American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

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

RE: CMS 1588-P: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers, (Vol. 77, No. 92) May 11, 2012.

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2013 proposed rule on the inpatient and long-term care hospital (LTCH) prospective payment systems (PPS). This letter addresses only the LTCH provisions.

While we greatly appreciate several provisions in the rule, such as a delay in full implementation of the "25% Rule" and a three-year phase-in of the so-called "one-time" budget neutrality adjustment, we have strong concerns with several aspects of these changes, as well as other elements of the regulation.

PROPOSED LTCH MARKET BASKET

The AHA supports CMS's proposal to replace the current rehabilitation, psychiatric and long-term care (RPL) market basket with a new LTCH-specific market basket. We agree that the new market basket will more closely align market-basket updates under the LTCH PPS with actual LTCH cost structures, which will produce greater accuracy in aggregate Medicare payments to LTCHs.

PROPOSED 12-MONTH EXTENSION OF 25% RULE RELIEF

The AHA is pleased by CMS's proposal to delay full implementation of the 25% Rule for 12 months. However, we are deeply disappointed that this delay will not take effect for all LTCHs this year. Specifically, under the proposed regulation, relief would not begin for one-third of LTCHs until July 1, 2013, providing relief one year after the 25% Rule takes effect on July 1, 2012 for these facilities.

Background. For LTCH referrals that exceed a specified threshold, the 25% Rule policy reduces the Medicare payment from the LTCH rate to a far lower amount equivalent to an inpatient PPS payment. With this policy, CMS seeks to reduce overall LTCH utilization by reducing LTCH admissions based on the origin of an LTCH referral. However, it completely disregards the patient's medical necessity for LTCH services. In other words, the policy establishes an arbitrary threshold, beyond which LTCHs face a significant payment penalty for admitting patients from a particular referral hospital, regardless of the patient's clinical characteristics. The rule was intended to reduce "inappropriate" admissions to LTCHs; however, the 25% Rule's focus on referral source rather than patient-level clinical criteria means that CMS would reduce LTCH payments for medically appropriate care in the LTCH setting. Currently, the 25% Rule is set at 50 percent for most hospital-within-hospital LTCHs and at 75 percent for other types of LTCHs, such as rural LTCHs, while some LTCHs, such as freestanding LTCHs, are exempt from the policy. CMS, thus far, has not executed the policy by recouping payments for discharges that exceeded an LTCH's 25% Rule threshold.

CMS explains that the proposed 12-month delay is intended to provide the agency with additional time to complete its research on an alternative to the 25% Rule. Accordingly, the proposed rule would allow two-thirds of the field to avoid temporarily transitioning their admissions and operational practices to comply with the fully implemented 25% Rule, requiring modification of these protocols only once under the new, post-25% Rule policy framework to be developed by CMS. **CMS's efforts to smooth the transition from the 25% Rule to a new regulatory policy are commendable, and *all* *LTCHs* should benefit from the transition without having to fully implement the 25% rule**.

CMS's proposal would require that 130 LTCHs fully transition to the onerous 25% Rule for one year, only to have to switch again to their current level under *Medicare, Medicaid and SCHIP Extension Act of 2007 (*MMSEA) and then again to a post-25% Rule regulatory framework. All LTCHs should gain the benefit of the 12-month delay as soon as possible. Below, we describe two approaches that CMS could implement immediately to eliminate the need for a segment of the field to wait until 2013 for relief.

Select a 12-month period not aligned with the cost-reporting period. The proposed rule links the 12-month period of 25% Rule relief to LTCH cost-reporting periods, but there is no need to make this connection. When selecting the 12-month period used by Medicare contractors to assess inpatient rehabilitation facility (IRF) compliance with the policy known as the "60% Rule," CMS did not use IRF cost-reporting periods. Instead, CMS selected a specific 12-month period to align the 60% Rule with its IRF policy and operational goals, without any linkage to cost-reporting cycles.

Separating the 12-month 25% Rule relief period would allow CMS to give the approximately 130 LTCHs that would otherwise have to wait until 2013 relief from full 25% Rule implementation from October 1, 2012 through September 30, 2013. Under this scenario, the 130 LTCHs would technically be subject to the fully implemented 25% Rule for a brief period of up to three months, during which time the AHA would strongly encourage CMS to refrain from enforcing the policy.

