



**American Hospital
Association**

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

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Submitted Electronically

Karen B. DeSalvo, M.D., MPH, MSc
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Suite 729-D
Washington, DC 20201

***Re: Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria;
Interoperability Updates and Regulatory Improvements (RIN 0991-AB92)***

Dear 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 notice of proposed rulemaking for the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements published in the Feb. 26 Federal Register.

In the proposed rule, the Office of the National Coordinator for Health Information Technology (ONC) seeks to address several goals concurrently, each noteworthy on its own:

- Revise and restructure some current 2014 certification criteria;
- Clarify the 2014 Edition certification criteria by codifying certain sub-regulatory guidance; and
- Propose new criteria for consideration in the 2017 Edition proposed rule.

The AHA strongly recommends ONC first focus on collaborating with the Centers for Medicare & Medicaid Services (CMS) to clarify current 2014 Edition certification criteria and implementation specifications to ensure that providers will be able to receive and use certified EHRs in a timeframe that enables successful attestation to meaningful use.

Introducing voluntary regulatory compliance between cycles of rulemaking that impose mandatory compliance will complicate, rather than mitigate, the significant and ongoing challenges already faced by providers who must use certified EHRs in order to participate in the Medicare and Medicaid EHR Incentive Programs. The current regulatory pace between final rule publication and start of compliance does not match the ability of providers and vendors to adjust.



Our comments first address the concept of a voluntary compliance edition of EHR certification; we then comment on provider challenges with receipt and use of 2014 Edition EHRs; and finally comment on criteria that will support successful and safe transitions from one version of certification criteria to another. Following these general comments, we have attached our comments to select questions asked in the proposed rule.

VOLUNTARY REGULATORY COMPLIANCE INTRODUCES RISK TO SUCCESSFUL ATTESTATION OF MEANINGFUL USE

The AHA recommends that ONC not pursue a voluntary regulatory compliance program and instead study the experience to date with existing certification criteria, support improvements in the testing infrastructure for EHRs, and accelerate the availability of implementation guidance. At the present time, we lack experience with the 2014 certified Edition EHR, and do not have the benefit of a comprehensive evaluation of what is working and what is not.

The transition to the 2014 Edition EHR has been disruptive for hospitals. Current policy requires all hospitals to upgrade to the 2014 certified Edition EHR in fiscal year (FY) 2014. This rule is applicable whether the hospital is new to the program, in its second year of meaningful use or beginning Stage 2. Of the 5,011 eligible hospitals, vendors will be required to support the 4,477 unique hospitals cited by CMS participating in the first three years of the program, while also bringing on board those who have yet to participate.

In the face of that large demand, the supply of certified EHRs has actually declined, as evidenced by the Certified Health IT Product List of April 14, 2014:

List of Certified EHRs for Inpatient Setting		
	Certified 2011 Edition	Certified 2014 Edition
Complete EHRs	370	29
EHR Modules	830	463

Source: ONC Certified Health IT Products List, <http://oncchpl.force.com/ehrcert>

At this time, many of our members report that they are waiting for delivery of software code or certified modules in order to install, test and train their staff to use of the 2014 certified Edition EHRs. Hospitals are finding that, while base systems have been certified, they are not being delivered in a timely manner, and vendors are uncovering errors in their software that must be patched. In addition, many essential components are either not available or not working as promised. Safe use of certified EHRs also depends on appropriate time for post-installation configuration and training. The typical implementation, from software assessment, installation, implementation, staff training and gathering of test data prior to data collection for subsequent CMS submission can take up to 19 months to do well. Hospitals waiting for delivery of recently

certified EHRs or delivered components will face significant challenges to implementation of products and collection of a calendar quarter of data necessary to meet meaningful use in 2014.

Voluntary regulatory compliance does not address these issues. Additionally, the use of required 2014 certified Edition and products certified under voluntary regulatory compliance in the marketplace simultaneously would introduce more instability. Specifically, the EHRs that would be certified under the voluntary compliance regulation would be required to undergo testing for interoperability with 2014 certified Edition products. However, the reverse would not be required.

