



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

June 17, 2014

Submitted Electronically

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0052-P
P.O. Box 8013
Baltimore, MD 21244-1850

Karen B. DeSalvo, M.D., MPH, MSc
National Coordinator for Health Information
Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

***Re: Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid
Electronic Health Record Incentive Programs for 2014; and Health Information Technology:
Revisions to the Certified EHR Technology Definition***

Dear Ms. Tavenner and Dr. DeSalvo:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed changes to the requirements for the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs for 2014.

The AHA greatly appreciates the increased flexibility the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) have proposed for eligible hospitals, critical access hospitals (CAHs), and physicians and other eligible professionals (EPs) in 2014. The flexibility offered in the proposed rule would support continued adoption of EHRs; without it, many providers are likely to conclude that they cannot meet meaningful use this year and abandon the program. That would be an unfortunate outcome for American health care, and unfair to providers, given that they would miss out on promised incentives despite their ongoing investments and be subject to future payment penalties for failure to meet meaningful use.

We strongly urge you to finalize, as quickly as possible, the proposal to expand providers' choice of certified EHR technology (CEHRT) to be used in 2014. The proposed flexibility is much needed and would offer more choice in the specific meaningful use requirements they must meet in 2014 (Stage 1 or Stage 2). However, we are concerned that the extremely late release of the proposed rule will limit its benefit to hospitals.



As discussed in more detail below, we also recommend that the agencies:

- **Provide greater flexibility in the electronic clinical quality measures reported;**
- **Clarify and simplify how the rule would be implemented;**
- **Recognize that 2015 also will be a transition year;**
- **Learn from Stage 2 before finalizing the start date for Stage 3; and**
- **Verify that the specific proposed changes to regulatory text support the intended flexibility.**

Congress established the EHR Incentive Programs in the American Recovery and Reinvestment Act of 2009 (ARRA) to provide needed funds to accelerate the widespread adoption and use of EHRs to improve health and health care. We share these goals, and America's hospitals have invested tremendous financial and human resources to make them reality. Hospitals also work every day to ensure adequate privacy and security for patients and their health information. According to data from CMS, however, as of mid-May 2014, fewer than 10 hospitals and 50 EPs had attested to Stage 2.

FINALIZE QUICKLY THE PROPOSED FLEXIBILITY IN CHOICE OF TECHNOLOGY

The AHA appreciates the flexibility afforded in the proposed rule and urges CMS and ONC to finalize the provisions on choice of the CEHRT used as quickly as possible and without any changes that would narrow the flexibility proposed.

Under the proposed rule, hospitals would have the flexibility to choose which technology to use to meet meaningful use in FY 2014. Hospitals would be able to:

- Retain and use their 2011 Edition CEHRT;
- Use a combination of 2011 and 2014 Edition CEHRT; or
- Use 2014 Edition CEHRT (as currently required).

CMS and ONC state that the version of CEHRT used "dictates the stage and version of the meaningful use objectives and measures" that a hospital can meet. Therefore, the rule proposes 10 different combinations of EHR versions and meaningful use requirements that could be possible in 2014. Specifically, CMS states that:

- If using only 2011 Edition CEHRT, hospitals must meet the 2013 Stage 1 objectives and measures (as finalized in the Stage 1 rules, and modified in the Stage 2 rules).
- If using a combination of 2011 and 2014 Edition CEHRT, hospitals may choose to meet the 2013 Stage 1 objectives and measures or the 2014 Stage 1 objectives and measures; or if they are scheduled to begin Stage 2 in 2014 under existing policy, they may choose to meet the Stage 2 objectives and associated measures.
- If using only 2014 Edition CEHRT, hospitals may choose to meet either the 2014 Stage 1 objectives and measures or the Stage 2 objectives and measures.

The proposed rule does not change any of the individual functional objectives and measures or the set of electronic clinical quality measures (eCQMs) already finalized in Stage 1 or 2 rulemaking. Nor does it change the reporting period for 2014, which for hospitals is a single federal fiscal year quarter, unless the hospital is reporting for the first time, in which case the reporting period is any continuous 90 days in FY 2014. Thus, the latest possible reporting period in FY 2014 for hospitals is July 1 – Sept. 30, 2014).