Issue an interim final rule. Alternatively, CMS could implement an interim final rule as soon as possible prior to the October 1, 2012 effective date of the final rule for this regulation, which the agency indicates it is seriously considering. Doing so would materially shorten the period under which the 130 LTCHs would technically be subject to the fully implemented 25% Rule. Interim final rules, with few exceptions not applicable here, typically have an effective date of 30 days following issuance. Under this scenario, the 130 LTCHs would technically be subject to the fully implemented 25% Rule for a brief period of time. To treat these LTCHs equitably, the AHA strongly encourages CMS to refrain from enforcing the policy during this gap period.

We see no legal or regulatory impediment to either of these proposed approaches, which could prevent an arbitrary, inequitable and harmful outcome for the subset of LTCHs that remain exposed to adoption of the full 25% Rule, beginning July 1.

ONE-TIME BUDGET NEUTRALITY ADJUSTMENT

The proposed rule includes a 3.75 percent one-time budget neutrality cut to ensure that any overpayment of LTCHs in FY 2003, the first year of the LTCH PPS, is not perpetuated in future years. CMS proposes to implement this 3.75 percent reduction of the LTCH standard rate over three years, beginning in FY 2013. **The AHA is very concerned that the methodology CMS used to calculate FY 2003 overpayments has yielded an erroneous over correction, and we urge CMS to modify its methodology to account for other payment policy changes that have been implemented since 2003. However, the AHA supports and appreciates CMS's proposal to phase-in cuts for the one-time budget neutrality adjustment over a three-year period.**

The proposed rule would implement the 3.75 percent one-time budget neutrality cut over three years, with a 1.266 percent reduction applied in FYs 2013, 2014 and 2015. In FY 2012, the cut would apply only to discharges occurring on or after December 29, 2012, following the expiration of the provision in the MMSEA, which prevented the implementation of this adjustment. In this regulation, CMS proposes the same methodology for the one-time budget neutrality adjustment that was introduced in the rate year (RY) 2009 proposed rule.

CMS's analysis estimates that LTCH PPS payments in FY 2003 were 3.75 percent greater than Medicare would have paid LTCHs under the prior cost-based system, known as TEFRA. To address this overpayment, CMS is using the discretionary authority it established in the FY 2007 rulemaking, the final year of the five-year phase-in of the LTCH PPS, and extended this authority in future rulemaking. CMS has stated that the agency's goal is not to recoup prior

overpayments, but to ensure that any overpayments that occurred in 2003, relative to what TEFRA would have otherwise paid, are not perpetuated in future years.

The proposed 3.75 percent cut is comprised of two parts. First, the 3.75 percent cut includes a 2.5 percent reduction to address CMS's estimated FY 2003 overpayments for cases paid under the LTCH PPS. The proposed cut also includes a 1.25 percent reduction to correct for FY 2003 overpayments for the short-stay outlier payments that were paid based on cost rather than using the LTCH PPS standard rate.

In examining CMS's approach to ensure that any FY 2003 overpayments are not perpetuated in FY 2013 and beyond, the AHA identified an overlooked element of the policy change related to short-stay outliers. Short-stay outlier cases were a significant element of the LTCH PPS in 2003, accounting for 20 percent of LTCH PPS payments and 48 percent of cases. Therefore, they were a significant portion of CMS's estimated 3.75 percent overpayment that year. However, any overpayment for such cases that occurred in 2003 did not continue throughout the entire 10-year period of the LTCH PPS, FYs 2003 through 2012 because CMS corrected the short-stay outlier overpayment in FY 2007 by reducing the payments from 120 percent of cost per case to 100 percent of cost per case. This change has yielded a material reduction in Medicare payments to LTCHs since 2007. We believe that the 2007 payment change for short-stay outlier cases, and the subsequent drop in Medicare payments, has not been properly accounted for in CMS's proposed 3.75 percent cut. This short-stay outlier payment policy correction directly pertains to CMS's current policy goal of preventing the perpetuation of any FY 2003 payment by mitigating, and perhaps eliminating, any perpetuation of overpayment that occurred in FY 2003.