PROVIDER CHALLENGES WITH CURRENT EDITION EHRs

Lengthy queues for EHRs are evidence of regulatory timelines that are too short and requirements that are too tight. According to CMS's March 2014 report to the Health IT Policy Committee on Stage 2 attestations, only nine hospitals have attested to having used the 2014 Edition EHR to meet either the revised Stage 1 or Stage 2 requirements through February 2014. This statistic is a clear indication that the current program requirements and timelines for the EHR Incentive Program and EHR certification are out of sync with operational realities and vendor capabilities. At a time when current participating providers and new providers are challenged to install and use 2014 Edition certified EHRs in accordance with the meaningful use timelines, a focus on proposed 2015 Edition certification is an unwelcome distraction. **At this half-way point in the first year for Stage 2, we strongly urge ONC to work with CMS to assess the number of Medicare EHR Incentive Program participants to date, the number that have attested to Stage 2 and to swiftly publish guidance that informs hospitals how any relief, including 2014 hardship exceptions from the attestation requirement, will be operationalized. Publishing such guidance will address an immediate problem and will be more beneficial to providers than consideration of certification criteria applicable in FY 2015.**

The current program costs are high and increasing. The AHA is concerned that the current EHR certification distorts the EHR market and raises costs. Certification should give health care providers a degree of assurance that the health IT, and in particular EHR technology products, they purchase will perform as promised and support achievement of meaningful use. The current approach makes providers dependent on their vendors – not just to qualify for incentives, but also to avoid payment penalties. AHA members report that this change in dynamics has manifested through rapidly escalating costs and aggressive pricing of individual certified functionalities. Mandatory EHR upgrades with each stage are costly and the workflow changes associated with this process are not comparable to a software patch. These distortions are exacerbated by limited vendor capacity to meet the accelerated demand caused by a requirement that all providers, regardless of meaningful use stage, transition to the most recent certified version of EHRs at the same time and at a rapid pace in the regulatory cycle.

Greater flexibility in the program requirements will support provider success. **The AHA recommends a more flexible process to support provider attainment of EHR Incentive Program requirements, including allowing providers in Stage 1 to use their 2011 certified Edition certified EHR technology to meet the Stage 1 requirements.** Requiring upgrades by

all providers has crowded an already lengthy queue for the acquisition and installation of certified products in an environment where fewer certified products are available.

In comments on the proposed 2014 Edition certification criteria, the AHA recommended that the ONC adopt principles to guide the development of new EHR certification criteria. The experience in the hospital field to date leads us to restate these recommendations, including:

- Carefully consider evidence of the impact of certification in the health IT market and ensure that certified products truly support providers along the journey of achieving meaningful use.
- Retract proposals that put regulatory requirements ahead of market experience, an example of which is the expansion of the number of reported hospital quality measures or the required adoption of Systematized Nomenclature of Medicine (SNOMED) as the vocabulary standard for the problem list.
- Base the provider's certification requirements on its stage of meaningful use, not the calendar year.

REVISE THE APPROACH TO CERTIFIED EHRs

Prioritize successful attainment of current requirements before advancing new ones. New regulations governing new editions of certification for EHRs and new requirements for meaningful use of EHRs should be set aside until the current Stage 2 requirements and 2014 Edition certification requirements are met by the vast majority of providers. With this prioritization of effort in mind, the AHA reiterates our request that HHS extend the regulatory timelines for 2014 and allow all providers greater flexibility in Stage 2. Specifically, all hospitals and physicians should have the option to make the transition to the 2014 Edition Certified EHR and the Stage 2 requirements (or the revised Stage 1 requirements, as applicable) over the course of 2014 or 2015.

