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/isa

RE: 2019 Interoperability Standards Advisory Reference Edition

Dear Mr. Posnack,

Thank you for this opportunity to comment on the 2019 Interoperability Standards Advisory Reference Edition.

As an electronic health records (EHR) developer based in Verona, Wisconsin, Epic actively encourages interoperability. Our first sites went live with Epic's interoperability application, Care Everywhere®, in 2008. As of 2014, all U.S. based Epic organizations use Care Everywhere to exchange patient data with each other and healthcare organizations who have implemented other EHR systems. Care Everywhere facilitates the exchange of more than 3.5 million patient records daily, over a third of which is with organizations using other vendors for health IT.

Epic participates in industry standards development 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. In addition to developing and implementing standards, we've taken a leadership role in the industry in interoperability governance. We co-founded The Sequoia Project's Carequality (www.carequality.org) initiative, which aims to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, and public HIEs, to interoperate freely with one another.

Given our strong support of interoperability, we urge consideration of the following as ONC continues to develop the ISA.

Sincerely,

Sasha TerMaat

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General Comments

We appreciate the incorporation of feedback from previous years and the opportunity to continue to contribute to the selection of interoperability standards. We agree that most of the standards proposed are appropriate for facilitating interoperability, and we've commented only in places where we disagree or have additional input.

We note that the standards identified 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.

Purpose

The ISA's stated purpose of providing the 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 U.S. industry specifically, and it might be helpful to clarify your intent since there are other considerations for international use cases and standards adoption.

Comments on Informative Characteristics

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. These categories are separate and not mutually exclusive concepts because a standard could be both in production and in a pilot stage. If the intent is for these categories to be mutually exclusive, it would be helpful to include a threshold for when a standard exceeds use on a "limited scale" and can be considered to be used in "Production." ONC should also clarify how this would differ from the Adoption Level characteristic.

Adoption Level

The adoption level system would be a more reliable and consistent metric if it was informed by quantitative data about the rate of implementation.

Comments on Proposed Standards

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

Allergies and Intolerances- Representing Patient Allergies and Intolerances; Medications

We note that class had previously been represented by the NDF-RT vocabulary during the earlier stages of the Meaningful Use/EHR Incentive Program. That vocabulary is being replaced by MED-RT, which should be listed here as a standard for representing allergies to classes of medication.

Family Health History – Representing Patient Family Health History

The Human Phenotype Ontology (HPO) developed by Robinson, et al. is a popular vocabulary standard within the genomics community, and is used by some Epic organizations to describe "phenotypic abnormalities" in a standard manner. The HPO uses information from the Online Mendelian Inheritance

in Man to generate its terms, and should be referenced in the ISA as a vocabulary standard for family health history/clinical genomics.

Pregnancy Status – Representing Patient Pregnancy Status

The applicable value sets linked from the Limitations, Dependencies, and Preconditions for Consideration section can be improved to better reflect how the standards are used in the industry today. Specifically, the following should be addressed:

- Pregnancy Status: The timeframe for *Recently Pregnant* needs to be defined for this to be useful. We recommend that 6 weeks (42 days) be the minimum amount of time. This data point could provide value for up to a year after delivery.
- In Estimated Delivery Date Determination, the values 3 and 5 day embryo transfer should be listed separately.
- Gestational age should be exchanged using total number of days.

Research – Representing Analytic Data for Research Purposes

Generally, we observe that CDISC is not an interoperability standard utilized in healthcare environments to support interoperability and analytics. While it is commonly used in research environments, it evolved alongside of, though not necessarily well-aligned with, the requirements for EHR interoperability for ONC certification. Specifically, the CCD and CDA standards with RxNorm, LOINC, and SNOMED terminologies are highly adopted by stakeholders in healthcare settings. If the purpose of the Adoption Level field in the ISA is to reflect usage in healthcare settings, ONC should revise the level of adoption downwards. This section should include the CCD and CDA standards for as well as the aforementioned terminologies related to interoperability of clinical data. The implementation maturity of CCD and CDA is "Production" and the adoption level should be high. Every organization using an ONC certified EHR already supports these. There are numerous related clinical domain specifications within this broad standard. For example, Meaningful Use Stage 2 and 3 uses CDA specifications for cancer registry reporting to support broad analytics on cancer patients.