We believe that the 2007 LTCH PPS correction to the short-stay outlier payment policy in FYs 2007 through 2012 offset a significant portion, and perhaps the entire amount, of any FY 2003 overpayment, by correcting a primary source of LTCH PPS overpayments that occurred in 2003. Independent analysis by The Moran Company found that Medicare short-stay outlier payments to LTCHs fell by 3.6 percent in FY 2007 under the new, lower short-stay outlier payment based on 100 percent of cost. This reduction continued in subsequent years, with short-stay outlier payments significantly lowered to 13 percent of LTCH payments in FY 2013, as estimated by CMS in the proposed rule, and short-stay outlier cases dropping to 30 percent of LTCH cases in 2012. The reduction in short-stay outlier payments reduced Medicare payments to LTCHs by approximately $382 million from FYs 2007 through 2012, according to analysis by The Moran Company.

In effect, CMS's correction of short-stay outlier overpayments in 2007 already reduced a significant portion of any perpetuation of overpayments that occurred in FY 2003. It follows that, if CMS had set short-stay outlier payments at 100 percent of cost beginning at the inception of the LTCH PPS, the overpayment that occurred FY 2007 would have been far less.

To accurately achieve its goal of preventing the perpetuation of LTCH payment errors from FY 2003, CMS's proposed budget neutrality adjustment methodology must be revised to account for the payment policy changes that already helped achieve this goal. We urge CMS to recalculate the proposed budget neutrality cut for 2003 payments in a manner that

incorporates the short stay outlier policy that CMS implemented in FY 2007. We believe this recalculation will yield a large reduction in, and perhaps the elimination of, the proposed 3.75 percent cut.

As further support for the need to recalculate the proposed budget neutrality adjustment, we note an additional factor for CMS to consider. As mentioned above, there has been a steady and significant reduction in short-stay outlier cases in the LTCH case mix since FY 2003. As part of its analysis, **The Moran Company replicated the budget neutrality calculation in the proposed rule, making a single adjustment for the reduction of the short-stay outlier population from 48 percent of cases in FY 2003 to 30 percent of cases in FY 2012. Adjusting for solely this factor and the related drop in short-stay outlier payments, Moran's calculation of the budget neutrality adjustment found that the proposed cut overcorrects by 1.0 percent, and should be negative 2.75 percent.** While CMS's omission of the impact on the proposed budget neutrality cut by the 2007 short-stay outlier payment policy change, as discussed above, on its own, warrants a recalculation of the proposed cut, this point separately challenges the accuracy of CMS's proposed 3.75 percent cut.

We urge CMS to recalculate the proposed cut by factoring these LTCH short-stay outlier payment and patient population changes into its analysis. And we urge the agency to fully disclose its re-tooled analyses of the one-time budget neutrality adjustment in the final rule.

VERY SHORT-STAY OUTLIERS

CMS proposes to implement the "very short stay outlier" (VSSO) payment cut for discharges occurring on or after December 29, 2012. This policy was implemented in the Rate Year (RY) 2008 LTCH PPS final rule. It expanded the LTCH SSO policy by providing an additional lower payment option for LTCH cases with the shortest lengths of stay, for discharges on or after July 1, 2007. In MMSEA, and later extended by the *Patient Protection and Affordable Care Act* (ACA), Congress placed a five-year hold on this policy through December 28, 2012.

SSO cases are defined as cases with a length of stay (LOS) up to five-sixths of the LTCH geometric mean length of stay for a particular MS-LTC-DRG. VSSOs are LTCH cases with an LOS that is less than or equal to the average inpatient PPS LOS, plus one standard deviation for the same MS-DRG. SSO cases are paid the lesser of the following option:

- 100 percent of the estimated cost of the case;
- 120 percent of the LTCH-DRG per diem amount multiplied by the covered LOS;
- the full LTCH-DRG; or
- a blend of 120 percent of the LTCH-DRG specific per diem amount and an amount comparable to the inpatient PPS per diem amount.

In the 2008 LTCH PPS rulemaking, CMS added a fifth payment option for VSSO cases, which would typically be the lowest of the five options:

- an amount comparable to the inpatient PPS per diem amount.

