National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Submitted electronically at: https://www.healthit.gov/standards-advisory/2016

Re: 2016 Interoperability Standards Advisory

Dear Dr. DeSalvo,

Thank you for this opportunity to comment on 2016 Interoperability Standards Advisory.

As you know, Epic is an electronic health records (EHR) developer based in Verona, Wisconsin. Our interoperability and industry standards experiences, as well as our broad general experience developing a sophisticated EHR and supporting the healthcare organizations that use it, inform the suggestions we make attached to this letter.

Epic participates in industry standards development in order to further interoperability efforts, including Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), National Council for Prescription Drug Programs (NCPDP), Standards & Interoperability Framework, and others. Epic staff have also chaired several HL7 and IHE committees. In addition to developing and implementing standards, we've taken a leadership role in the industry in interoperability governance. In February 2014, we helped to co-found The Sequoia Project's Carequality (www.carequality.org) initiative, which aims to go a step beyond the eHealth Exchange to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, and state HIEs, to interoperate freely with one another. We also are a supporting member of The Sequoia Project (fka Healtheway), which provides standards, rules, and a directory to power nationwide record sharing on the eHealth Exchange network.

Sincerely,

Peter DeVault
Epic

General comments

We agree that most of the standards proposed are the best available, and we've commented only in places where we disagree or have additional input.

Standards identified as the best available are at various stages of implementation and adoption. Users of the Standards Advisory will need to account for appropriate implementation timelines for their particular purpose. In some cases the best available standard is widely adopted and in other cases the best available standard remains immature.

In addition to assessing what is the "best available," ONC and the ISA should work with experts to evaluate how well the standard actually meets the current interoperability need. Public comment is the first step to doing so.

Purpose

The ISA's stated purposes of providing industry with a "single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs" seems reasonable, though we observe that the purpose seems focused on US industry specifically, and it might be helpful to clarify that since there are other considerations internationally.

Comments on "Best Available" Characteristics

#1: Standards Process Maturity

ONC might want to consider including "Mature" and "In Development" as additional stages. A standard might be final, but still not mature. After being in a final state, a standard might undergo several changes based on industry needs and realization. Examples of this are XDW from IHE-ITI and the implementation guide for Syndromic Surveillance.

#2: Implementation Maturity

We are not certain we would be able to use the definitions given to establish whether standards are being piloted or in production use; further clarification would be helpful.

#3: Adoption Level

The adoption level scale is confusing. If a standard has "21-40%" adoption, does that mean it has been incorporated into ~30% of HIT products? That it is in use in ~30% of healthcare organizations? That ~30% of these types of transactions use this standard?

Adoption is a critical factor to assess a standard in this context, but more specificity is needed for the scale to be implemented consistently.

The difference between 0% adoption and 20% adoption seems particularly significant, and there is no visual with zero filled circles. We recommend that another level be added to the scale for 0% adoption with a corresponding visual.

#4: Regulated

As currently worded, the "yes/no" status makes it appear that the standard is regulated by HHS. As we understand it, this characteristic is meant to show whether a standard is required in regulation. We recommend that the characteristic be re-named to "#4: In Regulatory Use".

There is also confusion on the scope of the regulations considered in the ISA. Is ONC considering state and other jurisdictional regulations as well as US national? How would ONC present a standard where 40/50 states require it but not the federal government? We recommend that ONC limits the scope to US national regulation and cites the regulation rather than listing a "yes/no" status.

#5: Cost

We hope that ONC realizes that while standards are created and distributed for free, there is a cost associated with developing the standard and sponsoring the volunteers from vendors as well as a cost associated in developing the software to adhere to the standard. We suggest use of more precise language such as "standards licensing cost" and "no standards licensing cost."

Comments on proposed standards

I-A: Allergies

We are not aware of a recommended code set for environmental allergens that are not related to any medication records.

I-B: Care Team Member

We recommend that ONC expands the scope of this section to "Healthcare Provider" and then creates a separate table for "Healthcare Provider *specialty/role*." ONC can then call out SNOMED-CT as the best available standard for Role.

For the interoperability need: Representing care team member (health care provider), the Consolidated CDA R2 strongly recommends the NUCC Healthcare Provider Taxonomy code set. We agree with the CCDA R2 recommendation.

A small correction: it's NPPES, not NPI, which "permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of 'person.'"

Regarding Adoption Level, our experience is that:

- Identification of healthcare provider specialty/role with SNOMED is not currently well adopted (0-20%)
- Identification of physicians who bill CMS with NPI in electronic health records is well adopted (81-100%), however, it is less clear to us what percent of the total population of caregivers are represented in physicians billing CMS. Across other roles, adoption is likely much lower, such as 21-40%.

