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Kaiser Foundation Health Plan
Program Offices

November 20, 2017

Steven Posnack
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

Submitted to www.HealthIT.gov

RE: ***ONC 2017 Interoperability Standards Advisory Reference Edition***

Dear Mr. Posnack:

Kaiser Permanente offers the following comments on the *2017 Interoperability Standards Advisory Reference Edition* ("ISA"), posted September 19, 2017 at the Office of the National Coordinator for Health Information Technology ("ONC") webpage.[1]

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with over 11.6 million members in eight states and the District of Columbia.[2] Kaiser Permanente is committed to providing high-quality, affordable health care services and improving the health of our members and the communities Kaiser Permanente serves.

We appreciate the opportunity to provide our feedback.

GENERAL COMMENTS

The health IT sector in the US would benefit from having a single, comprehensive, dynamic, web-based navigational catalogue of reference information about interoperable health IT standards. This should provide demonstrable value to identified audiences, including providers, health plans, vendors, standards development organizations ("SDO"), government (public

[1] https://www.healthit.gov/standards-advisory/draft-2017

[2]Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members

programs), policymakers, regulators, and others for specific high priority purposes. Having a single authoritative source of information is important when considering 1) the multiplicity of legislative, regulatory and sub-regulatory sources requiring specific standards for use; 2) standards currently implemented widely by the industry that are not required by regulations; 3) evolving and emerging standards that are still in development; and 4) the single authoritative sources for certain types of standards (e.g., the National Library of Medicine's Value Set Authority Center, the Agency for Healthcare Research and Quality's ("AHRQ") United States Health Information Knowledge Base, or the Global Unique Device Identification Database ("GUDID") of the Food and Drug Administration ("FDA").

We understand the ONC's desire to assess current health IT standards and coordinate the identification, evaluation and publication of standards for specified interoperability needs described in the ISA, but we remain concerned about:

- The lack of clarity around scope and purpose
- The organization of the content within and beyond the five core sections provided
- Confusion about ISA's intended audiences and benefits to those audiences
- The impact on clinician users of standards in the ISA
- The overall ongoing need for this work

We recommend that ONC conduct a formal assessment of the ISA's value to specified audiences, publish those findings, and adjust ongoing work on the ISA accordingly.

Scope and Purpose

The ISA does not describe the scope and breadth of ONC's current assessment of health IT; instead, it offers a variety of intended purposes that are confusing or conflicting.[3] These different statements illustrate the ongoing gap in clearly identifying and addressing specific needs. To add value, the ISA should be clearer about scope and purpose for the stakeholders who rely on its guidance.

We agree with the qualifying statements provided by ONC, particularly that the ISA is intended for informational purposes only, it is non-binding, and does not create or confer rights or obligations. ONC should place this disclaimer more prominently in the ISA portal and

[3] "The ISA is designed to be a coordinated catalog of standards and implementation specifications that can be used by different stakeholders to consistently address a specific interoperability need. "
"… In the event that a health IT developer or health care provider seeks to address a particular interoperability need, the ISA should serve as the first resource consulted to inform the selection of standards and implementation specifications…"
"Stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components are encouraged to look first to the ISA in order to more fully inform their goals. In that regard, standards and implementation specifications in the ISA and their associated informative characteristics are also available to help more fully inform policymaking. In this case, a standard or implementation specification's reference in the ISA may serve as the initial basis for industry or government consideration and action."
"While the ISA itself is a non-binding document, standards and implementation specifications listed in the ISA may be considered for rulemaking or other Federal requirements. However, those decisions would be made on a case-by-case basis by the administering organization."

Reference Edition document. More importantly, ONC should explain very clearly both what the ISA is and what it is not.

Audience
ONC should clearly address specific stakeholders the ISA is intended to serve, and the value this resource will provide for each. Based upon the current description in the ISA, it is difficult to determine who are the intended audiences and how they will use and benefit from the ISA. Examples would be valuable.

Content
The organization of the ISA appears haphazard. The original publication presented the standards in alphabetical order by the interoperability need being addressed. With each publication, new interoperability needs and standards are identified and simply added towards the end of the list within each major section. Standards are listed without considering inter-relationships and inter-dependencies between them.

Based on the outcomes of the assessment recommended above, ONC should reorganize the content of each major section. As material is added, ONC should consider the best location/section for new material. For example, all items related to demographic data should be grouped together in the same subsection or clearly cross-referenced. Currently, demographic items are dispersed throughout Section 1 without any order or structure, making it more difficult to search for and locate such information.

References and Web Links
Rather than re-publishing information that is publicly available from primary sources, the ISA should provide a reference or link to where the standards or other material are located. This will reduce duplication of effort, save resources, and ensure accurate, up-to-date information.

Privacy and Security
Critical interoperability standards for privacy and security are currently embedded within each interoperability need, and the information provided is not clear. Because the ISA has achieved a relatively mature stage in its publication, we suggest separating these elements and grouping/presenting them in a standalone major section within the ISA.

Regulatory vs. Non-regulatory
We recommend listing standards that are subject to a notice of proposed rulemaking ("NPRM") or required by regulation separately from standards that are not regulatory requirements. As we stated above, ONC should be more explicit that the ISA is sub-regulatory guidance, without the force of law.

To assist stakeholders in navigating the complex health IT regulatory/sub-regulatory landscape, ONC should use this opportunity to explain how various standards-setting policies and programs interrelate, overlap and differ. These include the Centers for Medicare and Medicaid Services Meaningful Use ("CMS MU") program regulations or related CMS regulations; the ONC 2015 Health IT Certification regulation; publications of Standards Development Organizations

("SDO"); and other federal standards-setting initiatives, including ONC's Standards and Interoperability ("S&I") program or the National Information Exchange Model ("NIEM").

Future Considerations

In the future, ONC's most effective role may be to convene Standards Development Organizations (SDOs) and the private sector in the creation of standards, then package a "library of standards" that organizations would reference for their implementation efforts.

Better semantic standardization is a prerequisite for better nationwide interoperability. We recommend refocusing the ISA on SNOMED CT, Laboratory LOINC, and RxNORM as central reference standards for semantic interoperability.

Conclusion

Kaiser Permanente hopes the comments and recommendations will help contribute to a stronger, more practical, realistic and achievable version of the ISA. Thank you for considering our comments. Please contact me (510-271-5639; email: jamie.ferguson@kp.org) or Lori Potter (510-271-6621; email lori.potter@kp.org) with any questions or concerns.

Sincerely,

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