CMS estimates that reinstituting the VSSO policy would reduce LTCH payments by approximately 0.4 percent in FY 2013.

The LTCH SSO policy and VSSO policies achieve two goals: they reduce Medicare spending on short-stay cases and they discourage LTCHs from admitting patients who are transferred from general acute hospitals who are expected to stay in the LTCH for a short time. The VSSO policy, which took effect in July 2007, may have seemed to be needed at that point in time. However, since its introduction, as discussed above, the SSO policy, especially under the 2007 payment reduction, has been very effective at reducing the population of short stay cases in LTCHs and overall Medicare payments for short stays. In light of the dramatic reduction of short stay cases under the SSO policy, it appears that the need for an additional disincentive for very short-stay cases has been reduced substantially. **Therefore, the AHA urges CMS to reconsider the merit of the VSSO policy before reinstating a policy that was originally introduced more than five years ago.**

In addition, **the AHA is concerned that this policy would further reduce payments for VSSO cases, even though they have an average level of acuity that is higher than other LTCH cases**. The proposed payment cut from 100 percent of cost under the existing LTCH SSO policy to the lower inpatient PPS-comparable per diem is not warranted given the clinical characteristics of the VSSO population relative to other LTCH patients. Based on 2010 MedPAR data, would-be VSSO cases are more acute and resource intensive than other LTCH cases, with an average case mix index of 1.20, which is notably higher than that of SSO cases at 0.97, and that of all LTCH patients, 1.10. VSSO cases also have a higher average number of secondary diagnoses than SSO cases, 4.5 versus 3.9. In addition, LTCH direct costs per day for proposed VSSO cases was $970 – much higher the $781 than for SSO cases and the $771 for all LTCH cases. **These data showing that the VSSO population is actually sicker than the overall SSO population raise significant concerns about the appropriateness of lowering Medicare payments for this subcategory of SSO cases. The AHA urges CMS to assess patient severity as part of a new evaluation of the current need for the VSSO cut.**

Medicare data on the prior general acute hospital stay for LTCH cases that would have been VSSOs under this regulation demonstrate that a significant portion of these cases were very high resource patients prior to LTCH admission. Data in the 2010 standard analytic file show that of the 117,396 patients transferred from a general acute hospital to an LTCH, 15 percent would have been VSSOs. Among these would-be VSSO cases, 23 percent were subject to the inpatient PPS transfer policy payment cut. This policy reduces payments to the general acute hospital for transfers to discourage the transfer of patients to an LTCH. For this group of LTCH VSSO patients, CMS's concern that a general acute hospital transferred a patient to an LTCH to achieve financial gain is eliminated, given the payment hit taken by the referring hospital *prior to* transfer. The primary motive for this category of transfers is the patient's need for the specialized medical services and personnel in an LTCH. Data on an additional subgroup of would-be LTCH VSSO cases, the 17 percent of cases that received an inpatient PPS high-cost outlier payment, identify additional VSSO cases that were also unusually high resource cases.

CMS has already acknowledged that LTCH cases that were high-cost outliers in the prior hospital stay are worthy of special consideration by carving these cases out of the LTCH 25% Rule. **Both the inpatient PPS outlier and transfer data validate that VSSO cases are often high-acuity cases that, despite their shorter length of stay in the LTCH, need LTCH-level services. These data raise serious questions about the need for reinstating the VSSO payment disincentive for all LTCH cases with the shortest lengths of stay, rather than continuing to rely on a single, highly effective policy – the current SSO policy.**

Based on these concerns, the AHA believes it is inappropriate for CMS to implement a further disincentive for short-stay cases through the VSSO policy based on the outdated rationale in the RY 2008 proposed rule. Rather, the AHA urges CMS to <u>first</u> complete a comprehensive re-evaluation of the VSSO policy, given that the need for this policy seems to no longer exist. Proceeding with implementation of the VSSO cut at this time is unjustified, especially given that this group of short-stay cases is sicker than other LTCH cases.