While complex, the CEHRT options provided would enable hospitals to meet the level of meaningful use that the technology currently used by their clinicians could allow them to achieve, taking into account their unique implementation circumstances. We strongly concur with the discussion in the preamble of the proposed rule that outlines delays in vendor certification and delivery of 2014 Edition CEHRT that left providers without sufficient time to fully implement the products and meet the meaningful use requirements for fiscal year (FY) 2014 (hospitals) or calendar year (CY) 2014 (EPs). See our [Dec. 19, 2013 letter](#) for an accounting of the challenges facing providers.

Due to the late timing of the proposed rule, we urge the agencies to finalize a rule that is at least as flexible as the proposal. The last-minute nature of the proposals poses significant risk and operational challenges to hospital leaders, who must make significant and consequential decisions about what actions to take to meet meaningful use during the last possible reporting period for FY 2014 (July – Sept. 2014) without the certainty afforded by a final rule. Indeed, the comment period for the rule does not close until after the final reporting period has begun. Thus, hospitals are essentially asked to act on faith that the agencies will finalize these proposals as written – while risking that they may not – without the benefit of a later reporting period to conform to more stringent final rules. Therefore, a final rule that narrows the proposed flexibility could unfairly cause significant financial and operational harm to hospitals.

PROVIDE ADDITIONAL FLEXIBILITY IN THE ECQMS REPORTED

The AHA believes that hospitals should have more flexibility in the eCQMs they choose to report, regardless of the specific stage of meaningful use they meet. Specifically, hospitals using a combination of 2011 and 2014 Edition CEHRT should be able to report either set of eCQMs, regardless of the stage of meaningful use met.

In the proposed rule, CMS and ONC state that the version of CEHRT used by a hospital to record, calculate and report the eCQM data will determine the choice of eCQMs available for reporting and the method of eCQM submission to CMS. The rule references two distinct sets of eCQMs:

- The 15 eCQMs that were defined in the original Stage 1 rule.
- The 29 eCQMs (of which hospitals must report 16) that were described in the Stage 2 final rule.

The agencies propose that:

- Hospitals that select 2011 Edition CEHRT for the 2013 Stage 1 meaningful use reporting would gather data, calculate and report via attestation the 15 eCQMs from the original Stage 1 rule.
- Hospitals that select a combination of 2011 and 2014 Edition CEHRT for 2013 Stage 1 meaningful use reporting would gather data, calculate and report via attestation the 15 eCQMs from the original Stage 1 rule. Eligible hospitals and CAHs may attest to data derived exclusively from the 2011 Edition for the portion of the reporting period for which the 2011 Edition EHR was in place.
- Hospitals that select a combination of 2011 and 2014 Edition CEHRT for 2014 Stage 1 or Stage 2 reporting would gather data, calculate and report 16 of 29 eCQMs, as required under the Stage 2 final rule, including the eCQM submission requirements contained in the Stage 2 final rule.
- Hospitals that select 2014 Edition CEHRT for 2014 Stage 1 or 2 reporting would gather data, calculate and report 16 of 29 eCQMs as required under the Stage 2 final rule, including the eCQM submission requirements contained in the Stage 2 final rule (as currently required).

In the Stage 2 final rule, CMS specifically removed reporting of eCQMs as an objective of meaningful use, and made it a separate requirement of meaningful use. Therefore, we believe that allowing providers to make separate decisions about the eCQMs to report and the functional objectives and measures to meet is most consistent with the underlying structure of the program.

We recommend that CMS allow hospitals using a combination of 2011 and 2014 CEHRT to choose the version of eCQMs they want to report, independent of the functional objectives and measures met. For example, a hospital that has implemented a combination of 2011 and 2014 Edition CEHRT may find, for example, that it can meet the 2014 Stage 1 or Stage 2 functional objectives, but has not yet been able to fully populate the data required to report the 16 of 29 eCQMs required under the Stage 2 final rule. In this scenario, the hospital may well be able to utilize its 2011 Edition CEHRT to calculate the 15 eCQMs from the original Stage 1 rule, and should be allowed to do so.

