

Association of
American Medical Colleges
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Via Electronic Submission (www.regulations.gov)

May 29, 2015

Karen B. DeSalvo, MD, MPH, MSc National Coordinator for Health Information Technology Office of the National Coordinator for Health Information Technology Attention: RIN 0991-AB93 Hubert H. Humphrey Building, Suite 729D 200 Independence Ave., SW Washington, DC 20201

Dear Dr. DeSalvo:

Re: 2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Proposed Rule of the Office of the National Coordinator for Health Information Technology (ONC or the Agency) titled 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. 80 Fed. Reg. 16804 (March 30, 2015). The AAMC is a not-for-profit association representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC believes this rule addresses many critical issues related to certification: increased vendor transparency and accountability, improved interoperability, and expanded data collection of important and sensitive social, psychological, and behavioral issues, including data collection to improve care for veterans and their families. However, the Association cautions against finalizing standards that are in draft form, or are not well-tested, lest those standards provide a roadblock to security or interoperability.

The AAMC and its members understand the important role of health IT in improving patient care and have an ongoing commitment to devote considerable resources of time and money to adopting and advancing health IT. While technology continues to develop, ONC has a

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responsibility to minimize disruption that could impede the delivery of efficient healthcare by harming provider-patient interactions.

The AAMC appreciates the opportunity to share our comments on several specific aspects of the certification program.

Surveillance, Transparency, and Accountability

ONC proposes to require increased disclosure on certain types of costs and limitations that could interfere with the ability of users to implement certified health IT, and to require that all adaptations and updates, including changes to user-facing aspects, made to certified health IT to be recorded monthly by ONC- Authorized Certification Bodies (ACBs).

The AAMC strongly supports accountability and transparency in health IT to maximize the quality of care and inform decision-making processes. The changes ONC recommends will allow hospitals and eligible professionals to better understand the costs and readiness of different software modules. The AAMC recognizes the importance of validating software through surveillance, but asks ONC to ensure that such surveillance does not create an unnecessary or significant burden on providers.

Decertification

The AAMC supports the exchange of health information and understands that ONC needs an avenue, such as decertification, to disallow vendors from proactively blocking the exchange of information. In exercising this option, however, ONC should consider the disruption that decertifying a product will have on providers utilizing it. The AAMC asks ONC to ensure that adequate measures will be put in place to protect providers who have adopted a decertified product, so that they will not be made ineligible for incentives or subject to penalties through no fault of their own. Given that transitioning from a decertified product would require significant time and resources, ONC should build in adequate time for providers to migrate to other systems and vendors. Additionally, the AAMC asks ONC to exercise its decertification authority with as much advance notice to providers as possible, and to only use this authority when absolutely necessary.

Social, Psychological, and Behavioral Data

The AAMC applauds ONC's proposal to include certification requirements for social, psychological, and behavioral (SPB) data. Inclusion of SPB data in the clinical record would offer significant opportunity for academic medical centers and the health system at large to improve community health, better manage patient population health, and conduct health equity research.

Given the sensitive nature of some of the data elements included in the proposed SPB panel, the AAMC encourages rigorous patient and community engagement to ascertain the most acceptable ways to gather SPB data in a clinical setting. Additionally, to maximize benefits to patients and

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communities, more work is needed on interprofessional training on the collection, extraction, and utilization of SPB data by health care teams to maximize benefits to patients and communities. The AAMC urges ONC to identify and collaborate with experts in this field to identify and disseminate best practices. The AAMC would be happy to work with ONC on this effort.

Addressing the request for feedback on how to ask patients SPB-related questions, the AAMC suggests looking at existing research such as work done at the University of California (UC) Davis Heath System, the first academic health system in the country to incorporate sexual orientation and gender identity as standard demographic elements in their EHRs. The AAMC encourages ONC to review the UC Davis experience as the Agency develops and finalizes patient questions (https://www.ucdmc.ucdavis.edu/medicalcenter/features/2013-2014/07/20130704_LGBT-EMR.html).

Military History

ONC also requests feedback regarding incorporating military history into the EHR. The AAMC believes military service cultural competency is critically important to caring for veterans and their families in both the public and private health sectors. As part of the Association's mission to improve the health of all, the AAMC fully supports inclusion of unique patient data related to military history into EHRs.

On April 18, 2014, the AAMC submitted comments¹ to ONC regarding the 2015 Edition EHR Standards and Certification Criteria Proposed Rule (RIN 0991-AB92). 79 *Fed.Reg.* 10880 (Feb. 26, 2014). In those comments, the AAMC strongly endorsed the ability for CEHRT to include questions about whether an individual (or their relations) served in the military.

The AAMC continues to support the inclusion of these questions, because the responses they garner will help providers to better serve veterans and their families. Therefore, the Association asks ONC to consider their placement in SPB data collection or other more appropriate locations. At a minimum, AAMC asks that ONC consider adding a question such as, "Have you or someone close to you served in the military?"

The collection of this information would help facilitate teaching of health conditions that are prevalent among military service members, veterans, and their relations (including mental health conditions). This is highly relevant clinical information that would vastly improve the ability to track adverse outcomes including morbidity, disability and suicide. For example, veterans have twice the risk of suicide as the average American. The inclusion of family members and individuals who identify as close to military service members can help track higher rates of depression and anxiety within those communities. Finally, this step would create the possibility of coordinated care across Department of Defense (DOD), Department of Veterans Affairs (VA), and community health care systems and significantly increase the range of health resources

¹ AAMC Comment Letter to ONC Re: 2015 Edition EHR Standards and Certification Criteria Proposed Rule (RIN 0991-AB92), April 18, 2014, https://www.aamc.org/download/377636/data/aamcjf-onccommentletter041814.pdf

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available to approximately 60 million Americans.

The AAMC encourages ONC to take into consideration the experiences of the DOD and VA in collecting and sharing information related specifically to veterans. Because universal standards for collecting and using this type of information do not yet exist, the AAMC asks ONC to approach this issue thoughtfully and with the goal of ensuring that all veterans and their relations benefit from certified health IT. The AAMC asks ONC to consider establishing a working group to further explore these opportunities and would value the opportunity to assist with this effort.

Pharmacogenomics

The AAMC generally supports the efforts of ONC and the National Institutes of Health to include genomic information in health IT to improve the quality and outcomes of care. As new types of care emerge, it is critical for health IT to both accommodate and facilitate this type of care through the use of pharmacogenomics.

Due to the sensitive information that genetic data contains (discovered and yet to be discovered), the AAMC urges ONC to strongly consider and address all matters and questions related to assuring that these functionalities will not lead to discrimination against individuals or their families who may be at risk of developing future health issues.

The AAMC asks that ONC gather and address comprehensive stakeholder feedback on possible ethical and legal implications of any gene-related functionality, and work to address issues that are identified. Furthermore, the Association appreciates the complexity and challenges ONC faces in assuring that health IT functionalities provide for the capture, exchange, and transmission of sensitive data in accordance with applicable federal and state privacy laws to protect patient privacy rights.

If you have any questions concerning these comments, please feel free to contact Ethan Kendrick, at ekendrick@aamc.org or at 202-741-5461.

Sincerely,

Janis M. Orlowski, MD, MACP Chief Health Care Officer

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