February 1, 2013

Submitted Electronically

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-3278-NC, Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting

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) request for information concerning hospital and vendor readiness for electronic health records (EHRs) to electronically report certain patient-level data under the hospital inpatient quality reporting (IQR) program.

Congress established the EHR Incentive Programs in the 2009 American Recovery and Reinvestment Act to provide needed funds to accelerate the widespread adoption and use of EHRs to improve health and health care. Hospitals have demonstrated their commitment to successful participation in multiple Medicare payment and quality reporting programs that require reporting on nearly 90 quality measures. The AHA strongly supports the goal of using EHRs to streamline quality reporting while increasing access to real-time information to improve care. However, hospitals will not be ready to routinely report clinical quality measures (CQMs) through EHRs until measure developers and vendors build e-specifications and EHRs that support efficient generation of accurate and reliable quality data. Significant work is needed to improve regulatory and technical processes before CMS can rely on the data produced via EHRs in the IQR program.

In CMS’s hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2013, the agency sought feedback on two options for transitioning data collection to automated reporting from EHRs. One option would be to select a date after which chart-abstracted data would no longer be used in the hospital IQR program if it is possible to report the data via certified EHR technology.
The other option would allow hospitals to submit the same measure for the hospital IQR program based on either chart abstraction or, when available, EHR-based reporting. In our June 2012 comment letter, the AHA urged CMS to allow the second option of reporting given that individual EHRs or hospitals may not be ready to report IQR measures electronically by a date certain.

Our comments below detail why we believe option two remains more realistic and viable as EHRs are not yet capable of routinely supporting reporting requirements under the hospital IQR program.

**Experience in Stage 1 meaningful use indicates hospitals have been unable to generate useable clinical quality data out of the certified EHRs.** We recommend that CMS accelerate a process by which measures endorsed for manual abstraction also are reviewed and specifically endorsed for automated reporting by EHRs. This endorsement should be included as a criterion for quality measure selection in programs authorizing the use of quality reporting by EHRs.

**Additional work on electronic specifications is needed before EHRs can support hospital IQR.** The AHA urges a revision to the current regulatory timeline for building the infrastructure needed to support clinical quality measurement in the EHR Incentive Program. In Stage 1 meaningful use, a rushed timeline and insufficient testing of certified EHRs led to an inability to generate useable clinical quality data out of the certified EHRs to meet the Stage 1 regulatory requirements. Vendor products supporting Stage 1 had to meet only very light testing requirements before being certified for the CQMs. The certification process for EHRs does not include testing the accuracy of the embedded measure calculations, nor does it look to see if the needed data are, in fact, available in the EHR. It requires only that vendors, using their own data, show that their product can electronically produce numerators, denominators and exclusions in the required standardized format.

CMS and the Office of the National Coordinator for Health Information Technology (ONC) are to be commended for including infrastructure improvements in the Stage 2 meaningful use final rule intended to address several Stage 1 data capture and reporting challenges. However, the process for supporting CQM reporting in the EHR Incentive Program remains problematic. The final rules for the Stage 2 meaningful use Incentive Program and 2014 edition of standards for certified EHRs were published in September 2012. The final electronic specifications necessary to automate CQM reporting through the certified EHRs arrived seven weeks after the final rule for the EHR Incentive Program. Six weeks later, revisions to the final electronic specifications were released. The final testing methods for EHRs were released one week prior to the revised electronic specifications, which is a concern as quality measure electronic specification requirements must be supported in the EHR testing requirements. The chart below illustrates the rushed timeline.
Changes in electronic specifications supporting hospital and critical access hospital CQM reporting by EHRs

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/4/2012</td>
<td>Stage 2 meaningful use final rule published, including CQMs reported starting in 2014</td>
</tr>
<tr>
<td>10/24/2012</td>
<td>Final CQM electronic specifications published</td>
</tr>
<tr>
<td>11/2/2012</td>
<td>Draft test procedures for the 2014 Edition EHR certification criteria released</td>
</tr>
<tr>
<td>12/7/2012</td>
<td>Interim final rule announcing changes to electronic specifications published</td>
</tr>
<tr>
<td>12/14/2012</td>
<td>Final test procedures for the 2014 Edition EHR certification criteria released</td>
</tr>
<tr>
<td>12/21/2012</td>
<td>Updated electronic specifications for CQMs published</td>
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</tbody>
</table>

