



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 – Draft for Comment*

Kaiser Permanente offers the following comments on the **2016 Interoperability Standards Advisory (“Draft 2016 Advisory”)**, posted as an “Open Draft” September 23, 2015 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 10 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.

A. GENERAL COMMENTS

As we understand it, this Draft 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. As an open draft, the Draft 2016 Advisory is intended to facilitate the interactive process for defining standards for future adoption, implementation, and use. Thus, the Draft 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.

However, in the broader context of Health IT – and not just Meaningful Use (“MU”) – ONC’s rationale for issuing the Draft 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 Draft 2016 Advisory fits into the broader context of Health IT, MU Stage 3 and beyond.

ONC should be more explicit about the purpose and application of the Draft 2016 Advisory. The industry needs to understand clearly the role of the Draft 2016 Advisory as sub-regulatory guidance, without the force of law. ONC needs to clarify distinctions between the Draft 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”).

ONC intends to update the Draft 2016 Advisory annually; however, an annual update process raises serious questions and concerns. Specifically, ONC should address how this proposed 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.). If the MU program is to continue, ONC would need to establish a 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.

A majority of standards and implementation specifications included in this Draft 2016 Advisory are in *final* form, in production, widely adopted, and regulated. We strongly recommend that ONC not include these standards in the Draft 2016 Advisory because the main scope and purpose of the Draft 2016 Advisory is to identify the best standards and implementation specifications *under development* specifically, those with significant potential to be finalized as standards, moved into production, and widely adopted in the near future. Including standards that are already in final status, in production, and widely adopted, will cause further confusion regarding whether the Draft 2016 Advisory is truly an “advisory” or a “regulatory” document.

SCOPE

The Draft 2016 Advisory states it will not include administrative/payment standards. If the Advisory process is to continue, this decision is short-sighted. We encourage 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 these standards as well.

COMMENTS ON “THE 2016 INTEROPERABILITY STANDARDS ADVISORY” SECTION

A key element missing from the Draft 2016 Advisory is a more detailed description of the actual process ONC will follow to assess and prioritize the identified standards and implementation

specification. This section of the Draft 2016 Advisory identifies “Best Available” characteristics of standards and implementation specifications, and six informative factors affecting best available determinations.

However, the Draft 2016 Advisory does not describe the methodology or analysis to measure identified standards against the best available characteristics. Additionally, the defined characteristics or the metrics used to assess each of the standards against each of the characteristics and factors noted in this section have not been described. It will be critical 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 Draft 2016 Advisory states that “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.

The Draft 2016 Advisory does not distinguish between standards from American National Standards Institute (“ANSI”) recognized SDOs, or similarly recognized international standards (e.g., International Standards Organization (“ISO”)), versus “standards” including guidance from unaccredited sources.

We recommend that ONC prioritize standards from accredited SDOs when both accredited and unaccredited sources exist.

B. COMMENTS ON “SECTION I: BEST AVAILABLE VOCABULARY/CODE SET/TERMINOLOGY STANDARDS AND IMPLEMENTATION SPECIFICATIONS”

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

The use of the term “Allergies” is vague and there should be clarity regarding a referral to the nature of the allergic reaction (e.g., rash) or the type of reaction (e.g., food, medication). In either case, SNOMED-CT is a reasonable standard vocabulary.

Regarding the general specification of SNOMED-CT throughout the Draft 2016 Advisory, additional detail should be included when possible and appropriate. SNOMED-CT is very comprehensive, and some concepts can be confused with others. Specifying a subset of SNOMED-CT will be helpful in clarifying the appropriate concepts. For example, concepts descending from “Food Allergy” are appropriate for identifying food allergies, but do not specifically include all possible food concepts.

Interoperability Need: Representing patient allergens: medications

NDF-RT is included in the “Limitations, Dependencies, and Preconditions for Consideration” section. If NDF-RT is to be recommended for representing medication classes, then it should be included as another Standard entry.

*Interoperability Need: Representing patient allergens: environmental substances (also **Question 4-5**)*

SNOMED-CT includes a range of environmental allergens and related findings. While it may not be complete, SNOMED-CT is a valid vocabulary standard for this Interoperability Need.

