

*Submitted Electronically*

June 21, 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-1349-P; Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Fiscal Year 2012; Changes in Size and Square Footage of Inpatient Rehabilitation Units and Inpatient Psychiatric Units; Proposed Rule***

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations – including approximately 1,000 inpatient rehabilitation facilities (IRF) – 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) 2012 proposed rule for the IRF prospective payment system (PPS).

### **PROPOSED FACILITY-LEVEL ADJUSTMENTS**

The proposed rule modifies the IRF PPS rural, low-income patient (LIP) and teaching-status adjustments. The current method for updating these adjustments is based on a three-year moving average of claims and cost report data. CMS uses a three-year rolling average to update the adjustments to provide year-to-year stability in Medicare payments; however, annual fluctuations in these adjustments do occur.

CMS believes that the current weighted regression methodology assigns greater weight to some facilities and, in effect, exaggerates the differences among different types of IRFs. As a result, CMS proposes to assign equal weight to all IRFs in the regression analysis used to estimate the IRF facility-level adjustment factors. CMS asserts that the primary



effect of the proposed change in methodology is to stabilize the facility-level adjustment factors over time and provide greater year-to-year stability in payments.

However, the proposed change would cause substantial swings in the three facility adjustments and raises concerns that CMS is creating even more volatility than the current annual fluctuations. As a result of the proposed change, the LIP adjustment would be reduced 59 percent, the teaching adjustment by 29 percent and the rural adjustment would be increased 18.7 percent. The AHA is very concerned about the potential impact of this change and our concerns are heightened due to the fact that CMS has not released sufficient data for stakeholders to duplicate CMS' analysis or model other alternatives.

**The AHA urges CMS to release the full set of data needed to model the impact of the proposals. We recommend that CMS delay changes until all needed information is available to the field and other viable reasons for volatility are tested or identified. Additionally, given the significant impact on some hospitals and units, we recommend that CMS use a transition now or in future rulemaking for hospitals and units that see reductions.**

#### **PROPOSED CHANGES TO IRF CLASSIFICATION CRITERIA**

**The AHA urges CMS not to use duplicative patient-level requirements as facility criteria.** At a minimum, CMS should restate its prior position that patient criteria are not to be used as a basis to declassify an IRF.

CMS proposes to revise and consolidate regulations regarding the criteria used to determine whether a provider is appropriately classified as an IRF, and can participate in the IRF PPS. CMS proposes to use selected aspects of current coverage and patient medical necessity criteria as facility classification criteria.

These patient criteria already are applied on a case-specific basis for patients admitted to IRFs and serve to demonstrate the individual patient's appropriateness to receive care in that setting. The addition of these patient-level requirements to unit classification criteria is unnecessary and confusing.

#### **PROPOSED IRF QUALITY MEASURES**

*The Patient Protection and Affordable Care Act (ACA)* requires CMS to establish a quality reporting program for the IRF PPS. The ACA mandates that CMS publish IRF quality measures by October 1, 2012 and, beginning October 1, 2013, apply a 2.0 percent payment reduction to IRFs that fail to report quality data. In this proposed regulation, CMS initiates the process of implementing an IRF 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 two 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 IRF field on a regular basis throughout the process of identifying measures that are specific to the patients treated in IRFs. As such, we urge the agency to carefully study and confirm measures that fit the IRF case mix.

In this regulation, CMS proposes two IRF quality measures:

- Catheter-associated urinary tract infections (CAUTI) rate per 1,000 urinary catheter days for intensive care unit (ICU) patients; 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 IRF admission or worsened since a previous IRF assessment.

Below, we make recommendations for the use of a present on admission (POA) indicator and the need for IRF-specific quality measures. We then make specific recommendations on the individually proposed measures.

***POA indicator.*** **We urge CMS to begin collecting POA information from IRFs.** In considering 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 IRF or whether it was POA. It is not uncommon for patients to be admitted to IRFs with 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 that was used for the inpatient PPS setting for a POA indicator in the IRF setting. This must be done prior to finalizing these proposed IRF measures.

***IRF-specific quality measures.*** **We urge CMS to use only quality measures that have been tested for use specifically in the IRF setting.** CMS is correct in recognizing that CAUTI and pressure ulcers are important harms that could occur to the patients in IRFs. However, the CAUTI measure that is proposed to be used in IRFs was written for use in the intensive care units of acute care hospitals. None of the quality measures proposed by CMS are specified for the IRF setting. IRF 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 CAUTI measure for use in IRFs and subsequently seek National Quality Forum (NQF) endorsement through an IRF steering committee.** We believe that because the basic construct for the measure already exists, the modifications and testing that may be needed to ensure the measure is appropriately specified for use in the IRF setting is relatively easy and doable within the time frame available before the data collection must begin.

