Kentucky Hospital Association
Representing Kentucky Health Care Organizations

June 30, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Field Electronically
Attention: **CMS-1607-P**

Re: CMS 1607-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record Incentive Program; Proposed Rule, May 15, 2014.

Dear Ms. Tavenner:

This letter is respectfully submitted on behalf of the Kentucky Hospital Association (KHA) member hospitals, including seven long-term acute care hospitals (LTACHs) located in Kentucky which provide specialized programs of care to chronically and critically ill and medically complex patients who are Medicare beneficiaries. KHA appreciates the opportunity to share our comments on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2015 proposed rule for the inpatient and LTACH prospective payment systems (PPS).

This letter addresses the proposed LTACH changes pertaining to interrupted stays; proposed additions to the LTACH quality reporting (LTACHQR) program; and, the agency's call for input on the site-neutral payment system that will, per a congressional mandate, be added to the LTACH PPS in FY 2016. KHA will submit comments separately on the agency's inpatient PPS proposals.

PROPOSED CHANGES TO THE GREATER THAN 3 DAY INTERRUPTED STAY POLICY

CMS has proposed the creation of a unified fixed-day threshold of 30 days for the greater than 3 Day Interrupted Stay Policy. **CMS's proposal to change the thresholds that apply to LTACH interrupted stays is unwarranted and should not be implemented.** Interrupted stays from LTACHs occur when a patient needs a different scope of services for a temporary period, which results in an LTACH patient being temporarily transferred to either a general acute care hospital, inpatient rehabilitation facility (IRF) or skilled nursing facility (SNF). This would lead the policy to apply to a greater number of cases discharged to short-term acute care hospitals (STACHs) and IRFs, and a fewer number of cases discharged to SNFs.

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CMS should maintain the current fixed-day thresholds for STACHs, IRFs and SNFs. In light of significant changes to the LTACH payment system — patient criteria and site-neutral payments — that are scheduled to begin a two-year phase in on October 1, 2015, **KHA opposes the proposal to change the current LTACH claims interrupted stay policy.**

In these situations, the duration of the interruption determines whether the LTACH will be eligible for one LTACH payment or two separate LTACH payments. For example, currently, LTACH interrupted stays of four to nine days to a general acute-care hospital will result in *one* LTACH payment for all services provided before and after the interruption. If this type of interrupted stay exceeds nine days in duration, however, the LTACH will receive *two* LTACH PPS payments – one for care provided prior to the interrupted stay, and a second payment for care provided after the interruption.

Under the proposed rule, CMS would change the current interrupted stay thresholds for all settings – general acute care hospitals, IRFs and SNFs – to 30 days. This would be a substantial increase in the threshold for interrupted stays to general acute care hospitals, a modest change for IRF interrupted stays, and a decrease of the SNF interrupted stay threshold.

Since most interrupted stays affected by this proposal are cases temporarily transferred to a general acute care hospital setting, the proposed expansion of the nine-day hospital threshold to 30 days is of primary concern. The most impactful portion of this policy is the change in the fixed-day threshold for STACHs from 9 to 30 days. For episodes of care that would be bundled under this policy, the intervening STACH stays were typically for unplanned medical events for treatment or services that are not available at the LTACH.

We believe that CMS has not conducted the necessary data analysis of LTACH claims to support the change to 30 days for all settings, and that the 30-day threshold was arbitrarily borrowed from the STACH readmission policy. CMS justifies this proposed change by referencing the 30-day thresholds used in the Hospital Readmissions Reduction Program (HRRP) and the Value-Based Purchasing Program (VBP). This analogy is inappropriate, as the interrupted stay threshold is not a quality initiative. While it may be appropriate to attribute health outcomes occurring 30 days post-discharge to a hospital stay, that does not correlate to mean that care provided 30 days post-discharge should be considered to be part of the initial admission.

At this time, HRRP only applies penalties for readmitted patients with one of three specific conditions, and the Hospital Inpatient Quality Reporting (IQR) Program. Both of these programs apply to STACHs—not to LTACHs. Both the HRRP and the IQR are initiatives designed to reward or penalize hospitals based on the quality of care delivered. The threshold for these programs should be based on the amount of time following discharge that health outcomes can be fairly attributed to the quality of care provided by the discharging hospital. The interrupted stay policy exists to ensure that a single hospital stay receives a single LTCH-PPS payment. The threshold for this policy should be based on the amount of time following discharge that additional hospital care can be fairly considered to be part of the original LTACH stay. It is worth repeating that the interrupted stay policy is not a quality initiative and should not be used as such. Unlike the HRRP and VBP programs, there is no risk adjustment. Also,

unlike the HRRP, the interrupted stay policy would only penalize readmissions to the same hospital, and is therefore not a reliable measure of quality.

