Submitted Electronically

June 20, 2011

Donald Berwick, M.D., M.P.P.
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–1518–P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations – including approximately 250 long-term care hospitals (LTCH) – and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the LTCH provisions in the Centers for Medicare & Medicaid Services’ (CMS) fiscal year (FY) 2012 inpatient prospective payment system (PPS) proposed rule. Our comments on the proposed changes to the inpatient PPS were submitted separately.

LTCH PPS UPDATE
The AHA supports CMS’ proposal to update the LTCH PPS without including an adjustment for documentation and coding. As CMS discussed, when the Medicare Severity Long Term Care Diagnosis Related Groups (MS-LTC-DRG) were implemented, for the vast majority of cases, LTCHs had either no opportunity or little reason to revise coding.

PROPOSED MODIFICATIONS TO THE AVERAGE LENGTH OF STAY REQUIREMENT
LTCHs are required to have an average length of stay (ALOS) greater than 25 days.
Under the proposed rule, CMS clarifies that both fee-for-service and Medicare Advantage (MA) days in a LTCH will be included in the calculation of a hospital’s ALOS for the purpose of assessing compliance with the 25-day requirement. However, the proposed rule does not specify the effective date for this policy change. We urge the agency to clarify the date on which MA days will be included in the LTCH ALOS calculation, which should be no earlier than October 1, 2011.

**PROPOSED REBASING AND REVISING OF THE RPL MARKET BASKET**

The AHA supports CMS’ work to rebase and revise the market basket used for inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs) and LTCHs, known as the RPL market basket. The AHA supports updating the market basket using 2008 cost reports. In addition, we urge CMS to continue its research to develop a market basket that is distinct to the LTCH PPS and that recognizes the differences between LTCHs compared to IRFs and IPFs.

**PROPOSED LTCH QUALITY MEASURES**

*The Patient Protection and Affordable Care Act* (ACA) requires CMS to establish a quality reporting program for the LTCH PPS. The ACA mandates that CMS publish LTCH quality measures by October 1, 2012 and beginning October 1, 2013, apply a 2.0 percent payment reduction to LTCHs that fail to report quality data. In this proposed regulation, CMS initiates the process of implementing a LTCH pay-for-reporting program one year before it is required to do so, and we appreciate the agency’s eagerness to share its thoughts about what measures it will use as early as possible. The agency proposes to publish three quality measures by October 2011 and to initiate data collection for the fourth quarter of 2012. Under this proposal, the penalty for non-reporting would begin October 1, 2013, which matches the ACA schedule.

We urge CMS to engage the LTCH field on a regular basis throughout the process of identifying measures that are specific to the high-acuity, long-stay population treated in LTCHs. As such, we urge the agency to carefully study and confirm measures that fit the LTCH case-mix.

In this regulation, CMS proposes three LTCH quality measures:

- **Catheter-associated urinary tract infections (CAUTI)** rate per 1,000 urinary catheter days for intensive care unit (ICU) patients;
- **Central line-associated bloodstream infections (CLABSI)** rate per 1,000 central line days; and
- **Pressure ulcers that are new or have worsened.** This measure captures the percentage of patients with one or more Stage II through IV pressure ulcers that occurred since LTCH admission or worsened since a previous LTCH assessment.

Below, we make recommendations in two overarching areas that apply to all of the proposed measures, including the application of a present on admission (POA) indicator
and LTCH-specific quality measures. We then make specific recommendations to the
individually proposed measures.

POA Indicator. **We urge CMS to begin collecting POA information from LTCHs.** In
considering all of these measures, CMS needs to pay particular attention to how it will
identify whether the infection or pressure ulcer developed after the patient was admitted
to the LTCH or was present on admission. It is not uncommon for patients to be admitted
to LTCHs with central lines, urinary tract catheters, or skin integrity issues. The absence
of a POA indicator may result in incorrect tallies. We recommend that CMS pursue the
timeline and implementation plan for a POA indicator in the LTCH setting that was used
for the inpatient PPS setting. This must be done prior to finalizing these proposed LTCH
measures.

