharge, unplanned discharge, and interrupted stay and will take these comments into consideration. CMS will post further details, including specifications, for this measure no later than January 31, 2012.

Comment:

Two commenters suggest that LTCHs should not be required to complete a discharge assessment on patients who become palliative care or hospice patients during their stay.

Response:

CMS thanks the commenter for this recommendation. CMS will post further details and guidance on this measure on the CMS LTCH Quality Reporting Web site no later than January 31, 2012:
https://www.cms.gov/LTCH-IRF-Hospice-Quality-Reporting/15_LTCHQualityReporting.asp

Comment:

One commenter indicated that the assessment forms do not address improvement in cases where patients are admitted with pressure ulcers on admission, even though improvement is an important measure of quality.

Response:

CMS thanks this commenter for this observation and input on improvement in pressure ulcer status as an indicator of quality. CMS will take this comment into consideration for future measures in the LTCH quality reporting program.

Comment:

One commenter expressed concern that Section H, Bladder and Bowel, appears on three of the LTCH CARE Data Set forms but only requests data pertaining to bowel incontinence only. The commenter recommended that CMS revise the forms to remove the reference to Bladder to avoid confusion.

Response:

CMS thanks the commenter for this suggestion and has taken this comment into consideration. In order to accommodate for future expansion of the LTCH CARE Data Set for future measures for the LTCHQRP, CMS has decided to retain this heading. CMS will include a clarification in the LTCH CARE Data Set Manual so as to avoid potential confusion of this and other section headings.