



**American Hospital
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May 29, 2015

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Acting Assistant Secretary for Health
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Suite 729-D
Washington, D.C. 20201

***Re: RIN 0991-AB93, 2015 Edition Health Information Technology Certification Criteria,
2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications
Proposed Rule***

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 proposed rule from the Office of the National Coordinator (ONC) for Health Information Technology (IT) to update standards, definitions and certification criteria, and revise the certification requirements for health IT. In a departure from previous certification rules, ONC has proposed a significant number of certification criteria that go beyond the technology required to support hospitals and other providers in meeting federal requirements for meaningful use of electronic health records (EHRs).

The AHA agrees with ONC's emphasis in the proposed rule on provisions to improve interoperability. We strongly support the creation of an efficient and effective infrastructure for health information exchange that facilitates the delivery of high-quality, patient-centered care across health care settings. Our members are actively engaged in building their information infrastructures and view information exchange as vital to care improvement, as well as to successful implementation of new models of care.

As the primary end users of EHRs, hospitals and health systems have a vested interest in purchasing systems that support their growing information-sharing needs. Yet, they report that the EHRs purchased during the past five years do not easily share information. Moreover, the cost and complexity of the many interfaces needed to connect systems today and the new transaction fees being imposed for information exchange do not represent a sustainable model for widespread sharing of health information.



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Given the significant investments already made in the adoption of EHRs to support health information exchange, the AHA urges ONC to finalize proposals in the 2015 Edition rule to increase the transparency and reliability of certified health IT through robust testing, increased surveillance of products in the field and increased disclosure requirements on vendors.

The AHA also believes that current experience with adopting and using new standards and certification criteria in meaningful use should inform the scope of change that should be included in a 2015 Edition final rule. While many of the individual criteria have merit, the cumulative result of numerous certification criteria should not divert needed attention from improvements in standards, certification criteria and implementation specifications that providers are required to use.

We urge ONC to prioritize improvements to standards and certification criteria required in certified EHRs that are necessary for the EHR Incentive Program. The 2014 Edition EHR certification requirements include 23 different standards for data vocabularies, content, transport and security that were built into and supported by certified EHRs. Some of the standards mandated for use were immature, such as Direct, and lack the necessary level of specificity to ensure that vendors interpret and implement them the same way. **We urge ONC to refrain from including immature standards in regulation. In addition, we encourage continued work with public and private stakeholders on pilots and demonstrations that can accelerate the maturity of standards.** While this may narrow the scope of a final 2015 Edition rule, we believe it will improve both the ability of vendors to develop technology in conformance with certification requirements and the ability of providers to successfully implement technology to meet regulatory requirements.

Our detailed comments are attached.

Thank you again for the opportunity to comment. If you have any questions, 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 & Development

American Hospital Association (AHA) Detailed Comments

TRANSPARENCY, ROBUST TESTING AND SURVEILLANCE ARE CENTRAL TO MEANINGFUL HEALTH INFORMATION TECHNOLOGY (IT) CERTIFICATION

Robust Testing is Necessary for All Certified Products. The AHA strongly supports more rigorous requirements for conformance testing of systems in support of interoperability. Specifically, the Office of the National Coordinator (ONC) should require that health IT modules undergo rigorous conformance testing that reflects real-world stress rather than ideal conditions. In addition, ONC should make the testing infrastructure for the 2015 Edition available by January 2017.

A more robust testing and certification process is urgently needed. While the current certification process involves some testing, it is not sufficient to meet the needs of end users. Hospitals continue to be unable to pull patient data from disparate sources to facilitate patient-centered care without impeding workflow. Given the significant investments hospitals have already made, we recommend using the testing and certification infrastructure as a starting point to improve interoperability. Additionally, as part of the conformance testing infrastructure, the federal government should support processes that permit the end user to access the testing infrastructure. This would give hospitals and other end users a way to better understand what is being tested, and how it is being tested.

Technical test beds should be widely available to developers and end users of electronic health records (EHRs) on an ongoing basis to support development, certification and assessment of standards that support interoperability. We recommend the inclusion of the National Institute of Standards and Technology (NIST) in a plan to advance the development of test beds. NIST has significant expertise in helping craft industry consensus on standards and developing methods to test standards conformance.