CLARIFY AND SIMPLIFY HOW THE RULE WOULD BE OPERATIONALIZED

The AHA recommends that CMS remove the proposed limitation on providers' ability to take advantage of the proposed flexibility. The proposed rule would limit the selection of an alternative approach to attesting in a manner consistent with the existing rules to hospitals that “could not fully implement 2014 Edition CEHRT to meet meaningful use for the duration of an EHR reporting period in 2014 due to delays in 2014 Edition CEHRT availability.” AHA members have expressed considerable concern that this limitation creates uncertainty that could limit the benefit of the proposed flexibility.

AHA members also are confused about the level of documentation that CMS would require them to provide as justification for taking advantage of the proposed flexibility, and the extent to

which their choice could be subject to future audit and possible denial, leading to recoupment of incentives and retroactive assessment of payment penalties. Given that the final rule will be released well after the last possible reporting period for 2014 begins on July 1, and hospitals will have no ability to re-attest to a different set of requirements if their eligibility for the flexibility is challenged, we believe the agency should minimize any uncertainty about who can take advantage of the proposed flexibility, and simply remove the limitation.

While we appreciate the limited examples provided in the rule of why a provider may not be able to “fully implement 2014 Edition CEHRT,” they are not sufficient to describe the myriad situations that exist on the ground. For example, the rule recognizes that “a delay in availability may limit a provider’s ability to fully implement 2014 Edition [CEHRT] across the facility,” and notes that hospitals may find it challenging to update and integrate multiple systems being used, or find that a system, once implemented in a live setting, still requires software patches or workflow changes. There are, however, many other aspects to meeting the 2014 Stage 1 and Stage 2 meaningful use requirements that could prevent a provider from fully implementing the 2014 Edition CEHRT. We provide a few examples below, but note that many more scenarios may be experienced in the field:

- A provider has received and installed 2014 Edition CEHRT, but has not yet been able to sufficiently test the software for safety.
- A provider has received and installed 2014 Edition CEHRT, but has not been able to complete training across all clinical and other staff.
- A provider has received and installed 2014 Edition CEHRT, but has not been able to completely integrate it with other important sources of data (such as lab and pharmacy systems).
- A provider has fully installed 2014 Edition CEHRT and is able to send Direct messages, but cannot find a sufficient number of other providers able to receive them to meet the Stage 2 measure for transitions of care.
- A provider has fully installed 2014 Edition CEHRT and established a patient portal, but the vendor has specified a technical approach that requires the provider to obtain patient emails to meet the first “view, download, transmit,” or VDT measure (patient has access), which patients are reluctant to provide.
- A provider has fully installed 2014 Edition CEHRT and established a patient portal but, despite concerted efforts, finds that fewer than 5 percent of patients want to use the portal to view, download or transmit their health information.

Given this variability in field experience, **the AHA recommends that CMS remove the limitation on eligibility. At a minimum, the agency should make clear in the final rule that many different scenarios could prevent a provider from fully implementing a 2014 Edition CEHRT, even beyond those specifically mentioned in the proposed rule. The agency also should carefully instruct its meaningful use auditors that a full range of individual circumstances can be expected to qualify a provider for this flexibility, including some that may not be foreseen by our comments or agency staff.**

Finally, AHA members have expressed considerable confusion about how, specifically, they would attest to being unable to fully implement the 2014 Edition CEHRT. It is our understanding from conversations with CMS staff that providers will check a box in the registration and attestation system that signifies their intent to take advantage of the proposed flexibility when they attest to meaningful use. We also understand that the agency will not request submission of additional documentation at the time of attestation. **We ask the agency to clarify its process, keep it as simple as possible, and refrain from asking for submission of supporting documentation at the time of attestation.**

2015 ALSO WILL BE A TRANSITION YEAR

The proposed rule states that, beginning in FY/CY 2015, all eligible hospitals and professionals will be required to use 2014 Edition CEHRT to report meaningful use, consistent with current rules. The reporting period would be 365 days for all providers, except the limited number in their first year of meaningful use, for whom the reporting period will be 90 days. Thus, the vast majority of hospitals will be expected to meet Stage 2 criteria in 2015, for 365 days.

