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: 2020 Interoperability Standards Advisory Reference Edition

Dear Mr. Posnack:

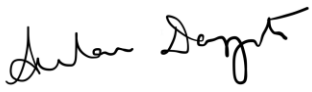
Thank you for this opportunity to comment on the 2019 Interoperability Standards Advisory Reference Edition.

Epic is a strong proponent of standards based interoperability; we enabled our customers to lead the first wave of health information exchange through our Care Everywhere module over 10 years ago.

Because of our commitment to standards-based exchange, 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. We've also taken a leadership role in the industry in interoperability governance by co-founding The Sequoia Project's Carequality initiative, which allows members of different exchange networks to interoperate with one another. This experience informs our comments below.

If you have any questions regarding our feedback, please contact us at info@epic.com. Thank you for your consideration.

Sincerely,



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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. We have commented in places where we disagree or have additional input.

# 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" is reasonable, but we observe that the result is a library focused on healthcare in the United States. It might be helpful to clarify that included standards are most appropriate for use in the United States, since there are additional considerations for international use cases and standards adoption.

# Comments on Informative Characteristics

## Adoption Level

The adoption level would be a more reliable metric if it were informed by quantitative data about the rate of implementation. Because reviewers have little understanding of how adoption level is assessed, it is unclear how a health IT developer would use the informative characteristic when designing their system. We recommend replacing the adoption level informative characteristic with one that details which entities in the health IT ecosystem implement a given standard in their systems. Our response to question 19-3 provides further information.

# Comments on Proposed Standards

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

### *Emergency Medical Services: Representing Health Care Data for Emergency Medical Services*

IHE has developed standards, such as the EMS Transport Summary (ETS) Profile, that use NEMSIS for data transmission between EMS and Emergency Department settings that ONC could consider for inclusion in the ISA. They have low adoption.

### *Medications: Representing Patient Medications*

NDC codes have broad adoption across the health IT industry and should have an adoption level of five.

When designing their health IT solutions, implementers of the NDC standard should note that manufacturers are permitted to reuse NDC values for different purposes.

### *Research: Representing Data for Biomedical and Health Services Research Purposes*

We observe that CDISC is not the standard used by healthcare organizations for research driven by EHR data. CDISC is used in research environments, but is not well-aligned with the requirements for EHR interoperability. The RxNorm, LOINC, and SNOMED terminologies have broad adoption by stakeholders in healthcare settings, and can be used for research purposes.

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 for CDISC standards downwards, and update the listing to include RxNorm, LOINC, and SNOMED terminologies with appropriate adoption levels.

### *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. 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 they may identify as a transgender female. Their identification does not always correspond with their presentation or any steps they have taken to transition.

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

### *Sex at Birth, Sexual Orientation and Gender Identity: Representing Patient Sex (At Birth)*

The purpose of this field needs to be clarified. If the intention is for this to capture the "legal" 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 should not be included in the applicable value set unless the purpose of the field is redefined to be clinical rather than administrative.

### *Sex at Birth, Sexual Orientation and Gender Identity: Representing Patient Identified Sexual Orientation*

Additional values differentiating between "Lesbian, gay, or homosexual" should be included in the ISA. Including a value to represent "Pansexual" or clarifying the value that best represents it from those available would also improve the ability to represent sexual orientation when exchanging patient data.

### *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.

### *Units of Measure: Representing Units of Measure (For Use with Numerical References and Values)*

Healthcare organizations using Epic support The Unified Code for Units of Measure standard in their systems. An adoption level of four, representing moderately high adoption in the industry would be appropriate.

## Section II: Content/Structure Standards and Implementation Specifications

### *Care Coordination for Referrals*

We recommend that ONC create a new interoperability need in Section II of the ISA called *Care Coordination for Referrals*. Closed loop referrals represent an area ripe for increased focus on standards development and adoption.

Participants in the 360X Project are developing recommendations to better facilitate closed loop referrals and care transitions across organizations and health IT systems. We support inclusion of the 360X Project's suggested topics, standards, and implementation specifications in the ISA.