Sex at Birth, Sexual Orientation and Gender Identity – Representing Gender Identity

The preconditions for consideration section should be expanded to define and distinguish patient gender identity from both legal sex (see our suggested additional field below) and patient sex assigned at birth. Specifically, gender identity is the patient's self-described and deeply held sense of gender that is not related to legal identification, insurance identification, or anatomy. For example, a person who was assigned "male" at birth may now identify as "female", or she may identify as a transgender female. Her identification does not necessarily correspond with her presentation or any steps she has taken to transition.

Additionally, "non-binary" has become a common term for an identity that is neither exclusively male nor female, while "genderqueer" is more commonly used to represent non-normative gender expression.

Sex at Birth, Sexual Orientation and Gender Identity – Representing Patient Identified Sexual Orientation

The applicable value set listed for SNOMED CT/HL7 Version 3 should be expanded to include "Asexual."

Sex at Birth, Sexual Orientation and Gender Identity – Representing Patient Sex (At Birth)

The purpose of this field needs to be more clearly and explicitly defined. If the intention is for this to capture the "official" sex that the patient was assigned at birth, then the applicable value set should be expanded to include HL7 Version 3 code "OTH", to accommodate patients from other countries that support values in addition to "Male" and "Female" on birth certificates. This is distinct from "Intersex", which is a clinical finding and not an assigned sex, and accordingly should not be included in the applicable value set unless the purpose of the field is redefined.

Sex at Birth, Sexual Orientation and Gender Identity – Representing Legal Sex (Recommended Interoperability Need)

The concept of Legal Sex should be added to this section of the ISA because of its distinct purpose from that of patient gender identity and sex assigned at birth. The purpose of this field would be to represent the sex by which the patient is identified on their legal documents. In addition to the values of "Male" and "Female", the values "non-binary" and "X" should be included in any applicable value set listed to states such as California and Oregon, where those values are officially recognized. Guidance should be provided to implementers that explains the distinction between legal sex, sex assigned at birth, and gender identity. As a pioneer in distinctly using these three data elements within patient medical records, Epic would welcome the opportunity to assist with efforts to develop this guidance.

Section II: Content/Structure Standards and Implementation Specifications

Admission, Discharge, and Transfer – Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers

The IHE Patient Administration Module Profile content pertains primarily to transactions/communication within an organization, rather than across organizations. If ONC's intention is to identify standards for the latter purpose, there are few relevant standards contained in that implementation specification, and focus should be placed on HL7 2.5.1 ADT message standard.

Admission, Discharge, and Transfer – Sending a Notification of a Long Term Care Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy

The HL7 2.5.1 ADT message standard is widely adopted by hospitals and outpatient practices for this purpose, much the same as it is for the Admission, Discharge, and Transfer – Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers interoperability need. Indeed, in many cases it is the preferred method. As such, it should be listed as a viable standard in addition to the NCPDP SCRIPT standard for the purpose of integrating admission, discharge, and transfer notifications between providers and pharmacies.

Electronic Prescribing – Allows a Prescriber to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP)

The RxHistoryRequest/RxHistoryResponse transactions of NCPDP SCRIPT Version 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing) as standards for integrating with state Prescription Drug Monitoring Programs (PDMPs). We are supportive of this inclusion and observe that vendors and states are working towards adopting the new standard across the industry. We note that this is the preferred integration mechanism because it presents data in a discrete, machine readable, and actionable manner. As such, we suggest ONC indicate the Implementation Maturity level as Pilot, and the Adoption Level at 1 out of 5.

SMART on FHIR is a single sign-on (SSO) mechanism by which a third party web application can be launched from within the EHR. This standard allows some context specific information, such as patient and user information, to be passed through to the third party system allowing streamlined access to the third party's data. The mechanism does not, however result in the addition of discrete, machine readable data to the EHR, limiting its utility. PDMPs are able to use this mechanism to integrate successfully with EHRs, as the Wisconsin and Maryland state PDMPs have done. As such, we encourage ONC to consider adding SMART on FHIR as an option for PDMP integration where it is not feasible (for legal or other reasons) to implement the NCPDP SCRIPT standards.

