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Kaiser Foundation Health Plan
Program Offices

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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 electronically on *www.HealthIT.gov*

RE: ***ONC 2016 Interoperability Standards Advisory – Final Version***

Kaiser Permanente offers the following comments on the **2016 Interoperability Standards Advisory ("2016 Advisory")**, posted January 19, 2016 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 10.3 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 we serve.

We appreciate the opportunity to provide our feedback.

GENERAL COMMENTS

The 2016 Advisory represents the model approach ONC intends to use to coordinate the identification, assessment, and determination of the best available interoperable standards and implementation specifications for industry use. The 2016 Advisory would facilitate the interactive process for defining standards for future adoption, implementation, and use. Thus, the 2016 Advisory should be interpreted as a non-binding indication of ONC's assessment of the best available standards and implementation specifications.

[1] https://www.healthit.gov/standards-advisory/2016

[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

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Best Available Specifications

The vast majority of standards and implementation specifications in all three sections (Code Sets, Content, Services) in the 2016 Advisory are in: 1) Final Status; 2) Production Level; 3) Widely Adopted State; and 4) Mandated/Regulated. One of the primary purposes of the Advisory is to identify promising standards that are in earlier stages of development with significant potential to be finalized, adopted and widely used.

Therefore, Kaiser Permanente recommends the Advisory should concentrate on such promising standards with significant potential to be finalized, moved into production, and widely adopted in the near future (balloted standards), rather than duplicating the list of fully mature standards, already in production and widely implemented, which are specified in regulations or which could be published in a separate document. From our analysis, the document lists 61 federally mandated and 85 unmandated final standards versus the 9 federally mandated and 43 unmandated balloted standards; the number of final standards is almost triple the number of balloted standards. This undermines the forward-looking intent of the 2016 Advisory and causes confusion regarding whether the 2016 Advisory is either an "advisory" or a "regulatory" document.

Kaiser Permanente also recommends that ONC modify the "Standards Process Maturity" levels to reflect one of the following: Final, Standard for Trial Use ("STU"), or Ballot in Development.

Beyond Meaningful Use

In the broader context of Health IT – and not just Meaningful Use ("MU") – ONC's rationale for issuing the 2016 Advisory is unclear. While ONC intends to assist the health care industry by providing its assessment of standards, it may instead create unnecessary confusion about selection, implementation, and use of standards, given current regulations for the Standards and Certification program and recommendations provided by the ONC Standards Committee and others. We fail to see how the 2016 Advisory fits into the broader context of Health IT, evolving MU Stage 3 and beyond.

ONC should be more explicit about the purpose and application of the 2016 Advisory. The industry needs to understand clearly the role of the 2016 Advisory as sub-regulatory guidance, without the force of law. ONC needs to clarify distinctions between the 2016 Advisory, the CMS MU program regulations, and the ONC 2015 Health IT Certification regulation, as well as the work of Standards Development Organizations ("SDO") and other federal standards-setting initiatives including ONC's Standards and Interoperability ("S&I") program or National Information Exchange Model ("NIEM").

Updating the Advisory

ONC intends to update the 2016 Advisory annually; however, an annual update process raises serious questions and concerns. Specifically, ONC should address how timing may change once the MU Stage 3 program is permanent (e.g., whether the assessment process and Advisories will continue, whether a different timeframe would be more consistent with industry capabilities to

adopt and implement, etc.). With a continuing and evolving MU program, ONC would need to establish an open, transparent, and balanced process to provide input to any future Advisory; part of this should be a decision about whether to publish Advisories under a regulatory or sub-regulatory process, or through a wholly new mechanism created by ONC to gather input.

ONC Tech Lab

ONC recently introduced the creation of a "Tech Lab" to focus on what contributions will improve standards and build consensus around those that best serve specific interoperability needs. "Standards Coordination" was identified as a key area of focus; Kaiser Permanente applauds efforts to improve interoperability. ONC should clarify how the outcomes of the Tech Lab testing and pilots will be incorporated into the annually updated Interoperability Standards Advisory. We recommend that ONC incorporate any lessons learned, outcomes or other benefits obtained from this effort into the Best Available Specifications section.

Scope

The 2016 Advisory will not include administrative/payment standards. If the Advisory process continues, this decision is short-sighted. Kaiser Permanente encourages ONC to allow an opportunity for public comment before finalizing its approach. Because clinical and administrative data are so closely entwined, it may be appropriate to consider administrative standards as well.

COMMENTS ON "THE 2016 INTEROPERABILITY STANDARDS ADVISORY" SECTION

A key element missing from the 2016 Advisory is a more detailed description of the specific process ONC will follow to assess and prioritize the identified standards and implementation specifications. This section of the 2016 Advisory identifies "Best Available" characteristics of standards and implementation specifications, and six informative factors affecting "Best Available" determinations.