### *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 has high adoption by hospitals and outpatient practices for this purpose, similar to the Admission, Discharge, and Transfer – Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers interoperability need. In many cases, it is the preferred method. 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.

### *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 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.

### *Allows a Long Term or Post-Acute Care to Request to Send an Additional Supply of Medication*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

### *Allows a Pharmacy to Notify a Prescriber of Prescription Fill Status*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

### *Allows a Pharmacy to Request a Change to a Prescription*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

An adoption level of one is appropriate for NCPDP SCRIPT 2017071. After 1/1/2020, it should increase to level three, as organizations will adopt the transactions for this use case using the updated standard.

### *Allows a Pharmacy to Request a New Prescription For a New Course of Therapy or to Continue Therapy*

We anticipate that there may be increased adoption of NCPDP SCRIPT 2017071 transactions for this use case after 1/1/2020.

We recommend adding a note to the Limitations, Dependencies, and Preconditions section acknowledging that federal regulations requires use of NCPDP SCRIPT 2017071, and that as a result, there may be limited value in systems implementing a FHIR based approach.

*Allows a Pharmacy to Request Additional Refills*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

Transactions for this use case have high adoption. We recommend updating the adoption level to five for NCPDP SCRIPT 10.6, and anticipate similar adoption of NCPDP SCRIPT 2017071 after the 1/1/2020 cutover.

*Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer*

We recommend removing NCPDP SCRIPT 2013101 from this use case in the ISA because federal regulation names NCPDP SCRIPT 2017071 as the required standard.

*Allows a Prescriber or a Pharmacy to Request a Patient's Medication History*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

Transactions for this use case have been adopted by many entities. We recommend updating the adoption level to four, for NCPDP 10.6 and anticipate similar levels of adoption for NCPDP SCRIPT 2017071 after the 1/1/2020 cutover.

*Allows a Prescriber to Cancel a Prescription*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

We observe moderate adoption of transactions for this use case in the industry. We recommend updating the adoption level to three, for NCPDP 10.6 and anticipate similar levels of adoption for NCPDP SCRIPT 2017071 after the 1/1/2020 cutover.

*Allows a Prescriber to Communicate Drug Administration Events*

NCPDP SCRIPT 2017071 is the appropriate standard to list for this use case. We do not observe high adoption of transactions for the use case, and recommend an adoption level of zero.

*Allows a Prescriber to Communicate with a REMS Administrator*

NCPDP SCRIPT 2017071 is the appropriate standard to list for this use case. We do not observe high adoption of transactions for the use case, and recommend an adoption level of zero.

*Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing*

In NCPDP SCRIPT 2017071, the ability to prescribe medication using weight-based dosing is encapsulated in the ability of a prescriber to send a new prescription to a pharmacy. Weight-based dosing should not be listed as a separate interoperability need. Similarly, while the Structured and Codified Sig Format Implementation Guide includes the ability to prescribe using weight-based dosing, it

would be more appropriate to list it only in the new prescription use case. Both standards should have an implementation maturity of Pilot.

*Allows a Prescriber to Recertify the Continued Administration of a Medication Order*

NCPDP SCRIPT 2017071 is the appropriate standard to list for this use case. We do not observe high adoption of transactions for the use case, and recommend an adoption level of zero.

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

We do not observe high adoption of FHIR or CDS Hooks based approaches for health IT systems to interact with PDMPs. We recommend that this ISA section indicate that PDMPs and EHRs exchange data using NCPDP SCRIPT standards to avoid stakeholder confusion.

*Allows a Prescriber to Request, Cancel or Appeal Prior Authorization for Medications*

The NCPDP Formulary and Benefits v3 standard is not appropriate for this use case.

The ASC X12 standard should have an implementation maturity of Pilot, and adoption level of one.

*Allows a Prescriber to Send a New Prescription to a Pharmacy*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

Transactions for this use case have high adoption. We anticipate similar adoption of NCPDP SCRIPT 2017071 after the 1/1/2020 cutover.

