



June 26, 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

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:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 286 long-term care hospitals (LTCHs), the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2015 proposed rule for the inpatient and LTCH prospective payment systems (PPS).

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



PROPOSED CHANGES PERTAINING TO INTERRUPTED STAYS

CMS's proposal to change the thresholds that apply to LTCH interrupted stays is unwarranted and should not be implemented. Interrupted stays from LTCHs occur when a patient needs a different scope of services for a temporary period, which results in an LTCH patient being temporarily transferred to either a general acute care hospital, inpatient rehabilitation facility (IRF) or skilled nursing facility (SNF). In these situations, the duration of the interruption determines whether the LTCH will be eligible for one LTCH payment or two separate LTCH payments. For example, currently, LTCH interrupted stays of four to nine days to a general acute-care hospital will result in *one* LTCH payment for all services provided before and after the interruption. If this type of interrupted stay exceeds nine days in duration, however, the LTCH will receive *two* LTCH 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, as shown in the table below.

Table 1						
Interrupted Stays of Greater than Three Days						
Destination	Current Threshold	Proposed Threshold				
General Acute Care Hospital	4-9 days					
IRF	4-27 days	4-30 Days				
SNF	4-45 days					

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 our primary concern. This change would pose a material fiscal impact on LTCHs – 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 LTCH interrupted stay threshold. CMS merely states that the 30-day inpatient PPS window is a more appropriate benchmark for the LTCH interrupted stay policy because it is used by researchers for quality measurement and is "clinically meaningful."

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CMS is incorrectly comparing the LTCH interrupted stay policy and the inpatient PPS readmissions policy, which, in fact, address fundamentally different clinical care scenarios. For LTCH interrupted stays, the intent is for the patient to be temporarily discharged to another setting (most commonly a general acute care hospital) to access a clinical service the LTCH lacks, and then return to the LTCH. In contrast, when general acute care hospitals discharge a patient, the hospital's expectation is that the patient will not return for a continuation of that admission. Given this crucial incongruence, we urge CMS to provide a comprehensive justification for its proposal to change the current interrupted stay policy. In addition, we ask the agency 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 LTCH. Absent a thorough explanation of the improvements CMS is seeking to achieve through this change to LTCH 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.

In addition, the AHA is concerned with the lack of transparency in CMS's data and its limited availability. When initially implementing the current LTCH 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.

Because of these concerns, the AHA urges CMS to withdraw its LTCH interrupted stay proposal. The LTCH 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 AHA 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 LTCHS

Finally, the AHA supports CMS's proposal to eliminate the current policy that pertains to interrupted stays in co-located LTCHs. The policy applies a payment adjustment to co-located LTCHs that, within a cost-reporting period, have more than 5 percent of their discharges transferred to the co-located general acute-care hospital, IRF, SNF or inpatient psychiatric facility, and later re-admitted to the same LTCH. Currently, LTCHs that exceed this cap are paid one LTCH PPS payment that covers both segments of LTCH service, regardless of the length of

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the interrupted stay. However, with the proposed removal of this cap, payment for interrupted stays would be determined by the duration of the interruption relative to the separate policies for "three-day or less interruption of stay" and "greater than three-day interruption of stay."

PROPOSED CHANGES TO THE LTCHOR PROGRAM

CMS proposes three new measures for the FY 2018 LTCHQR 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 LTCHQR program beginning with FY 2016 payment determinations.

FY 2018 MEASUREMENT PROPOSALS

Beginning with the FY 2018 payment determination, CMS proposes that LTCHs report two measures assessing functional status, and one healthcare-associated infection (HAI) measure of ventilator-associated events (VAEs). The AHA applauds the agency for proposing measures that address measurement gap areas for LTCHs. 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 LTCHQR program. We appreciate the agency's recognition of the MAP's recommendations in its measurement proposals.

However, the AHA does not support adding these three proposed measures to the LTCHQR program at this time because we are concerned that none is fully ready for implementation in LTCHs. Indeed, none of the three measures is NQF-endorsed. The AHA 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 LTCHQR 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.

<u>VAE Outcome Measure</u>. The proposed measure was developed by the Centers for Disease Control and Prevention (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 LTCHs, as well as the health risks of VAEs for the "older, medically complex population in LTCHs," makes it an appropriate measure for the LTCHQR program.