I-E: Family Health History

We agree with ONC's assertion that "some details around family genomic health history may not be captured by SNOMED-CT." There is also ongoing discussion on whether this standard needs to be extended to add consent information, such as when family member A is reporting information about family member B and whether family member B has consented to the sharing of this information. ONC should continue to track these considerations in the ISA.

I-G: Gender Identity, Sex, and Sexual Orientation

Given the inclusion of these items in 2015 Edition certification, the Regulated column should be updated.

Interoperability Need: Representing patient gender identity

SNOMED-CT is the appropriate terminology to code Gender Identity, though specific terms suggested in other regulations are not the best available, specifically the SNOMED CT codes 407377005-Female-to-male transsexual and 407376001-Male-to-female transsexual. "Transsexual" is considered offensive in some contexts, and as the purpose of this field is to determine the individual's gender identity, "transsexual" is not appropriate. In addition, SNOMED CT code 446131000124102-Identifies as non-conforming gender would be more appropriate as "Identifies as gender-variant."

Interoperability Need: Representing patient sexual orientation

We want to clarify that this interoperability need covers the standards for the field for self-identified patient sexual orientation, which is different than what partners the patient takes. We would like to also note that the Health Information Technology Standards Committee (HITSC) has called for national discussion on the appropriate manner to store this information.

I-H: Immunizations

Interoperability Need: Representing immunizations – administered

We disagree with the assertion that National Drug (NDC) codes "do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries". In fact, NDC codes often pose challenges because they are too specific for most use cases. The same vaccine can have a different NDC for the Unit of Use and the Unit of Sale, combination vaccines can have a different NDC for each component, and each manufacturer has a different NDC for the same immunization. Furthermore, NDC codes change regularly and a list of NDC codes needs to be maintained by each system participating in the exchange. We are aware of many healthcare organizations that currently have a difficult time maintaining which NDCs correspond with which immunizations that they keep in stock. If they were to get an NDC from another organization that gives slightly different immunizations, it is likely that they would not be able to identify which immunization it is.

Instead, we recommend CVX as the primary standard for identifying immunizations and allowing NDC to be used as an optional piece of data. CVX is a self-contained code set that is already widely used to identify immunizations. NDCs are more widely used to identify drugs and rely on systems to cross-reference a drug database to get additional information before it can be used effectively.

I-J: Lab Tests

The recommendation that organizations not using LOINC codes should "maintain and publish a mapping of their codes to the LOINC equivalent until migration to LOINC has occurred" is concerning. This would negate any incentive lab systems have to switch to using LOINC as other

groups can use this published mapping data to interact with the lab. This also defeats the purpose of having LOINC codes available since the destination system still has to map both local and LOINC codes.

II-C: Clinical Decision Support

The Knowledge Artifact allows HIT developers to import decision support rules created by a third party into an HIT module. Decision Support Services (III-B), on the other hand, allow the decision support rules to be stored in a third party's server and the HIT module queries it for decision support. Both of these options are essentially two different models for addressing the same need. We recommend the advisory structure be altered to list these two options together.

II-D: Drug Formulary & Benefits

NCPDP Formulary and Benefits v3.0 is the standard used by the industry and should continue to be used as it was a recent transition to version 3.0.

Real Time Prescription Benefit Inquiry (RTPBI) should continue to be monitored, however there is still no standard for it so it should not be included in the Advisory at this time. Furthermore, it is likely that it will exist alongside the existing NCDPD Formulary and Benefits v3.0 and will not replace it entirely.

II-E: Electronic Prescribing

<u>Interoperability Need: Pharmacy notifies prescriber of prescription fill status</u>

These transactions have very low adoptions (0-20%).

<u>Interoperability Need: A prescriber's ability to obtain a patient's medication history</u>

We would like to clarify that both the "Medication History Request" and "Medication History Response" transaction need to be implemented.

We would like to clarify that this is a transaction that could also be between a prescriber and a pharmacy benefit manager (PBM), not uniquely between a prescriber and a pharmacy.

II-G: Images

<u>Interoperability Need: Exchange of imaging reports</u>

There are separate 'best available' standards for inter-organization exchange of imaging reports as compared to electronic access to imaging reports within one organization. For inter-organization

exchange, the standards listed are the best available. Within an organization, HL7 V2 is the standard that is most widely used and works well.

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results

The LRI 2.5.1 specifications standard available for culture results is not mature enough and should be listed as a Limitation. This standard does not sufficiently clarify how to send discrete culture results, which can create different interpretation of the results across labs. At the very least, clear guidelines to specify the quantity and the organism should be established in order to ensure labs are aligned.