FHIR is not an appropriate standard to list for this use case. NCPDP SCRIPT 2017071 is required by federal regulations, and meets the needs of stakeholders. Introducing FHIR could result in fragmentation and additional burden on stakeholders in the market.

*Allows a Prescriber to Send a Prescription to a Pharmacy for a Controlled Substance*

It would be appropriate to continue to list the NCPDP SCRIPT 10.6 standard for this interoperability need until 1/1/2020, when NCPDP SCRIPT 2017071 will replace it. We suggest acknowledging the cutover to NCPDP SCRIPT 2017071 in the Limitations, Dependencies, and Preconditions section.

Transactions for this use case have been adopted by many entities. We recommend setting the adoption level to four for NCPDP 10.6, and anticipate similar levels of adoption for NCPDP SCRIPT 2017071 after the 1/1/2020 cutover.

*Allows for Communication of Prescription Information Between Prescribers and Dispensers*

The use case described by this interoperability need is required functionality associated with other use cases in the ISA, such as "Allows a Prescriber to Send a New Prescription to a Pharmacy." We recommend discontinuing its listing as a distinct interoperability need.

*Images: Format of Radiology Reports for Exchange and Distribution*

We do not observe broad adoption of the IHE MRRT implementation specification. We recommend setting the adoption level at zero.

*Images: Medical Image Formats for Data Exchange and Distribution*

The ISA should clarify that the adoption level reflects DICOM's usage when exchanging data between an imaging modality and PACS. An adoption level of two would better reflect the standard's usage when exchanging medical images between organizations.

*Patient Identification Management: Patient Demographic Record Matching*

We have not observed broad adoption of the Implementation Guide for Expressing Context in Direct Messaging. We recommend an adoption level of one.

*Public Health Reporting: Reporting Newborn Screening and Birth Defects to Public Health Agencies*

The IHE NANI implementation specification should have a Standard Process Maturity designation of Final.

*Research: Data Collection for Submission to Registries and Reporting Authorities*

The IHE-RFD implementation specification has limited adoption related to research interoperability with EHRs. We recommend revising the Adoption Level downward from its current level of 4 out of 5 to 1 out of 5 better reflect its use in the industry.

*Research: Pre-population of Research Forms from Electronic Health Records*

We observe 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. We recommend setting the adoption level at one.

We've observed an increase in the usage of FHIR and SMART on FHIR based approaches to fill in Research Forms. Those standards should be listed here with high adoption, since many health IT systems already support them to meet certification requirements. Relevant resources include ResearchStudy, ResearchSubject, Medications, Problems, and Observations.

*Research: Registering a Clinical Trial*

Study representation is supported by IHE RPE and IHE CRPC. We recommend adding those two standard profiles to this section. 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.

We recommend inclusion of the FHIR Clinical Research Study resource as an applicable standard for this interoperability need. It has pilot level maturity and low adoption. More information can be found at https://www.hl7.org/fhir/researchstudy.html.

*Research: Submission of Clinical Research Data Contained in EHRs and Other Health IT Systems for General Purpose or Preserving Specific FDA Requirements*

Although the IHE-RFD standard profile 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.

CDISC ODM has low adoption in health IT systems used by healthcare organizations. Its adoption level should be revised downward to reflect this. We recommend no more than a level 2 or 3.

The IHE-RPE implementation specification has high adoption amongst healthcare organizations that interface their EHR with research systems, and has been used in production for ten years. As such, we recommend ONC revise the adoption level to 4.

*Research: Submission of Clinical Research Data to FDA to Support Product Marketing Applications*

CDISC is not used by EHRs. CDA and FHIR should be referenced in this section as relevant for submission of clinical data from EHR systems.

*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 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. Further, RFD adoption is low for research use-cases. We recommend removing IHE-RFD from this section. If it persists in the ISA, the adoption level should be lowered to level one or two.

