



November 9, 2020

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: 2021 Interoperability Standards Advisory Reference Edition

Dear Mr. Posnack:

Thank you for this opportunity to comment on the 2021 Interoperability Standards Advisory Reference Edition.

Epic is a strong proponent of standards-based interoperability. Healthcare organizations using Epic's software have used standards to exchange clinical charts for more than ten years, and currently exchange more than 6 million patient charts each day. More than 40% of that exchange is with organizations that use other EHR systems.

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,

A handwritten signature in black ink, appearing to read "Danielle Friend", is enclosed in a light gray rectangular box.

Danielle Friend
Epic



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.

Comments on ISA Content

Vocabulary/ Code Set/Terminology Standards and Implementation Specifications

Representing Data Provenance

For many data elements, there continues to be ambiguity on the individual or entity that is considered to be the “Author” for the purposes of representing and exchanging data provenance, and therefore there continues to be ambiguity in the definition of the Author Time Stamp and the Author Organization. We recommend noting this limitation in the section for Representing Data Provenance.

The two data elements listed for Data Provenance are included in the USCDI, but CMS has not yet established a deadline for provider organizations to adopt technology certified to ONC’s Cures Edition certification criteria for participation in its regulatory programs. Stakeholders have begun adoption of the HL7 FHIR Provenance Resource listed in anticipation of CMS requiring adoption of updated Certified EHR technology. We recommend updating its Implementation Maturity to be Production and an Adoption Level of one.

Representing Data for Biomedical and Health Services Research Purposes

While CDISC is often used in biomedical research contexts, it is not typically used to represent clinical data stored in EHRs, which is also used for research purposes. The RxNorm, LOINC, and SNOMED code systems have broad adoption by stakeholders in healthcare settings, are used for research based on EHR data and are also used to represent data when exchanged between clinical systems. We recommend including those code systems for this interoperability need, and noting the distinction in the Limitations, Dependencies, and Preconditions for Consideration section. They are widely used in EHRs, so they should have a Standards Process Maturity of Final, an Implementation Maturity of Production, and an Adoption Level of five.

Representing Patient Sex (At Birth)

We recommend including the HL7 NullFlavor values of OTH, ASKU, and NASK to the list of applicable value sets and starter sets. While not required by ONC certification, these values convey more clinically accurate information for intersex patients and aligns with the growing number of administrative jurisdictions that permit values in addition to male and female when documenting sex at birth.

Conversely, coding the sex of these patients as M or F could imply data about their anatomy that is incorrect. For example, an assigned female at birth intersex patient may have ovotestes rather than ovaries. OTH would likely be a more descriptive than M, F, or UNK. ASKU could also be appropriate, as intersex patients were/are frequently kept from knowing their medical history. Further, capture of Sex Assigned at Birth as a distinct data element varies widely across the industry (some only record values for newborns, some only record values for gender-diverse patients, some do not record data for any patients). In cases where Patient Sex at Birth is not captured discretely, NASK would convey more meaning than UNK.



Content/Structure Standards and Implementation Specifications

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

Systems frequently use the HL7 2.5.1 ADT Messages standard for this use case. We recommend this section include that standard, with an Implementation Maturity of Production and an Adoption Level of five.

The Census transaction is no longer part of the NCPDP SCRIPT standard; it is part of the NCPDP Specialized 2017071 standard. We recommend replacing the reference to the NCPDP SCRIPT 2017071 standard with the NCPDP Specialized 2017071 standard for this interoperability need. Since CMS and ONC have finalized requirements to adopt the NCPDP SCRIPT version 2017071 standard instead of the NCPDP SCRIPT version 10.6 standard, stakeholders have correspondingly increased their adoption of the NCPDP Specialized 2017071 standard despite it not being federally required. We recommend an Implementation Maturity of Production, and an Adoption Level of three for the NCPDP Specialized 2017071 standard. We also recommend reducing the Adoption Level of NCPDP SCRIPT version 10.6 to three for this use case since it is no longer federally required.