It is only by thorough and widely available testing that true interoperability can be achieved. Rigorous conformance testing of EHRs and of interfaces to ancillary systems that connect to EHRs (such as laboratory information systems) is urgently needed. It will support greater confidence that certified products may be reliably used to meet regulatory and market requirements. Conformance testing for interoperability also would communicate to vendors that the products required for use in federal programs must have “built in” interoperability, rather than the current scenario in which information sharing is “added on” via multiple point-to-point interfaces post-certification.

Surveillance of Products in the Field is Important to Learn about Products in Use. ONC proposes to build on existing surveillance responsibilities of ONC Authorized Certification Bodies (ONC-ACBs) by specifying requirements and procedures for in-the-field surveillance of certified products. This would be done through unscheduled inspections of products in use and

through greater scrutiny applied to products that are the subject of complaints. Greater transparency of the information disclosed during the testing and certification process is a good starting point for insight on the ability of certified products to support interoperability. Rigorous testing and insight into the testing tools likewise will build confidence in the performance of certified products.

The AHA supports ONC's proposal for enhanced surveillance of certified EHRs as a necessary complement to the disclosure and testing requirements used to support certification. ONC also proposes to require the ONC-ACBs to report complaints received concerning certified health IT to the National Coordinator. We urge ONC to share what is learned from the field surveillance in order to promote improved understanding about the functionality of products in the market.

Additionally, we recommend that ONC establish a visible, centralized source of information about vendor and product performance. ONC should provide a single location to share information about how well EHR products and their vendors support interoperability. This includes the disclosures proposed in the rule, the findings from field surveillance, and complaints received. ONC should also consider additional transparency metrics about how well EHR products and their vendors support interoperability. A single, centralized source of information about vendor and product performance will best serve providers seeking to make decisions about products. Visible, comparative information will also give vendors an opportunity to understand where they can improve performance. This concept is comparable to the many reporting requirements that Medicare places on providers and health plans, such as Hospital Compare or the Medicare Advantage Star ratings.

Greater Transparency About Vendor Products and Practices Is Central to Supporting Interoperability. The AHA supports ONC's proposal to require vendors to disclose **additional provider costs needed to use the health IT functionality**, such as a "one-time" fee to integrate the certified health IT with a hospital's other certified technology or a health information exchange. ONC also proposes that vendors disclose in detail any limitations on the certified health IT module, such as additional licensing fees or upgrades that may be required in order to fully utilize the certified product, or limits on customization or configuration. Awareness of potential costs of interface development and configuration improves the ability to compare costs across products in the market.

The AHA supports ONC's proposal to require additional disclosure of documentation for interoperability. We support requiring vendors to disclose technical details about the interface to their product, system or devices that will enable providers to understand how a given product, as designed, interprets and uses standards. This would allow providers to determine product performance and give purchasers of EHRs the knowledge needed to make more informed choices.

ONC SHOULD FOCUS ON CERTIFICATION CRITERIA THAT SUPPORT THE CURRENT AND FUTURE NEEDS OF THE SYSTEM OVERALL

The AHA recommends that ONC carefully evaluate the demand for certification efforts beyond those needed to support meaningful use and prioritize certification criteria that support the current demand for interoperability. With this approach, any additional certification should expand and deepen the use of existing national standards, rather than charting new territory. From the hospital perspective, certifications that would support information exchange with other care settings that are not part of meaningful use are logical next steps. For example, the EHR Incentive Program requires the electronic exchange of health information to support the transmittal or capture of a summary of care record for a patient receiving care across the care continuum. In many instances, the setting of care that follows the inpatient setting is the post-acute setting. Currently, many post-acute care settings do not yet have well-developed EHRs that can receive data in standardized form. The optional certification criteria included in the proposed rule may support identified needs that could benefit from support by EHRs, but the criteria run the risk of impeding the readiness of standards to support existing regulatory requirements on participants in the EHR Incentive Programs.