CMS is incorrectly comparing the LTACH interrupted stay policy and the inpatient PPS readmissions policy, which, in fact, addresses fundamentally different clinical care scenarios. For LTACH interrupted stays, the intent is for the patient to be *temporarily* discharged to another setting (most commonly an SRACH) to access a clinical service the LTACH lacks, and then *return* to the LTACH. In contrast, when STACHs discharge a patient, the hospital's expectation is that the patient will not return for a continuation of that admission. Given these crucial dissimilarities, KHA urges CMS to provide a comprehensive justification for its proposal to change the current interrupted stay policy. In addition, we ask CMS to discuss how the proposed threshold changes would improve the delivery of patient care and related outcomes for patients who undergo an interrupted stay to access medically necessary services that are not provided by the LTACH.

CMS states that it conducted a review of claims data that show interrupted stays at IPPS hospitals (STACHs) comprise the vast majority of interrupted stays under this policy. This change would pose a material fiscal impact on LTACHs – estimated by CMS to be a $130 million reduction in FY 2015.

CMS has not provided a sound rationale or policy basis for this proposed $130 million cut. Rather, the proposed rule offers only a brief explanation citing the 30-day window used by the inpatient PPS readmissions reduction and quality reporting programs as being a better benchmark for the LTACH interrupted stay threshold. CMS merely states that the 30-day inpatient PPS window is a more appropriate benchmark for the LTACH interrupted stay policy because it is used by researchers for quality measurement and is "clinically meaningful."

In addition, the KHA is concerned with the lack of transparency in CMS's data and its limited availability. When initially implementing the current LTACH interrupted stay policy in FY 2003, the agency based the threshold lengths on extensive analysis of Medicare claims data, which was shared with stakeholders and subject to public comment. Unfortunately, CMS did not follow this best practice in this rule. The publicly available data sets (MedPAR and the standard analytical files) do not provide sufficient information for stakeholders to study the hospital impact of this proposed policy. Further, it is our understanding that some of the data, such as the occurrence span codes, are provided only in the research identifiable files, which are available only to organizations that undertake the time-consuming application and approval process by the CMS Privacy Board. CMS should follow the procedures similar to the analyses performed in the past when changes were made to the interrupted stay policy. LTACHs should then be provided the opportunity to review CMS' reasoning and data analyses.

It is also worth noting that the average cost per claim for LTACH discharges that would be affected by this policy ($42,657) exceeds the average payment per claim ($38,604). On average these cases are losing money under the current regulatory scheme. Therefore, if CMS were to further reduce payments by treating both episodes of treatment as a single discharge, this would introduce financial strain that could impede appropriate clinical decisions, increase care fragmentation and reduce overall quality of care to Medicare beneficiaries.

Absent a thorough explanation of the improvements CMS is seeking to achieve through this change to LTACH interrupted stays, this proposal merely serves as a $130 million cut, per CMS's estimate in the proposed rule. Moreover, the agency failed to include the cost of this provision in the proposed rule's estimate of budgetary impact. Doing so would yield a more accurate and transparent impact estimate for this regulation, and would move the overall impact from a net positive of 0.8 percent to a net *negative* impact.

KHA opposes CMS' proposal to abandon the longstanding policy of using fixed-day thresholds specific to each provider type for defining greater than 3-day interrupted stays. This change is not supported by any data analysis specific to LTACHs and the interrupted stay policy, which CMS has performed each time the interrupted stay policy has been adopted or changed in the past. The proposed 30-day threshold appears to have been arbitrarily – and inconsistently – borrowed from the HRRP and IQR program, two STCH programs that do not relate to interrupted stays.

CMS should recognize that different types of services are provided at STCHs, IRFs, and SNFs and at different levels of care. By using the provider-specific thresholds, the current interrupted stay policy is able to capture the differences between these settings and the care that a beneficiary requires in the middle of an LTACH stay.

Because of these concerns, the KHA urges CMS to withdraw its LTACH interrupted stay proposal. The LTACH field already faces significant financial and operational upheaval with the FY 2016 transition to site-neutral payment, as discussed below. CMS should first implement this paradigm shift in FY 2016 and then assess whether any problems related to interrupted stays exist under the transformed payment system. **However, should CMS elect to proceed with this policy – which the KHA strongly opposes – the agency should, at the very least, transition the implementation of these interrupted stay changes over several years.**

PROPOSED INTERRUPTED STAY CHANGE FOR CO-LOCATED LTACHS

Finally, the KHA supports CMS's decision to eliminate the five percent readmission rule that pertains to interrupted stays in co-located LTACHs. The policy penalizes LTACHs which readmit patients discharged to their host hospitals by applying a payment adjustment. If this readmission rate exceeds 5 percent, all such readmissions are treated as interrupted stays. Because a hospital can only be identified as violating the 5 percent threshold at the end of the year, CMS must enforce this policy through a reconciliation process. As a consequence, CMS acknowledges that this policy has limited effects on provider decisions, and offers limited value to the Medicare program. KHA agrees with the assessment provided by CMS, and believe the 5 percent readmission policy should be eliminated, regardless of other interrupted stay policy decisions.