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

We recommend including Carequality's Subscriptions Implementation Guide in this section as an Emerging Implementation Specification. The Standards Process Maturity Level should be In Development, Implementation Maturity should be pre-pilot, and the Adoption Level should be zero. More information can be found here: <http://build.fhir.org/ig/DavidPyke/CEQSubscription/>.

Care Coordination for Referrals: Referral to a Specialist – Request, Status Updates, Outcome

Some health IT developers have adopted IHE Patient Care Coordination Technical Framework: 360 Exchange – Closed Loop Referral (360X) implementation specification in their products used in production. Other health IT developers are actively working toward adoption of the standard, and we anticipate that production use will increase. We recommend updating the Implementation Maturity to Production and the Adoption Level to two.

Drug Formulary and Benefits: Allows Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescriber Systems

We recommend setting the Adoption Level of the NCPDP Real Time Prescription Benefit Standard at one. Many industry stakeholders exchange real time prescription benefits, but not all use the NCPDP RTPB standard to do so.

The HL7 FHIR DaVinci Provider Data Exchange Implementation Guide linked from the page of this interoperability need is not appropriate for inclusion in this section of the ISA. This FHIR interface defined by the implementation specification is intended for use in the patient/consumer context, not by prescriber systems.

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

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this



interoperability need. We recommend setting the Adoption Level of Version 10.6 at one, and the Adoption Level of Version 2017071 at two.

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

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at one, and the Adoption Level of Version 2017071 at three.

Electronic Prescribing: Allows a Pharmacy to Request a New Prescription for a New Course of Therapy or to Continue Therapy

NCPDP SCRIPT Version 2017071 is federally required for this interoperability need according to CMS regulations. We recommend noting that consideration so that stakeholders do not mistakenly implement the HL7 FHIR Medication Request standard to meet this interoperability need.

Electronic Prescribing: Allows a Pharmacy to Request Additional Refills

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at two, and the Adoption Level of Version 2017071 at four.

We recommend clarifying that FollowUpRequest is an element within the RxRenewalRequest in the Limitations, Dependencies, and Preconditions for Consideration section. As written, stakeholders reviewing the ISA might mistakenly assume FollowUpRequest is a distinct transaction.

Electronic Prescribing: Allows a Pharmacy to Request Additional Refills

We are not aware of any stakeholders using NCPDP SCRIPT 2013101 for this interoperability need. We recommend removing it from the ISA.

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

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at one, and the Adoption Level of Version 2017071 at four.

Electronic Prescribing: Allows a Prescriber to Cancel a Prescription

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at two, and the Adoption Level of Version 2017071 at three.

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

We recommend removing this as a distinct interoperability need from the ISA. Weight-based dosing for a medication order is a functional need of the health IT system used by a prescriber. The weight-based medication order can then be prescribed using electronic prescribing standards in the same manner as any other prescription.



Electronic Prescribing: Allows a Prescriber to Request, Cancel, or Appeal Prior Authorization for Medications

The NCPDP Formulary and Benefits Version 3 and ASC X12 standards listed do not themselves enable a prescriber to request, cancel, or appeal prior authorization for medications, nor are they technically required to complete a prior authorization transaction. Rather, they are means by which a prescriber can determine whether prior authorization is required for a particular medication.

We recommend removing those standards from the list, and instead noting in the Limitations, Dependencies, and Preconditions for Consideration section how they can be used to support workflows for electronic prior authorization.

Allows a Prescriber to Send a New Prescription to a Pharmacy

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at two, and the Adoption Level of Version 2017071 at four.

The Limitations, Dependencies, and Preconditions for Consideration section states that the NewRxRequest transaction is “required for interoperability purposes,” which is inaccurate. CMS requires use of the NewRxRequest transaction for entities whose scope of practice requires them to electronically request a new prescription. However, ONC has recognized that not all actors would need to use this type of message, depending on their scope of practice, and made adoption of the NewRxRequest transaction optional in certification as a result.

Electronic Prescribing: Allows a Prescriber to Send a Prescription to a Pharmacy for a Controlled Substance

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at two, and the Adoption Level of Version 2017071 at four.