LTCH QUALITY REPORTING

The ACA mandated reporting of quality measures to begin no later than FY 2014. Failure to report quality measures LTCHs will subject LTCHs to a 2 percent reduction to their annual market-basket updates. In the FY 2012 inpatient PPS final rule, CMS finalized three measures for the FY 2014 LTCH Quality Reporting (LTCHQR) program. This year, CMS proposes to include the three previously finalized measures for FY 2015 and beyond. CMS also proposes five new measures for the FY 2016 program. For the majority of measures proposed for the LTCHQR program, CMS also proposes to require submission of a "LTCH CARE data set." However, CMS failed to include any specifics on the LTCH CARE data set in this or prior rules. **The AHA is very concerned about the proposed requirement for the submission of a LTCH CARE data set and the substance of what may be required; details have been released only informally and without stakeholder input**.

<u>Need for an assessment tool for LTCHs</u>. The AHA urges CMS to develop an assessment tool specifically for LTCHs that would enable a thorough understanding of the severity of patients treated in LTCHs. **We do not believe an appropriate assessment tool currently exists for LTCHs. We also do not believe the LTCHQR program is the appropriate context for developing a tool or adequate justification for requiring use of an assessment tool.**

The LTCH benefit is a very important post-acute setting of care for severely ill patients, yet we are limited in truly understanding the full benefit LTCHs provide because, unlike all other post-acute care settings, there is no assessment tool required for LTCHs. We share CMS's desire for an LTCH assessment tool. However we are concerned that CMS is prematurely pushing a tool (the "CARE tool") that has been used only in a demonstration program and not sufficiently tested and validated as the preferred assessment tool for LTCHs.

The *Deficit Reduction Act of 2005* mandated a Post-Acute Care Payment Reform Demonstration (PAC-PRD). As part of the implementation of the PAC-PRD, CMS developed the CARE tool, which it piloted with several inpatient acute hospitals and post-acute providers, including 28

LTCHs. We submitted a lengthy list of problems (http://www.aha.org/advocacy-issues/letter/2011/110620-cl-fy12prpltachpps.pdf) that our members identified with the CARE tool. That list is still valid. While the CARE Tool may be a starting point for a discussion about an LTCH assessment tool, it should not be used in its current form. It would need significant streamlining, and would benefit from public input.

Implementation of the statute. Requiring LTCHs to submit an assessment tool goes beyond what the statute requires and Congress intended. Section 3004 of the ACA requires "each long-term care hospital to submit to the Secretary **data on quality measures**" (emphasis added). In the FY 2012 inpatient PPS final rule, CMS finalized three measures for reporting on discharges beginning on October 1. Throughout the rulemaking, CMS stated it would require submission of a "subset" of the CARE tool to populate a pressure ulcer measure in the LTCHQR program. While CMS finalized this requirement without providing any detail to the public on what the "subset" included, the CARE tool has a subset of requirements for "skin conditions" pertaining to classifying pressure ulcers. After the final rule was issued, CMS subsequently released the details of what information it intended to collect as part of its *Paperwork Reduction Act* (PRA) submission (September 2, 2011). Upon reviewing the PRA package, it appears that the so-called "subset" is actually the entire CARE tool, in addition to a new data requirement for pressure ulcers.

Requiring the entire CARE tool forces LTCHs to submit data to CMS that goes well beyond the scope of "quality measures." For example, LTCHs would be required to submit: (1) the highest level of schooling achieved; (2) race/ethnicity; (3) therapy information; (4) neurologic information; (5) dietary/nutrition information; (6) marital status; and (7) occupation for every patient treated in a LTCH. None of these seven factors is needed to populate the pressure ulcer measure, nor are they included as data elements in the National Quality Forum- (NQF) endorsed measure for pressure ulcers. These data are intended for research purposes, rather than for reporting quality measures.

We urge CMS to clarify that only the pressure ulcer-specific data items in the CARE tool will be required for reporting. The definition of "LTCH CARE data set" should include only those data elements needed to populate the pressure ulcer measure. Requiring more goes beyond what Congress directed for quality measure reporting.

LTCH CARE data set concerns. **We urge CMS to delay submission of the LTCH CARE data set because LTCHs have been given insufficient time to prepare.** We have heard from several of our LTCH members that they have not had enough lead time to begin reporting using the LTCH CARE data set for discharges beginning on October 1. In the FY 2012 inpatient PPS final rule, CMS stated that it intended to release the detailed specifications for the LTCH CARE data set no later than January 31, 2012. However, CMS did not release the data set until April 27, 2012. Unfortunately CMS's delay of over a full calendar quarter also has delayed the state of readiness for LTCHs. In addition, CMS held a LTCHQR program training on May 1. This meeting marked the first formal opportunity to communicate the details of the LTCHQR program to the public – giving LTCHs less than six months' advance notice on the detailed data elements that must be submitted before the program begins.