MATURE STANDARDS MUST BE INCLUDED IN CERTIFICATION CRITERIA FOR THE EHR INCENTIVE PROGRAM

Based on Centers for Medicare & Medicaid Services (CMS) data and input from the hospital and health system field, it is clear that we do not yet have sufficiently mature standards and a robust health information exchange infrastructure to fully support current information exchange requirements, let alone the important new information exchange objectives contemplated for Stage 3 of the EHR Incentive Program. To allow time for existing standards to mature, **the AHA recommends that ONC maintain current certification criteria that support Stage 2 meaningful use wherever possible in the 2015 Edition.**

Retain the Meaningful Use Data Set Rather than Introduce a New Common Clinical Data Set (CCDS) for the 2015 Edition Certification Criteria. Providers are working to become proficient with the Stage 2 Meaningful Use Data Set, and the AHA encourages ONC to support the current requirement before adding new data requirements. We further urge ONC not to place regulatory requirements ahead of standards readiness and market experience. The additional data fields that are incorporated into the Stage 3 CCDS are new. They would involve significant effort to implement and transition the data elements necessary to support the standard summary of care record. Furthermore, they may not yet be based on mature standards.

Currently, providers do not have the technology to capture all the data elements proposed for inclusion in the CCDS. For example, capturing Unique Device Identifier (UDI) data would be a new Stage 3 requirement for vendors and providers. The AHA supports the implementation of the UDI because of its promise to improve medical device safety and create supply chain efficiencies. However, we are in the early stages of implementation and it is not yet fully developed as a standard. **We encourage ONC to work closely with the Food and Drug**

Administration (FDA), device manufacturers and standards development organizations to come to agreement on the standards to support the UDI.

The scope of medical devices that will have the UDI is vast, and includes everything from bandages to implantable cardiac devices. The actual UDI on a medical device will be as long as 75 characters. The number will contain both a device identifier and a production identifier that includes details such as the lot, serial number and expiration date. To get the UDI, a device manufacturer must go to one of three agencies chosen by the FDA to issue the UDI. Each agency has its own format for the UDI, so it is not a single standard, but multiple standards. FDA also allows each manufacturer to choose the automated identification technology to place on the device label (type of barcode, radio frequency identification (RFID), etc.). To be useful in practice, we must have a single set of standards that are used for both the UDI and automated identification technology. While there are standards groups working through these issues, we do not yet have mature, well-understood and tested standards. **Working through the standards and implementation issues with the UDI is a precursor to including the UDI as a data element in the CCDS.**

Refrain from Using the Standard for Application Program Interfaces (APIs) as It Is Not Yet Ready to Support Health Information Exchange. ONC proposes to include APIs in the Base EHR definition. The API is software available as part of the EHR and intended to allow a provider to give a recipient of health information the choice to access the information through a third-party application (app.) The use of APIs in support of meaningful use objectives such as patient electronic access to health information and coordination of care holds promise to support the levels of health information exchange that is sought today and needed for the future. However, the standards for APIs are immature, and we lack the single, consensus standards for APIs in health care that will allow for their efficient use. Without that, each vendor will create a unique API, and we will face the same challenge of multiple approaches, rather than a single, standard approach. In the private sector, the Argonaut project holds the promise of developing the Fast Healthcare Interoperability Resources standard, but its work is in an early stage of development relative to the current scale of information exchange that is expected among clinicians and consumers. The use of APIs holds promise, but we lack evidence of their readiness in any clinical setting. We also lack insight on the number of different EHR vendors engaged in the API standards development work. As we have learned from painful experience in Stage 2 of meaningful use, standards must be mature prior to inclusion in programs where provider use is required. We encourage ONC to support and advance the work that will result in a single consensus standard for open-source APIs.

Develop a Model to Mature Standards Through Pilots and Demonstrations Rather Than Adoption in Regulation. While multiple standards have been included in the meaningful use program, many of them are immature. As a result, vendors have the flexibility to interpret and implement them differently. Hospitals and health systems find it challenging to share information to support clinical care because of unique system configurations and unique implementation of standards by vendors. The result is that sharing and integrating data across EHRs is complex and costly due to unique interfaces supporting data exchange. Sometimes, it is simply not possible. Federal programs to mature draft standards through pilots or demonstration

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projects would signal federal support for innovation without imposing an immature standard on the entire provider community. By relying on evidence from real-world pilots that a draft standard can be scaled for ubiquitous use and become a mature standard, the federal government can then use the regulatory process to advance use of the standard, if there is sufficient evidence that regulation is needed.