PROPOSED CHANGES TO THE LTACHQR PROGRAM

CMS proposes three new measures for the FY 2018 LTACHQR program and updates the submission requirements for several of the program's existing measures. The agency also proposes data completeness standards and a data validation process for the LTACHQR program beginning with FY 2016 payment determinations.

FY 2018 MEASUREMENT PROPOSALS

Beginning with the FY 2018 payment determination, CMS proposes that LTACHs report two measures assessing functional status, and one healthcare-associated infection (HAI) measure of ventilator-associated events (VAEs). The KHA applauds the agency for proposing measures that address measurement gap areas for LTACHs. Indeed, the Measure Applications Partnership (MAP) – a multi-stakeholder group convened by the National Quality Forum (NQF) to provide pre-rulemaking input on measures under consideration for CMS quality measurement programs – has encouraged CMS to adopt both functional status and HAI measures in the LTACHQR program. We appreciate the agency's recognition of the MAP's recommendations in its measurement proposals.

However, the KHA does not support adding these three proposed measures to the LTACHQR program at this time because we are concerned that none is fully ready for implementation in LTACHs. Indeed, none of the three measures is NQF-endorsed. The KHA has repeatedly and consistently urged CMS to use only NQF-endorsed measures in federal quality reporting programs because NQF endorsement provides assurance that the measure has been tested, can reliably and accurately collect data, is feasible to implement and is usable. **We believe the VAE measure is a promising addition to the LTACHQR program, and we encourage CMS to re-propose the measure once it has obtained NQF endorsement. However, the two functional status measures require significant changes before they are appropriate for use in any public reporting program.** Our detailed comments on each proposed measure are provided below.

Proposed Ventilator-Associated Event (VAE) Outcome Measure.

The definition of the Ventilator-Associated Event (VAE) Outcome Measure, which is used by the Centers for Disease Control (CDC), and reported through the National Health Safety Network (NHSN), was changed in January 2013 and July 2013. Further modifications were made in January 2014. The change in the definition no longer uses the Ventilator –Associated Pneumonia (VAP) bundle. The previously used VAP bundle, referenced in the proposed rule, was applicable to Intensive Care Units. The VAP bundle is outdated, and in any event, it is not an appropriate measure for LTACHs.

The proposed measure was developed by the CDC, and CMS proposes to collect measure data using the CDC's National Healthcare Safety Network (NHSN). While the measure is not yet NQF endorsed, CMS indicates that the prevalence of ventilator use in LTACHs, as well as the health risks of VAEs for the "older, medically complex population in LTACHs," makes it an appropriate measure for the LTACHQR program.

There is no data currently available on the new definition of the VAE, such as what causes a VAE and what factors determine whether it was preventable. Also, there are no National Quality Forum endorsed measures for VAEs in the LTACH setting, which CMS itself points out. 79 Fed. Reg. 28268.

Some LTACHs are voluntarily reporting on the new VAE Outcome Measure to the CDC through the NHSN. Data is expected to be available in 2015. **KHA believes it is premature to adopt a VAE outcome measure for LTACHs at this time, because there is no data currently available on VAEs in the LTACH setting. KHA recommends that CMS delay adopting any outcome measure for VAE in the LTACH setting until further data is available, the measure is studied in LTACHs, and standards of care are developed for preventing VAEs.**

A significant reason to delay adoption of a VAE outcome measure is the absence of NQF endorsement. KHA recommends that the agency clarify what measure results it intends to report. Specifically, we urge that CMS report only the two standardized infection ratios (SIRs) in the NHSN specifications – ventilator-associated conditions (VAC) and infection-related ventilator associated complications (IVACs). CMS states in the rule that VAE "incorporates a range of ventilator-associated events, including ventilator-associated pneumonia (VAP), pulmonary edema, acute respiratory distress syndrome, sepsis, and atelectasis." This description suggests that each of these fives conditions is measured discretely and then combined into a single summary measure. Yet, as specified by NHSN, VAE is defined not by these conditions, but instead by quantitative changes in specific pathophysiologic parameters. These include a decline in a patient's oxygenation level after a period of stability or improvement on the ventilator, evidence of infection or inflammation (e.g., elevated body temperature), and laboratory evidence of respiratory infection. These changes could be due to a variety of clinical conditions including, but not limited to, the ones mentioned in the proposed rule. As suggested by the NHSN specifications, the use of quantitative parameters is appropriate at this time because available definitions of specific conditions leading to VAEs are fairly subjective, which could lead to unreliable or invalid data collection and reporting. For example, many VAP definitions rely on the interpretation of chest radiographs, which include some inherent variability. Other VAP definitions use signs or symptoms that may not be documented the same way in all medical records.

