2016 Interoperability Standards Advisory

Best Available Standards and Implementation Specifications

Office of the National Coordinator for Health IT

FINAL VERSION

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The Interoperability Standards Advisory represents the Office of the National Coordinator for Health Information Technology's current thinking and is for informational purposes only. It is non-binding and does not create nor confer any rights or obligations for or on any person or entity.

Executive Summary

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 determination of the "best available" interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs.

The 2016 Interoperability Standards Advisory (2016 Advisory) remains focused on clinical health information technology (IT) interoperability and is published at https://www.healthit.gov/standards-advisory/draft-2016. For detailed background on the Advisory, its purpose, and its processes please review the 2015 Advisory. When compared to the inaugural 2015 Advisory, the 2016 Advisory has been significantly updated and expanded in the span of less than one year. These updates and improvements are due largely to the two rounds of public comment and recommendations from the HIT Standards Committee.

At a high-level, the most substantial changes between the 2015 and 2016 Advisory are structural changes to the way in which the content is organized, presented, and annotated. This includes the following:

1) Instead of referencing a general "purpose," a section's lead-in is framed to convey an "interoperability need" – an outcome stakeholders want to achieve with interoperability.
2) A set of six informative characteristics are now associated with each referenced standard and implementation specification to give readers an overall sense of maturity and adoptability.
3) Associated with each "interoperability need" are two subsections:
    a. The first subsection identifies any known limitations, dependencies, or preconditions associated with best available standards and implementation specifications.
    b. The second subsection identifies Section I known "value sets" and for Sections II and III "security patterns" associated with best available standards and implementation specifications. In Section I, this subsection identifies the most applicable subset of the identified codes or terms for the specified interoperability need. For Sections II and III, this subsection identifies the generally reusable security techniques applicable to interoperability need(s) without prescribing or locking-in particular security standards.
4) A security standards sources appendix is included to point stakeholders to the entities that maintain and curate relevant security standards information.
5) A "projected additions" section was added to identify new interoperability needs suggested by stakeholders in response to the draft 2016 Advisory and on which public comment is sought related to their formal addition to the next year's Advisory.
6) A summary of public comments received that were not incorporated into the 2016 ISA applicable to each section, as well as a summary of ONC planned action or rationale as to why they were not included (see Appendix IV).
7) A revision history section has been added at the end of the document.

The 2016 Advisory includes revisions and additional descriptive text for several of the six informative characteristics. The "standards process maturity" characteristic was revised to include "balloted draft" instead of "draft" to more clearly indicate formally approved drafts by a standards development organization from those that are early "works in progress." The "adoption level" characteristic was revised to change the "bubble" indication from being a percentage range (i.e., 21%-40%) to a qualitative range (i.e., "low-medium"). Its description also includes more information for stakeholders in terms of the basis by which the adoption level was assigned.

Per the process first established with the publication of the 2015 Advisory, this document represents the final 2016 Advisory and will now serve as the basis on which future public comments and HIT Standards Committee

recommendations are sought. The comment period on this version to being the 2017 Advisory process will begin in early 2016. Your continued feedback and engagement is critical to improve and refine the Advisory.

Scope

The standards and implementation specifications listed in this advisory focus explicitly on clinical health IT systems' interoperability. Thus, the advisory's 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). The advisory does **not** include within its scope administrative/payment oriented interoperability purposes or administrative transaction requirements that are governed by HIPAA and administered by the Centers for Medicare & Medicaid Services (CMS).

Purpose

The ISA is meant to serve at least the following purposes:

1) To provide 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.
2) To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available.
3) To document known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability need.

The 2016 Interoperability Standards Advisory

The following represents an updated list of the best available standard(s) and implementation specification(s) in comparison to previous Advisories. The list is not exhaustive but it is expected that future advisories will incrementally address a broader range of clinical health IT interoperability needs.

While the standards and implementation specifications included in the advisory may also be adopted in regulation, required as part of a testing and certification program, or included as procurement conditions, the advisory is non-binding and serves only to provide clarity, consistency, and predictability for the public regarding ONC's assessment of the best available standards and implementation specifications for a given interoperability need. It is also plausible, intended, and expected for advisories to be "ahead" of where a regulatory requirement may be, in which case a standard or implementation specification's reference in an advisory may serve as the basis for industry or government action.

