



American Hospital
Association®

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

May 2, 2016

Karen DeSalvo, M.D.
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, DC 20201

RIN 0955-AA00, ONC Health IT Certification Program: Enhanced Oversight and Accountability

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 Office of the National Coordinator (ONC) for Health Information Technology's (IT) proposal to make modifications to the ONC Health IT Certification Program published in the March 2 *Federal Register*. The proposed rule would provide for ONC's direct review of certified health IT, as well as permit ONC to assess non-conformities and prescribe corrective actions for health IT developers to address them. The proposed rule also would bring the authorization and oversight of testing laboratories directly under ONC and make available to the public identifiable surveillance results.

Hospitals have expended considerable time and resources in the implementation of electronic health records (EHRs) over the past five years. The most recent AHA survey data indicate that, by 2014, 75 percent of hospitals had at least a basic EHR in place, which is almost five times the share in 2010. The AHA strongly believes that the primary goal of the federal certification program is to give health care providers the assurance that certified health IT products will perform as described and are fit for their intended purpose – enabling clinicians at hospitals to quickly and easily document and review the care they provide; order medications, labs and other tests; and share the information with other clinicians and patients in support of safe and effective care. In order to revise the health IT certification program to accomplish this goal, **the AHA supports the ONC's proposal for increased transparency of surveillance results. We recommend that ONC prioritize actions that will increase confidence in the certification criteria and testing of health IT. Finally, the AHA recommends that ONC support existing initiatives to develop a framework to identify health IT safety incidents to inform certification and surveillance.**



INCREASE TRANSPARENCY OF CERTIFIED HEALTH IT SURVEILLANCE RESULTS

Surveillance of certified health IT in health care settings offers insight on products' ability to meet regulatory requirements and support a provider's health care quality and improvement initiatives. In the 2015 Edition Certification Criteria rule, ONC enhanced the surveillance requirements for certified health IT as a complement to the disclosure and testing requirements used to support certification.

ONC proposes to increase transparency requirements through the publication of surveillance results on a quarterly basis by the ONC Authorized Certification Bodies (ONC-ACB). **The AHA supports this proposal, as it will facilitate access to information that can inform providers as well as those working to improve the metrics and actual performance of certified health IT. We also support the proposal to publish hyperlinks to the surveillance results on the ONC website to facilitate access to the information in one location.**

We recommend that ONC include additional functionality on its website so that stakeholders may specifically learn how certified health IT products support interoperability. Visible, comparative information will give vendors an opportunity to understand where performance can be improved in support of provider needs to exchange health information. Transparency and communication about certified health IT through one known point of information will support the education of all stakeholders working to achieve widespread interoperability.

STRENGTHEN THE CERTIFICATION CRITERIA AND THE TESTING OF HEALTH IT TO SUPPORT PROVIDER REQUIREMENTS

Hospitals have expended considerable time and resources implementing EHRs, yet the certified EHRs hospitals are required to purchase under the Medicare EHR Incentive Program do not readily support program requirements or their health care improvement goals. For example, while a majority of hospitals can send and receive data via an EHR, using a Web portal or through a health information exchange (HIE), only 40 percent of hospitals can use the information they receive, meaning that the records are integrated into the hospital's EHR without the need for manual data entry. In fact, only about a quarter of all hospitals can find, send, receive and use electronic information due to a number of barriers.¹ Examples of barriers include the lack of EHRs among other care partners or compatibility between EHR systems. In addition, directories or other tools to locate other providers are not widely available. Certification should fully support providers with user-friendly, cost-effective products that meet performance criteria aligned with regulatory or accreditation requirements.

The certification program for health IT was transitioned from a temporary to a permanent program in 2011. Since that time, ONC has modified the program four times. In the proposed rule, ONC states that prior modifications addressed stakeholder concerns and certification ambiguities and that this proposed rule addresses new concerns identified through program administration and from stakeholders (81 Fed Reg. 11057). **The AHA commends ONC for**

¹ AHA Annual Survey, Health Information Technology Supplement, FY 2014.

continuing to review and refine the certification program and offers the following recommendations.

