



# Interoperability Standards Advisory (ISA) Deep Dive

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Standards Advisory Lead, Office of Technology, ONC  
November 30, 2018



# Agenda

- Introductions
- ISA Basics
- New/Future Functionality Highlight
- Process/Timelines
- 2018 Comments Overview
- Panel Discussion
  - » Interoperability Standards Priorities Task Force Update
  - » American Clinical Laboratory Association White Paper
- Q&A

## What is the ISA?

- A single, public list of the standards and implementation specifications that can best be used to address specific interoperability needs.
- Reflects the results of ongoing dialogue, debate, and consensus among industry stakeholders.
- Documents known limitations, preconditions, and dependencies as well as other helpful information.
- Serves as an informational resource, is non-binding and does not create or confer any rights or obligations for or on any person or entity.
- Available at [www.healthit.gov/ISA](http://www.healthit.gov/ISA)

## How is the ISA be used?

- Stakeholders who administer government and non-governmental procurements, testing, certification or grant programs to look first to the ISA to meet their interoperability needs.
- Developers of health IT to look first to the ISA for available and appropriate standards/implementers specifications to support interoperability efforts.
- Implementers and users of health IT products to ensure purchased products include standards that support their specific interoperability needs
- The ISA and their associated informative characteristics are also available to help more fully inform policy and implementation efforts, including limitations, dependencies or preconditions for use.

- Introduction
- Section I: Vocabulary/Code Set/Terminology
- Section II: Content and Structure
- Section III: Services
- Section IV: Models and Profiles
- Section V: Administrative
  - » Under each section, there are Subsections with numerous Interoperability Needs
  - » Specific standards and implementation specifications support each Interoperability Need

- Characteristics and other helpful information for each standard and implementation specification listed for each interoperability need
  - » Standards Process Maturity
  - » Implementation Maturity
  - » Adoption Level
  - » Federally Required
  - » Cost
  - » Test Tools
  - » Limitations, Dependencies, Preconditions and Other Qualifying Information
  - » Applicable Value Set(s) and Starter Set(s) and Security Patterns
- Appendixes for “Sources for Privacy and Security Standards” and Educational / Informational Resources

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▶ [Patient Identification Management](#)

## Documenting and Sharing Care Plans for a Single Clinical Context



Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 <a href="#">↗</a>	Balloted Draft	Pilot	● ● ● ○ ○	Yes <a href="#">↗</a>	Free	Yes <a href="#">↗</a>
<i>Emerging Standard</i>	<i>HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3</i> <a href="#">↗</a>	<i>In Development</i>	<i>Pilot</i>	● ○ ○ ○ ○	<i>No</i>	<i>Free</i>	<i>No</i>
<i>Emerging Implementation Specification</i>	<i>HL7 Resource Care Plan (v3.0.1)</i> <a href="#">↗</a>	<i>Balloted Draft</i>	<i>Pilot</i>	● ○ ○ ○ ○	<i>No</i>	<i>Free</i>	<i>No</i>

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
<ul style="list-style-type: none"> <li>The care plan as expressed in the C-CDA standard does not attempt to represent the longitudinal care plan; rather it represents a “snapshot” of a care plan at a single point in time for transmission to other providers and teams to ensure continuity of care.</li> <li>The Care Plan Domain Analysis Model is used as a reference model for C-CDA care plan documents in the context of the longitudinal care plan.</li> <li>FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the <a href="#">HL7 wiki</a> <a href="#">↗</a>.</li> <li>See <a href="#">CDA</a> and <a href="#">FHIR</a> projects in the Interoperability Proving Ground.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>



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Section IV: Models and Profiles

Section V: Administrative Standards and Implementation Specifications

## Introduction to the ISA

**\*\*The 2018 annual comment and review period is now closed.\*\***

The Interoperability Standards Advisory (ISA) process represents the model by which the Office of the National Coordinator for Health Information Technology (ONC) will coordinate the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, and research purposes. ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific interoperability needs they seek to address. Furthermore, ONC encourages further pilot testing and industry experience to be sought with respect to standards and implementation specifications identified as "emerging" in the ISA. For historical background on the ISA please review [prior ISA publications](#).