I-B: Care Team Member

Interoperability Need: Representing care team member (health care provider)

The “Need” is to identify the health care provider. The notes in “Limitation” point out that SNOMED-CT has a subset for “subject role in the care setting.” “Subject role” is a different concept than the identification of the provider and should be included as a distinct “Interoperability Need.”

I-D: Race and Ethnicity

Interoperability Need: Representing patient race and ethnicity

As genomic data is incorporated into medical practice and ultimately electronic health records, these categories become less relevant and useful as the genetic data supersedes them.

The “Limitations” section calls out CDC Race and Ethnicity Code Set Version 1.0 as a valuable resource for more refined consideration of race and ethnicity. This should be listed as an alternative standard.

I-F: Functional Status/Disability

*Interoperability Need: Representing patient functional status and/or disability (also **Question 4-5**)*

If the intent of the Advisory is to present best available standards/ specifications/vocabularies, then we encourage ONC to include International Classification of Functioning, Disability and Health (“ICF”). We also recommend consideration of other Functional Status standards/specifications/vocabularies submitted by experts and/or the public.

I-H: Immunizations

Interoperability Need: Representing immunizations – historical

Interoperability Need: Representing immunizations – administered

CVX and MVX are documented as code tables in HL7, but these two tables were developed by, and are maintained by, the CDC. That becomes clear if the reader follows the hyperlink. We suggest that CDC should be identified as the owner of these tables in this Advisory. Perhaps as a comment in the “Limitation” section.

Note that the correct names of CVX and MVX are: CVX – Vaccines Administered, and MVX – Manufacturers of Vaccines.

We see MVX is included in the “Historical” entry, but not the “Administered” entry. The discussion on MVX in the “Limitations” section of the historical entry points out the potential usefulness of MVX, paired with CVX, in specifying the *administered* vaccine. We suggest that MVX be added as a standard to the administered entry.

I-I: Industry and Occupation

*Interoperability Need: Representing patient industry and occupation
(also Question 4-5)*

We recommend referencing the U.S. Department of Labor, Bureau of Labor Statistics, and Standard Occupational Classification.

I-J: Lab tests

Interoperability Need: Representing laboratory tests and observations

The discussion of LOINC versus SNOMED-CT in the “Limitations” section is unclear and request additional clarity regarding “Categorical.”

“The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology.”

I-K: Medications

Interoperability Need: Representing patient medications

RxNorm is a good choice for representing patient medications. It permits identification at a variety of levels of granularity. However, if a patient only recalls being on a beta-blocker, RxNorm does not have drug categories directly. There is a linkage between RxNorm and NDF-RT for medication categories. We suggest that NDF-RT be added as another standard in the table rather than just a comment under RxNorm. At the same time we also recommend that ONC consider adding NDC as another standard for representing patient medications. While we believe RxNorm is the better choice for medication identification, there are points in the prescription life cycle where NDC is useful, for example, at dispense, for claims, in report from payers.

I-P: Radiology (interventions and procedures)

Interoperability Need: Representing radiological interventions and procedures

The “Limitations” section discusses the Radlex/LOINC work to create a common data model. Until the two are aligned, we suggest that Radlex continue to be listed as a standard.

I-Q: Smoking Status

Interoperability Need: Representing patient smoking status

The “Limitations” section describes the limitations of SNOMED-CT relative to severity of dependency, quit attempts, lifetime exposure, and use of e-cigarettes. We concur with this assessment, but questions whether these are vocabulary concerns or attributes (additional observations) of the assessment of the patient's smoking status. The comment remains valid. We suggest adding text to acknowledge that these are not necessarily aspects of smoking status to be addressed by vocabulary.

New I – T: Clinical Quality Terminologies

ONC should consider adding a new sub-section under Section I to include clinical quality terminologies such as

- QUICK – Quality Improvement Clinical Knowledge
- CQL – Clinical Quality Language

C. COMMENTS ON “SECTION II: BEST AVAILABLE CONTENT/STRUCTURE STANDARDS AND IMPLEMENTATION SPECIFICATIONS”

II-B: Care Plan

Interoperability Need: Documenting patient care plans

In addition to the listed Implementation Guide, there are a number of care plan related projects in industry groups and SDOs. Some of these are more specialized than others. We recommend identifying multiple specific Implementation Guides each of which may meet different needs.