For these reasons, the NHSN measure reports two SIRs – VAC and IVAC – that are not intended to be a simple roll up of the five conditions listed in the proposed rule. Patients are considered to have a VAC if their oxygenation level worsens according to specified clinical parameters. Patients have IVACs if, in addition to worsening oxygenation, they also show certain clinical parameters indicative of an infection. The VAE measure's data collection protocol does not gather data for discrete conditions. We believe the agency intends to use the NHSN specifications, and we strongly urge it to report the measure in a manner consistent with those specifications.

<u>Percent of LTACH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function</u>.

Process measures should focus on whether the care that is actually delivered would improve the patient's outcome. Process measures that are developed for LTACHs should have a direct impact on

patient outcomes in LTACHs to be useful in improving quality of care in LTACHs. There should be evidence that the process affects the outcome. To the extent possible, process measures adopted for LTACHs should be based on research in the LATCH setting.

The proposed quality measure for "Percent of LTACH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function" is based on the CARE tool. The CARE tool was not specifically developed for LTACH patients. While the proposed measure may be appropriate in the SNF setting and in the Inpatient Rehabilitation Facility (IRF) setting, it is not appropriate for the patient population in LTACHs. Most LTACH patients are not functional on admission, and a significant percent are not functional during their stay. Therefore, their functional ability is not routinely assessed. In general, functional status measures assess the extent to which patients regain the ability to perform activities (or "functions") essential to daily living.

CMS proposes to collect the measure using a modified version of the LTACH Continuity Assessment Record and Evaluation (CARE) data set. At the times of admission and discharge, trained clinicians would be required to numerically score the level of independence that patients demonstrate on several assessment items, including self-care, mobility, cognition, communication and bladder continence. Additionally, LTACH clinicians would be required to record a numerical functional goal score at admission for at least one of the assessment items. The measure was initially developed as part of the Post-Acute Care Payment Reform Demonstration (PAC-PRD) project, and CMS continued to fund the development of the measure after the conclusion of the project.

The majority of LTACH patients would not meet any of the functional measures. By way of example, the items pertaining to walking, picking up objects, and car transfers are not applicable to LTACH patients on admission; most are also not applicable to LTACH patients on discharge. While bed mobility is relevant, a transfer from the bed to a chair is not possible for a significant percent of LTACH patients. Also, the proposed functional process measure is not sensitive to the types of subtle functional improvements that may be seen in LTACH patients.

The cognitive function assessment tool does not measure baseline cognition because of the variation in LTACH patients' clinical conditions and mental status. LTACH patients are extremely fragile, and there cognition is affected by small changes, such as the time of day and the clinical condition of the patient, for example, whether or not the patient's electrolytes are in balance at the time of the assessment, or whether a dialysis patient is pre- or post-dialysis when assessed. The questions in the cognitive function assessment tool merely provide a snapshot of a patient at a given time on a given day. They do not provide a true reflection of the patient's cognitive functioning. Also, to complete the cognitive assessment portion of the functional assessment tool requires diagnostic expertise beyond the expertise of a nurse, such as the expertise of a clinical psychologist.

It would be an extremely labor intensive activity for LTACHs to report on each of the items listed for the proposed functional status quality measures. It would require LTACHs to expend significant time

and resources in order to report data, whose value in measuring quality in the LTACH setting is questionable.

CMS proposes to exclude three categories of patients from the functional status quality measure: (1) patients with incomplete stays due to a medical emergency, (2) patients who leave the LTACH against medical advice, and (3) patients who die in the LTACH. Interrupted stay patients also should be excluded. An interrupted stay patient is "discharged" from the LTACH and then "readmitted" to the LTACH within a certain fixed period under the 3 day or less interrupted stay policy and the greater than 3 day interrupted stay policy. There is no reason to assess the patients' admissions twice and the patients' discharges twice. Furthermore, doing so may result in an inaccurate assessment of the patient's condition. In the event interrupted stay patients are not excluded, then only the initial admission (not the readmission) and the last discharge (not the discharge which precedes the interruption in the stay) should be assessed.

For the reasons stated above, KHA does not support the adoption of the proposed functional status quality measure for percent of LTACH patients with an admission and discharge functional assessment and a care plan that addresses function. In the event the proposed measure is adopted KHA recommends that LTACH interrupted stay patients be excluded.

With this said, KHA agrees that functional status is an important measurement gap for LTACHs, and commends CMS for funding measurement development in this area. **However, as currently designed, the measures are not ready for adoption in the LTACHQR program. We are especially concerned that the measures have not been adequately tested in LTACHs to ensure they are feasible to implement, and yield accurate performance data. We strongly urge CMS to undertake additional LTACH-specific measure testing.**

The information presented in the draft specifications suggests that reliability and validity testing of these two measures has been performed in 34 facilities. However, this testing was performed in five different types of facilities – STACHs, IRFs, SNFs, home health agencies and LTACHs. It is unclear how many testing sites were LTACHs. The measure developer draws favorable conclusions about the reliability and validity of the measures based on the testing data across all facility types. Yet, the goal of the measures under development is to assess care in LTACHs. As such, we believe measure testing should be oriented toward this intended use.