In addition to obtaining NQF endorsement of the VAE outcome measure, we recommend 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 —

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ventilator-associated conditions (VAC) and infection-related ventilator associated complications (IVACs). CMS states in the rule that VAE "incorporates a range of ventilatorassociated 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.

Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function. The proposed measure assesses the percentage of LTCH patients who have functional status assessments completed at both admission and discharge and who have a care plan that addresses function. 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 LTCH 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, LTCH 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 AHA agrees that functional status is an important measurement gap for LTCHs, and commends CMS for funding measurement development in this area. **However, as currently designed, the measures are not ready for adoption in the LTCHQR program.** We are

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especially concerned that the measures have not been adequately tested in LTCHs to ensure they are feasible to implement, and yield accurate performance data. We strongly urge CMS to undertake additional LTCH-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 – general acute care hospitals, IRFs, SNFs, home health agencies and LTCHs. It is unclear how many testing sites were LTCHs. 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 LTCHs. 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 LTCHs. 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 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 "LTCHs 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 LTCH 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 LTCHs. 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 LTCHs seeking to benchmark their quality improvement efforts, and to consumers seeking to understand the quality of care in LTCHs, 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 LTCHs to address its reliability issues.

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.

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.

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Moreover, we urge CMS to carefully assess whether all of the items included in the proposed functional status assessment are necessary and appropriate for LTCHs, as several of them had low response rates in the PAC-PRD pilot. For example, LTCHs did not respond to the self-care items between 44 and 53 percent of the time. Several mobility function items had non-response rates over 60 percent. 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 AHA also recommends CMS use the experience of LTCHs in implementing the CARE tool-derived measures to shape measure development efforts. LTCHs are in the early phases of using selected portions of the LTCH 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 whether 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 LTCH. 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 LTCH, and a patient's pre-existing conditions.

Change in Mobility Functional Status among LTCH 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 LTCH CARE data set. CMS proposes to risk adjust each LTCH's score, and indicates that it would incorporate specific items into the LTCH CARE data set to help perform the risk adjustment calculations.

The AHA does not support the addition of this measure to the LTCHQR at this time. We refer the agency to our discussion about our concerns with the LTCH 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 LTCHs 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 LTCHQR MEASURES

<u>Patient Influenza Vaccination Measure</u>. CMS proposes to alter the data collection and submission deadlines by creating two data collection periods and submission deadlines for each

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.

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.

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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 LTCH 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 AHA supports this proposal.**

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

DATA SUBMISSION REQUIREMENTS

For the FY 2016 LTCHQR program, CMS proposes to establish, for the first time, data completeness standards and a measure validation process for the LTCHQR program. CMS proposes that LTCHs 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.

Data Completeness. LTCHs currently submit measure data using two mechanisms. Some measures are collected using the LTCH 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 LTCHs must submit data via the OIES 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 LTCH's submitted LTCH 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 LTCHs to complete all data fields required for measure numerator and denominator data. The AHA 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 LTCHQR 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 LTCHs. 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

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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 LTCH CARE data set. CMS proposes to perform validation on a random sample of 260 LTCHs, and would randomly select five LTCH CARE data set assessments from each LTCH in the validation group. CMS contractors would then request medical record data from the LTCHs and compare the data elements in the patient chart to the quality measure data submitted by the LTCH 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 LTCHs selected for validation must achieve at least a 75 percent validation score.

The AHA 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 LTCHQR program. As is the case for the IQR program validation process, we recommend that CMS annually announce which LTCHs will be subject to validation, and disseminate information about when these LTCHs 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 LTCHQR, CMS should recognize LTCHs for good-faith efforts to comply with both sets of requirements.

<u>Reconsiderations and Appeals Process</u>. In last year's LTCH PPS final rule, CMS finalized a reconsideration and appeals process for LTCHs beginning with FY 2015 payments that allows LTCHs to appeal findings of non-compliance with the LTCHQR 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 AHA supports this proposal.**

INPUT ON SITE-NEUTRAL PAYMENTS FOR FY 2016

The Bipartisan Budget Act of 2013 (BiBA) brought major change to the LTCH field by adding a site-neutral payment feature to the LTCH 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 LTCH cases:

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

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3) having a rehabilitation or psychiatric principal diagnosis.

