American Hospital Association

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January 29, 2013

Submitted Electronically

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Farzad Mostashari, M.D., ScM
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Re: RIN 0991-AB89 and RIN 0938-AR7, Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program; Interim Final Rule, December 7, 2012.

Dear Ms. Tavenner and Dr. Mostashari:

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) and Office of the National Coordinator for Health Information Technology's (ONC) interim final rule that includes revisions to the 2014 Edition Electronic Health Record (EHR) Certification Criteria and Stage 2 of "meaningful use" under the Medicare and Medicaid EHR incentive programs, respectively.

Congress established the Medicare and Medicaid EHR incentive programs in the *American Recovery and Reinvestment Act of 2009* to provide much-needed funds to support the transition to an e-enabled health care system. America's hospitals have invested tremendous financial and human resources to adopt EHRs to improve clinical care and patient health. Hospitals also work every day to ensure adequate privacy and security for patients and their health information.

The AHA appreciates CMS and ONC's responsiveness to the need for corrections in the regulations, and we support a number of specific provisions in the interim final rule that will help eligible hospitals and critical access hospitals (CAH) meet meaningful use requirements. However, we are concerned about the unrealistic timelines in the rulemaking process that require the publication of technical changes soon after the publication of the final regulation in order to make the requirements workable. Our comments and recommendations on specific parts of the rule are below.

CHANGES TO THE STAGE 2 EHR INCENTIVE PROGRAM FINAL RULE

Minimum Case Threshold Exemption. **The AHA supports the revisions to the Stage 2 EHR incentive program final rule to adopt a minimum case number threshold exemption for quality measure reporting for eligible hospitals and CAHs and its availability in fiscal year 2013.** We also are supportive of the exemption availability to eligible hospitals and CAHs in any stage of meaningful use. As a result of this change, eligible hospitals and CAHs with five or fewer inpatient discharges per quarter or 20 or fewer inpatient discharges per year in a given clinical quality measure (CQM) denominator population will be exempted from reporting on that CQM. This exemption is available to eligible hospitals and CAHs in any stage of meaningful use. In our April 30, 2012 comment letter on the proposed rule for Stage 2 meaningful use, the AHA recommended CMS adopt a minimum case number threshold for quality measure reporting. We have heard from several CAHs that the stroke measures required for Stage 1 reporting are not responsive to their patient populations. Many CAHs do not encounter even a single case of stroke in a given calendar year.

Alternative Measure for Stage 2 Structured Electronic Laboratory Results. **The AHA supports the addition of an alternative measure for the Stage 2 meaningful use objective for eligible hospitals and CAHs to provide structured electronic laboratory results**. The alternative provides an additional option, allowing eligible hospitals and CAHs to include non-electronic lab orders received from ambulatory providers in the meaningful use measure denominator and allows the hospitals to choose the denominator to report. We believe that eligible hospitals and CAHs should receive credit for their electronic reporting to ambulatory providers regardless of the form in which the lab order was received.

Technical Corrections to Electronic Specifications for CQMs. **The AHA recommends a revised process for electronic specifications for clinical quality measurement in the EHR incentive program so that electronic specifications are appropriately vetted prior to inclusion in final rulemaking**. The events that led to revised electronic specifications for Stage 2 indicate that the regulatory process remains too rushed to articulate accurate and feasible reporting requirements. In Stage 1, 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 have been certified for the CQMs with very light testing requirements. 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. ONC and CMS are to be commended for including infrastructure improvements in the Stage 2 final rule intended to address several Stage 1 data capture and reporting challenges. However, the process for including CQMs in the EHR incentive program remains problematic.

The final rules for Stage 2 meaningful use in the EHR incentive program and the 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 one month 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 two weeks 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 CQM reporting by EHRs	
9/4/2012	Stage 2 meaningful use rule published, including CQMs reported starting in 2014
10/24/2012	Final CQM electronic specifications published
11/2/2012	Draft test procedures for the 2014 Edition EHR certification criteria released
12/7/2012	Interim final rule announcing changes to electronic specifications published
12/14/2012	Final test procedures for the 2014 Edition EHR certification criteria released
12/21/2012	Updated electronic specifications for CQMs published

The AHA recommends revising the timeframe for the regulations to allow electronic specification vetting, testing and evaluation of test 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 also 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. Additionally, 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.

CHANGES TO THE 2014 EDITION OF STANDARDS FINAL RULE

Updating the Data Element Catalog (DEC). **The AHA supports revisions to the 2014 edition of standards final rule that reduce barriers to hospitals seeking to successfully meet meaningful use requirements. We also recommend greater transparency in the development, maintenance and updating of the DEC to allow for more insight and opportunity to comment on this important element in the regulatory requirements for meaningful use**.

The interim final rule states that updating the DEC is necessary to align the DEC with data capture expectations expressed in the 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 mentioned in the 2014 standards proposed rule and thereby available for public comment.

The *Patient Protection and Affordable Care Act* authorizes the Department of Health and Human Services (HHS) to contract with the National Quality Forum to convene the multi-stakeholder Measure Applications Partnership (MAP) to review and recommend quality measures for

inclusion in federal health care programs. The MAP will consider more than 500 quality measures and will share recommendations in a report to HHS in March. That review includes a consideration of the data elements necessary for each quality measure. We strongly recommend that meaningful use requirements defer to the MAP on the issue of quality measures included in the EHR incentive programs.

Additionally, we recommend greater transparency in the process by which the DEC and the electronic specifications are maintained and amended. It remains unclear how the errors in the DEC and the quality measure electronic specifications were identified, how they were corrected, and what assurance exists that the revisions will be correct. In total, hospitals must report nearly 90 quality measures. Given the explosion of quality measure reporting requirements, it is essential that there be transparency in the HHS programs supporting electronic measure reporting and collaboration with providers who will report the quality measures.

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/

Rick Pollack
Executive Vice President