Evidence from the August 2012 final report on the development of the CARE tool indicates there is significant room to improve the reliability of the measures when used in LTACHs.[1] One gauge of reliability is "inter-rater reliability," which assesses whether two people collecting the same measure obtain the same measure results. This test of reliability is especially appropriate for the functional status measures because it relies on data collection by multiple clinicians. The level of agreement between the

[1] See RTI International, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report. August 2012. All three volumes of the report are available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.

raters can be quantified using a Kappa statistic that returns a result between 0 and 1; the higher the Kappa statistic, the better the agreement between raters. The 2012 CARE tool final report indicates that "LTACHs appear to have slightly lower rates of items than other settings." Additionally, several specific self-care and mobility items have Kappa statistics that categorize inter-rater reliability as only fair (Kappas of between 0.21 and 0.40) or moderate (0.41 to 0.60). These items include eating (0.446), oral hygiene (0.331), toilet hygiene (0.339), lower body dressing (0.447), sit to stand (0.551), and chair/bed to chair transfers (0.556). We also note that these testing results are based on an ineffective sample size of only 46 LTACH patient records.[2]

These levels of reliability are insufficient for a national quality reporting program. Fair or moderate reliability may be acceptable for exploratory studies or internal improvement efforts. However, CMS is proposing to implement these measures on a national scale across all LTACHs. In addition, the collection and reporting of these measures would require substantial resources. In order for such an investment of resources to return value to LTACHs seeking to benchmark their quality improvement efforts, and to consumers seeking to understand the quality of care in LTACHs, it is essential that the measure yield accurate results. The available evidence suggests these measures, as currently constructed, fall well short of that standard. At a minimum, CMS should re-test the measure in significantly more LTACHs to address its reliability issues.

Moreover, we urge CMS to carefully assess whether all of the items included in the proposed functional status assessment are necessary and appropriate for LTACHs, as several of them had low response rates in the PAC-PRD pilot. For example, LTACHs did not respond to the self-care items between 44 and 53 percent of the time.[3] Several mobility function items had non-response rates over 60 percent.[4] The draft specifications accompanying the proposed rule do not describe how CMS has updated the measures to account for these low response rates, or suggest that CMS has done further investigation to understand why the response rates to some items were so low.

The KHA also recommends CMS use the experience of LTACHs in implementing the CARE tool-derived measures to shape measure development efforts. LTACHs are in the early phases of using selected portions of the LTACH CARE tool to collect the pressure ulcer measure and will soon begin to report CARE tool-derived measures of patient influenza vaccination and patient falls. Early experience in collecting data on the pressure ulcer measure highlights some important opportunities for improvement in the CARE tool. For example, the CARE tool does not capture if conditions are present on admission (POA) to a facility. For pressure ulcers, a POA indicator is critical in determining whether a pressure ulcer developed as a result of the care provided by an LTACH. A POA indicator also would be important in performing any risk adjustment of functional status measures, as it allows the developers to distinguish between complications associated with care at the LTACH, and a patient's pre-existing conditions.

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[2] See RTI International, *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing, Volume 2 of 3.* August 2012. Referenced numbers are on the table on pp. 45-46.

[3] See RTI International, *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report, Volume 1 of 3.* August 2012. p. 100.

[4] *Ibid.*

Change in Mobility Functional Status among LTACH Patients Requiring Ventilator Support. The proposed measure would assess the change in mobility functional status scores from admission to discharge among patients on ventilator support. The data to calculate this measure would be derived from the mobility assessment item scores collected using the LTACH CARE data set. CMS proposes to risk adjust each LTACH's score, and indicates that it would incorporate specific items into the LTACH CARE data set to help perform the risk adjustment calculations.

The KHA does not support the addition of this measure to the LTACHQR at this time. We refer the agency to our discussion about our concerns with the LTACH CARE tool-derived functional status measures as outlined in the previous section; these concerns also apply to this measure. We also note that the PAC-PRD testing information showed concerning rates of missing data for several items assessing function at admission. These data are critical to performing risk adjustment. For example, 35 percent of LTACHs were unable to report the items on admission mobility function and 34 percent were unable to report self-care items.[5]

UPDATES TO PREVIOUSLY FINALIZED LTACHQRMEASURES

Patient Influenza Vaccination Measure. CMS proposes to alter the data collection and submission deadlines by creating two data collection periods and submission deadlines for each fiscal year, instead of requiring that flu vaccination data be submitted once at the end of each flu season. CMS indicates that because the patient flu vaccination measure is collected using the LTACH CARE data set, it wishes to align the data collection and submission timeframes with those of the other measure (pressure ulcers) collected using that tool. **The KHA supports this proposal.**