The AHA estimates that 47 percent of FY 2012 LTCH cases would fall in the site-neutral category. The scope and design of this legislative provision is under close scrutiny by the AHA 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, which our analysis indicates is a problem under the BiBA criteria.

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 LTCH cases, including site-neutral cases, or solely the cases that remain eligible for the traditional LTCH 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 LTCH claims, or separate outlier pools for traditional LTCH PPS cases and site-neutral cases. The AHA appreciates CMS's request for input. We have conducted a variety of analyses to better understand these and related issues, and share our insights and recommendations below.

When designing the new two-tiered payment system, we encourage CMS to develop options that promote stability in LTCH 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 LTCH PPS payments to continue to be paid in a manner that is as similar as possible to the current LTCH 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 LTCH PPS portion of the system intact for the higher-severity cases that require the unique types of services provided by LTCHs.

In addition, given the anticipated complexities of designing and later adjusting policies to manage this sweeping change in LTCH 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.

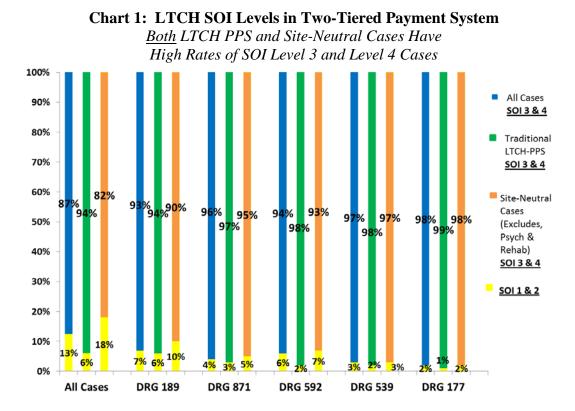
SITE-NEUTRAL CASES HAVE VERY HIGH SEVERITY OF ILLNESS

When analyzing the most recent Medicare claims data, the AHA found that both categories of LTCH cases under the new two-tiered payment system – the site-neutral cases and the traditional LTCH PPS cases – have very high levels of severity of illness⁶ (SOI). The chart below shows SOI levels for all LTCH cases and for the five MS-LTC-DRGs with the greatest volume of site-

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."

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neutral cases.⁷ The blue bars show all LTCH discharges, the green bars show the traditional LTCH cases that do not fall within BiBA's site-neutral definition, and the orange bars show the cases that fall within BiBA's site-neutral definition.



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 LTCH 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 LTCH cases that is not clinically distinct from the traditional LTCH PPS claims.

Specifically, the data above show that the site-neutral cases (in orange) have almost the same rates of extreme (SOI 4) and major (SOI 3) SOI levels as the cases that will remain eligible for a traditional LTCH PPS payment (in green). (The SOI level 1 and 2 cases are shown in yellow, on the bottom of each bar.) Yet, under BiBA, the two categories of cases would be subject to materially different levels of payment. 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

⁷ Top five site-neutral MS-LTC-DRGs by volume: <u>DRG 189</u> Pulmonary Edema & Respiratory Failure; <u>DRG 871</u> Septicemia w/o MV 96+ hours w MCC; <u>DRG 592</u> Skin ulcers w MCC; <u>DRG 539</u> Osteomyelitis w MCC; and <u>DRG 177</u> Respiratory Infections & Inflammations w MCC. Source: 2010-2012 Standard analytical files, FY 2014 IPPS and LTCH PPS Final Rules, and 2012 MEDPAR.

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 LTCH-level services required by highly acute beneficiaries. We do not believe that this outcome was the intent of Congress and, as such, the AHA continues our advocacy efforts to refine these criteria.

WEIGHTING OF THE TWO-TIERED PAYMENT SYSTEM

The AHA and partnering associations simulated LTCH PPS weights under the BiBA criteria to assess the merit of setting relative payment weights using all LTCH cases, including the cases that meet the site-neutral definition, versus using only the cases that meet the criteria for a traditional LTCH PPS payment. We then calculated the weights using only the cases that would be paid a traditional LTCH PPS rate. This analysis, as shown in Table 2, 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 only the cases in the traditional LTCH PPS payment tier. The minimal difference in average case weights, 1.1116 (all cases) versus 1.2676 (only traditional LTCH PPS cases) re-emphasizes our 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 LTCH cases from each other. In addition, when looking only at the MS-LTC-DRGs represented by the traditional LTCH PPS cases, the average case weight is extremely similar, 1.2886 versus 1.2676.