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 it is not removed, implementation maturity should be Pilot and current adoption level should remain 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 recommend including it in this section.

*Segmentation of Sensitive Information – Data Segmentation of Sensitive Information*

There is important policy work that must be done prior to it being possible to safely or effectively implement the DS4P standard.

The ISA should be updated to clarify that the DS4P Implementation Guide is not federally required.

The Consent2Share FHIR profile has not yet reached an adequate level in the standards development maturity process for health IT developers to implement it consistently in their systems.

*Summary Care Record: Support a Transition of Care or Referral to Another Health Care Provider*

The HL7 Clinical Notes Implementation Specification is relatively new to the industry. We recommend setting the adoption level at one.

## Section III: Standards and Implementation Specifications for Services

*Push Exchange: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems*

The adoption level of the IHE XDR implementation specification should be five. Epic supports large volumes of exchange using this implementation specification with other vendor platforms, and our users have adopted it.

*Consumer Access/Exchange of Health Information: Push Patient Generated Health Data into Integrated EHR*

While health IT systems have the capability to meet this interoperability need, there is low adoption amongst health care organizations and patients. We recommend setting the adoption level at one.

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

ONC certified health information technology is required to use Direct. 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 setting the adoption level to four or five.

*Image Exchange: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain*

Our experience in working with standards for image exchange is that there is little adoption of the DICOMweb standard. While many vendors may have support for this standard, joint testing has revealed workflow 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. We recommend setting the adoption level at one.

*Image Exchange: Exchanging Imaging Documents Within a Specific Health Information Exchange Domain*

Our experience in working with standards for image exchange is that there is little adoption of the DICOMweb standard. While many vendors may have support for this standard, joint testing has revealed workflow 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. We recommend setting the adoption level at one.

*Query: Query for Documents Outside a Specific Health Information Exchange Domain*

The IHE-XCA and IHE-XCPD implementation specifications have broad adoption across the health IT industry. We recommend setting the adoption level at five.

# Questions

*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.*

Epic participates in numerous standards development organizations' initiatives and other industry discussions about interoperability. However, it is rare for us to refer to the ISA in our work as EHR

developers, and we observe that it is rarely used by others in the industry. We 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 look to the ISA for relevant standards.

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

Additional enhancements to the ISA could help improve users' experience. ONC should consider:

- Improving navigation. The expansion/collapsing of headers and sub headers on the left side of the screen remains cumbersome. Adding a scroll bar so that it scrolls separately from the page of the ISA that users are reading would be helpful, as would keeping inactive sub headers collapsed by default.
- 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 it is not always clear how those interoperability needs are "bucketed" within each section.
- Adding additional educational material. For example, ONC could explain the difference between standards and implementation specifications, both of which are often listed under a single interoperability need. ONC could also include illustrative examples of how standards and implementation specifications are used practically in workflows. For example, explaining how vocabulary versus content/structure vs services standards are used could help provide additional context.

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 aim to educate themselves on the interoperability landscape in different domains.

*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?*

The adoption level characteristic is not valuable in its current form because it is not clear to users how ONC arrives at its determination. Because of this users of the ISA are unable to meaningfully use the adoption information to inform design or implementation decisions for their system.

Instead, an informative characteristic that might be valuable would be one detailing which entities in the health IT ecosystem would implement a particular standard or implementation specification. For example, explaining that clinical EHR systems have not adopted FHIR as the standard for cross-

organizational record exchange, but that patient-facing apps often leverage an EHR's FHIR APIs to consume data could help provide additional context to those unfamiliar with health IT standards.

*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 that collecting specialty-specific interoperability needs and standards similar to the Opioid Use Disorder section could aid stakeholders seeking to improve the interoperability of their health IT in a targeted manner. For instance, healthcare organizations reviewing the section could gain an understanding that completing LOINC and SNOMED mapping within their system would facilitate more seamless exchange of discrete patient data.

We defer to clinical stakeholders to assess which specialties or care settings should be prioritized.