Interoperability Standards Advisory: A Historical and Structural Overview

Prepared for the HITAC Interoperability Standards Workgroup

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Agenda

1. ISA Overview

2. Historical Background/Evolution

3. Structure
   A. Sections
   B. Sample Interoperability Need
   C. Specialty Care and Settings Tags
   D. ISA Publications: 2015-2022
   E. Recent ISA Updates
   F. How to Submit Comments
What is the ISA?

• 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, research and administrative purposes.

-About the ISA, available at https://www.healthit.gov/isa/about-isa
How is the ISA used and By Whom?

• Stakeholders

• Developers of health IT

• Implementers and users of health IT products

• The ISA and its associated informative characteristics are available to help more fully inform policy and implementation efforts, including limitations, dependencies or preconditions for use.
Ongoing Process

• 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 or January that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change.
Interoperability Standards Advisory (ISA)
Structural Evolution: Key Milestones 2015-2022

- 10-year Vision Paper to Achieve an Interoperable Health IT Infrastructure Publishes (June 2014)
- Shared Nationwide Interoperability Roadmap Version 1.0 Draft publishes, incorporates release of first draft ISA for public comment (Jan. 2015)
- Shared Nationwide Interoperability Roadmap Version 1.0 Final publishes (Oct. 2015)
- Second Draft ISA for public comment publishes (Aug. 2015)

- December 2015
  - 80 pp, PDF
  - Significant structural changes per two rounds of public comment, Health IT Standards Committee recs
  - Interoperability Needs, 6 new 'Best Available' standards and implementation specification characteristics, Appendices Added
  - Limitations, Dependencies, Preconditions & Value Sets subsections added to Interop Needs
  - Transport standards dropped per Health IT Standards Committee

- January 2017
  - 92 pp, PDF
  - Interactive Web Version Introduced
  - Streamlined Interoperability Need titles
  - New Appendices: (i) Models & Profiles; (ii) State and Local Public Health Agencies Web Version
  - Specialty Care and Settings Tags (Pediatrics and Opioids) February 2019
  - Care Coordination for Referrals, Clinical Notes, Cognitive Status Subsections Added Web Version
  - Redesigned for ease of use

- November 2018
  - Four SDOH Interoperability Needs Added
  - New subsection on COVID-19
  - New Specialty Care and Settings tag for COVID-19 Interoperability Needs Web Version
  - CMS
  - Linkage to USCDI, SVAP

- 8th Annual Reference Edition releases January 2022
  - 269 pp, PDF
  - Additions to COVID-19, SDOH, SO/GI Web Version
  - Specialty Care/Settings page Added for SDOH-related Interoperability Needs (March 2021)
High Level ISA Structure

• Section I: Vocabulary/Code Set/Terminology
• Section II: Content/Structure
• Section III: Services/Exchange
• Section IV: Administrative
• Informational Appendices (4)
• Specialty Care and Settings Tags (4)
Sample ISA Interoperability Need

Allows a Prescriber to Send a New Prescription to a Pharmacy

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard / Implementation Specification</th>
<th>Standards Process Maturity</th>
<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Federally required</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>NCPDP SCRIPT Standard, Implementation Guide, Version 2017071</td>
<td>Final</td>
<td>Pilot</td>
<td>●●●●●</td>
<td>No</td>
<td>$</td>
<td>Yes</td>
</tr>
<tr>
<td>Standard</td>
<td>NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</td>
<td>Final</td>
<td>Production</td>
<td>●●●●</td>
<td>Yes</td>
<td>$</td>
<td>Yes</td>
</tr>
<tr>
<td>Emerging Standard</td>
<td>HL7 FHIR Medication Requests</td>
<td>In Development</td>
<td>Pilot</td>
<td>Feedback Requested</td>
<td>No</td>
<td>Free</td>
<td>No</td>
</tr>
</tbody>
</table>

Limitations, Dependencies, and Preconditions for Consideration:

- The following transactions need to be implemented for interoperability purposes:
  - SCRIPT 10.6 & SCRIPT 2017071 -
    - NewRx: This transaction is a new prescription sent from the prescriber to the pharmacy electronically so that it can be dispensed to a patient.
  - SCRIPT 2017071 -
    - NewRxResponseDenied: This transaction is a denied response to a previously sent NewRxRequest (if approved, a NewRx would be sent)
    - A NewRxResponseDenied response may occur when the NewRxRequest cannot be processed or if information is unavailable.
- Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to...