HL7 v2 ORM^O01 message transactions can be used to transmit controlled substance prescriptions from a prescriber to a pharmacy. We recommend including it in this section of the ISA with a Standards Process Maturity of Final, Implementation Maturity of Production, and Adoption Level of one.

We note that the DEA does not require the use of NCPDP SCRIPT prescribing standards. Rather, certain DEA requirements for electronic prescribing of controlled substances can be met by conditionally requiring certain fields included in the NCPDP standard. We recommend clarifying the Limitations, Dependencies, and Preconditions section to reflect this.

We recommend removing the text in the Limitations, Dependencies, and Preconditions section regarding the SUPPORT for Patients and Communities Act, because it is misleading. The DEA has acknowledged in its rulemaking process that NCPDP is not the only standard that can be used for communicating prescriptions for controlled substances, and that there are reasonable exceptions and other situations where using an alternative standard (such as HL7 messages) may be appropriate.



Electronic Prescribing: Allows a Provider to Request a Patient’s Medication History from a State Prescription Drug Monitoring Program (PDMP)

The NCPDP SCRIPT Version 2017071 standard is used in Production to meet this interoperability need. We recommend updating the Implementation Maturity for its listing in this section of the ISA to reflect this and recommend the Adoption Level be set at two.

Epic’s software integrates with PDMPs in the 49 states that use them, however none of them use the NCPDP SCRIPT Version 20130101 for this interoperability need. We recommend removing it from this section of the ISA to avoid misleading users of the ISA.

The SMART on FHIR implementation specification is used in production for this interoperability need in some jurisdictions. We recommend updating its Implementation Maturity to Production in this section of the ISA.

We recommend removing the statement that a “PDMP must evaluate the Consent for accurate reporting” from the section on Limitations, Dependencies, and Preconditions for Consideration, because it is not accurate. PDMPs in many jurisdictions do not rely on patient consent. We also recommend clarifying that the transactions listed as “[needed] for interoperability purposes” apply only if the implementing entity is using NCPDP SCRIPT standards for integration. They would not be applicable for SMART on FHIR integrations, for example.

Electronic Prescribing: Allows for Communication of Prescription Information Between Prescribers and Dispensers

NCPDP SCRIPT Version 10.6 is no longer federally required. Because NCPDP SCRIPT Version 2017071 is now federally required in its place, we have seen increasing adoption of that standard for this interoperability need. We recommend setting the Adoption Level of Version 10.6 at two, and the adoption level of Version 2017071 at four.

Electronic Prescribing: Allows for the Exchange of State Prescription Drug Monitoring Program (PDMP) Data

The purpose of this interoperability need is ambiguous. We recommend clarifying whether it is intended to document standards available for exchanging data between two or more PDMPs, or whether it is intended to document standards available for reporting dispense information from a pharmacy to a PDMP.

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

We recommend removing the Consent2Share profile from this interoperability need, since it appears to be an abandoned project. See [https://chat.fhir.org/#narrow/stream/179166-implementers/topic/Consent2Share\(C2S\).20on.20FHIR](https://chat.fhir.org/#narrow/stream/179166-implementers/topic/Consent2Share(C2S).20on.20FHIR) for more information.

Public Health Reporting Case Reporting to Public Health Agencies

We recommend removing the IHE Retrieve Form for Data Capture and the IHE Structured Data Capture implementation specifications from this interoperability need. We are not aware of entities using these standards for patient identifiable data for public health reporting purposes.



The HL7 CDA R2 eICR and Reportability Response implementation specifications are in use in all fifty states for reporting to public health agencies. We recommend updating the Adoption Level for those standards to three and noting the Implementation Maturity as Production.

Public Health Reporting: Newborn Screening Results and Birth Defect Reporting to Public Health Agencies

We recommend removing the HL7 Version 2.5.1 Laboratory Results Interface implementation specification since it is not intended or used for this interoperability need.

