April 8, 2013

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

RE: CMS-3276-NC, Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs, February 7, 2013

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 respond to the Centers for Medicare & Medicaid Services’ (CMS) request for information (RFI) on the use of Clinical Quality Measures (CQMs) reported under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program and other reporting programs.

The AHA strongly supports the goal of using EHRs to streamline quality reporting while increasing access to real-time information to improve care. However, we are concerned about the challenges and significant burden placed on providers to meet multiple, often non-aligned quality measurement and reporting requirements. Hundreds of quality measures exist in federal quality reporting programs, and providers also must collect and report on quality measures to fulfill requirements from accrediting bodies, state governments and private insurers. Although providing additional reporting options through non-governmental sources could have merits, we believe it is critical for CMS to consider the infrastructure necessary to support accurate and robust reporting and urge caution in allowing non-federal organizations to report CQMs.

Our detailed comments below expand on these issues and respond to several of the questions presented in the RFI.
QUALITY MEASUREMENT ENDORSEMENT PROCESS

The AHA strongly believes that the federal quality measure endorsement process must be followed for measures reported to federal programs, including any measures reported via EHRs or registries.

In the past decade, there has been an unprecedented expansion in the number and type of quality measures on which hospitals and their affiliated physicians are required to report. Federally mandated pay-for-reporting, value-based purchasing (VBP) and other performance programs are key drivers behind this growth. The Measure Applications Partnership (MAP), a public-private, multi-stakeholder partnership mandated by the Patient Protection and Affordable Care Act (ACA) and convened by the National Quality Forum (NQF) to review measures under consideration for use in federal programs, reviewed more than 500 measures in more than 20 federal payment and reporting programs between December 2012 and February 2013. The MAP recommended the most important and reliable measures for inclusion in federal programs.

The acceleration in the volume of measures that providers are required to report underscores the need for solutions to address the escalating burden associated with these requirements. One way to mitigate the reporting burden is to have a measure endorsement process that ensures that only the best available quality measures are used in federal programs. The multi-stakeholder measure endorsement process conducted by the NQF uses several evaluation criteria to ensure that measures have adequate evidence suggesting the topic is important to measure and report, and that the evidence supporting the measure is scientifically sound. Moreover, the process seeks to recommend measures that produce reliable, accurate measure results, which are feasible to collect. **The AHA believes that regardless of the mechanism of reporting, measures in federal programs should be endorsed by the NQF. Measures that are not NQF endorsed or MAP recommended should be removed from any federal health program. Electronic-specified measures should be separately reviewed and endorsed.**

In addition, any measures reported to federal programs through registries should go through the MAP pre-rulemaking review process. The ACA requires that CMS use this multi-stakeholder process to provide input on quality measures before they are included in formal rules. To ensure the consistency of the MAP review process, CMS must also take steps to ensure that review cycles are fully synchronized. For example, 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 Inpatient Quality Reporting (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. **CQMs endorsed by NQF for manual abstraction should not be viewed as endorsed for automated reporting by EHRs.** To date, no measures have been shown to generate comparable results from automated reporting and manual abstraction. The manually abstracted measures are tested before they are endorsed and validated after they are in use to ensure accuracy. Yet, the automated measure reporting has not undergone similar testing in advance of validation while in
use. Thus, measures included in meaningful use require distinct NQF review and endorsement before they can be considered reliable enough to substitute for hand abstracted measures.

**INFRASTRUCTURE FOR DATA COLLECTION AND REPORTING**

The AHA believes a robust infrastructure for data collection and reporting is required to support quality reporting to federal and non-federal programs.

A technology infrastructure that supports feasible, reliable and accurate reporting is essential to reducing the reporting burden placed on providers. To be usable, however, automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Experience in Stage 1 of the EHR Incentive Program indicates that the current approach to automated quality reporting does not deliver on that promise. Providers and vendors have encountered significant issues with the electronic specifications, which contain known errors and were never field tested. For example, the existing electronic CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than the meaningful use Stage 1 requirements will produce. Moreover, the certification process for EHRs specifically does not include testing the accuracy of the embedded measure calculations, nor does it examine 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 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 AHA continues to have significant concerns about the reporting of quality measures through EHRs, as detailed in our comment letters on the proposed rules for Stage 2 of meaningful use, the interim final rule for the EHR Incentive program, the RFI on readiness of EHRs to support IQR and the RFI on Stage 3 of meaningful use. In particular, we are concerned that the technical specifications for the measures are not accurate and have not been sufficiently field-tested to ensure that quality data reported from EHRs are valid, reliable and comparable to measures reported by manual abstraction of data.