When one standard or implementation specification is listed as the "best available," it reflects ONC's current assessment and prioritization of that standard or implementation specification for a given interoperability need. When more than one standard or implementation specification is listed as the best available, 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.

"Best Available" Characteristics

The 2015 Advisory introduced several "characteristics" and additional factors by which standards and implementation specifications were determined to be the "best available." For example, whether a standard was in widespread use or required by regulation. Public comment and feedback from the HIT Standards Committee

indicated that more explicit context for each standard and implementation specification would benefit stakeholders and clearly convey a standard's relative maturity and adoptability.[1]

This added context will allow for greater scrutiny of a standard or implementation specification despite its inclusion as the "best available." For instance, a standard may be referenced as best available, yet not be widely adopted or only proven at a small scale. Public comment noted that in the absence of additional context, stakeholders could inadvertently over-interpret the "best available" reference and apply a standard or implementation specification to a particular interoperability need when it may not necessarily be ready or proven at a particular scale.

The 2016 Advisory uses the following six informative characteristics to provide added context. When known, it also lists an "emerging alternative" to a standard or implementation specification, which is shaded in a lighter color, and italicized for additional emphasis.

Interoperability need: [Descriptive Text]

Standard/ Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Standard	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Section I: Applicable Value Set(s): Sections II & III: Applicable Security Patterns for Consideration:
• Descriptive text with "(recommended by the HIT Standards Committee)" included in cases where the HIT Standards Committee recommended the text, and on which public feedback is sought.	• Descriptive text

The following describes the six characteristics that were added to the Advisory in detail. This detail is meant to better inform stakeholders about the maturity and adoptability of a given standard or implementation specification, and provides definition for the terms and symbols used throughout the Advisory. These definitions remain similar in nature to those presented in the Draft 2016 Advisory, but have been modified slightly to provide additional clarity as requested by public comments. Stakeholders should consider all six characteristics together to gain insight into the level of maturity and adoptability of the "best available" standards provided within the Advisory.

#1: Standards Process Maturity

This characteristic conveys a standard or implementation specification's maturity in terms of its stage within a particular organization's approval/voting process.

- ***"Final"*** – when this designation is assigned, the standard or implementation specification is considered "final text" or "normative" by the organization that maintains it.
- ***"Balloted Draft"*** – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU) or in a "trial implementation" status by the organization that maintains it and has been voted on or approved by its membership as such. This designation does not include standards and implementation guides that are unofficial drafts and early "works in progress".

[1] This approach uses a subset of the key attributes described in "Evaluating and classifying the readiness of technology specifications for national standardization Dixie B Baker, Jonathan B Perlin, John Halamka, Journal of the American Medical Informatics Association May 2015, 22 (3) 738-743; DOI: 10.1136/amiajnl-2014-002802

#2: Implementation Maturity

This characteristic conveys a standard or implementation specification's maturity based upon its implementation state.

- ***"Production"*** – when this designation is assigned, the standard or implementation specification is being used in production to meet a health care interoperability need.
- ***"Pilot"*** – when this designation is assigned, the standard or implementation specification is being used at limited scale or only as part of pilots to meet a health care interoperability need.

#3: Adoption Level

This characteristic conveys a standard or implementation specification's approximate and average adoption level in health care within the United States. Presently, it is based on ONC's analysis of several factors, including, but not limited to: 1) whether and/or how long a standard or implementation specification has been included in regulation for health IT certification (if applicable) or another HHS regulatory or program requirement; 2) feedback from subject matter experts, and 3) public comments.

The adoption level also considers the scope of stakeholders and stakeholder groups that would use the standard and implementation specification to address the specified interoperability need and attempts to display it as such, with the understanding that the designation is a generality and not a pre-defined measured value.

The following scale is used to indicate the approximate, average adoption level among the stakeholders that would use a standard or implementation specification to meet the specified interoperability need:

- "*Unknown*" Indicates no known status for the current level of adoption in health care.
- ●○○○○ Indicates low adoption.
- ●●○○○ Indicates low-medium adoption.
- ●●●○○ Indicates medium adoption.
- ●●●●○ Indicates medium-high adoption.
- ●●●●● Indicates high or widespread adoption.