Conflicting information regarding the data reporting period and submission deadline for the LTCH CARE data set for FY 2014. In the FY 2013 inpatient PPS proposed rule, CMS indicates that it previously finalized a data collection period of October 1 – December 31, 2012, with data due no later than May 15, 2013 for all of the finalized measures. We believe this statement is incorrect. CMS only finalized this time period for the infection measures (76 FR 51753). **CMS has never proposed or finalized a data reporting period or submission deadline for the pressure ulcer measure for the FY 2014 LTCHQR program**. The data reporting period and submission deadline have been communicated to LTCHs only through sub-regulatory requirements. In addition, CMS included only preamble language in the FY 2012 inpatient PPS final rule – there is no regulatory requirement for submission of the LTCH CARE data set. If CMS believes it has required data reporting and submission of the LTCH CARE data set for FY 2014 in regulation, we urge the agency to provide a citation of this requirement in the FY 2013 inpatient PPS final rule.

Improper notice regarding the data submission method for the LTCH CARE data set for FY 2014. CMS has not articulated any details in regulation regarding the submission method of the LTCH CARE data set. CMS has a long history of proposing requirements to: register for a quality reporting program; designate an Administrator; complete a Notice of Participation; allow for a review process once data have been submitted; acknowledge data accuracy and completeness (annual); and allow for appeal. CMS has articulated all of these requirements for every quality program, with the exception of the LTCHQR program. For example, in this proposed rule, CMS makes proposals for these requirements for the Psychiatric Quality Reporting Program (77 FR 28112 through 28115) and the Cancer Quality Reporting Program (77 FR 28067 through 28068). The LTCHQR program does not include similar proposals.

In our review of the documents CMS made available on April 27, chapter four of the LTCH CARE data set manual requirements seems to require LTCHs to submit data to CMS's Quality Improvement Evaluation System (QIES) and Assessment Submission and Processing (ASAP) System. For all other quality reporting programs, CMS has proposed such data submission methods through regulation. **We urge CMS to propose use of the QIES and ASAP systems through the regulatory process, not through a sub-regulatory mechanism.** Until CMS has done so, it has failed to provide the public with a proper notice and comment period. We have a number of outstanding concerns with the QIES and ASAP modules, including whether they have been pilot tested, the overall burden of reporting into the systems, and whether the systems have been validated.

In addition to the QIES and ASAP requirements, CMS's sub-regulatory manual requires collection of the LTCH CARE data set by a provider with an educational background of a registered nurse or higher. This requirement is totally inappropriate. In the history of quality reporting programs, CMS has never dictated the level of education a provider must have to collect quality data. This overly burdensome requirement is unjustified. Further, it is inappropriate to make such a labor-intensive requirement outside of the regulatory process. **The AHA urges CMS to immediately reverse its decision to require data collection by a provider with an educational background of a registered nurse or higher**.

Data collection for FY 2014. The AHA supports CMS's proposals for FY 2014 data collection for the infection measures; however, we do not support CMS's proposals for FY 2014 data collection of the pressure ulcer measure. Last year, CMS finalized collection and submission of the infection measures through the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) and submission of the pressure ulcer measure through a "subset of the CARE tool." This year, CMS proposes to use the same data collection tools, previously finalized, for FY 2014 and subsequent fiscal years. We do believe that the NHSN system will be ready for reporting of the infection measures. However, we do not feel that the LTCH CARE data set will be ready, for all of the reasons stated above.

Measures proposed for FY 2015. We support including the infection measures in the FY 2015 program; however, we do not support including the pressure ulcer measures in the FY 2015 program. The NHSN system is fully functional, and inpatient acute hospitals have been submitting data into NHSN under a federal mandate since January 2011. Although, we still have concerns regarding the validation of the infection measures (http://www.aha.org/advocacy-issues/letter/2012/120619-cl-ipps.pdf), we believe it is important to move forward with these infection measures in the LTCHQR program.