Applicable Security Patterns for Consideration:

- Secure Message Router - securely route and enforce policy on inbound and outbound messages without interruption of delivery.
- Authentication Enforcer - centralized authentication processes.
- Authorization Enforcer - specifies access control policies.
- Credential Tokenizer - encapsulate credentials as a security token for reuse (e.g., - SAML, Kerberos).
- Assertion Builder - define processing logic for identity, authorization and attribute statements.
- User Role - Identifies the role asserted by the individual initiating the transaction.
- Purpose of Use - Identifies the purpose for the transaction.
ISA Content – Specialty Care and Settings Tags

Interoperability Standards

The Interoperability Standards Advisory (ISA) has been established to provide a framework for the development of "recognized" interoperability standards.

ISA Content

ISA Sections
- Vocabulary/Coding Set/Terminology
- Content/Structure
- Services/Exchange
- Administrative
- Appendices
  - Sources of Security Standards and Security Patterns
  - Models and Profiles
  - Educational and Informational Resources
  - State and Local Public Health Readiness for Interoperability

News & Updates

The 2022 ISA Reference Edition is now available. The public comment period for the Standards is open until November 30, 2022.

About ISA

The ISA is frequently updated to include improvements made based on recommendations received from public comments and subject matter expert feedback. Read more about the ISA's purpose and scope.

Specialty Care and Settings
- COVID-19
- Opioids
- Pediatrics
- Social Determinants of Health


Table of Contents

The Table of Contents of ISA's sections.
Specialty Care and Settings Tag: Social Determinants of Health

Social Determinants of Health

This page identifies interoperability needs, associated technical standards, and implementation specifications across the IGA that support certain priority functions in health IT, including EHRs, for the Social Determinants of Health (SDOH). It is not exhaustive and focuses on specific SDOH domains (example: food, housing and on referrals/coordinated care); many other standards may be relevant but are not tagged specifically under SDOH at this time. ONC welcomes feedback to add to this list, and improve these standards and specifications.

Vocabulary/Code Set/Terminology

- Allergies and Intolerances
  - Representing Patient Allergies and Intolerances; Environmental Substances

- Functional Status/Disability
  - Representing Patient Functional Status and/or Disability

- Preferred Language
  - Representing Patient Preferred Language (Presently)

- Race and Ethnicity
  - Representing Patient Race and Ethnicity

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

- Social, Psychological, and Behavioral Data
  - Representing Alcohol Use
  - Representing Depression
  - Representing Drug Use
  - Representing Exposure to Violence (Intimate Partner Violence)
  - Representing Financial Resource Strain
  - Representing Food Insecurity
  - Representing Housing Insecurity
  - Representing Level of Education
  - Representing Physical Activity
  - Representing Social Connection and Isolation
Current and Historical ISA Publications include:

- 2016 ISA - Final Version (published December 2015)
  - 2016 ISA Public Comments
- 2016 ISA - Draft (published August 2015)
  - 2016 Draft ISA Public Comments
- 2015 ISA (published January 2015)
  - 2015 ISA Public Comments

Health information technology (Health IT) makes it possible for health care providers to better manage patient care through secure use and sharing of health information. Health IT includes the use of electronic health records (EHRs) instead of paper medical records to maintain people's health information.
Recent ISA Updates

Check here regularly for the latest updates to the ISA. Please note, that revisions to individual interoperability needs (such as adding/removing of standards or changes to their informative characteristics) are not included here. Revision history is available on each ISA page. In addition, 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. Once logged in, look for the blue "change notification" button at the bottom of the interoperability need page, or at the bottom of this page to be notified of any changes across the ISA.

An RSS Feed that captures all changes made to the ISA is also available for visibility into more granular ISA updates.

- March 29, 2022 — Added Representing Patient Address and Representing Patient Names Interoperability Needs within Section I: Demographics.
- March 18, 2022 — Added Section I: Biologies and Representing Biological Products Interoperability Need.
- March 15, 2022 - Added Adverse Event Reporting Interoperability Need within Section II: Public Health Reporting.
- Fall 2021 - Numerous changes made to address public comments received and prepare the 2022 Reference Edition, including but not limited to:
  - Changed Vocabulary/Code Set/Terminology: Laboratory, adding two Interoperability Needs and removing one:
    - Added Representing Laboratory Test Ordered
    - Added Representing Laboratory Test Performed
    - Removed Representing Laboratory Tests
  - Changed Vocabulary/Code Set/Terminology: Tobacco Use Interoperability Need from:
Timeline & Comment Submission


- Comments now open (ISA web-based version)
  - Annual Review and Comment period opens summer 2022 (2023 ISA Reference Edition)

- To comment, create an account at 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 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.

- Can be added to an RSS feed for real-time updates
Questions?

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Find the ISA at:
https://www.healthit.gov/isa/