The AHA strongly recommends that CMS shorten the reporting period for 2015 to 90 days for all hospitals, CAHs and EPs. As acknowledged in the proposed rule, a central reason for the challenges being faced today is the requirement for a nation-wide, simultaneous upgrade to a new certification level for EHR technology. The flexibility in 2014 is helpful, but in reality provides only three months of additional time for providers to get up and running with Stage 2 requirements using the 2014 Edition technology. As outlined in our [Dec 19, 2013 letter](#), it takes 19 months to efficiently and safely move from having the software to being able to attest to the next stage of meaningful use – assuming a three-month reporting period. Interim steps include software assessment (three months); installation, implementation and training across all clinicians and staff (eight months); building up to the more stringent performance metrics (five months); and meeting the metrics for the reporting period (three months). Most hospitals received their 2014 Edition CEHRT in spring or summer 2014 (with some still waiting), and will need until summer 2015 to complete their transition.

We believe a 90-day reporting period would keep all providers moving forward to meet Stage 2, while giving them additional time to undertake the many workflow and other changes required by Stage 2. We prefer any continuous 90 days in the fiscal year to a period matching a fiscal year quarter because it allows more flexibility in when providers begin their reporting period. In addition, it allows vendors to better manage the large number of providers seeking support as they begin and end their reporting periods by spreading these dates over the year, and not bunching them into four specific days (the start and end of the fiscal quarter).

In addition, the Stage 2 rules are very challenging to meet, and while the proposed rule does not address the definition of Stage 2, we continue to believe that CMS should provide additional flexibility for Stage 2. Specifically, the rules make unwarranted assumptions about the level of information exchange that is possible by specifying “view, download, and transmit” and “transitions of care” requirements that are beyond the capacity of today’s exchange

infrastructure. Hospitals are successfully using EHRs to improve the quality of patient care and reduce medical errors. However, the rate of adoption has been less robust among other care settings – such as skilled nursing facilities and home health agencies – that are logical recipients of hospital data. Similarly, patients are just beginning to use tools, such as patient portals, that hospitals make available to allow direct, electronic access to their medical records, but the practice is not yet commonplace.

The lack of a widespread information exchange infrastructure among non-hospital providers and the nascent patient use of “portals” makes it extremely challenging for hospitals to meet those Stage 2 meaningful use requirements that hold hospitals responsible for ensuring non-hospital providers and patients access information electronically. Hospitals also have found that the sheer volume of information they must exchange runs contrary to best clinical practice. It is unfair to hold hospitals accountable, and consider them to have failed at meaningful use, when they cannot find other providers ready to receive information electronically, or have patients that are not ready to use the portal.

Furthermore, the program rules themselves disadvantage hospitals because there is a mismatch in the timing of requirements on hospitals and EPs. Specifically, hospitals are expected to be sending Direct messages to EPs (Oct. 1) before the rules require EPs to have the capacity to receive them (Jan. 1). Therefore, it is almost impossible for hospitals to meet the “transitions of care” objectives for a full year. **While we continue to believe that the Stage 2 requirements that make hospitals’ success contingent on the actions of others should be removed, a 90-day reporting period in 2015 would at least afford hospitals more time to develop the relationships and information exchange structures to engage their external partners.**

LEARN FROM STAGE 2 BEFORE SETTING THE START DATE FOR STAGE 3

The AHA believes it is too soon to finalize the start date of Stage 3 as FY 2017 for hospitals, as proposed. Instead, CMS should specify that the 2014 Stage 1 and Stage 2 criteria will be effective until updated by future rulemaking. This approach is consistent with the policy CMS adopted in the 2010 Meaningful Use Final Rule, which made the Stage 1 criteria effective until updated by future rulemaking (FR 75(144):44322, July 28, 2010).