Interoperability Need: Support the transmission of a laboratory's directory of services to health IT

These standards are the best available for new implementations but they don't bring a large benefit for organizations that have already implemented successful lab integrations. eDOS is not a widely used or developed standard. References to this standard in future regulation should carefully consider that organizations that have already been successful should not need to redo their integrations.

II-I: Patient Education Materials

The usefulness of the standard for requesting context-specific education materials is dependent upon the availability and complexity of these materials from resource vendors. This should be listed in the Advisory under "Limitations, Dependencies, and Preconditions for Consideration."

II-J: Patient Preference/Consent

Depending on how it's implemented, IHE Basic Patient Privacy Consents (BPPC) can lead to data segmentation. Patient safety is a crucial aspect of data segmentation standards due to the impact of removing clinically relevant information from patient charts so that it is not accessible to providers. Given that BPPC has not been evaluated for impact on patient safety or clinical workflows, we strongly encourage delaying the endorsement and adoption of a standard in this space until more research is done.

An Adoption Level of 4 for BPPC seems high as based on our experience, US adoption of BPPC is near zero.

An Adoption Level of 4 for IHE Cross Enterprise User Authorization (XUA) also seems high. Is this Adoption Level rating the use of SAML, which XUA uses, rather than XUA?

II-K: Public Health Reporting

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies

Our experience suggests an Adoption Level of the IG listed for antimicrobial use reporting as 21-40%. Adoption of antibiotic resistance using the specified IG is much lower (0-21%) as it is a much newer standard.

The most recent Implementation Guide is HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1. We recommend this as the best available implementation specification.

Interoperability Need: Case reporting to public health agencies

The Structured Data Capture (SDC) methods do not currently restrict vocabulary to standard vocabulary sets. This is a limitation that should be added for consideration.

II-L: Quality Reporting

Interoperability Need: Reporting aggregate quality data to quality reporting initiatives

The Advisory should also list the published CMS implementation guides.

Interoperability Need: Reporting patient-level quality data to quality reporting initiatives

The Advisory should also list the published CMS implementation guides.

CMS requires QRDA R3 for 2016, so it would seem more appropriate to list this standards as production, rather than pilot. If QRDA R2 needs to be listed, it should be listed as obsolete because it is no longer accepted for submission.

II-M: Representing clinical health information as a "resource"

You indicated the FHIR Test Tool Availability as "No," however there are FHIR validators currently available online. These include:

- Project Crucible
- Touchstone Project
- FHIR Furore Resource Validator

Specifying FHIR alone as the best available specification is not sufficient to meet the interoperability need of representing data as a resource – there must also be clinical vocabularies for data

represented. Without standardization of terminologies across healthcare organizations and vended products, we risk continuing the trend of balkanization of healthcare data exchange due to implementation variances. In other sections of the ISA, we define specific profiles or templates of a data exchange model, and the same should be done for FHIR. The Argonaut project is a visible and successful project to meet that need. The base FHIR specification also does not meet the interoperability need to provide sufficient security patterns for data exchange. We propose that the security patterns proposed as part of the Argonaut project, which provides a standard and industry-recognized means to authenticate access to clinical data, and limit which data a particular user is authorized to use via OAuth2, be included in the ISA.

II-N: Segmentation of sensitive information

It is premature to propose a data segmentation standard, whether DS4P or a different standard, without addressing the safety concerns inherent in such standards as a limitation. The Data Segmentation for Privacy Initiative Version 1.1 states: "Patient safety implications of sending partial datasets, with portions of data removed to comply with Patient Consent Directives or jurisdictional regulations is a policy consideration and not within the scope of this Use Case" (page 9). Patient safety is a crucial aspect of data segmentation standards due to the impact of removing clinically relevant information from patient charts so that it is not accessible to providers.

For example, Obligation and Refrain Policies may require Health IT systems and healthcare organizations to hide documents or certain information, such as medications, from providers. This information should not be hidden because it can adversely impact patient care. Consider a scenario where a patient who is taking lithium for bipolar disorder is later prescribed a diuretic for hypertension by a cardiologist who is not able to view the patient's lithium prescription. Lithium can interact with a diuretic, resulting in a neurological disorder or death.

As an alternative to the data segmentation standard, we suggest that patients who are interested in segmenting their health information opt out of clinician-to-clinician exchange and instead use the features available in personal health records (PHRs) to construct a document with information they feel comfortable sharing.

III-A: An unsolicited "push" of clinical health information to a known destination

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between systems

The distinction between individuals and systems regarding an unsolicited "push" of clinical health information is unnecessary. Only the XDM part of the XDR-XDM specifications is applicable to sending to individuals since the base specification is Direct (SMTP). Minimal metadata is defined in the base IHE-XDR specifications. This minimal metadata extension allows you to push to a

destination with a patient that may not be known to the destination and whom you cannot strongly identify. It is unrelated whether this is between systems or between individuals.