The 2018 ISA has been updated to include improvements made based on recommendations received from public comments and subject matter expert feedback. To learn more about major revisions of the ISA, please review [recent ISA updates](#). Registered users may subscribe to change notifications to be alerted by e-mail of all revisions to individual interoperability needs or for ISA-wide changes. Anyone may become a registered user by submitting an [account request](#). Once logged in, look for the blue "change notification" button at the bottom of the interoperability need page, or at the bottom of the home page to be notified of any changes across the ISA.

### Scope

Starting with the 2017 ISA, the ISA's focus expanded to more explicitly include public health and health research interoperability. Thus, its scope includes electronic health information created in the context of treatment, and subsequently used to accomplish a purpose for which interoperability is needed (e.g., a referral to another care provider, public health reporting, or research). In late 2017, and included in the 2018 Reference Edition, the ISA now also includes interoperability needs related to Administrative functions within healthcare. These additions were made through coordination with CMS, and it is anticipated to include other administrative healthcare interoperability needs throughout 2018.

The ISA is not exhaustive but it is expected to be incrementally updated to include a broader range of health IT interoperability needs. When more than one standard or implementation specification is listed it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry can efficiently interoperate more than one. It may also reflect the fact that there is an ongoing transition from the use of one standard towards a new version or even next-generation approach.

As noted in previous ISA publications, a standard listed in one section is not intended to imply that it would always be used or implemented independent of a standard in another section. To the contrary, it will often be necessary to combine the applicable standards from multiple sections to achieve interoperability for a particular clinical health information interoperability need.

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## Advanced Search ISA Standards

Use CTRL to multiple select for Adoption Level, Type, & Test Tool Availability

**Adoption Level**  Medium  Medium-High  High  
**Type**  Standard  Standard for Observations  Standard for Observation values  
**Test Tool Availability**  Yes  Yes\$  Yes - Open  
**Cost**   
**Federally Required**   
**Implementation Maturity**  Pilot  Production  Feedback Requested  
**Standards Process Maturity**  Final  Balloted Draft  In Development  
**Standard/Implementation Specification**   
**Search Using Keywords**

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

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 <a href="#">↗</a>	Production	High	Yes

### Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination and Information System User

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
IHE-XDR (Cross-Enterprise Document Reliable Interchange) <a href="#">↗</a>	Production	High	Yes

### Interoperability Need: Representing Immunizations – Historical

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
HL7 Standard Code Set CVX—Clinical Vaccines Administered <a href="#">↗</a>	Production	High	Yes

### Interoperability Need: Representing Immunizations – Administered

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
HL7 Standard Code Set CVX—Clinical Vaccines Administered <a href="#">↗</a>	Production	High	Yes
National Drug Code <a href="#">↗</a>	Production	High	Yes

### Interoperability Need: Representing Patient Medications

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Use CTRL to multiple select for Adoption Level, Type, & Test Tool Availability

**Adoption Level**:    
**Type**:    
**Test Tool Availability**:    
**Cost**: 
**Federally Required**: 
**Implementation Maturity**:  Pilot  Production  Feedback Requested
 **Standards Process Maturity**:  Final  Balloted Draft  In Development

**Standard/Implementation Specification**: 
**Search Using Keywords**:

**Interoperability Need: Medical Image Formats for Data Exchange and Distribution**

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
Digital Imaging and Communications in Medicine (DICOM)	Production	Medium	No

Direct (Applicability Statement for Secure Health Transport v1.2)

[View all results for Direct.](#)

**Interoperability Need: Representing Patient Allergic Reactions**

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
LOINC	Production	Medium	No
SNOMED CT	Production	Medium-High	No

**Interoperability Need: Representing Patient Allergies and Intolerances; Medications**

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
RxNorm	Production	Medium-High	Yes
SNOMED CT	Production	Medium	No
Medication Reference Terminology (MED-RT)	Pilot	Feedback Requested	No