Because the CAUTI measure has not been tested in the IRF setting, we believe finalizing the measure is premature. Fortunately, since the measure is basically sound and possible adjustment of the specifications for the IRF setting is a more modest task than developing an entirely new measure, we believe CMS can easily engage in the work that needs to be done on the CAUTI measure 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 measure in next year's rule, CMS will send a strong signal to the field about its intent to make CAUTI data publicly available, even while it works to ensure the measure will yield reliable and comparable data.

Further, we have expressed many concerns regarding the capacity of CDC's National Healthcare Safety Network (NHSN), the system in which CMS proposes to collect IRF data to populate the CAUTI measure. Approximately 4,000 inpatient PPS hospitals are required to report a blood stream infection measure to the NHSN this calendar year (data are due Aug. 15) and the CAUTI measure in calendar year 2012. The influx of inpatient PPS data represents a significant new burden on the system, and we are still unsure if the system will be able to handle it. That an additional set of hospitals, IRFs, will need to register, learn how to use NHSN and begin reporting data, may be well beyond the scope of NHSN. These changes are significant enough to justify a delay for finalizing the IRF measure until CMS and the 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 measure 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 an IRF quality measure endorsement especially since IRF patients are different in that they receive three hours of

therapy per day. We also recommend that CMS implement a POA indicator to identify complications that occur outside of the IRF setting. We recommend that CMS and CDC transition data reporting to NHSN by bringing all inpatient PPS hospitals on board first, followed by IRFs and other types of hospitals. Finally, we urge CMS to closely monitor the progress of the NQF maintenance review for CAUTI. Because these issues must be addressed prior to selecting the CAUTI measure, we recommend a one-year delay before the measure is finalized in the IRF pay-for-reporting program.

*Pressure ulcers that are new or have worsened.* Like the CAUTI measure, the proposed pressure ulcer measure is not specified for the IRF 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' IRF pay-for-reporting program, the nursing home pressure ulcer measure is not appropriate for the IRF setting. Nursing homes are a vastly different setting of care from IRFs. IRF patients require hospital-level, physician-led post-acute care because of their therapy each day, while nursing home patients have far lower medical-acuity, resource use and therapy time. **We urge CMS to work with the measure developer to refine the pressure ulcer measure for use in IRFs and subsequently seek NQF endorsement through an IRF 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 IRF 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 IRF and inpatient PPS versions of the pressure ulcer measures so that both capture the same range of wound staging. While the IRF 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.

We are also concerned about the data tools CMS intends to require IRFs to use to populate the pressure ulcer measure. CMS discusses three data sources: Nursing home data through the minimum data set; IRF data through modifications of IRF-patient assessment instrument (PAI); and data collection through the CARE tool. Among these three data sources, CMS does not make a specific proposal on which source will be used for populating the IRF pressure ulcer measure. We seek clarification from CMS as to its intention for collecting these data. Rather than layering multiple data reporting protocols, given that IRFs already have a reliable means of submitting data, CMS should take every step to first utilize the existing IRF-PAI data. To facilitate additional data collection for

the IRF pay-for-reporting program, it may be necessary to expand upon or refine IRF-PAI metrics to better serve the needs of the quality program. It would be more effective to make such changes, when feasible, than to increase provider reporting burden by requiring multiple channels for submitting IRF data to CMS.

Further, since there is no indication of which data will be used, there are also no detailed measure specifications available for review. The public must have access to the measure specifications in order to make an informed assessment and provide feedback during the comment process.

We urge CMS to implement a POA indicator to identify complications that occur outside of the IRF 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.

Comprehensive all-cause risk-standardized readmission measure. The proposed rule notes that CMS is considering a 30-day comprehensive all-cause risk-standardized readmission measure for FY 2014. 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 do not support including the all-cause, all-condition risk-standardized measure in the IRF pay-for-reporting program. Rather, we urge CMS to replace the all-cause readmission measure with a condition-specific readmission measure that only pertains to unplanned, related readmissions.

Alternative IRF quality measures. We urge CMS to take steps to quickly incorporate a discharge or function-related quality measure in the IRF pay-for-reporting program. Doing so would place appropriate quality emphasis on a key element of IRF care – the restoration of function to allow beneficiaries to return to their communities following a hospitalization. As noted, IRFs are the only Medicare setting that provides hospital-level care that is focused on treating both the medical needs of patients, as well as the rehabilitation needs of patients who are seeking to optimize lost physical and cognitive function in order to return to the community. CMS should also give consideration to a number of existing measures such as discharge to community, noting that it is important that any discharge-related goal be used for only those patients for whom discharge to community is the clinical goal. Additional measures that may also be appropriate for the IRF setting may be measuring a length of stay efficiency measure or a functional independence measure score increase. CMS should move decisively to include at least

Donald Berwick, M.D., M.P.P.

June 21, 2011

Page 7 of 7

one of the existing function or discharge-related outcomes measures in the initial set of measures used for the IRF pay-for-reporting program.

Thank you for your consideration of our comments. If you have any questions, please feel free to contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320 or [rarchuleta@aha.org](mailto:rarchuleta@aha.org).

Sincerely,

/s/

Rick Pollack  
Executive Vice President