III-B: Clinical Decision Support Services

Adoption HL7 V3: Decision Support Service Release 2 is unknown or close to zero. Pilots have been done on standards that are conceptually similar but not using the identified standard.

There are two additional initiatives that are working on standards for clinical decision support services that should be considered in this advisory:

- IHE Guideline Appropriate Ordering Profile
- HL7 CDS Workgroup's CDS Hooks Initiative

III-C: Image Exchange

We would like clarification whether ONC means to include XDS-I.b rather than the deprecated XDS-I.

A test tool is available for XDS-I through the University of Quebec.

III-D: Provider Directory

Currently, over 70 percent of the healthcare organizations we support are exchanging provider directories that contain demographic information and Direct addresses for providers, hospitals, clinics, and other healthcare facilities. Healthcare organizations use these directories to successfully exchange summary of care documents during transitions of care.

Based on our experience, we agree that a standard way of sharing provider data will improve care coordination by facilitating the discovery of the next healthcare provider during a transition of care. IHE's Healthcare Provider Directory (HPD), however, is not mature enough to support the needs of provider directories for healthcare organizations. HPD is currently in trial status and doesn't appear to be ready to move to the final test status.

HPD also has a number of flaws that will make it very challenging to implement and use practically. For example, HPD doesn't support associations between key data elements. If a provider has three addresses and three fax numbers in a directory, a directory consumer can't tell which address goes with which fax number. If a directory consumer chooses the wrong fax number, patient health information may be transmitted to the wrong place, which is a potential HIPAA breach and privacy issue.

There is no widely adopted alternative to HPD, but the draft standard for FHIR already presents a better alternative. Like HPD, FHIR is also in draft and is not widely adopted. However it has already solved key problems we've identified with HPD, and is much easier to implement. We are actively working to engage the Argonauts and HL7 to define how FHIR should be used to exchange provider directories. We advise against promoting HPD. In our experience, most of the industry doesn't support or promote the standard and would prefer a RESTful implementation.

III-E: Publish and Subscribe

Adoption for NwHIN Specification: Health Information Event Messaging Production Specification is 0-21%. We are not familiar with any groups using a publish/subscribe method on the eHealth Exchange. Instead we recommend IHE DSUB, as it is more well-defined than NwHIN.

Questions

4-1 [General] 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.

> The new approach of organizing, presenting, and annotating the content in the 2016 Advisory is improved and helpful. We agree that framing standards as an "interoperability need" is the better approach as stakeholders can then list the standards and implementation guides we believe are appropriate and the pros and cons of each.
>
> We also recommend that the ISA includes a "considered and rejected" section to discuss standards that were evaluated and do not yet meet the criteria for inclusion. This allows for more transparency in the ISA process and allows readers to know whether a standard they are considering is an appropriate standard or one no one has investigated.
>
> We ask for clarification in situations where multiple code sets are listed under an Interoperability Need, such as under I-O: Procedures, Interoperability Need: Representing medical procedures performed, where three code sets are listed. Is the Advisory stating that all code sets are required, no code set is favored, or that one code set is required and others should be provided if known?
>
> ONC should consider additional interoperability needs for inclusion in the Advisory, including:

- **Birth Reporting**: we recommend the IHE Birth and Fetal Death Reporting-Enhanced standard.
- **Death Reporting**: we recommend the IHE Vital Records Death Reporting standard.

4-2 [General] 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

ONC might want to consider including "Mature" and "In Development" as additional stages. A standard might be final, but still not mature. After being in a final state, a standard might undergo several changes based on industry needs and realization. Examples of this are XDW from IHE-ITI and the implementation guide for Syndromic Surveillance.

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#5: Cost

We hope that ONC realizes that while standards are created and distributed for free, there is a cost associated with developing the standard and sponsoring the volunteers from vendors as well as a cost associated in developing the software to adhere to the standard. We suggest use of more precise language such as "standards licensing cost" and "no standards licensing cost."

We called out assessments we believe to be inaccurate in the comments above.

4-3 [General] 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.

We called out specific thoughts in the comments above.

4-6 [Section II] Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

We agree that more generalized survey instruments should be considered. Rather than the IHE Profile Retrieve Form for Data Capture, we recommend Structured Data Capture (SDC). SDC is a profile that builds on Retrieve Form for Data Capture. They both support the same low-bar-to-entry method to transmit (called URI). Building on that, SDC then supports far more effective methods than Retrieve Form for Data Capture does as its Encoded option now provides more detail than RFD's does. The response may be HTML or structured XML. If the response is XML, it provides great detail for how to structure that XML.