#4: Federally Required

This characteristic (provided as a "*Yes*" or "*No*") conveys whether a standard or implementation specification has been adopted in regulation, referenced as a federal program requirement, or referenced in a federal procurement (i.e., contract or grant) for a particular interoperability need. Where available, a link to the regulation has been provided.

#5: Cost

This characteristic conveys whether a fee is involved to purchase, license or obtain membership for access or use of the recommended standard or implementation specification.

- "*$*" – when this designation is assigned, it signifies that some type of payment needs to be made in order to obtain the standard or implementation specification.
- "*Free*" – when this designation is assigned, it signifies that the standard or implementation specification can be obtained without cost. This designation applies even if a user account or license agreement is required to obtain the standard at no cost.

#6: Test Tool Availability

This characteristic conveys whether a test tool is available to evaluate health IT's conformance to the standard or implementation specification for the particular interoperability need.

- *"Yes"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.
- *"Yes*[$]*"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and has a cost associated with its use. Where available, a hyperlink pointing to the test tool will be included.
- *"Yes – Open"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is available as open source with rights to modify. Where available, a hyperlink pointing to the test tool will be included.
- *"No"* – When this designation is assigned, it signifies that no test tool is available for a standard or implementation specification.
- *"N/A"* – When this designation is assigned, it signifies that a test tool for the standard or implementation would be "not applicable."

The Structure of the Sections

In Sections I through III, and for the purposes of the lists that follow, a specific version of the standard or implementation specification is not listed unless multiple versions of the same standard are referenced. The standards and associated implementation specifications for clinical health IT interoperability are grouped into these categories:

- *Vocabulary/code sets/terminology* (i.e., "semantics").
- *Content/structure* (i.e., "syntax").
- *Services* (i.e., the infrastructure components deployed and used to fulfill specific interoperability needs)

At the recommendation of the HIT Standards Committee and further supported by public comments, we have removed the "transport" section which previously referenced low-level transport standards. It was removed because 1) it was deemed to not provide additional clarity/value to stakeholders; and 2) the standards and implementation specifications in the "services" section included them as applicable. Thus, focusing on that section in addition to vocabulary and content were deemed more impactful and necessary.

In Section IV, we have included projected additions to the ISA for which public input is requested.

In Section V, we have included questions for which public input is requested.

And lastly, as noted in the 2015 Advisory, this Advisory is not intended to imply that a standard listed in one section 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 purpose.

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

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• SNOMED-CT may not be sufficient to differentiate between an allergy or adverse reaction, or the level of severity	• Value Set Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4

Interoperability Need: Representing patient allergens: medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●○	Yes	Free	N/A
Standard	NDF-RT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee)	• Grouping Value Set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. The codes from the following value set should be selected in the following order of preference: NDF-RT -> RxNorm -> UNII -> SNOMED CT • Medication Drug Class (2.16.840.1.113883.3.88.12.80.18) (NDFRT drug class codes) • Clinical Drug Ingredient (2.16.840.1.113762.1.4.1010.7) (RxNORM ingredient codes

Interoperability Need: Representing patient allergens: food substances							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Grouping Value set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. • Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes

Interoperability Need: Representing patient allergens: environmental substances							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Grouping Value set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. • Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT substance codes).

I-B: Health Care Provider

Interoperability Need: Representing care team member (health care provider)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	National Provider Identifier (NPI)	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• For the purpose of recording a care team member, it should be noted that NPPES permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of 'person'. • Some care team members may not have an NPI and may not wish to apply for one as noted above. • NPI taxonomy may not have sufficient enough detail to describe all roles associated with an individual's care team	• No Value Set

I-C: Encounter Diagnosis

Interoperability Need: Representing patient medical encounter diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●○	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED-CT code system)

Interoperability Need: Representing patient dental encounter diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• SNODENT; 2.16.840.1.113883.3.3150

I-D: Race and Ethnicity

Interoperability Need: Representing patient race and ethnicity							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. • The high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic or public health reporting purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions. • LOINC provides observation codes for use in the observation / observation value pattern for communicating race and ethnicity.	• Race (5 codes): Race Category Excluding Nulls urn:oid:2.16.840.1.113883.3.2074.1.1.3 • Race (extended set, 900+codes): Race urn:oid:2.16.840.1.113883.1.11.14914 • Ethnicity: Ethnicity urn:oid:2.16.840.1.114222.4.11.837