Electronic Prescribing – Allows a Prescriber or Pharmacy to Request a Patient's Medication History

The RxHistoryRequest/RxHistoryResponse transactions of NCPDP SCRIPT Version 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing) as standards for integrating with state Prescription Drug Monitoring Programs (PDMPs). We are supportive of this inclusion and observe that vendors and states are working towards adopting the new standard across the industry. As such, we suggest ONC indicates the Implementation Maturity level as Pilot, and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Prescriber or Pharmacy to Request a New Prescription

Generally, the ability for a prescriber to create a new prescription, and send that prescription electronically using the NewRx transaction, versus a pharmacy requesting a new prescription using the NewRxRequest transaction, represents very different interoperability needs and use cases, and have different levels of adoption in the industry. We recommend ONC splits these use cases into two different interoperability needs in the ISA to better reflect how they are utilized, and so their maturity and adoption levels can be measured and assessed individually.

The NewRx transaction of NCPDP SCRIPT Version 2017071 was recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of its inclusion as a standard that allows prescribers to create and electronically transmit new prescriptions to pharmacies. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Pharmacy to Request Additional Refills

The RxRenewalRequest/RxRenewalResponse transactions of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of allowing a pharmacy to request additional refills. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Pharmacy to Request a Change to a Prescription

The RxChangeRequest/RxChangeResponse transactions of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of allowing a pharmacy to request a change to a prescription. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Prescriber to Cancel a Prescription

The CancelRx/CancelRxResponse transactions of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of

allowing a pharmacy to cancel a prescription. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Pharmacy to Notify a Prescriber of Prescription Fill Status

The RxFill/RxFillIndicatorChange transactions of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of allowing a pharmacy to notify a provider of prescription fill status. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer

The RxTransferRequest/RxTransferResponse/RxTransferConfirm transactions of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of allowing a pharmacy to request, respond to, or confirm a prescription transfer. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Electronic Prescribing – Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing

We have observed the Structured and Codified Sig implementation specification in production environments of organizations using Epic, but it is not yet widely adopted within the industry for all NCPDP SCRIPT transactions. Therefore, we recommend an Implementation Maturity of Production but an adoption level of 1 out of 5. We also note that contrary to what the Limitations, Dependencies, and Preconditions for Consideration section indicates, Vehicle, Site of Administration, Duration, Maximum Dose Restriction and Indication are not required elements. ONC should clarify this point in the ISA.

The transactions allowing communication of Structured Sig Information of NCPDP SCRIPT 2017071 were recently named by CMS in 42 CFR 423.160 (Standards for E-Prescribing). We are supportive of their inclusion for the purpose of communicating structured and codified sig information between prescribers and pharmacies. We observe that industry stakeholders are actively working towards adopting the new standard. As such, we suggest ONC indicates the Implementation Maturity as Pilot and the Adoption Level at 1 out of 5.

Family Health History (Clinical Genomics) – Representing Family Health History for Clinical Genomics

The lab results interface for HL7 version 2 includes a section that regards genomic information, specifically variants. While it is not widely adopted, it should be referenced as an option for this interoperability need until the FHIR specifications for this need are finalized.

Images

It is not clear what the distinction between the interoperability needs *Format of Medical Imaging Reports for Exchange and Distribution*, and *Format of Radiology Reports for Exchange and Distribution* is in the advisory. Standards listed in the former are used to communicate reports for an individual patient's study, while the latter identifies an IHE profile that is used to exchange the general structure of a report used to document on specific study types.

Patient Preferences/Consent – Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers

The implementation specification IHE Basic Patient Privacy Consents (BPPC) is listed with an Adoption Level of 2. Our experience working with organizations, both those who use our software and those who do not, does not support this level. We are not aware of any site or vendor in the United States using or actively working towards implementing this standard. Because patient consent is an important component of health information exchange and interoperability, we would be interested in ONC or others providing more information about where/how this implementation specification is utilized by stakeholders to warrant the listed Adoption Level.