While the AHA agrees that a pressure ulcer measure would be a highly relevant measure for the LTCH patient population, the problems we stated above regarding the LTCH CARE data set would compromise collection of data for the pressure ulcer measure for the FY 2015 program. We also are concerned about the technical merits of the pressure ulcer measure. In the proposed rule, CMS indicates that the pressure ulcer measure, which is only NQF-endorsed for the nursing home setting, will be undergoing a review to expand the scope of the measure to the LTCH setting. CMS does not provide any additional detail on this process. There is no link to any NQF documents, nor is there a link to detailed measure specifications on what LTCHs are required to submit in order to populate this measure. The public has not been given proper notice on how this measure is defined and, therefore, is unable to provide meaningful comment to CMS on the merit of this measure. An important part of the NQF endorsement process is demonstration of sufficient measure testing. Since CMS has failed to pilot test the LTCH CARE data set as a collection instrument, it is unlikely that the pressure ulcer would receive NQF-endorsement for expansion to the LTCH setting.

Data collection for FY 2015. We support CMS's proposals for FY 2015 data collection for the infection measures; however, we do not support CMS's proposals for FY 2015 data collection of the pressure ulcer measure. For the reasons above, we feel the infection measures should be included in the LTCHQR program for FY 2015. However, since we do not support including the pressure ulcer measure in the LTCHQR program for FY 2014, we also do not support the proposals for its data collection in FY 2015.

Measures proposed for FY 2016. We support including the health care worker vaccination measure in the FY 2016 program; however, because the LTCH CARE data set would be the collection tool, we do not support including patient flu and pneumonia vaccination, ventilator bundle and restraint per 1,000 patient days measures in the FY 2016 program.

The majority of these measures would be reported for discharges beginning January 2014 through the LTCH CARE data set.

Influenza vaccination coverage among health care personnel. **We support including the influenza vaccination coverage among health care personnel measure in the LTCHQR program.** This measure captures the total percentage of health care personnel who receive the influenza vaccination and has been finalized for the inpatient quality reporting (IQR) program (reporting begins January 2013). We did not support including this measure in the IQR program in response to last year's inpatient PPS proposal, in part, because the measure was still being tested and had not completed the NQF endorsement process. Since then, CDC has completed testing and this measure is now NQF-endorsed.

Influenza and pneumonia vaccination measures. **We do not support including the influenza and pneumonia measures in the LTCHQR program**. These measures capture the total percentage of patients who were appropriately given a seasonal influenza or pneumococcal vaccine. Both of these measures were finalized in the IQR program (reporting begins January 2012). **We are concerned that CMS has missed an important connection between the IQR and the LTCHQR programs.** Approximately 83 percent of LTACH fee-for-service (FFS) discharges for FY 2011 had a preceding inpatient stay or was transferred from an inpatient facility. Therefore, nearly 83 percent of Medicare patients treated in LTCHs already will have been vaccinated in the inpatient acute setting prior to their LTCH stay. We are concerned that requiring these vaccination measures in LTCHs will lead to over-vaccination of patients who already have been vaccinated. Not only is this a waste of resources, it is a significant safety concern.

Ventilator bundle. **While the AHA supports the inclusion of a quality measure on ventilator services, we do not support including the proposed ventilator bundle in the LTCHQR program until it has undergone pending maintenance endorsement by the NQF.** The proposed measure consists of four components: 1) elevation of the head of patient's bed (≥ 30 degrees); 2) daily sedation interruption and assessment of readiness to wean; 3) peptic ulcer disease prophylaxis; and 4) deep vein thrombosis prophylaxis. This measure was originally NQF-endorsed specifically for intensive care unit (ICU) patients in acute care hospitals, and CMS states in the proposed rule that the measure is undergoing maintenance review at the NQF. CMS provides a link to the NQF patient safety complications project in the proposed rule. However, the ventilator bundle measure is not being reviewed under that project. We have contacted the NQF and have found that the ventilator bundle measure is scheduled to undergo maintenance review under the infectious disease project. That project has not yet begun, meaning it will be several months before this measure completes the NQF process. Because it is essential to complete review of this measure, and the NQF review process is not complete, we are unable to support this measure at this time. Further, many of our members are concerned that including this process of care ventilator measure will be a step backward for those hospitals that already have the robust outcomes infection-related measures that LTCHs are commonly using today. We encourage CMS to pursue outcome-based measures.