I-E: Family Health History

Interoperability Need: Representing patient family health history							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee)	For Diagnosis and Conditions: • Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED-CT code system) For genomic data: • Gene Identifier: HGNC Value Set • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature

I-F: Functional Status/Disability

Interoperability Need: Representing patient functional status and/or disability							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	***[See Question 4]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Public comments were varied for this interoperability need. We heard the strongest support for SNOMED-CT and ICF standards, but at this time do not have enough information to warrant inclusion of either standard for this interoperability need.	• Feedback requested

I-G: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing patient gender identity							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Unknown	Unknown	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• Feedback requested

Interoperability Need: Representing patient sex (at birth)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	For Male and Female, HL7 Version 3 Value Set for Administrative Gender; For Unknown, HL7 Version 3 Null Flavor	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s)
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1

Interoperability Need: Representing patient-identified sexual orientation							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Unknown	Unknown	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• Feedback requested

I-H: Immunizations

Interoperability Need: Representing immunizations – historical							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Standard Code Set CVX—Clinical Vaccines Administered	Final	Production	●●●●●	Yes	Free	N/A
Standard	HL7 Standard Code Set MVX -Manufacturing Vaccine Formulation	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • When an MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated providing further specificity as to the vaccines administered.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set

Interoperability Need: Representing immunizations – administered							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Standard Code Set CVX—Clinical Vaccines Administered	Final	Production	●●●●●	No	Free	N/A
Standard	National Drug Code	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • RxNorm: Vaccine Clinical Drug 2.16.840.1.113762.1.4.1010.8 • RxNorm: Specific Vaccine Clinical Drug urn:oid:2.16.840.1.113762.1.4.1010.10

I-I: Industry and Occupation

Interoperability Need: Representing patient industry and occupation							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	***[See Question 4]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Public comments were varied for this interoperability need. We heard the strongest support for National Institute for Occupational Safety and Health (NIOSH) list, which includes an Industry and Occupation Computerized Coding System (NIOCCS), U.S. Department of Labor, Bureau of Labor Statistics, Standard Occupational Classification, and National Uniform Claim Committee Health Care Taxonomy (NUCC) codes standards, but at this time do not have enough information to warrant inclusion of either standard for this interoperability need.	• Feedback requested

I-J: Lab tests

Interoperability Need: Representing numerical laboratory test results (observations)(questions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology. • Where LOINC codes do not exist, it is possible to request a new LOINC term be created. A number of factors may determine the length of time required for a new code to be created.	• A value set at this granularity level (numerical) does not exist. The list of LOINC Top 2000+ Lab Observations OID: 1.3.6.1.4.1.12009.10.2.3

I-K: Medications

Interoperability Need: Representing patient medications							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	RxNorm	Final	Production	●●●●●	Yes	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●○○	No	Free	N/A
Standard	National Drug File – Reference Terminology (NDF-RT)	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals. • NDF-RT allows for representing classes of medications when specific medications are not known. • Immunizations are not considered medications for this interoperability need.	• Grouping Value Set: Medication Clinical Drug 2.16.840.1.113762.1.4.1010.4 ▪ Medication Clinical General Drug (2.16.840.1.113883.3.88.12.80.17) ▪ Medication Clinical Brand-specific Drug (2.16.840.1.113762.1.4.1010.5) (RxNorm). • Grouping Value Set: Clinical Substance 2.16.840.1.113762.1.4.1010.2 ▪ Medication Clinical Drug (2.16.840.1.113762.1.4.1010.4) (RxNorm) ▪ Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII) • Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT).