In addition, the Stage 2 requirements should be more flexible, in recognition that many of the mandated objectives – such as “transitions of care” and the patient portal to support “view, download and transmit” of data – are new and make providers' success dependent on the actions of others. This approach supports those that have or are ready to move ahead in FY 2014, while those needing additional time to get it right will have time to do so. Flexibility in the Stage 2 requirements would ensure that hospitals can build out the necessary processes and relationships for new and important objectives that also require actions by others. For example, hospitals must ensure that their affiliated physicians and post-acute care partners can receive summary of care documents sent using the Direct standard and a Direct secure email address – something very few can do today. Flexibility also is needed because under the current “all or nothing” compliance regimen, hospitals and physicians missing a single portion of a single objective by a single percentage point will fail meaningful use and be subject to subsequent and significant payment penalties, in addition to missed incentive payments.

Include mature standards ready for provider use. Because the use of certified EHRs is required for providers to attain meaningful use, the standards included in certification requirements must be mature. ONC should review standards for whether they are fully developed but also the

readiness of the standard for widespread implementation in EHRs that will be used in a clinical environment. The preamble to this rule states that the current regulatory cycle has resulted in rulemaking that must anticipate “industry readiness one to two years post-rulemaking.” However, a regulatory cycle that is too short does not allow time for a reasonable assessment by standards development organizations or government of the readiness to adopt the standards in technology. The regulatory cycle also must allow time for providers to assess and adjust workflows to accommodate new technology requirements.

As an example, ONC proposes to adopt the updated Consolidated CDA (CCDA) standard as the format used to document a summary of care in the 2015 Edition certification criteria. The proposed rule also states that this updated version of the CCDA was voted upon by standards development stakeholders in 2013. However, the updated version has not yet been published, has not been available for review in its entirety and has not been scrutinized to assess its readiness for use in EHRs to document a summary of care.

Similarly, the rule seeks comment on the potential usefulness of expanding electronic clinical quality measure export options to include a Quality Reporting Document Architecture (QRDA) Category II to support bulk reporting of patient level quality data. At this time, the QRDA Category II standard is under consideration by standards development stakeholders and is not fully developed. **The AHA recommends that ONC adopt a regulatory pace that allows for evidence-based analysis of the maturity of standards to support new regulatory requirements. In addition, the AHA recommends that ONC engage with the standards development community and CMS to identify pilot implementations as alternatives to a voluntary certification framework. This framework should include a mechanism to test emerging standards. At the same time, ONC and CMS should de-couple the testing process from provider payment regulatory cycle.**

Focus on advancing interoperability. Simply stated, hospitals have found that the infrastructure to support the level of health information exchange required in Stage 2 meaningful use is not yet sufficiently developed. Progress has been slow. The nation does not yet have a fully functioning network of health information exchanges. As a result, meeting some Stage 2 requirements reliant on information exchange, such as sending summary of care documents in support of transitions of care, are difficult for providers to achieve. The March 2014 Government Accountability Office (GAO) report, *Electronic Health Records: HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones*, GAO-14-242, references challenges to information exchange linked to insufficiency of standards:

“While standards for electronically exchanging information within the EHR Program exist, providers reported that standards may not be sufficient in some areas. Information that is electronically exchanged from one provider to another must adhere to the same standards in order to be interpreted and used in EHRs, thereby permitting interoperability. Several providers stated that they often have difficulty exchanging certain types of health information with other providers that have a different EHR system due to a lack of sufficient standards to support exchange.”

The report adds that “[the Department of Health and Human Services (HHS)], including CMS and ONC, developed and issued a strategy document” to advance information exchange,

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including principles to advance standards and interoperability. **The AHA recommends that ONC follow its strategy document, incorporate the GAO recommendations (below) and prioritize the work supporting the robust health information exchange needed by providers for success in Stage 2:**

“Develop and prioritize specific actions that HHS will take consistent with the principles in HHS’s strategy to advance health information exchange; and develop milestones with time frames for the actions to better gauge progress toward advancing exchange, with appropriate adjustments over time.”

Remain mindful that regulatory requirements should not expand the digital divide. The AHA remains concerned that the current meaningful use and certification timelines will exacerbate the digital divide. Studies have repeatedly shown that small and rural providers do not have the same resources as larger ones to adopt health IT. A series of recently published articles in *Health Affairs* found “large urban hospitals continue to outpace rural and nonteaching hospitals in adopting EHR systems.” In order to accommodate smaller and rural providers who will be at the end of vendor queues, and to reduce the likelihood for a growing “digital divide” among providers, additional flexibility is needed in the transition to the 2014 Edition EHR and Stage 2. We believe such flexibility in meeting Stage 2 requirements will allow more providers to succeed, and keep the program moving forward.