II-I: Patient Education Materials

Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge form online resources

In the Interoperability Need, “knowledge form” should be “knowledge from.”

II-K: Public Health Reporting

Interoperability Need: Case reporting to public health agencies

The link for “Structured Data Capture Implementation Guide” is broken. The correct link is <http://hl7.org/fhir/2015May/sdc.html>

II – F: Family health history (clinical genomics)

To support future interoperability needs in this area, HL7’s Clinical Genomics workgroup has begun work on a Fast Healthcare Interoperability Resources (“FHIR”) profile for Genetic Observation to support reporting of clinical genetic and genomics findings. As of October 2015, this is in the very early stages.

II – L: Quality Reporting

ONC should consider including in this section the following additional standards and implementation specifications:

- HQMF (DSTU)
- CQL-based HQMF (DSTU)
- QDM-based HQMF (DSTU)

II – M: Representing clinical information as a “resource”

It would be useful to explicitly define what a resource is according to the HL7 definition. (Found at <https://www.hl7.org/fhir/resource.html>)

As of October 2015, FHIR is in draft standard for trial use 2 (“DSTU 2”) having incorporated learning from DSTU 1 as well new resources developed since the previous version was published. The history of changes can be found at: <https://www.hl7.org/fhir/history.html>.

As for testing tools, there are a number of public websites available that are FHIR servers available for testing FHIR clients and resources. The list of such servers is available at: http://wiki.hl7.org/index.php?title=Publicly_Available_FHIR_Servers_for_testing.

D. COMMENTS ON “SECTION III: BEST AVAILABLE STANDARDS AND IMPLEMENTATION SPECIFICATIONS FOR SERVICES”

III – A: Unsolicited push of clinical information to a known destination

As an emerging alternative standard, FHIR using RESTful transport may make sense as a means of providing expected routine updates of specific information within a secure messaging environment. The environment could be within an integrated delivery system or across an extended network appropriately secured.

E. COMMENTS ON “SECTION IV: QUESTIONS AND REQUESTS FOR STAKEHOLDER FEEDBACK”

General

There is extensive reference to Draft Standards, Draft Standards for Trial Use, (“DSTU”) in the Draft 2016 Advisory. Granted, these reflect current work in the HIT standards community to address information and interoperability requirements and, it is important to note “Emerging Standards.” However, we are concerned that the draft standards may be incorporated into regulatory, rather than guidance, documents. By their nature, draft standards are fluid and subject to ongoing revision and is therefore not an appropriate reflection of the standard. Care should be taken not to endorse draft standards as final and complete.

FHIR is a special example of a draft standard. There is enormous effort and excitement behind FHIR, which has the potential to streamline implementation and advance interoperability. But, it is a *draft* standard. Given FHIR's high visibility, it cannot and should not be excluded from the

Draft 2016 Advisory. However, we encourage ONC to address the potential for changes to FHIR and how that may impact this Draft 2016 Advisory.

Question 4-1: *In the 2015 Advisory, each standard and implementation specification was listed under a “purpose.” Prior public comments and HIT Standards Committee recommendations suggested that the Advisory should convey a clearer link to the ways in which standards need to support business and functional requirements. This draft attempts to do so and lists standards and implementation specifications under more descriptive “interoperability needs.” Please provide feedback on whether revision from “purpose” to “interoperability need” provides the additional requested context and suggestions for how to continue to improve this portion.*

“Interoperability Need” is more descriptive than “Purpose.” However, since all of the entries are labeled with this phrase it is less useful. In order to address “the ways in which standards need to support business and functional requirements,” we question if there should be more purposes than just interoperability need.

Question 4-2 - *For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or “unknown” information.*

1. Standards Process Maturity

The Draft 2016 Advisory offers only two options for conveying this characteristic: Final and Draft. The most important aspect missed by these two options is the time factor, such as the length of time the standards or implementation specifications been in Final or Draft status. This is particularly important when looking at the Draft option. Some of the Draft standards included in the document have had draft status for several years. Other Draft standards in the document have been in draft for only a few weeks. Registering the length of time the standard has been effective will be valuable.