Falls with Major Injury. CMS finalized this measure in last year's LTACH PPS rule for the FY 2018 LTACHQR program. LTACHs were to begin collecting measure data on Jan. 1, 2016 using the LTACH CARE data set. However, in order to accommodate planned updates to the LTACH CARE data set, CMS proposes to delay measure collection until April 1, 2016. Therefore, for FY 2018 reporting, LTACHs would be expected to submit three quarters of data instead of four quarters. For the FY 2019 program, however, LTACHs would still be required to submit a full calendar year of data. **The KHA supports this proposal.**

DATA SUBMISSION REQUIREMENTS

Proposed LTCHQR Program Completion Thresholds and Data Validation Thresholds for the FY 2016 Payment Determination and Subsequent Years

For the FY 2016 LTACHQR program, CMS proposes to establish, for the first time, data completeness standards and a measure validation process for the LTACHQR program. CMS proposes that LTACHs that do not comply with all data submission requirements – including the completeness and validation requirements – will be subject to a 2 percent reduction to the annual payment update, per the statute.

[5] See RTI International, *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report, Volume 1 of 3.* August 2012. p. 82.

Data Completeness. LTACHs currently submit measure data using two mechanisms. Some measures are collected using the LTACH CARE data set and are submitted using CMS's Quality Improvement Evaluation System (QIES), while HAI measures are submitted using the CDC's NHSN. CMS proposes that LTACHs must submit data via the QIES that are at least 80 percent complete, while data submitted using the NHSN must be 100 percent complete. CMS states that QIES data will have met its proposed completeness threshold if 80 percent of an LTACH's submitted LTACH CARE data set assessments contain 100 percent of the required quality data items completed. For the HAI measures submitted via NHSN, CMS proposes to require LTACHs to complete all data fields required for measure numerator and denominator data. **The KHA believes that data completeness standards will facilitate more accurate public reporting in the future, and we support CMS's proposed numerical standards. However, we recommend the agency apply the standards no earlier than FY 2017 payment determination, instead of FY 2016.** The FY 2016 data collection period for most LTACHQR measures is Jan. 1 – Dec. 31, 2014. Thus, a significant amount of data for FY 2016 has already been collected and submitted. It would be inappropriate and unfair to apply to the data completeness standards to data submitted before the standards were even proposed and, therefore, known to LTACHs. Indeed, in the hospital IQR program, changes to data submission standards are proposed in advance of – not during or after – the data collection period. However, it would be reasonable to implement the standards for FY 2017 payment determination, as the FY 2017 data collection periods for most measures are Jan. 1 – Dec. 31, 2015.

Measure Validation. Measure validation processes are used in other CMS quality reporting programs, such as the hospital inpatient quality reporting (IQR) program, to ensure that measure data have been accurately collected, thereby enhancing the accuracy of measure results. For FY 2016, CMS proposes to validate only the pressure ulcer measure collected using the LTACH CARE data set. CMS proposes to perform validation on a random sample of 260 LTACHs, and would randomly select five LTACH CARE data set assessments from each LTACH in the validation group. CMS contractors would then request medical record data from the LTACHs and compare the data elements in the patient chart to the quality measure data submitted by the LTACH to CMS, identifying any differences that would affect the measure rate. The contractor would then calculate a percentage of matching data elements, creating a validation score. CMS proposes that LTACHs selected for validation must achieve at least a 75 percent validation score.

The KHA supports CMS's proposed validation approach. However, as with the data completeness standards, we recommend the agency implement the validation standards no earlier than FY 2017, instead of FY 2016, payment determination. Validation is an important step to ensuring that hospitals are collecting measure data appropriately, and that any publicly reported measure data are accurate. However, we believe it would be inappropriate to validate data submitted for FY 2016 payment determination, as much of those data were submitted before CMS's proposal. **We also recommend that the agency make the validation process as transparent as possible, particularly since it is new to the LTACHQR program.** As is the case for the IQR program validation process, we recommend that CMS annually announce which LTACHs will be subject to validation, and disseminate information about when these LTACHs should expect to begin receiving requests for medical records. We also recommend that CMS undertake educational sessions once the process is finalized to ensure that facilities understand

how the submitted information will be evaluated. Lastly, given that the validation and data completeness standards are new to the LTACHQR, CMS should recognize LTACHs for good-faith efforts to comply with both sets of requirements.