Thank you for the opportunity to comment on this proposed rule. Responses to specific requests for comment follow in conformance with the published format. If you have questions about our comments or would like more information, please contact me 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

Attachment

AHA Response to Select Questions in the Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements (RIN 0991-AB92)

1. Unique Device Identifier (UDI):

The NPRM proposes to adopt 2015 Edition certification criterion focused on EHR technology's ability to record UDI information about implantable devices. More specifically, EHR technology would have to enable a user to electronically record the UDI of an implantable device and other relevant information (such as a procedure note or additional information about the device) as part of a patient's "implantable device list." EHR technology would also be required to allow a user to electronically access and view a patient's list of UDIs and other relevant information associated with a patient's implantable devices. In addition, the EHR technology would need to be able to parse the UDI in order to extract and allow a user to view the "device identifier" and "production identifier" portions of the UDI. The UDI proposal, including its rationale, serves as the basis for the UDI's inclusion in several certification criteria:

- 170.315(a)(20) - Implantable Device list.
- 170.315(b)(1) – Transitions of care.
- 170.315(b)(6) – Data portability.
- 170.315(e)(1) – View, download, and transmit to third party.
- 170.315(e)(2) – Clinical summary.

AHA Comment:

The AHA has long supported development of a UDI. We recognize the potential for UDI data to reduce medical errors, promote patient safety and facilitate effective surveillance. The process to develop EHR standards to capture the UDI information via auto identification and data capture (AIDC) technology has been initiated but the standards do not exist at this time. Given the lack of EHR standards to support the inclusion of the UDI in the EHR, it is premature to include the UDI as certification criteria at this time.

To promote safe and efficient use of a UDI, we recommend that the EHR have the capacity to support the capture of the UDI information based upon the AIDC technology used by the labeler. The EHR user should not be able to electronically record the UDI. Given the lengthy alphanumeric symbol that will comprise the UDI, user-entered UDI information will increase the risk of harm due to inaccurate capture of the UDI.

The UDI final rule from the Food and Drug Administration (FDA) created a six-year timeframe to implement the requirement that device labels and packages include a UDI based on international standards. Class III devices are required to bear the UDI by September 2014 with the opportunity for a one-year extension. Full implementation will occur by September 2020. There is sufficient time to consider certification criteria for inclusion of the UDI in EHRs during the next cycle of regulation for the mandatory 2017 EHR certification.

2. Elimination of the Complete EHR Option

The NPRM proposes to discontinue use of the Complete EHR definition as a regulatory concept beginning with the 2015 Edition EHR certification criteria.

AHA Comment:

The AHA opposes the proposal to eliminate the complete EHR certification option. This proposal will impose additional burden on providers in the attainment of meaningful use. Currently, providers have the responsibility to meaningfully use the certified EHRs. The duty to ensure that certified products meet the certification criteria should not be placed on providers, too. The proposal to eliminate the complete EHR option will place undue burden on all providers to assess the combination of Base EHR, EHR Modules and all other capabilities that are necessary to meet the functional objectives and measures and successfully report electronic clinical quality measures (eCQMs). Not all providers have the internal resources sufficient to make the additional technology assessments that would be required when putting together modules that collectively satisfy regulatory requirements for certification. In addition, with the lack of clarity on the privacy and security certification requirements — currently not applicable to the certified EHR modules — it is premature to propose an elimination of the complete EHR option at this time.

The AHA disagrees with an alternative referenced in the NPRM, specifically to define a Complete EHR as “EHR technology that has been developed to meet, at a minimum, all mandatory certification criteria of an edition of EHR certification criteria adopted by the Secretary for either an ambulatory setting or inpatient setting and meets the Base EHR definition.” Changing the designation of a Base EHRs to a Complete EHR does not address functionality required to meet all of the requirements of meaningful use.