Public Health Reporting: Reporting Cancer Cases to Public Health Agencies

We recommend removing the IHE Structured Data Capture implementation specification from this interoperability need, since it is not used to report cancer cases to public health agencies.

We also recommend removing the 2012 Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, since it has been superseded by the HL7 CDA Release 2 Reporting to Public Health Cancer Registries implementation specification. Correspondingly, we recommend increasing the Adoption Level of the HL7 CDA Release 2 Reporting to Public Cancer Registries implementation specification to two.

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

The HL7 FHIR AdverseEvent standard can be used to populate research forms that report adverse events in the course of a clinical trial. We recommend including it in this section with an Implementation Maturity of Pilot, and an Adoption Level of one.

Segmentation of Sensitive Information: Data Segmentation of Sensitive Information

The HL7 FHIR R4 Security Labels should have a Standards Process Maturity of Balloted Draft instead of Final; this standard is only for trial use and is not a normative ANSI-accredited standard. The Limitations, Dependencies and Preconditions for Consideration section inaccurately states that document-level DS4P is required in the C-CDA General Header. We recommend removing this statement to avoid misleading reviewers of the ISA.

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

Industry entities have begun adoption of the IHE Patient Care Coordination Technical Framework: 360 Exchange – Closed Loop Referral (360X) implementation specification in their products. We recommend setting the Adoption Level at two.

Epic-using organizations extensively use many of the templates included in the HL7 Implementation Guide for CDA Release 2 Consolidated CDA Templates specification to meet this interoperability need. We recommend updating the Implementation Maturity to Production and setting the Adoption Level to five.

We are not aware of any entity that has adopted the HL7 FHIR DaVinci Payer Coverage Decision Exchange (PCDE) implementation guide for use in production. We recommend a pre-pilot Implementation Maturity and Adoption Level of zero.

Unique Device Identification: Defining a Globally Unique Device Identifier

The Limitations, Dependencies and Preconditions for Consideration section states that the FDA will phase in a Unique Device identification system with a final compliance date of September of 2020. We



note that in July 2020, the FDA announced that it will exercise enforcement discretion for this requirement for certain types of devices until September 24, 2022. We recommend updating the section to reflect that change.

Standards and Implementation Specifications for Services and Exchange

Clinical Decision Support Services: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care

The CDS Hooks Services 1.0 Implementation Specification should have a Standards Process Maturity of Balloted Draft, Implementation Maturity of Pilot, and an Adoption Level of one. We recommend updating the hyperlink to direct ISA users to its page on the HL7 website: <https://cds-hooks.hl7.org/1.0/>.

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

Because OAuth 2.0 is widely adopted by healthcare organizations to offer patients access to view, download, or transmit their data using apps (even though patient usage of such technologies remains low), the SMART on FHIR implementation specification should have a Standards process Maturity of Balloted Draft, an Implementation Maturity of Production, and an Adoption Level of four. We recommend updating the hyperlink to direct ISA users to its page on the HL7 website: <http://hl7.org/fhir/smart-app-launch/index.html>.

Healthcare Directory, Provider Directory: Listing of Providers for Access by Potential exchange Partners

The HL7 FHIR DaVinci Provider Data Exchange (PDex: Plan Network Directory) implementation specification should have an Implementation Maturity of pre-pilot and an Adoption Level of zero. We are not aware of any entities implementing this standard in production.

Query: Data Element Based Query for Clinical Health Information

We observe broad adoption of the HL7 FHIR DSTU2 Argonaut Data Query implementation guide. We recommend setting the Adoption Level at four. Entities have also begun adoption of the HL7 FHIR R4 US Core implementation specification. We recommend setting its adoption level at two.

We are not aware of any entities using the HL7 FHIR DaVinci Clinical Data Exchange (CDex), Payer Data Exchange (PDex), or Health Record Exchange (HReX) implementation guides. We recommend setting the Implementation Maturity at pre-pilot and the Adoption Level at zero.

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

The HL7 FHIR DocumentReference resource implementation specification should have a Standards Process Maturity of Final, an Implementation Maturity of Production, and an Adoption Level of two. Epic-using organizations have begun adoption of this FHIR resource.