Reconsiderations and Appeals Process. In last year's LTACH PPS final rule, CMS finalized a reconsideration and appeals process for LTACHs beginning with FY 2015 payments that allows LTACHs to appeal findings of non-compliance with the LTACHQR program. CMS proposes to continue this process for FY 2016, and indicates that the reconsideration process will take into account the proposed data completeness and validation requirements. **The KHA supports this proposal.**

INPUT ON SITE-NEUTRAL PAYMENTS FOR FY 2016

The Bipartisan Budget Act of 2013 (BiBA) brought major change to the LTACH field by adding a site-neutral payment feature to the LTACH PPS for cases that meet qualifying criteria. This significant change takes effect for cost reporting periods beginning on or after Oct. 1, 2015. The far lower site-neutral rates, to be set at an inpatient PPS-equivalent level, will apply to LTACH cases:

- lacking three or more days of intensive care unit services during an immediately prior stay in an inpatient PPS hospital;
- lacking a Medicare-severity long-term care diagnosis-related group (MS-LTC-DRG) for ventilator services of at least 96 hours; and
- having a rehabilitation or psychiatric principal diagnosis.

The KHA agrees with AHA's estimates that 47 percent of FY 2012 LTACH cases would fall in the site-neutral category. The scope and design of this legislative provision is under close scrutiny by the KHA and will continue to be the subject of an advocacy effort to refine the statute to ensure that highly acute patients do not remain in the site-neutral category.

In the proposed rule, CMS seeks input regarding several key design features for the new site-neutral payment component. In particular, the agency has requested input on whether the new weighting methodology for the two-tiered system should utilize all LTACH cases, including site-neutral cases, or solely the cases that remain eligible for the traditional LTACH PPS payment, with the site-neutral cases being assigned the relevant weight from the inpatient PPS. The agency also seeks feedback on whether the new two-tiered payment system should have one high-cost outlier pool for all LTACH claims, or separate outlier pools for traditional LTACH PPS cases and site-neutral cases. The KHA appreciates CMS's request for input. We agree with AHA's analyses and recommendations below.

When designing the new two-tiered payment system, we encourage CMS to develop options that promote stability in LTACH payments from year to year. Dividing the payment system into two tiers means that smaller numbers of cases could be used to set the weights, which could cause large year-to-year fluctuations. Allowing the cases that will remain eligible for traditional LTACH PPS payments to continue to be paid in a manner that is as similar as possible to the current LTACH PPS would align with the congressional intent in BiBA to create a separate and distinct payment apparatus for site-neutral

payments for lower-acuity cases. It would leave the traditional LTACH PPS portion of the system intact for the higher-severity cases that require the unique types of services provided by LTACHs.

In addition, given the anticipated complexities of designing and later adjusting policies to manage this sweeping change in LTACH payment, we urge CMS to continue to actively engage stakeholders in all aspects of its policy development process. CMS should employ a variety of channels, such as technical expert panels and open forums, on an ongoing basis both in advance of issuing the FY 2016 proposed rule, and in the period of policy refinement that is sure to follow the initial implementation of the new two-tiered system.

SITE-NEUTRAL CASES HAVE VERY HIGH SEVERITY OF ILLNESS

When analyzing the most recent Medicare claims data, both categories of LTACH cases under the new two-tiered payment system – the site-neutral cases and the traditional LTACH PPS cases – have very high levels of severity of illness[6] (SOI).

While we recognize that the site-neutral criteria are set in legislation and that CMS is required to implement this law, we feel compelled to note that BiBA's effort to divide LTACH cases into distinct categories based on acuity, and to pay the lower-acuity cases a far lower rate, warrants further examination and, ultimately, modification. As written, the BiBA criteria have yielded a site-neutral category of LTACH cases that is not clinically distinct from the traditional LTACH PPS claims.

As a result, unless changed, any high-severity cases (especially SOI levels 3 and 4) in the site-neutral category would most likely be severely underpaid with an inpatient PPS-equivalent payment. Therefore, without modification of BiBA's criteria, beneficiaries with SOI levels 3 and 4 who fall into the site-neutral category are likely to face major access challenges, as inpatient PPS-equivalent rates will not cover the costs of the traditional LTACH-level services required by highly acute beneficiaries. We do not believe that this outcome was the intent of Congress and, as such, the KHA continues our advocacy efforts to refine these criteria.

WEIGHTING OF THE TWO-TIERED PAYMENT SYSTEM

The AHA and partnering associations simulated LTACH PPS weights under the BiBA criteria to assess the merit of setting relative payment weights using all LTACH cases, including the cases that meet the site-neutral definition, versus using only the cases that meet the criteria for a traditional LTACH PPS payment. They then calculated the weights using only the cases that would be paid a traditional LTACH PPS rate.[7] This analysis, as shown in Table 1, found that both weighting approaches produce relative weights for the MS-LTC-DRGs that are quite similar, regardless of whether they are based on all cases or

[6] Severity of illness (SOI) was measured using the APR-DRG grouper, which assesses the acuity level of each claim using a four-point scale that takes into account co-morbidities, age, procedures, and principal diagnosis. SOI level 4 captures "extreme severity;" SOI 3 captures "major severity;" SOI 2 captures "moderate severity;" and SOI 1 captures "minor severity."