Table 2							
	Weights Set Using All LTCH Cases (Incl. Site-Neutral)		Weights Set Using Traditional LTCH PPS Cases Only (Excl. Site-Neutral)				
	All MS-LTC-DRGs	Only MS-LTC- DRGs Used to Pay Traditional LTCH PPS Cases	Only MS-LTC-DRGs Used to Pay Traditional LTCH 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 LTCH PPS cases are highly concentrated in a few MS-LTC-DRGs. In fact, in our simulation, 41 percent of the traditional LTCH PPS cases would fall in only three MS-LTC-DRGs; in contrast, only 28 percent of all cases fall into these MS-LTC-DRGs, as shown in the Table 3. The simulation also shows that the proportion of cases in "novolume MS-LTC-DRGs" would grow considerably – 35 percent of the MS-LTC-DRGs are no-

⁸ The simulation used FY 2014 LTCH 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.

volume DRGs when basing weights on all cases, and this rate increases to 46 percent when using only the traditional LTCH PPS cases. Managing the traditional LTCH 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 LTCH 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.

Table 3						
Top Three MS-LTC-DRGs (by volume)	% of All LTCH Cases	% of All Traditional LTCH PPS Cases (non site-neutral cases)				
207 : Respiratory system diagnosis w ventilator support 96+ hours	11%	20%				
189 : Pulmonary edema & respiratory failure	10%	14%				
871 : Septicemia w/o MV 96+ hours w MCC	6%	7%				
Total (do not add up due to rounding)	28%	41%				

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

The AHA also assessed the impact of using a single high-cost outlier pool for all LTCH cases versus using distinct pools for each level of the two-tiered payment system. Our analysis, based on weights calculated using all LTCH 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 LTCH 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 LTCH 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.

Table 4								
Two-Tiered System (Fully implemented)	One 8% Outlier Pool		Two 8% Outlier Pools					
	Traditional LTCH PPS	Site- Neutral	All Cases	Traditional LTCH PPS	Site- Neutral	All Cases		
Fixed-Loss Threshold	\$37,369		\$17,537	\$70,816				
Outlier %	4.9%	20.4%	8.0%	8.0%	8.0%	8.0%		

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Given that high-severity, high-cost patients are found in both levels of the two-tiered payment system, as discussed above, the AHA 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 LTCH 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 LTCH 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 LTCH 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.

PROPOSED PAYMENT ADJUSTMENT FOR A CANCER LTCH

The BiBA mandated a study of Medicare payment rates and regulations for the sole "cancer LTCH." In addition, the BiBA granted CMS the authority to pay this cancer LCH using a methodology similar to the cost-based rates paid under the Tax Equity and Fiscal Responsibility Act (TEFRA), which was in effect prior to the implementation of the LTCH PPS in FY 2003. In the proposed rule, CMS reviews the findings of its analysis of 2010 Medicare claims data for the cancer LTCH and similar LTCHs. This analysis found that, due to its unique case mix, the cancer LTCH had a negative margin for Medicare patients, which was much lower than that of comparable LTCHs. The regulation also notes that Congress has endorsed the unique clinical role filled by the cancer LTCH through distinct statutory treatment, including the BiBA mandate. Based on this analysis and the BiBA authority, CMS proposes to pay the cancer LTCH a TEFRA-like payment for cost reports beginning on or after Oct. 1, 2014. The AHA supports this proposal. We encourage CMS to grant to the cancer LTCH the same process that allows other TEFRA hospitals to receive an adjustment to their TEFRA rate-of-increase ceiling, which applies when extraordinary circumstances, such as natural disasters, occur, or where a significant rate distortion has occurred since the base cost-reporting period.

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Thank you for the opportunity to comment. If you have any questions about our comments, feel free to contact me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

/s/

Linda E. Fishman Senior Vice President Public Policy Analysis & Development