

September 23, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health & Human Services

Submitted electronically on <https://www.healthit.gov/isa/>

Re: ONC Draft 2019 Interoperability Standards Advisory Annual Update Request for Comments

Dear Dr. Rucker:

Kaiser Permanente welcomes the opportunity to offer the following comments on the draft *2019 Interoperability Standards Advisory*,¹ as ONC prepares to update the ISA for the 2020 “Reference Edition.”

The Kaiser Permanente Medical Care Group is the largest private integrated healthcare delivery system in the U.S., with 12.3 million members in eight states and the District of Columbia.² We are committed to providing high-quality, affordable health care services and improving the health of our members and the communities we serve. To help us achieve that mission, we have implemented KP HealthConnect,[®] a secure Electronic Health Record (EHR) system to support the delivery of healthcare services to our members and to enhance communications among providers.

We appreciate the opportunity to provide feedback on ONC’s ongoing efforts to improve and enhance the Interoperability Standards Advisory (ISA).

General Comments

We appreciate ONC’s desire to identify, evaluate, and coordinate current health IT standards, and to refer its regulated entities to standards for specified interoperability needs. Based on our long experience with interoperable health information exchange, we recommend the agency consider several factors during its assessment.

Standards Maturity

¹ <https://www.healthit.gov/isa/>

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 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente’s members.

First, ONC should assess the standards process maturity of recommended standards in a manner that is more consistent with the methods used by standards development organizations (SDOs). This consistency should improve ONC's ability to judge which new standards are ready to be implemented. ONC should support industry usage needs on leading edge technology such as Fast Healthcare Interoperability Resources (HL7® FHIR® R4 (v4.0.0)).

Measuring Standards Use vs Measuring Interoperability

In addition, ONC should replace its current qualitative assessments of implementation and adoption of standards with objective quantitative methods, for example, by considering the number of patient records, or the number or percentage of users, or the number of transactions using each standard. However, ONC should be very clear that measuring the use of standards is not the same as measuring interoperability.

While system connectivity can be assessed by measuring technology standards use, the effective use of interoperable health IT (thus, information to support health care delivery) will require different concepts and measures. Determining whether the right information about the right individual was available to the provider at the right time means going beyond transactional technology standards to focus on the availability and comprehensiveness of information content at the point of use and clinical care delivery.

Thus, we urge ONC to help broaden the concept of interoperability, defining it in terms of information availability, information usability, and clinical outcomes, rather than transactional processes, technologies, and methods. Information usability is different from system usability, which concerns user interface design and functionality. Usability of information across systems involves whether the information accessed by a provider while delivering patient care is useable for clinical decision making and effective care delivery, as well as whether the information was actually used. Usability of information is critical in determining whether interoperability was achieved; NIST has demonstrated that it can be measured.³

Administrative Transactions

ONC would enhance the ISA's value by expanding it to include health care administrative transactions. We strongly recommend ONC consider this addition for the next iteration.

Patient-Generated Health Data

To promote the benefits of patient-generated health data (PGHD) and consumer devices, ONC should address the interoperability of EHR systems with mobile health platforms, including consumer devices as well as FDA registered or regulated remote devices. There is scant information in the 2019 ISA Reference Edition regarding mobile devices, mobile medical apps, or their interoperability. The complexity, abundance, and variety of use cases for mobile devices and PGHD argues for strict adherence to a limited set of national standards to avoid overloading certified Health IT with conflicting demands for software development and deployment.

ISA References

Finally, ONC should ensure comprehensive compatibility of the ISA with ONC's other frameworks or publications that reference it, such as the Trusted Exchange Framework and Common Agreement (TEFCA), U.S. Core Data for Interoperability (USCDI), and A.P.I. Resource Collection in Health

³ <https://www.nist.gov/programs-projects/health-it-usability>

(ARCH). ONC should clarify that the ISA is only a reference of available, potential standards, not a compilation of recommended or mandatory standards for entities eligible for certain programs, or for TEFCA participants. For example, when the TEFCA references the ISA, it should clearly note the ISA's informational status. USCDI and ARCH should address additional FHIR resources that are significant for clinical decision support, electronic clinical quality measurement, and reporting (e.g., HL7's Da Vinci Project).

Comments to Questions 19-1 through 19-4

19-1: In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

We support ONC's efforts to better understand ISA use. ONC should evaluate the ISA's usefulness, ideally through an evaluation conducted by an independent, unbiased third party. ONC should publish findings in a transparent and constructive manner and adjust ongoing work on the ISA accordingly.

19-2: Are there additional features or functionality ONC could make to the ISA website that would enhance the user experience?

Giving users the ability to filter standards by federal requirements would enhance functionality. Reference hyperlinks should connect users to the applicable federal regulation or statute; consistent maintenance should ensure all hyperlinks link to the most current version of the underlying requirements.

19-3: The adoption level, along with other informative characteristics about standards/ implementation specifications, was introduced to the ISA in August, 2015, and currently represents ONC's "best guess" at current adoption based on a number of factors. Is the adoption level characteristic as it stands valuable information for stakeholders, or should it be retired or replaced with other information?

As mentioned above, ONC's assessment of standards adoption levels would benefit from a more objective, quantitative approach. ONC should consider relying on standards development organizations (SDOs) to perform their own assessments of implementation maturity and adoption. ONC should work with SDOs to formalize a more structured and consistent approach to these assessments.

19-4. The specialty care/settings pages were added in 2019, and represent a collection of related Interoperability Needs that pertain to a particular setting or type of specialty care (i.e., pediatrics, treatment for opioid use disorder). Are there additional specialty care/settings specific collections that would be beneficial for inclusion?

We agree there is value in specialty care/settings collections. However, we are concerned there is also a risk that too many types of specialties will make the ISA even more complex (e.g., opioid use and mental health). While there is a trend toward providing more specialized standards and codes, deciding whether to add these to the ISA should involve collaboration between the National Institutes of Health (NIH) and specialty societies, (e.g., M codes for oncology).

Introduction to the ISA Comments of Select Sections

Scope

ONC should consider creating a section for Pharmacogenomics and Genomic data in addition to family history. This new section should include references to existing and new Genomic content standards, leveraging SDO collaboration (e.g., GA4GH Global Alliance for Genomics and Health). ONC should also include a new section that references personal health devices. (See our general comments above about PGHD.)

Cost

We recommend ONC clarify the relationship between a government-required standard and the cost to meet that requirement. We propose changing the language in Section #5 to more clearly state that relationship, as follows (our comments in italics/strike-through):

This characteristic conveys whether a fee is involved to purchase, license, or obtain membership for access or use of the recommended standard or implementation specification. *This characteristic does not include costs associated with implementing the standard or implementation guide.*

- “\$” – when this designation is assigned, it signifies that some type of payment needs to be made in order to obtain the standard or implementation specification. Where known, the estimated cost for access will be provided.
- “Free” – when this designation is assigned, it signifies that the standard or implementation specification can be obtained without cost. *A no cost* ~~This designation applies even if a user account or license agreement is may be required to obtain the standard at no cost, but is not meant to imply that there are no costs associated with implementation~~

Conclusion

Kaiser Permanente looks forward to continuing to work with ONC to improve the ISA. We appreciate your willingness to consider our comments. Please feel free to contact me at (510)-271-5639 (email: jamie.ferguson@kp.org) or Lori Potter at 510-271-6621 (email lori.potter@kp.org) with any questions or concerns.

Sincerely,



Jamie Ferguson
Vice President
Health IT Strategy and Policy