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**Adoption Level**  
 Select All  
 Feedback Requested  
 Low  
 Low-Medium

**Type**  
 Standard  
 Standard for Observations  
 Standard for Observation values  
 Implementation Specification

**Test Tool Availability**  
 Yes  
 Yes\$  
 Yes - Open  
 No

**Cost**  
 - Any -

**Federally Required**  
 - Any -

**Implementation Maturity**  
 Pilot  Production  
 Feedback Requested

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 Final  Balloted Draft  
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**Search Using Keywords**

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Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
Direct (Applicability Statement for Secure Health Transport v1.2)	Production	Medium-High	Yes

### Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
Direct (Applicability Statement for Secure Health Transport v1.2)	Production	Low-Medium	Yes

### Interoperability Need: Push Patient-Generated Health Data into Integrated EHR

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
Direct (Applicability Statement for Secure Health Transport v1.2)	Production	Medium	Yes

### Interoperability Need: View, Download, and Transmit Data from EHR

Standard/Implementation Specification	Implementation Maturity	Adoption Level	Federally Required
Direct (Applicability Statement for Secure Health Transport v1.2)	Production	Medium-High	Yes



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SOURCE

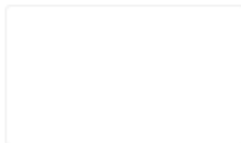
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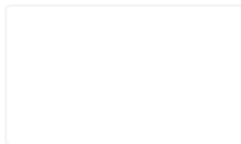
TODAY



### Reporting Newborn Screening and Birth Defects to Public Health Agencies

by ISA Team / now

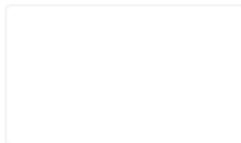
[no content]



### Health Care Claims or Equivalent Encounter Information for Retail Pharmacy Claims

by ISA Team / 2min

Added rows for Medicaid Subrogation specifications.



### Health Care Claims or Equivalent Encounter Information for Retail Pharmacy Supplies and Professional Services

by ISA Team / 4min

Added emerging standard for Medicaid Subrogation.



### Representing Relationship Between Patient and Another Person

by ISA Team / 6min

[no content]

# Preview: Specialty Care and Settings Views

## Opioids

This page identifies interoperability needs, associated technical standards, and implementation specifications within the ISA that support certain high priority functions in health IT, including EHRs, in the delivery of healthcare to prevent and treat opioid use disorder (OUD) and other substance use disorders (SUDs) and is not exhaustive. These interoperability needs, standards, and specifications also support other medical specialties and practice settings. ONC welcomes feedback to add to this list, and improve these standards and specifications.



### Section I

#### Social, Psychological, and Behavioral Data

- Representing Social Connection and Isolation
- Representing Exposure to Violence (Intimate Partner Violence)
- Representing Financial Resource Strain
- Representing Level of Education
- Representing Stress
- Representing Depression
- Representing Physical Activity
- Representing Alcohol Use

### Section II

#### Care Plan

- Documenting and Sharing Care Plans for a Single Clinical Context

#### Electronic Prescribing

- Allows a Prescriber or a Pharmacy to Request a New Prescription
- Allows a Prescriber to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP)

#### Segmentation of sensitive information

- Data Segmentation of Sensitive Information

### Section III

#### Consumer Access/Exchange of Health Information

- Push Patient-Generated Health Data into Integrated EHR

- The web-based version of the [ISA](#) is updated frequently throughout the year, as new comments from stakeholders come in or as changes occur, with a call for review and comments in late Summer timeframe
- ONC publishes a static “[Reference Edition](#)” of the ISA (PDF) each December that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change.



# Timeline

- The annual ISA review and comment period closed October 1.
- ONC staff reviewing comments and updating the ISA. The 2019 Reference Edition to be published by end of 2018.
- Comments open again in early January, with a late Summer/early Fall timeline for 2019 Annual Review and Comment period.
- To comment, create an account at [www.healthit.gov/ISA](http://www.healthit.gov/ISA)
  - » Click “log in” at top right of screen.
  - » Click top-center tab to “create new account”, fill in account details, and complete captcha to submit request.
  - » ISA team will approve your user account (usually in just a few hours), and you’ll get an email confirming your account.
  - » Navigate to comment on individual ISA pages, or submit consolidated comments at the ISA introduction page.