The proposed start of Stage 3 is Oct. 1, 2016, the first day of FY 2017. While hospitals may be ready for Stage 3 on that date, there is no evidence to support that assertion. To the contrary, experience to date suggests that rushing toward another aggressive deadline for Stage 3 could jeopardize program success. Furthermore, no one, including CMS and ONC, can judge readiness for providers to meet Stage 3 in the absence of the specific criteria that will be required. It would, therefore, be more appropriate to wait until the Stage 3 rules themselves are finalized to codify the start date in regulation.

As of mid-May 2014, fewer than 10 hospitals and 50 EPs had attested to Stage 2. The limited success suggests that the aggressive timeline is not the only challenge. As we and others have noted, providers face significant roadblocks in building out the necessary processes and

relationships for “view, download, and transmit” and “transitions of care.” The proposed rule helps providers to navigate through the 2014 time crunch, but does nothing to address the underlying Stage 2 problems, including the “all-or-nothing” approach that means failure to meet even a single measure by a single percentage point equates to overall failure. **The AHA urges CMS and ONC to take the time to thoroughly evaluate experience under Stage 2 before moving on to Stage 3.**

The AHA has consistently recommended that all providers be given at least three years at each stage of meaningful use. If providers have only 24 months between stages, as the 2017 start would allow, there is almost no point at which they are optimizing use of their existing system, rather than working to implement the next version. At best, this is an unwelcome state of “churn” in hospital IT systems that distracts them from the core business of caring for patients; at worst, it introduces significant safety concerns as the rush to meet regulatory mandates threatens to undermine solid implementation practices. Therefore, **if the agency feels compelled to set a start date for Stage 3 at this time, it should be no sooner than FY 2018 for hospitals.**

VERIFY THE PROPOSED CHANGES TO REGULATORY TEXT SUPPORT INTENDED FLEXIBILITY

The preamble to the proposed rule makes it quite clear that CMS and ONC intend for eligible hospitals, CAHs and EPs to have additional options for demonstrating EHR meaningful use in 2014. However, the proposed rule would make only one change to the CMS EHR Incentive Program regulations at Part 495, a revision to the definition of “Adopt, Implement or Upgrade:” under 42 CFR 495.3012. The AHA is concerned that additional changes to Part 495 may be needed to permit use of all the options discussed in the proposed rule. We note, for example, that §495.6(b), (f) and (g), which address Stage 1 criteria for eligible hospitals and CAHs, make repeated references to changes “[b]eginning in 2014.” These references address changes in objectives, measures, exclusions and related requirements. This could be interpreted to mean that a hospital or CAH using only 2011 Edition CEHRT (or a combination of 2011 and 2014 Edition CEHRT) *in 2014* might not actually be able to meet meaningful use objectives and measures that were applicable *for the 2013 payment year*, as clearly intended by the proposed rule preamble. In other words, under this scenario, an eligible hospital or CAH might not be able to simply repeat what it did in 2013 in order to meet EHR meaningful use requirements in 2014. This potential problem could also affect EPs, as evidenced by use of the same “[b]eginning in 2014” language throughout §495.6(a), (d) and (e). This obviously arises if one believes that the regulatory references to 2014 in §495.6 mentioned above were originally intended to refer to FY or CY 2014, not to 2014 Edition CEHRT.

In sum, the AHA requests that CMS carefully assess whether additional changes to the regulation text at Part 495 are needed to explicitly authorize the practical use of the full array of options discussed in the proposed rule. Following such an assessment, if the agency concludes that additional regulatory changes are not required, we ask that the final rule preamble explicitly acknowledge that this is the case and explain CMS’s rationale for this conclusion. Our goal is to ensure that eligible hospitals, CAHs, EPs and other stakeholders have a clear understanding of the options for meeting EHR meaningful use requirements in FY or CY 2014.

Marilyn B. Tavenner and Dr. Karen DeSalvo

June 17, 2014

Page 9 of 9

In particular, we want to ensure that providers will be able to satisfy EHR meaningful use requirements in 2014 by meeting the meaningful use objectives and measures that were applicable for the 2013 payment year.

We appreciate the opportunity to provide comment on this important proposed rule. If you have any questions or need further information, please do not hesitate to contact me, Chantal Worzala, director of policy (cworzala@aha.org), or Diane Jones, senior associate director of policy (djones@aha.org).

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis & Development