The HL7 Implementation Guide for CDA, Release 2: Consent Directives, Release 1 is listed here as a standard for recording patient consent to access/share their health information. However, including consent directives in the CDA provides little value because most exchange networks require providers to obtain patient consent prior to exchanging a CDA with another provider. We are concerned about the inclusion of the IHE APPC standard in the ISA because it promotes data segmentation within patient records in the EHR and during exchange. Data segmentation poses significant patient safety concerns, as it could lead to providers making decisions with incomplete information.

Research – Pre-population of Research Forms from Electronic Health Records

We observe extremely limited adoption of the implementation specification IHE-RFD by clinical research management systems, sponsor data capture systems, popular open source and stand-alone electronic data capture systems (EDCs) despite support by EHRs for over a decade. . . If the purpose of the Adoption Level field in the ISA is to reflect adoption level inclusive of interoperability with healthcare environments, it should be revised significantly downwards.

Research – Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements

As noted in the prior section, although the IHE-RFD standard has been supported by the EHR vendor community for many years, we observe that it has a low adoption rate in practice due to a lack of support from research sponsors/systems. We recommend ONC revise the Adoption Level field to 1 out of 5 to better reflect the extent of adoption for supporting interoperability with EHRs which to our understanding, is the focus of this section.

In general, the HL7 CDA standard has a high adoption rate across the healthcare industry. Because it is a requirement of ONC certified software, and it is the primary standard used to support the interoperability of health IT, we recommend the adoption level be revised to 5 out of 5 to reflect its widespread use among all organizations using an ONC certified EHR. As such, the "Federally required" value should be changed to "Yes" to be consistent with ONC certification requirements for EHRs as interoperability with EHRs is the primary focus of this section.

Similar to our comments on CDISC standards we included for Research in Section I of the ISA, the adoption of this standard is low in the healthcare setting, and the Adoption Level in the ISA, particularly for ODM, should be revised downward to reflect this. We recommend no more than a level 2 or 3.

The IHE-RPE implementation specification is widely adopted amongst healthcare organizations that interface their EHR with research systems, and has been used in production for nearly ten years. As such, we recommend ONC revise the adoption level to 4 out of 5 to reflect its widespread use.

Limitations, Dependencies, and Preconditions:

If the intent of this section is highlight how organizations should consider leveraging their EHR and considerations related to FDA 21 CFR Part 11, it should be noted that the FDA guidance of September 2013 regarding Electronic Source Data in Clinical Investigations states explicitly, on line 23, that the **"FDA does not intend to assess compliance of EHRs with part 11."** On lines 21 and 22, the guidance states that "The performance standards for these computer systems may be regulated by other authorities" and then defers to 45 CFR Part 170 which is the foundation on which ONC has built EHR certification requirements for Meaningful Use. Certified EHRs already meet the expectations of the FDA with respect to 21 CFR Part 11.
(http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf)

The recent July 2018 Guidance for Industry regarding the Use of Electronic Health Record Data in Clinical Investigations reconfirms this stance. On page 7 the Guidance states, "Under the ONC Health IT Certification Program, certified EHR technology would be in compliance with applicable provisions under 45 CFR part 170. EHR technology with certified capabilities generally has clear advantages, because many of the certification requirements are aimed toward ensuring interoperable data sharing and enabling processes to keep electronic data confidential and secure. In particular, all EHR technology certified under the ONC Health IT Certification Program is required to meet certain privacy and security protection requirements for an individual's health information (see 45 CFR 170.314(d)(1) through (8) and 45 CFR 170.315(d)(1) through (11)). FDA encourages the use of such certified EHR systems together with appropriate policies and procedures for their use."