The vast majority of industry entities engaging in query exchange favor and use the IHE-XCPD (Cross-Community Patient Discovery implementation specification over the IHE-PIX (Patient Identifier Cross Reference) implementation specification. Few entities use the IHE-PIX (Patient identifier Cross-Reference) implementation specification; its Adoption Level should be revised to one.



We recommend combining the eHealth Exchange’s implementation specifications to a single line, since all of them are required to engage in exchange using that network. The corresponding Adoption Level for the eHealth Exchange’s implementation specification should be two.

Carequality’s Query-Based Document Exchange Implementation Guide has been used in production since 2016. Its Standards Process Maturity level should be Final, its Implementation Maturity should be production, and its Adoption Level should be five. Nearly all Epic customers exchange via the Carequality network, and numerous other networks and vendors have become Carequality implementers.

The CommonWell Health Alliance Specification Services implementation specification should have an Implementation Maturity of Production and an Adoption Level of two.

We note that while the implementation specifications from the eHealth Exchange and Carequality are publicly available, the eHealth Exchange and Carequality charge fees to their respective participants and implementers to participate in their network.

Query: Query for Documents Within a Specific Health Information Exchange Domain

We are not aware of any entities using the HL7 FHIR DaVinci Clinical Data Exchange (CDex) or Provider Data Exchange (PDex) implementation specifications. We recommend setting the Implementation Maturity at pre-pilot.

Proposed Interoperability Need: Provider Facing Context Synchronization: Synchronize Clinical Content Across Disparate Applications

We recommend adopting a new interoperability need for Provider Facing Context Synchronization Across Disparate Applications. This section could include the FHIRCast implementation specification, which has a Standards Process Maturity of Balloted Draft, and Implementation Maturity of Production, and an Adoption Level of two. It is not federally required, has no cost, and has a testing tool available. More information can be found at <https://fhircast.hl7.org/specification/STU1/>.

Proposed Interoperability Need: Inpatient Clinical Attribute Exchange: Exchange Patient List Clinical Attributes

We recommend adopting a new interoperability need for Inpatient Clinical Attribute Exchange. This section could include the Argonaut Patient Lists implementation guide that is under development. The objective of the Argonaut’s implementation guide is to support apps that want to retrieve a list of patients that a given provider is seeing today (or other search criteria) along with clinical attributes associated within the context of that list of patients.

The Argonaut Patient Lists implementation guide should be listed as an Emerging Implementation Specification, with a Standards Process Maturity of in development, an Implementation Maturity of pre-pilot, and an Adoption Level of Zero. It is not federally required, and a test tool is not available.

More information about the project can be found at the following webpages.

https://argonautwiki.hl7.org/Argonaut_Current_Projects

<https://hackmd.io/AfJ9YNb6TNGeDSuAaHln1g#Patient-Lists-API>



Administrative Standards and Implementation Specifications

Administrative Transactions to Support Clinical Care: Referral Certification and Authorization for Pharmacy Transactions

NCPDP Versions D.0, F2, 2013101, and 2017071 standards are not used for referrals today. The NCPDP Telecommunication Standard Implementation Guide Version D, Release 0 (D.0) is used for Pharmacy Claims Adjudication. We recommend refocusing this interoperability need on Pharmacy Claims adjudication to accurately reflect the use of the D.0 standard in Pharmacy Claims Adjudication and updating the Adoption Level of the D.0 standard to five. We recommend removing the other standards listed.

The ISA solicits feedback on the usage of Emerging Transactions within the NCPDP SCRIPT Standard for Referrals. We are not aware of entities implementing these transactions for Referral Certification and Authorization for Pharmacy Transactions.

Operating Rules to Support Administrative Transactions: Operating Rules to Support Electronic Prescribing Transactions

The NCPDP Operating Rules for the Formulary and Benefit Standard v10 should have an Implementation Maturity of Pilot. We are not aware of any entities adopting this standard for use in production.