Restraint rate per 1,000 patient days. **We do not support use of the restraint per 1,000 patient days measures in the LTCHQR program.** This measure captures the rate of patients in restraint for every 1,000 patient days. This measure is not NQF-endorsed. We are concerned that this measure has never been tested in the LTCH setting, nor any other setting of care. We also are concerned that this measure is not harmonized with the hours of physical restraint use measure that is proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program. It is illogical that CMS would use two completely different measures that essentially measure the same outcome in two of its quality reporting programs.

Insufficient consideration of recommendations from the Measure Application Partnership (MAP). **We urge CMS to more stringently align its proposal in the final rule with the 2012 recommendations made by the MAP.** The MAP is a multi-stakeholder board charged with making annual recommendations to the Secretary regarding which measures should be included in national quality reporting programs. The MAP was mandated by the ACA and functions under appropriated dollars from the Department of Health and Human Services (HHS). It conducted a review of measures from HHS in early 2012, including all of the measures proposed for the FY 2016 LTCHQR program. The MAP did not recommend any of the five measures that CMS has proposed. Rather, the MAP only "supported the direction" of these measures – meaning the MAP felt the measures were not ready for implementation in the LTCHQR program.

Data collection for FY 2016. We support CMS's proposals for FY 2016 data collection for the NHSN measures; however, we do not support CMS's proposals for FY 2016 data collection for the LTCH CARE data set measures. The NHSN data collection for the Central Line-associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures will be a continuation of a proven data collection process for FY 2016. Also, reporting of the health care worker vaccination measure in the LTCHQR program will follow after a proven process has been developed for reporting the same measure by all inpatient acute hospitals. However, the same level of confidence cannot be afforded to data collection through the LTCH CARE data set.

Improper notice regarding how the FY 2016 LTCH CARE data set measures will be reported. CMS does not provide any detail on how the influenza and pneumonia vaccination measures, ventilator bundle and restraint measures would be reported. In the proposed rule, CMS states that it has not yet completed development of the data set and that since the forms are still under development, it cannot provide a burden estimate for data submission of these measures. CMS states that it will prepare a PRA package for these measures in the future. **Making a PRA package available after measures have already been finalized does not afford the public adequate notice.** The process CMS underwent last year by finalizing the pressure ulcer measure before the PRA package was released is unacceptable; CMS should not repeat that process in this rulemaking cycle. We urge CMS to refrain from finalizing any data collection requirements when it has not fully developed or disclosed those requirements to the public.

Process for retention of LTCHQR measures. We do not support CMS's proposal to automatically adopt measures for all subsequent payment determinations unless the

measures are proposed for removal, suspension or replacement. Quality measurement is an evolving process and measures can and do change from year-to-year. What may be the standard of care in one year may not be the standard in subsequent years.

Estimate of burden. We are concerned that CMS is underestimating the overall burden the LTCHQR program will have on LTCHs. CMS provides estimates of what it believes the burden will be for submitting the NHSN measures. However, CMS does not provide any data on what the burden will be for the submission of the LTCH CARE data set. The PRA package that CMS released in September, 2011 indicates that CMS estimates each LTCH will devote 50 hours annually to submission of the pressure ulcer measure. This 50-hour estimate assumes an assessment takes approximately 20 minutes per patient. However, several of our members believe it will take a minimum of two hours per patient to complete an assessment. Further, our members anticipate needing to devote a minimum of one full-time employee to collect the LTCHQR program data.

In this proposed rule, CMS states that it does not anticipate the burden of adding four new measures that would be submitted through the LTCH CARE data set to be burdensome because the new measures will be built on the preexisting tool that was developed for the pressure ulcer measure. However, this assumption is incorrect because CMS improperly estimated the initial pressure ulcer measure burden. It is unfair to the public to finalize measures when a proper estimate of burden is not fully disclosed.

We appreciate your consideration of our recommendations. If you have any questions, please contact me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320, or rarchuleta@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President