LTCH-specific quality measures. **We urge CMS to use only quality measures that
have been tested for use specifically in the LTCH setting.** CMS is correct in
recognizing that CAUTI, CLABSI and pressure ulcers are important harms that could
occur to the patients in LTCHs. However, the measures that currently exist and that are
proposed to be used in LTCHs were written for use in the intensive care units of acute
care hospitals. None of the quality measures proposed by CMS are specified for the
LTCH setting. LTCH patients have a far higher level of medical complexity than the
patients treated in general acute hospitals, as indicated by the level of MS-LTC-DRG
complicating conditions and co-morbidities and major complicating conditions and co-
morbidities as compared to inpatient PPS. **We urge CMS to work with the Centers for
Disease Control and Prevention (CDC) to refine the CLABSI and CAUTI measures
for use in LTCHs and subsequently seek National Quality Forum (NQF)
endorsement through a LTCH steering committee.** We believe that because the basic
construct for the measures already exists, the modifications and testing that may be
needed to ensure the measures are appropriately specified for use in the LTCH setting is
relatively easy and doable within the time frame available before the data collection must
begin.

Because the measures have not been tested in the LTCH setting, we believe finalizing
these measures is premature. Fortunately, since the measures are basically sound and
possible adjustment of the specifications for the LTCH setting is a more modest task than
developing entirely new measures, we believe CMS can easily engage in the work that
needs to be done on these measures and then finalize the tested version next year. By
indicating in this year’s final rule that it intends to engage in the needed testing and
potential revisions, and then adopt the revised measures in next year’s rule, CMS will
send a strong signal to the field about its intent to make CAUTI and CLABSI data
publicly available, even while it works to ensure the measures will yield reliable and
comparable data.

We further note that the CDC CLABSI measure was implemented for inpatient PPS
national reporting in calendar year (CY) 2011 and CAUTI is scheduled for national
reporting in CY 2012. We have expressed many concerns regarding the capacity of
CDC’s National Healthcare Safety Network (NHSN), the system in which inpatient PPS hospitals submit the CLABSI measure, to support all of the data collection activities being asked of it. The influx of inpatient PPS data represents a significant new burden on the system, and we are still unsure if the system is able to handle it. In another year, the capacity of the system will be tested again with the influx of inpatient PPS CAUTI data. To add to that, the need for an additional set of hospitals, the LTCHs, to register, learn how to use NHSN, and begin reporting data, may be well beyond the scope of NHSN to handle. These changes are significant enough to justify a delay for finalizing the LTCH measures until CMS and CDC are sure the NHSN system can handle additional provider types and CDC’s technical assistance personnel are prepared to provide the assistance that will be needed by these systems that have never before worked with NHSN. By delaying the selection of the CAUTI and CLABSI measures until October 2012, CMS will still comply with the ACA deadline while also having an expanded window during which the NHSN system can be modified to accept data from additional provider types.

In addition, in the fall of 2010, the NQF launched a patient safety steering committee to do a maintenance review of the CDC’s measures. Once a measure is endorsed, the NQF will typically review a measure approximately every three years. When the NQF launched the patient safety committee, another measure developer, the National Surgical Quality Improvement Program (NSQIP) also submitted measures for urinary tract infections. The NSQIP measure is a competitor to the CDC’s CAUTI measure, as both measures pertain to the same population and the same infections. Many stakeholders responded and urged the NQF to select only one best in class measure pertaining to urinary tract infections. The NQF board of directors determined that a best in class decision was appropriate, meaning the NQF would be endorsing either the CDC measure or the NSQIP measure, but not both measures. No decision has been made for these measures, and therefore, the state of endorsement remains in flux. Until NQF makes its final decision, we cannot be sure that the CDC measures will remain NQF-endorsed. We, therefore, urge CMS to delay implementation of these measures for one year. We encourage CMS to partner with NQF, under its funding mechanism through section 1890A of the ACA, to finalize this patient safety steering committee work.

We recommend that CMS partner with NQF to pursue a LTCH quality measure endorsement and recommend that CMS implement a POA indicator to identify complications that occur outside of the LTCH setting. We recommend that CMS and CDC transition data reporting to NHSN by bringing all inpatient PPS hospitals on board first, followed by LTCHs and other types of hospitals. Finally, we urge CMS to closely monitor the progress of the NQF maintenance review for CLABSI and CAUTI. Because these issues must be addressed prior to selecting the CLABSI and CAUTI measures, we recommend a one-year delay before these measures are finalized in the LTCH pay-for-reporting program.

Pressure ulcers that are new or have worsened. Like the CLABSI and CAUTI measures, the proposed pressure ulcer measure is not specified for the LTCH setting. CMS proposed a pressure ulcer measure specified and NQF-endorsed for use in nursing homes.
While using a measure of pressure ulcers may be appropriate for inclusion in CMS’ LTCH pay-for-reporting program, the nursing home pressure ulcer measure is not appropriate for the LTCH setting. Nursing homes are a vastly different setting of care from LTCHs. LTCH patients require hospital-level, physician-led post-acute care, while nursing home patients have far lower medical-acuity and resource use. We urge CMS to work with the measure developer to refine the pressure ulcer measure for use in LTCHs and subsequently seek NQF endorsement through a LTCH steering committee.