The AHA recommends revising the timeframe for the regulations to allow electronic specification vetting, testing and evaluation of the results prior to their inclusion in final rulemaking. Hospitals are investing considerable financial and human capital in implementing EHRs and need certainty that the technology supports the development of valid, reliable and feasible automated measurement. We recommend CMS monitor and publicly report on the implementation and use of automated CQM reporting in Stage 2, including barriers that may arise to successful reporting. We also recommend a formal 60-day comment period to allow time for stakeholder input on the proposed inclusion of electronic CQMs in any CMS program.

**EHRs are not yet supporting a broad group of CQMs endorsed by the National Quality Forum (NQF).** The National Quality Strategy has provided a framework for a common set of national priorities for quality improvement and public reporting, and the National Priorities Partnership provides a forum for the promotion of a parsimonious selection of quality measures that reduce the burden of collection. The Patient Protection and Affordable Care Act authorized the Department of Health and Human Services (HHS) to contract with the NQF to convene the multi-stakeholder Measure Applications Partnership (MAP) to review and recommend quality measures for inclusion in federal health care programs. The MAP is reviewing more than 500 quality measures used in more than 20 programs, with more than 100 applicable to hospitals. The hospital IQR program includes 50 measures. The EHR Incentive Program for 2014 will include 29 available measures for hospital reporting, of which hospitals may select 16 on which to report. Of the 29 measures, 21 are included in the hospital IQR program in 2013. However, four of these measures are not NQF-endorsed, and three others are endorsed with a qualification. The asynchronous MAP and meaningful use timelines result in CQM selection for meaningful use more than one year before the review of measures by MAP. The AHA recommends that all CQMs must be reviewed and endorsed by the MAP prior to inclusion in any federal health program. CQMs endorsed for manual abstraction should not be viewed as endorsed for automated reporting by EHRs and thus measures included in meaningful use require distinct NQF review and endorsement. Measures that are not NQF endorsed should be removed from any federal health program.

**Variation in electronic measure specification must be constrained when included in quality reporting and payment programs.** To date, the quality measure specifications used in the EHR Incentive Program have varied for each additional stage. This degree of variability will not support the longer term analysis of reported quality measure results required in value-based purchasing. Changes to a measure from a baseline period through the performance period can
have a big impact on the hospital’s overall level of performance on a measure. The AHA has long supported CMS’s position to make sub-regulatory changes to quality measures. However, we recommend that the inclusion of electronic measures in the hospital IQR program include a transparent process to indicate when a measure is altered and how CMS will ensure that the alteration does not arbitrarily affect hospitals’ total performance scores.

**Tools supporting successful EHR reporting must be reviewed and tested prior to increasing the use of EHRs in quality measure reporting.** ONC created the Data Element Catalog (DEC) to provide clarity on the data elements expected to be captured in support of 2014 CQM electronic specifications and to support the testing of EHR products that will be certified for use in 2014. However, we remain concerned that the DEC was included in the 2014 standards final rule, but was not specifically described in the 2014 standards proposed rule and was not therefore subject to public comment. The task of reviewing the DEC and other tools that support successful quality measure reporting should be undertaken prior to a determination that EHRs can support hospital IQR program requirements. Given the explosion of quality measure reporting requirements, it is essential that there be transparency in HHS programs supporting electronic measure reporting and collaboration with providers who will report the quality measures.