Additionally, we believe it is important for CMS to evaluate its current receipt of electronic quality measure data submitted from multiple sources and the actions that may be required to enable more widespread participation in this reporting approach. System barriers to the submission of data, validation of the accuracy of the data submitted and a timely process to address identified omissions or inaccuracies will be vital to instill confidence that results calculated by CMS are identical to results determined by the deemed non-federal organization submitting the data.
QUALITY MEASURE REGISTRIES

The AHA urges CMS to take steps to ensure that non-federal quality measure registries used by federal programs submit reliable and accurate data. Specifically, CMS should develop criteria ensuring registries have the technical capabilities needed to report quality data. Moreover, those registries must be transparent in their methodologies and able to provide timely feedback to providers on performance.

The number and type of data registries has greatly expanded in recent years. However, the rigor of the data collection, validation and reporting capabilities of these registries is varied. To ensure consistency and rigor in data reporting from registries, CMS should develop evaluation criteria that ensure participating registries can report reliable, valid data to federal programs. For example, registries should have experience with collecting and managing large volumes of confidential patient-level data. They should also have processes for validating data submitted to them by providers to ensure it reflects actual performance.

It also is critical that registries are transparent about their methodologies for collecting data and setting performance benchmarks. Providers strive to be data-driven when identifying improvement opportunities and implementing enhanced care processes. To effectively use metrics to track progress, providers must know what information is being collected, as well as the performance targets. They also must have access to detailed data that allows them to understand exactly where their performance falls short. For example, if the registry uses a composite of several measures, hospitals should have information on their scores on each component of the composite, along with a benchmark for each component. Without this level of transparency, there is a significant risk that resources will be misdirected.

Performance data collected by registries must also be made available to providers in a timely fashion. Moreover, before any data are reported publicly, providers should have an opportunity to review data and make any needed corrections. Quality measurement and reporting are inherently complex activities. Timely reports, coupled with a pre-public reporting review process would help ensure that performance is measured accurately, and that consumers use the correct information to evaluate providers. For example, in the Physician Feedback Program, CMS is working with a contractor to develop confidential feedback reports for eligible professionals (EPs) that illustrate the performance on both cost of care and quality measures. An entity submitting quality measures data on behalf of EPs must be able to support the data requirement for the Physician Feedback program, particularly the expected frequency of the feedback reports to EPs. AHA recommends a similar criterion for non-federal organizations that would submit data to Medicare to satisfy quality reporting requirements.

The AHA is concerned about the potentially substantial costs of using registry reporting during a transition period to electronic reporting. Requirements to report to multiple registries add additional costs to providers for quality reporting compliance. Shifting quality reporting requirements to non-federal registries would add significant costs to providers. Registries often require subscription fees for providers to participate in them, and providers that participate in multiple registries may face higher costs. Moreover, accurately obtaining data for
reporting to registries often requires the expertise of clinical personnel using detailed chart-abstraction protocols. In the future, with the maturity of EHRs and electronic reporting of health information, costs associated with the review and transmission of quality data for reporting purposes could decline. In the meantime, however, CMS should carefully balance the benefits of aggregated reporting by non-federal organizations with expected increased costs to providers who are not reporting to non-federal agencies.

CORE MEASURE REPORTING

The AHA believes that core measure reporting should be enhanced to support alignment and reduce the measure reporting burden. In our comment letter on the calendar year 2013 physician fee schedule proposed rule, the AHA supported CMS’s proposal to establish a core measure set for EPs. We urge CMS to move in this direction within the context of selecting measures for federal programs that also are reported to non-federal organizations. Given the intent to use the data submitted from PQRS in the physician value-based modifier or physician VBP program, it is advantageous to require more robust core measure reporting. To facilitate successful reporting, we urge CMS to articulate a clear vision and measurement framework that would ease the transition from the current approach into a comprehensive set of quality measures that can produce statistically reliable differentiations that would be used to adjust payment in the physician VBP program. The AHA also urges CMS to learn from the process that has allowed for seamless transition from a pay-for-reporting program to hospital VBP; from the outset of the hospital pay-for-reporting program, core measures were required.

In conclusion, America’s hospitals are committed to fulfilling quality measurement and reporting requirements across several federal and non-federal programs. However, we remain concerned about the challenges and significant burden placed on providers who are trying to meet multiple, often non-aligned quality measurement and reporting requirements. As CMS moves forward, we urge you to consider a construct that balances the opportunities for streamlined reporting with the need for parsimony in the measures selected, maturity of the reporting infrastructure, transparency in the methodology for data collection and performance benchmarks, validation of the reported data and consideration of the cost of provider participation.

Thank you for the opportunity to respond to this request, and we commend CMS for soliciting stakeholder input. If you have any questions, please contact me or Akin Demehin, senior associate director of policy, at (202) 626-2365 or ademehin@aha.org, or Diane Jones, senior associate director of policy, at (202) 626-2305 or djones@aha.org.

Sincerely,

/s/

Ashley Thompson
Vice President and Deputy Director, Policy
American Hospital Association