Beyond the overarching concerns described above, we also are concerned about the definition of “have worsened” and how data will be collected to populate the measure. We urge CMS to delay implementation of the LTCH pressure ulcer measure until the numerator can be better specified by eliminating the component intended to capture wounds that “have worsened.” Staging wounds is a difficult and often subjective process that produces variable results. In addition, the proposed measure doesn’t define “worsened,” which will further heighten the unreliability of data findings for this measure.

We also suggest that CMS harmonize the LTCH and inpatient PPS versions of the pressure ulcer measures so that both capture the same range of wound staging. While the LTCH proposal includes wound Stages II through IV, the inpatient PPS measure only includes Stages III and IV. Such alignment would facilitate cross-site data comparisons that would be helpful for policy work to improve transitions of care, reduce preventable readmissions and related delivery system reforms.

CMS proposes to collect the data for populating the pressure ulcer measure based on the post-acute assessment instrument known as the Continuity Assessment Record & Evaluation (CARE) tool, which is currently under development through a CMS demonstration. As noted in the proposed rule, the demonstration involved a limited sample (28) of LTCHs. The regulation also notes that CMS has not yet completed development of the instrument. Further, CMS is scheduled in the near future to send a report to Congress, which stakeholders have been awaiting for some time, on the progress of the CARE tool. Once this information is made public, LTCHs and other interested stakeholders will be able to comment in an informed and thoughtful way on the proposal to use such data elements to calculate quality metrics.

Several key steps must occur before CMS proceeds with requiring the CARE tool as part of the quality data collection strategy. The use of the CARE tool for the purpose of submitting quality data for public reporting has not been reviewed by the NQF, which is an essential step before finalizing the pressure ulcer measure for LTCHs. Further, the proposed rule requests public comment on the use of the CARE tool components without providing any measure specifications, which stakeholders need to review in order to provide meaningful input. While the policy intent of the CARE tool may be appropriate and valuable, it is premature for the agency to treat the incomplete tool as a data submission instrument.
In April 2011, the AHA hosted a teleconference with a cross-section of organizations that participated in the Post-Acute Care Payment Reform Demonstration (PAC-PRD). Approximately 70 organizations participated in this meeting and participants raised the following concerns:

- Most sites reported that inter-rater reliability was not conducted in their facility.
- The tool does not adequately capture the clinical status of medically complex patients – especially the lack of stability for high severity of illness patients, which is typically associated with hospital-level post-acute patients.
- By providing an assessment of the patient at a fixed point in time, the tool is not able to capture fluctuations in clinical status, which are common for hospital-level, post-acute patients. Due to this shortcoming, the clinical snapshots produced by the tool may not be representative of the patient’s overall level of acuity – and the resources provided to the patient’s care – during the stay.
- For medically complex patients, the post-acute admission assessment does not capture all pertinent information that describes the acuity of the patient since the CARE tool assessment is completed prior to the completion of the patient’s evaluation by the physician and medical team, including laboratory tests.
- The tool does not capture all medications needed for high-acuity patients.
- The tool does not capture all physician care, such as care provided by consulting specialists, and physician time needed to adapt patients’ medications.

We urge CMS to implement a POA indicator to identify complications that occur outside of the LTCH setting. In addition, CMS should work with the measure developer to remove the “have worsened” aspect of the pressure ulcer measure and the agency should continue its evaluation of the CARE tool and make any necessary changes. Finally, we recommend that CMS work with a measure developer to create measure specifications to populate the pressure ulcer measure. Because these issues must be addressed prior to selecting the pressure measure and will likely be a multi-year effort, we recommend that CMS indefinitely delay implementation of the pressure ulcer measure.

Future Measure Considerations. In addition to the three measures proposed, CMS is also soliciting comments on a list of additional measures it is considering for future years of the program. Among the measures listed, we encourage CMS to consider measures in the areas of ventilator care and readmissions. The AHA fully supports efforts to reduce and measure readmission rates. However, our research has indicated that the causes of readmissions are complex and there are no shelf-ready solutions that can be applied globally to reduce all readmissions. We have found that concentrating on specific groups of patients with a common diagnosis, such as congestive heart failure, has yielded positive results. As such, we support including condition-specific readmission measures that pertain to unplanned, related readmissions.
Thank you for your consideration of our comments. If you have any questions, please contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President