However, the 2016 Advisory does not describe the methodology or analysis to measure identified standards against the "Best Available" characteristics in detail. Additionally, the defined characteristics or the metrics used to assess each of the standards against the characteristics and factors have not been described. It will be critically important for ONC to include this information not only for full transparency, completeness, and trustworthiness of the process but also to ensure the validity and reliability of the assessments performed for each identified standard and implementation specification.

The 2016 Advisory states that the "Best Available" designation is intended to prompt dialogue; however, there is no detail about how and when such dialogue will occur or be governed, who will be involved, and what decision-making process will be used to revise and finalize the list. Open and transparent decision-making is required and the differing interests of relevant stakeholder groups (such as clinicians, vendors, payers, patients, and researchers) must be balanced in the process.

The 2016 Advisory does not distinguish between standards from American National Standards Institute ("ANSI") accredited SDOs, or similarly recognized international standards (e.g., International Standards Organization ("ISO")), versus unaccredited "standards" including guidance from sources that may not follow the requirements of voluntary consensus standards bodies as set forth in the National Technology Transfer and Advancement Act of 1995 (PL 104-113) and OMB circular A-119 as revised in 2016. Kaiser Permanente recommends that ONC prioritize standards from accredited SDOs when both accredited and unaccredited sources exist, and that only qualifying voluntary consensus standards published by organizations adhering to the ANSI Essential Requirements of 2016 or the Decisions and Recommendations of the World Trade Organization Committee on Technical Barriers to Trade (TBT) should be recommended as "Best Available" standards or used in relevant conformity assessment activities.

Best Available Characteristics

The 2016 Advisory began to identify the need for vocabulary harmonization across standards. We support vocabulary harmonization for the clinical record using SNOMED-CT and LOINC. For administrative purposes, those clinical standards should be translated into ICD, CPT, or HCPCS codes, etc. Standards intended for data collection and other non-clinical purposes should not be required as part of the EHR. For example, the Clinical Data Interchange Standards Consortium ("CDISC") standards use vocabularies that are not in sync with the HL7 standards or implementation guides used in clinical records, such as the HL7 Consolidated-Clinical Document Architecture ("C-CDA").

It is essential for semantic interoperability to successfully harmonize vocabularies across all standards and implementation guides that express the same concepts. The next iteration of the Advisory should include vocabulary harmonization as a criterion. During the transition and convergence, the industry could start by indicating the level of harmonization similar to the "Best Available" characteristics, while ONC works with the National Library of Medicine ("NLM") and the respective SDOs to harmonize the variant vocabularies.

SECTION IV: PROJECTED ADDITIONS TO THE 2016 ADVISORY

To gain benefits from the use of patient-generated health data (PGHD) and consumer devices ONC should consider the interoperability needs and standards for EHR systems with mobile health platforms including consumer grade devices as well as FDA registered or regulated remote devices. Currently despite a proliferation of apps, proprietary exchange mechanisms result in little interoperability across mobile apps and devices. Despite the technical promise of emerging standards such as HL7 FHIR a lack of authoritative governance and coordination over the development, management, and use of these standards may quickly deflate the bubble of expectations in this area. The complexity, abundance, and variety of use case scenarios for mobile devices and PGHD argues for strict adherence to a limited set of national standards to avoid overloading certified HIT with conflicting demands for software development and deployment. At the same time, the impact of this branch of interoperability upon EHR clinician user workflows should be considered carefully before including such standards in a future Advisory.

Appendix II: Sources of Security Standards

Because data can flow between mobile devices and PHR or EHR, it is important to explore security and privacy issues associated with the consumer mobile context.

OASIS and other security related standards were mentioned in public comments, but not specifically addressed in the final 2016 Advisory. This may be resolved as the security patterns are filled out. OASIS, and related standards, should be included in Appendix II

Privacy involves what to protect and security dictates how to protect it. Thus, we would recommend renaming this section to "Sources of Security and Privacy Standards" to be consistent with several of the standards currently denoted. This section could be further supplemented with the Fair Information Practice Principles ("FIPPS").

Lastly, since HIPAA requires the Secretary of Health and Human Services to adopt standards developed by ANSI-accredited standards developers ("ASDs") whenever possible, providing a link to the ASDs may be beneficial. Many of these are now embedded in the standard/ implementation specification sections of the document.

CONCLUSION

We hope our comments and recommendations will help contribute to a stronger, more practical, realistic and achievable version of the 2016 Advisory.

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,

Jamie Ferguson
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