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October 24, 2016

B. Vindell Washington, M.D.
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: 2017 Draft Interoperability Standards Advisory

Dear Dr. Washington:

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 Draft 2017 Interoperability Standards Advisory (ISA). The AHA commends the Office of the National Coordinator for Health Information Technology (ONC) for its ongoing work to identify and assess standards and implementation specifications that support the interoperability of health information. 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 view the ability to gather, share and use health information efficiently and effectively as vital to care improvement, as well as to successful implementation of new care delivery models.

To best inform stakeholders of standards and specifications that can be used to fulfill specific clinical interoperability needs, **the AHA urges ONC to provide more specific information on the characteristics and metrics it has used to assess the readiness of standards and implementation specifications for use in clinical care.** Our specific recommendations for doing so follow.

In the introduction to the Draft 2017 ISA, ONC states that the changes from the 2016 ISA pertain to content and framing. Notably, the Draft 2017 ISA discontinues the use of the label “best available” to describe the standards included and, instead, provides a place to reference field experience with the standard. The Draft 2017 ISA provides additional information on the maturity and adoptability of the standards and implementation specifications. Specifically, ONC provides information on:



- Standards Process Maturity
- Implementation Maturity
- Adoption Level
- Federally Required
- Cost
- Test Tool Availability

For 2017, ONC also is transitioning to a web-based resource with the inclusion of links related to each of the attributes of standards and implementation specifications. Our recommendations for how ONC could build upon this improved platform to increase stakeholders' ability to judge the readiness of specific standards are outlined below.

Provide greater detail about the characteristics and metrics used to distinguish between standards that are considered mature and those that are characterized as emerging. The Draft 2017 ISA states: "where available, a link to published maturity assessments based on known published criteria about the standards is also provided." Unfortunately, links to maturity assessments are not included in the standards or implementation specifications included in Section I (Vocabulary and Code Set), Section II (Content and Structure) or Section III (Standards and Implementation Specifications for Services) of the Draft 2017 ISA. **The AHA urges ONC to prioritize outreach to organizations conducting maturity assessments so that future iterations of the ISA can include this reference. In addition, the AHA recommends that ONC use the ISA to make publicly available the feedback it receives on the adoption experience of standards and implementation specifications.**

In Appendix III, ONC notes its intention to follow progress on projects related to care planning and include the resulting standards and implementation specifications in future ISA updates. The AHA recommends that ONC work with the Centers for Medicare & Medicaid Services (CMS) on this activity so that ONC's efforts are consistent with the requirement in the CMS final rule revising the requirements for discharge planning for hospitals, critical access hospitals (CAHs) and home health agencies (HHAs).

Include information on the readiness of standards for provider use. **The AHA recommends that the 2017 ISA also include information on actual standards use in the real world, and not just adoption.** The Draft 2017 ISA uses the term "adoption level" to indicate whether a standard has been adopted in health care and a graphic to indicate the level of adoption, from low to high, for a particular standard. However, experience to date indicates that a standard may have a high adoption rate as a result of a health information technology (IT) certification requirement, although it does not meet provider needs. The Direct standard is an example of this misalignment. 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. Many providers use Direct to share clinical information. But the standard has proven hard to use and does not always support existing clinical workflows. To evaluate the ability of a standard to support interoperability, the draft 2017 ISA must assess the successful use of the included standards, not just adoption. Additionally, the majority of the standards included in the Draft 2017 ISA do not indicate whether a test tool is available to evaluate conformance to

the standard or the implementation specification. Positive results from conformance testing will add confidence that a standard is ready to support the interoperability needs of providers.

Disseminate information about the use of identified standards to support interoperability. **The AHA recommends that ONC support the work of private-sector initiatives that are educating stakeholders about the availability and readiness of standards, especially as they pertain to interoperability.** Support for standards implementation through the development of educational materials, funding for technical assistance, national provider calls and ongoing support will be crucial to the successful adoption of standards and implementation specifications that are updated regularly and federally required.

Provide additional information on the characteristics of the standards and implementation specifications. **The AHA recommends the addition of a hyperlink to information on the standard or implementation specifications that are in the pilot stage of implementation.** We agree with the use of hyperlinks to direct stakeholders to additional detail on the standard or implementation specification. Including access to information on pilot projects would further inform stakeholders about how standards perform.

The AHA recommends that ONC include an additional reference and a hyperlink when a standard or implementation specification is required in federal programs other than those that fall under ONC's purview. The AHA appreciates that the Draft 2017 ISA added a hyperlink that enables a connection to the federal requirement when a standard is required for a federal program. However, in the Draft 2017 ISA, this "Yes" link only directs the reader to ONC requirements, such as the 2014 Edition Health IT Certification Criteria or the 2015 Edition Health IT Certification Criteria. Where applicable, references to the requirements of other agencies would be helpful. For example, a link to the federal requirement for implementation specifications supporting the reporting of patient-level quality data to federal quality reporting initiatives redirects the reader to the 2015 Edition Health IT Certification Criteria and the Cypress testing tool for the Electronic Health Record (EHR) Certification of electronic clinical quality measures. A reference to information on the electronic clinical quality measure requirements promulgated by CMS and the CMS testing tools available to support successful attainment of those federal requirements would be an important addition for stakeholders. In another example, the reference to a federal requirement to report unique implantable device identifiers is noted but the Draft 2017 ISA does not include a link to additional information. The reference to the action by the Association for Healthcare Resource and Materials Management (AHRMM) to convene and host a Learning Unique Device Identifier (UDI) Community is appreciated, but information from the Food and Drug Administration on the status of the multi-year activity to implement the UDI also would support stakeholder insight on this activity.

The AHA also recommends that ONC continue to make a static PDF of the ISA available as well as develop an appendix to capture the resources that are linked to the respective characteristic that accompanies each standard or implementation specification. The web-based resource and the PDF support distinct needs by stakeholders, and we urge ONC to maintain both options to access this resource.

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Thank you for the opportunity to comment. The consistent use of mature standards is essential to solving the interoperability challenges facing our nation. Please contact me if you have questions or feel free to have a member of your team contact Diane Jones, senior associate director, policy, at djones@aha.org or (202) 626-2305.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis & Development