EXHIBIT A

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

The Centers for Medicare and Medicaid Services (CMS) received comments from two provider associations 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 Long-Term Care Hospitals (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.

Pressure ulcers are high-volume and high-cost adverse events across the spectrum of health care settings from acute hospitals to home health. 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. Patients in the LTCH setting may have medically complex conditions, and are therefore at high risk for the development, or worsening, of pressure ulcers.

The CMS measure development contractor, RTI International, 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 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 setting by a consensus organization. We are also unaware of any other measures of pressure ulcers that have been approved by voluntary consensus standards bodies. For these reasons, we proposed and posted for public comments [http://www.gpo.gov/fdsys/pkg/FR-2011-05-05/pdf/2011-

9644.pdf, published May 5, 2011] and finalized and responded to public comments [http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-19719.pdf, published August 18, 2011] 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.

Comment:

One commenter recommends that 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 suggestion and will take this under advisement.

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 are not relevant to the patient's medical condition or are 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 used by the quality reporting system to match admission and discharge/expired assessments of a patient's stay and hence necessary to complete at both assessments.

Comment:

Two commenters believed that the burden calculation was underestimated.

Response:

CMS appreciates this concern and has taken these concerns under advisement. CMS believes that the information to populate vast majority of items in the LTCH CARE Data Set is being collected as part of clinical processes and health care delivery for all LTCH patients. The burden estimate provided in the PRA does not reflect the assessment itself. Rather, is the additional time that will be required to retrieve the data from patient medical record, enter the data onto the form and transmit the form to the LTCH quality reporting system. Hence, it is not reflective of the assessment time for delivery of clinical care 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. The Stage I 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, adapted for the LTCH setting, 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 reporting on additional quality measures for the LTCH Quality Reporting Program, 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.