**CMS first should report the results of the EHR Incentive Program Electronic Reporting pilot program.** In CMS’s hospital outpatient PPS proposed rule for calendar year 2013, the agency proposed to extend the ongoing EHR Incentive Program Electronic Reporting pilot program for hospitals and critical access hospitals for one year. In our August 2012 comment letter, the AHA recommended that CMS modify its pilot program to field test the measures used in the EHR Incentive Program and determine the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR. In addition, the AHA recommended that CMS establish a clear process to manage updates to specifications for quality measures, and a mechanism through which vendors and providers could offer feedback on problematic or unclear measures. In order to facilitate meaningful consideration of the readiness of hospitals and vendors for EHR support of IQR, the AHA recommends that CMS evaluate and report the results of the Electronic Reporting pilot program so that the findings can inform all stakeholders about successes and challenges.

**The use of EHRs for quality reporting currently results in additional reporting burden compared to manual abstraction.** The AHA recommends CMS commission a study to assess whether a CQM yields the same result when the data is manually abstracted or gathered by the EHRs. The majority of the CQMs that hospitals must select from for meaningful use reporting are measures that hospitals report via chart abstraction or claims data as part of other required quality measurement and reporting programs. Despite this overlap, the burden of quality measure reporting appears to increase with EHRs. One example is evident in the misalignment of the electronic measures guidelines and the CMS Core Measures. Specifically, the electronic measures use two code sets (ICD-9 and SNOMED-CT), whereas the CMS quality measures use only the ICD-9 code set to define the patients included in the denominator populations. This results in two separate definitions of patient populations and twice the amount of abstracting work.
The AHA believes the value of quality measurement and reporting requirements should be balanced with recognizing the significant burden the requirements place on hospitals and other providers. In the past decade, there has been an unprecedented expansion in the number and type of quality measures hospitals are required to report. Federally mandated pay-for-reporting, value-based purchasing and other performance programs have been key drivers behind this growth. Hospitals are required to report nearly 90 measures. In addition to federal requirements, hospitals also must collect and report on quality measures to fulfill requirements from accreditors, states and private insurers.

The AHA supports efforts to synchronize multiple quality measurement and reporting requirements. Methods of measuring and reporting hospital performance require both human and capital resources and some methods are particularly costly. For example, chart-abstracted measures require a hospital staff person to manually review a patient’s medical record against criteria defined in a measure to determine performance. Accurate abstraction of chart-based measures often is not possible without clinically credentialed personnel, leading hospitals to incur higher costs when required to report additional chart-abstracted measures. Moreover, many chart-abstracted measures are highly detailed and complex, requiring significant time to review. For example, research conducted at a small group of hospitals on behalf of the AHA shows the surgical care improvement measures that are part of the hospital IQR program have a specifications manual that is more than 170 pages. Once the data are abstracted, hospitals also incur expenses to contract with vendors that transform the data into a usable form for reporting and analysis by CMS.

Many chart-abstracted measures have significant value in measuring performance. However, they must be implemented with care given the resources needed to use them. Other measures have lower front-end data collection costs, but still require significant time and expense to review and report. Quality measures reported via claims (e.g., mortality and readmissions rates) rely on coding to report performance. However, hospitals must review performance reports for accuracy, as well as educate coding and other administrative staff to ensure accurate recording of the information used to derive the measures. Similarly, measures collected through survey tools, such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience instrument, require that hospitals pay a vendor to collect and report on performance.

In conclusion, we recommend that CMS enhance outreach and collaboration opportunities for measure developers, vendors and providers early in the electronic specification for CQM process so that challenges can be identified by providers who are expected to report the measures and vendors who are expected to support accurate reporting. It is clear that considerable work needs to be done by measure stewards, developers and all health care stakeholders to make electronic CQMs valid and reliable.
Thank you again for the opportunity to comment. If you have any questions, please contact me, Chantal Worzala, director of policy, at (202) 626-2313 or cworzala@aha.org, or Diane Jones, senior associate director of policy, at (202) 626-2305 or djones@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President, Public Policy Analysis and Development

cc: Farzad Mostashari, MD, ScM, National Coordinator for Health Information Technology

Patrick Conway, MD, MSc, chief medical officer for CMS and director of the Center for Clinical Standards and Quality

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