## 2018 Comments Overview

- ISA review and comment period: 7/31-10/1
- 74 comments posted on individual ISA pages, including 21 “consolidated” comment letters
  - » 320 recommendations from the letters
  - » 397 total recommendations to address
  - » More than 40 organizations/individuals
- Work happening now to finalize updates for 2019 Reference Edition.



The Office of the National Coordinator for  
Health Information Technology

## Panel Discussion

Steven Lane, MD, MPH, FAAFP  
Co-Chair, ISP Task Force  
ONC HIT Advisory Committee

Tom Sparkman  
Vice President, Government Relations  
ACLA



# Interoperability Standards Priorities Task Force Charge

- **Overarching Charge:** To make recommendations on priority uses of health information technology and the associated standards and implementation specifications that support such uses.
- **Specific Charge:** The ISP Task Force will:
  1. Make recommendations on the following:
    - Priority uses of health IT (consistent with the Cures Act’s identified priorities);
    - The standards and implementation specifications that best support or may need to be developed for each identified priority; and
    - Subsequent steps for industry and government action.
  2. Publish a report summarizing its findings.

# Priority Uses – Task Force Survey Results

Topic	Rank	Total Points
Orders & Results	1	39
Medication/Pharmacy Data	2	29
Evidence-Based Care for Common Chronic Conditions	3	28
Closed Loop Referrals	4	25
Other	5	23
Social Determinants of Health	6	15
Cost Transparency	7	12

Footnotes: 1. Voting as of 8/29/18  
2. Voting was weighted as follows:  
Rank of 1 = 5pts, Rank of 2 = 3pts, Rank of 3 = 1pt

# ACLA – Best Practice Recommendation

## ACLA Best Practice Recommendation for Administrative and Clinical Patient Gender used for Laboratory Testing and Reporting



### Overview

Every patient has experience with the provider's "patient demographic form"<sup>1</sup> which is typically completed and/or verified annually upon check in for a doctor's appointment or required for admission/registration at a care facility. Typically, these forms collect patient demographic information, such as patient name, address, contact info, date of birth, marital status, race, language, and 'sex' or 'gender', often represented as a male/female checkbox.

Since the 2004 Executive Order that prompted a national movement toward digital electronic health records, the creation of the Office of National Coordinator, the CMS Meaningful Use Electronic Health Record (EHR) Incentive Program, and most recently, the 21st Century Cures Act, the health care industry has made significant progress toward realizing the goal of 'Interoperability' as defined in 21<sup>st</sup> Century Cures Act:

“(10) INTEROPERABILITY.—The term ‘interoperability’, with respect to health information technology, means such health information technology that—

“(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

“(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

“(C) does not constitute information blocking as defined in section 3022(a).”.

Reliable patient demographic data is crucial to achieve interoperability; it is used to match patients so providers can retrieve all health care records, is used in research and data analytics to discover trends and cures, and even for administrative tasks such as clinical decision support, patient matching, trending, billing, claims, eligibility and bed assignment for inpatients.

Laboratories results are used in many medical decisions Laboratories may be located inside or adjacent to care facilities (hospitals, rehab facilities, nursing homes, doctor's offices, etc.) or established as a specimen processing center where the lab never sees the patient. The reliability of the demographic data provided to process the laboratory test is critical for a precise result. Some tests results are dependent on the patient's age, derived from the date of birth, and the patient's biological/chromosomal sex, sometimes referred to as the sex assigned at birth<sup>2</sup>. Additionally, results may be flagged to alert the provider based on the patient's age or biological/chromosomal gender. For

<https://www.acla.com/acla-best-practice-recommendation-for-administrative-and-clinical-patient-gender-used-for-laboratory-testing-and-reporting/>



# Questions?

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