[7] The simulation used FY 2014 LTACH PPS policy parameters, including weights calculated by The Moran Company using a FY 2012 dataset created from the calendar year 2011 and 2012 inpatient standard analytical files.

only the cases in the traditional LTACH PPS payment tier. The minimal difference in average case weights, 1.1116 (all cases) versus 1.2676 (only traditional LTACH PPS cases) re-emphasizes the concern that, despite the significant difference in *payment* under the two-tiered system, the criteria set forth in BiBA do not sufficiently distinguish the two categories of LTACH cases from each other. In addition, when looking only at the MS-LTC-DRGs represented by the traditional LTACH PPS cases, the average case weight is extremely similar, 1.2886 versus 1.2676.

Table 1

	Weights Set Using All LTACH Cases (Incl. Site-Neutral)	**Weights Set Using Traditional LTACH PPS Cases Only (Excl. Site-Neutral)**	
	All MS-LTC-DRGs	Only MS-LTC-DRGs Used to Pay Traditional LTACH PPS Cases	Only MS-LTC-DRGs Used to Pay Traditional LTACH PPS Cases
Total Cases	131,347	69,789	69,789
Average Case Weight	1.1116	1.2886	1.2676
Highest Weight	6.3956	6.3956	6.2450
Lowest Weight	0.2269	0.3998	0.3788

We also are concerned that the traditional LTACH PPS cases are highly concentrated in a few MS-LTC-DRGs. In fact, in the simulation, 41 percent of the traditional LTACH PPS cases would fall in only three MS-LTC-DRGs; in contrast, only 28 percent of all cases fall into these MS-LTC-DRGs. The simulation also shows that the proportion of cases in "no-volume MS-LTC-DRGs" would grow considerably – 35 percent of the MS-LTC-DRGs are no- volume DRGs when basing weights on all cases, and this rate increases to 46 percent when using only the traditional LTACH PPS cases.

Managing the traditional LTACH PPS tier of the new system – with this atypically concentrated case mix – will likely present challenges for CMS and providers alike as the agency attempts to maintain relative payment stability from year to year. This will likely be particularly difficult in the initial years of the two-tiered system, as we expect the LTACH field will undergo a substantial reduction of overall volume and shifts in case mix as providers adapt to the new site-neutral payment component. Therefore, we urge CMS to consider policies to mitigate instability, such as constructing the weights based on a rolling average of data encompassing several years.

HIGH-COST OUTLIER PAYMENTS UNDER THE TWO-TIERED PAYMENT SYSTEM

KHA also agrees with AHA's assessment of the impact of using a single high-cost outlier pool for all LTACH cases versus using distinct pools for each level of the two-tiered payment system. The analysis, based on weights calculated using all LTACH cases, found that a single 8 percent outlier pool would yield a fixed-loss threshold of $37,369, which is far higher than the fixed-loss threshold in the proposed rule, $15,730. Using two 8 percent outlier pools produced a fixed-loss threshold for the traditional LTACH PPS cases of $17,537, and a $70,816 fixed-loss threshold for the site-neutral tier of the payment system. The

analysis using weights calculated using solely the traditional LTACH PPS cases produced very similar results. Under both weighting approaches, the unusually high fixed-loss threshold for site-neutral cases is due to the far lower average payments for these cases in combination with the 8 percent cap.

Given that high-severity, high-cost patients are found in both levels of the two-tiered payment system, as discussed above, the KHA believes it is important to maintain distinct high-cost outlier pools for each tier. In addition, based on our analysis of FY 2012 claims, we believe that having two high-cost outlier pools would preserve a fixed-loss threshold for the traditional LTACH cases that is relatively similar to the current threshold, as well as give CMS the flexibility to adapt each threshold as needed for each tier of the new system to mitigate volatility. Such flexibility will be crucial, especially in the early years, as providers adjust to the new system. In addition, the inpatient PPS-equivalent rates that will be paid for site-neutral LTACH cases are established in the inpatient PPS in a manner that accounts for the inpatient PPS high-cost outlier pool. This is a further rationale for site-neutral LTACH cases paid an inpatient PPS equivalent rate to remain eligible for high-cost outlier payments.

To further promote stability and preserve the policy intent of high-cost outlier payments, we also believe it is warranted to explore whether a high-cost outlier pool target other than 8 percent may be appropriate – especially for the site-neutral category of claims. The goal of revising the outlier pool amount must be to avoid access problems that could occur as a result of underpayment for high-severity (and higher cost) cases, as discussed above. The underpayment is of particular concern for cases in the site-neutral category.

We appreciate the opportunity to express our comments and concerns with the Proposed Rule. We look forward to working with CMS on improving the LTACH PPS FY 2015 and related policies in the Proposed Rule in accordance with these comments. If you have any questions about our comments, feel free to contact me or Steve Miller at (502) 426-6220 or ngalvagni@kyha.com or smiller@kyha.com.

Sincerely,

Nancy C. Galvagni

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Senior Vice President