2. Implementation Maturity

As with the previous characteristics, knowing how long a standard or implementation specification has been in Production or in Pilot will be an important dimension to include. Particularly for the Pilot option.

For the Pilot option, it is also very important to depict the scale of the pilot and its results. Some of the pilots are only test pilots between two entities. Some are large-scale pilots. Some pilots are highly successful but others are less so. Knowing this, along with the temporality element discussed above, will contextualize better the real state of each of the standards and implementation specifications.

3. Adoption Level

This characteristic should only apply to standards and implementation specifications that have “in production” status under the Implementation Maturity characteristic. Characterizing

standards and implementation specifications that are in a Pilot state of Implementation Maturity as being “adopted” at any level seems inconsistent with the definition of Pilot state. There are a number of instances in the document where standards and implementation specifications that are in Pilot status are characterized as being adopted at various levels. This should be corrected.

4. Regulated

There are some standards that are adopted in either legislation or in state regulations. Those should be also considered when defining whether a standard is “regulated” or not.

5. Cost

Valuable information. No comments.

6. Test Tool Availability

Valuable information. No comment.

Question 4-3: *For each standard and implementation specifications, there is a table that lists security patterns. This draft only includes select examples for how this section would be populated in the future. Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.*

The examples of “security patterns,” appear to address a number of specific points. As more of the security patterns are populated, these points may provide structure and direction in describing and defining the security patterns.

The Interoperability Standards Advisory (“ISA”) states that the goal of this subsection is to identify the generally reusable security techniques applicable to interoperability need(s) without prescribing or locking-in particular security standards. However, the security patterns seem to be derived from the Standard/Implementation Specification provided which contradicts the stated intent.

The correlation between the standards and/or implementation specifications is not clear. Where multiple standards and/or implementation specifications are listed, there is no mapping to identify if all of the security patterns are applicable, or if it is possible that the patterns would not apply to the standard but only select implementation specifications.

Lastly, not all of the entries are specific to security. For example, inclusion of a patient consent indicator would be more consistent with a privacy requirement than a security requirement. Guidelines as to what would produce an entry would be helpful.

Question 4-4: *For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.*

In general, this section was useful in advising if additional considerations are warranted. However, there are inconsistencies in the examples provided. Under Section III-A, references to SMTP and S/MIME were retained from the previous version of the ISA but the information for Hypertext Transfers Protocol (“HTTP”) 1.1 RFC 723x (to support RESTful transport approaches) and Transport Layer Security (“TLS”) Protocol Version 1.2 RFC 5246 for the security were both eliminated. Guidelines for what is included (or not) and rationale for change should be established.

Another consideration for this section is those technologies that are no longer considered secure such as SHA-1 and SSL2.0. Understanding that this is a moving target, consideration should be given to NIST establishing a database where the status of an existing standard and/or implementation standard could be verified would be helpful.

Section II: Content / Structure

Question 4-6: Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

Yes, the IHE Profile Retrieve Form for Data Capture should be considered as a standard in this Advisory. In general, “other standards under consideration” would be a good addition to the document format. As expressed in the introduction, this would stimulate conversation on applicability of standards.

Section III: Services

Question 4-10: The 2015 Advisory’s Section III, Transport has since been removed with content representation migrated as applicable within Section IV Services. What is your view of this approach?

The information, though not appearing in its own section, was moved in part to the new table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. If included, particularly as certain technologies are deemed as less secure or no longer best in breed, this information should continue to be reflected either in this document or in the previously suggested NIST security standard look up functionality under 4.4.

Appendix II: Sources of Security Standards

Question 4-11: Are there other authoritative sources for Security Standards that should be included in Appendix II?

It was interesting that OASIS and other security related standards were mentioned in some comments, but they are not specifically referenced. This may be resolved as the security patterns are filled out. But, OASIS, and related standards, should be included in Appendix II

Understanding that privacy tells you what to protect and security tells you how to protect it, we would recommend that there be consideration to renaming this section to be “Sources of Security

and Privacy Standards” to be consistent with several of the standards currently denoted. This 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 for whom their standards are integral to interoperability may be beneficial. Many of these are already imbedded 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 Draft 2016 Advisory. Please contact Jamie Ferguson 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,



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