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf

Research – Submit Adverse Event Report from an Electronic Health record to Drug Safety Regulators

The IHE-RFD Clinical Research Document (CRD) and Drug Safety Content (DSC) Implementation Specifications make use of the CCD. CCDs do not, inherently, represent the characteristics of research-related adverse events in the manner that would be sufficient for reporting to drug safety regulators. Although RFD would support a workflow to serve up an eCRF, and certain elements such as lab values and medications could be automatically populated, specification of the attributes necessary for adverse event reporting, such as event attribution and grading, would need to be manually added to the form since those attributes are not included within a CCD. Additionally as noted above, RFD adoption is exceptionally low industry-wide for research use-cases. We recommend removing IHE-RFD from this section. If not removed, comments should be added to limitations and the adoption level should be lowered significantly (1 or 2).

The IHE-CRPC implementation specification listed under this interoperability need does not currently characterize adverse events for interfacing to drug safety regulators. We recommend removing it from this section. If not removed, implementation maturity should be Pilot and current adoption would be appropriately marked as low.

The FHIR Adverse Events resource is a draft standard being developed by the Regulated Clinical Research Information Management (RCRIM) at HL7/FHIR to meet this interoperability need. We strongly recommend including it in this section.

More information can be found at http://wiki.hl7.org/index.php?title=FHIR_Adverse_Event_Resource and https://www.hl7.org/fhir/adverseevent.html.

Research – Complete Disease Registry Forms and Submit to Reporting Authority (ACC)

As noted earlier, the IHE-RFD implementation specification has extremely limited adoption related to research interoperability with EHRs. As such, we again recommend revising the Adoption Level downward from its current level of 4 out of 5 to 1 out of 5 better reflect its utilization in the industry.

Due to the requirement of all ONC certified EHRs to support CDA, we recommend revising its adoption level to 5 out of 5 and indicating that it is Federally required for ONC EHR certification.

Research – Registering a Clinical Trial

We recommend inclusion of the FHIR Clinical Research Study resource as an applicable standard for this interoperability need.

Study representation is commonly supported by IHE RPE and IHE CRPC. We recommend adding those two standards to this section following above. With respect to some basic trial registration information, CRPC in this section should have a somewhat higher adoption level than suggested in earlier sections. We recommend RPE have an adoption level of 4 of 5 and CRPC have an adoption level section of 2 or 3 of 5.

The FHIR ResearchStudy Resource should also be included in this section as a standard, with pilot level maturity and low adoption. More information can be found at https://www.hl7.org/fhir/researchstudy.html.

Segmentation of Sensitive Information – Data Segmentation of Sensitive Information

Our work with healthcare providers has repeatedly raised the concept of data segmentation as a significant risk to patient safety. As such, we are worried about the ISA referencing standards that promote data segmentation in a manner that could lead to providers acting with incomplete information and potentially causing preventable harm to patients.

As an alternative, we support tagging CDA documents with an indication that it contains highly sensitive information, so providers are both aware of the sensitivity of the information, and able to take appropriate action with that knowledge.

Section III: Standards and Implementation Specifications for Services

Clinical Decision Support – Providing Patient Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support

The CDS Hooks standard (https://cds-hooks.org/ and http://wiki.hl7.org/index.php?title=201801_CDS_Hooks) is an increasingly popular standard used to integrate external clinical decision support services with the EHR. While we note efforts are increasing to harmonize this standard with the clinical reasoning FHIR standard, until that is realized, the CDS Hooks standard should be listed as an alternative. We recommend the following associated attributes:

Standards Process Maturity: Balloted Draft
Implementation Maturity: Production
Adoption: 2/5
Federally Required: No
Cost: Free
Test Tool Availability: Yes - https://sandbox.cds-hooks.org/

Consumer Access/Exchange of Health Information – View, Download, and Transmit Data from EHR

After taking into consideration the requirement of ONC certified health information technology to use Direct, it is surprising that the adoption level of this implementation specification is listed as only 2 out of 5. All Epic-using organizations are live with this functionality, and we know that numerous sites using other vendors for their health information technology have adopted this standard. We recommend that the adoption level be revised to level 4 or 5.

Image Exchange

Our experience in working with standards for image exchange is that there is very little adoption of the DICOMweb standard. While many vendors may have support for this standard, joint testing has revealed significant issues that require resolution before it is ready for use in production. Such resolutions will require work from both implementing vendors and the DICOM workgroup.