The AHA recommends that ONC work with the National Institute for Standards and Technology to support the establishment of a conformance testing infrastructure, including technical test beds. As we noted in our comments on the 2015 Certification Criteria proposed rule, the current certification process involves some testing, but 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 made already, the AHA recommends a more robust testing and certification infrastructure as a starting point to improve the certification program. Additionally, as part of the conformance testing infrastructure, the AHA renews the call for the federal government to 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 for conformance to real-world stress rather than ideal conditions. The ONC's April 8 request for information seeks input on the metrics to assess whether and to what extent widespread exchange of health information through interoperable certified EHR technology has occurred. Certified health IT that is rigorously tested for the ability to support interoperability will be an important factor within the emerging set of metrics.

The AHA recommends that ONC and the ONC-ACBs establish a process in which providers can offer feedback on certified health IT. The proposed rule states that "ONC could become aware of information from the general public, interested stakeholders ONC-ACBs or by any other means that indicates that certified health IT may not conform to the requirements of its certification..." (81 Fed Reg. 111062). More targeted engagement by ONC with providers, in collaboration with the Centers for Medicare & Medicaid Services (CMS), would support feedback from end-users with specific concerns based on their in-the-field experience. The education, outreach initiatives and tools used by CMS to engage providers on eHealth issues – such as an online platform, provider calls or meetings – could serve as a model for ONC engagement with providers.

Should ONC finalize the proposal that ONC conduct health IT surveillance that is independent of and may be in addition to any review conducted by ONC-ACBs, the AHA recommends that ONC clarify the manner in which the program will work in alignment with the ONC-ACBs to reduce uncertainty for providers concerning oversight of certified health IT. The proposed rule states that ONC anticipates that the direct review of certified health IT would be relatively infrequent yet the ONC's direct involvement would necessitate distinct processes for receipt of certified health IT complaints, case management of complaints received, investigations conducted and corrective action plans developed.

SUPPORT EXISTING INITIATIVES TO DEVELOP A FRAMEWORK TO IDENTIFY HEALTH IT SAFETY INCIDENTS

ONC proposes to assume a direct role in the oversight of certified health IT to assess non-conformities and prescribe corrective actions for health IT developers, including suspension or termination of the certified health IT product. To distinguish the scope of the ONC-ACB assessment of certified health IT products, ONC references the purpose of the ONC that is stated in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009:

The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that ...improves health care quality, reduces medical errors, reduces health disparities and advances the delivery of patient centered medical care (Public Health Service Act §3001(b)(2))

In the proposed rule, ONC further states that some non-conformities of certified health IT may be more fitting for it to address:

Nonconformities with certified health IT may arise that pose a risk to public health or safety, including, for example, capabilities (certified or uncertified) of health IT directly contributing to or causing medical errors (see section 3001(b)(2) of the PHSA). In such situations, ONC is directly responsible for reducing medical errors through the certification of health IT and ONC-ACBs may not have the expertise to address these matters.

The direct engagement by ONC in the review of certified health IT presumes a level of maturity in a taxonomy for health IT safety that is not yet realized. **The AHA recommends that ONC collaborate with existing private-public initiatives that are developing a framework for the identification of health IT safety incidents to expand knowledge for all stakeholders.** Current reporting may or may not include health IT as a specified factor due to the absence of common understanding about health IT safety incidents. Initiatives such as the ECRI Institute's Partnership for Health IT Patient Safety are analyzing safety reports from several sources in order to develop a taxonomy for health IT safety incidents and to educate all stakeholders to raise the level of awareness of the role of health IT within health care's culture of safety. ONC and its federal partners should continue to engage in this important work and use the lessons learned to inform future certification criteria, metrics used in health IT surveillance and transparency of surveillance results that include safety criteria. **In addition, if ONC finalizes a rule that includes review of capabilities of uncertified health IT within the context of examining non-conformities of certified health IT, the AHA recommends that ONC work with other federal partners to improve the general understanding of areas of oversight by the respective agencies.**

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Thank you for the opportunity to comment on the proposed rule. 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/

Thomas P. Nickels
Executive Vice President