Image Exchange – Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain

The XCPD and PIX implementation specifications listed for this interoperability need should be listed on separate lines as they are separate transactions that are used to accomplish separate goals. Our experience is that some organizations always use the two together, but others have been very successful using XCPD across affinity domains without PIX. As such, they should be listed separately to reflect the difference in transaction purpose, and to accurately reflect how the specifications are used in practice in the industry.

Publish and Subscribe – Publish and Subscribe Message Exchange

While we have heard of some international interest in supporting the IHE DSUB specification, we are not aware of any vendor or site in the United States adopting this standard for use. As such, the adoption level of 3 out of 5 seems to be overstating its use in the industry in the United States.

Query – Query for Documents Outside a Specific Health Information Exchange Domain

Similar to our comments above for Image Exchange, the XCPD and PIX implementation specifications listed in this interoperability need should be individually listed on separate lines. This better reflects that they are separate transactions used to accomplish different goals, and aligns with their use in the industry today.

Questions

18-1. 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 are deeply involved in standards organizations and industry discussions about interoperability. We note, however, that we rarely refer to the ISA in our work as EHR developers and observe that it is rarely

used by others in the industry. We primarily see our role as a contributor to the ISA, adding to it from our experience in the industry because we hope that when stakeholders are starting a new interoperability initiative (e.g. a state setting up a registry), they are looking to the ISA for standards they could pull from.

18-2. Over the course of 2018, some new functionality has been added to the ISA, with more enhancements expected through 2018 and 2019. Are there additional features or functionality that would enhance the user experience?

The organization of the ISA could use further improvement. Specifically, ONC should consider:

- Additional explanation of the structure of the ISA in the introductory section. The organization structure is confusing to new users because in the introduction, ONC describes "sections" and "interoperability needs," but does not explain that the granular interoperability needs are bucketed and rolled up into higher level topics within each section.
- Explaining the difference between standards and implementation specifications, both of which are often listed under a single interoperability need. Adding an explanation and organizing by whether a listing is a standard or implementation specification would further enhance the structure and clarity of the ISA.

The "View ISA as a Single Page" option could be improved further from its current state. Specifically:

- Section headers are not present on the page
- Domains into which the interoperability needs are organized in other views of the ISA are not incorporated into this view
- The URL for the page says: https://www.healthit.gov/isa/sites/default/files/ISA_2017.html while the top of the page lists the date and time that it was generated leading to ambiguity as to whether stakeholders are viewing the current ISA, or a past version.

We recommend improving the "View ISA as a Single Page" web page to be aligned in organizational style across all formats of the ISA.

Furthermore, new users/reviewers of the ISA are frequently confused by the distinction between the Reference Edition ISA, and the "current" ISA, which is a "living" document. ONC should consider adding additional text or visual enhancements to make the distinction clearer. This could include a landing page that allows stakeholders visiting the page to actively choose whether to navigate to the Reference or "Live" edition of the ISA.

We also think ONC should consider adding additional descriptive text with each interoperability need. Doing so would clarify the use case/purpose the standards listed are intended to fill, and reduce ambiguity and confusion, especially amongst those who are looking to educate themselves on the interoperability landscape in different domains.

18-3. Is the existing ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and/or profiles that should be listed? Are models and profiles useful for inclusion in the ISA?

Listing models and profiles using the current format of the ISA may provide some informative value to users. While there are technical differences between standards and profiles, listing profiles and models with high level characteristics may provide some reference or educational value.

18-4. Are there additional informative or educational resources that can be provided to help stakeholders better understand the ISA, health IT standards, interoperability, etc?

We note that ONC does not provide insight into informative characteristics listed next to standards in the ISA. ONC should use quantifiable metrics in determining the adoption and implementation maturity levels of the standards it lists, and make those metrics known. Doing so would allow stakeholders and users of the ISA to both gain a better understanding of the landscape of a listed interoperability need, and allow stakeholders to provide clearer feedback on the standards as they are used in the industry.