I-L: Numerical References & Values

Interoperability Need: Representing units of measure (for use with numerical references and values)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	The Unified Code for Units of Measure	Final	Production	●●○○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations. • Per public comments received, some issues with UCUM in the laboratory domain remain unresolved. • The abbreviations used for a few of the units of measure listed in the UCUM standard are currently on lists of prohibited abbreviations from the Institute for Safe Medication Practice (ISMP). • Some abbreviations for units of measure include symbols which may be in conflict with other HL7 standards. • Some abbreviations for units are nonstandard for human understanding. For example, if a result for a White Blood Cell count is 9.6 x 103/µL, the UCUM recommendation for rendering this value in a legacy character application is 9.6 x 10*3/uL. Because the "*" is a symbol for multiplication in some systems. This recommendation may result in errors either by the information system or the human reading the result. • Some other abbreviations used in UCUM are not industry standard for the tests that use these units of measure.	• Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes)

I-M: Patient Clinical "Problems" (i.e., conditions)

Interoperability Need: Representing patient clinical "problems" (i.e., conditions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Depending on the patient problem, more than one SNOMED-CT code may be required to accurately describe the patient problem (e.g., left leg fracture requires the use of two SNOMED CT codes)	• Problem 2.16.840.1.113883.3.88.12.3221.7.4

I-N: Preferred Language

Interoperability Need: Representing patient preferred language							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	RFC 5646	Final	Production	Unknown	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language.	• Language urn:oid:2.16.840.1.113883.1.11.11526 (based off RFC 4646. This will be updated to reflect RFC 5646)

I-O: Procedures

Interoperability Need: Representing dental procedures performed							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	Code on Dental Procedures and Nomenclature (CDT)	Final	Production	●●●●○	Yes	$	N/A
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• Feedback requested	• SNODENT; 2.16.840.1.113883.3.3150

Interoperability Need: Representing medical procedures performed							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A
Standard	the combination of CPT-4/HCPCS	Final	Production	●●●●●	Yes	$	N/A
Standard	ICD-10-PCS	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• Feedback requested	• Feedback requested

I-P: Imaging (Diagnostics, interventions and procedures)

Interoperability Need: Representing imaging diagnostics, interventions and procedures							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Radlex and LOINC are currently in the process of creating a common data model to link the two standards together to promote standardized indexing of radiology terms as indicated by public comments and HIT Standards Committee recommendations.	• Feedback requested

I-Q: Tobacco Use (Smoking Status)

Interoperability Need: Representing patient tobacco use (smoking status) observation result values or assertions (answers)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• According to the HIT Standards Committee, there are limitations in SNOMED-CT for this interoperability need, which include not being able to capture severity of dependency, level of use, quit attempts, lifetime exposure, and use of e-Cigarettes.	• Current Smoking Status urn:oid:2.16.840.1.113883.11.20.9.38

I-R: Unique Device Identification

Interoperability Need: Representing unique implantable device identifiers							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	HL7 Harmonization Pattern for Unique Device Identifiers	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020.	• Feedback requested

I-S: Vital Signs

Interoperability Need: Representing patient vital signs							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62

Section II: Best Available Content/Structure Standards and Implementation Specifications

II-A: Admission, Discharge, and Transfer

Interoperability Need: Sending a notification of a patient's admission, discharge and/or transfer status to other providers							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

II-B: Care Plan

Interoperability Need: Documenting patient care plans							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
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	Balloted Draft	Pilot	Unknown	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Feedback requested	• Feedback requested

II-C: Clinical Decision Support

Interoperability Need: Shareable clinical decision support							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.	Balloted Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Feedback requested	• Feedback requested

II-D: Drug Formulary & Benefits

Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	NCPDP Formulary and Benefits v3.0	Final	Production	●●●●●	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• NCPDP Formulary and Benefits v3.0 does not provide real-time patient-level benefit information. • The HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

II-E: Electronic Prescribing

Interoperability Need: A prescriber's ability to create a new prescription to electronically send to a pharmacy							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "New Prescription" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Prescription refill request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Refill Request" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Cancellation of a prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Unknown	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Cancel" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Pharmacy notifies prescriber of prescription fill status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Unknown	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Fill Status" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: A prescriber's ability to obtain a patient's medication history

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Both the "Medication History Request" and "Medication History Response" transactions need to be implemented for interoperability purposes. • Both the prescriber and the receiving pharmacy or pharmacy benefits manager (PBM) must have their systems configured for the transaction in order to facilitate successful exchange.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

II-F: Family health history (clinical genomics)

Interoperability Need: Representing family health history for clinical genomics

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Version 3 Standard: Clinical Genomics; Pedigree	Balloted Draft	Production	●○○○○	Yes	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1	Balloted Draft	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• According to the HIT Standards Committee, there is no available vocabulary to capture family genomic health history. • According to the HIT Standards Committee, further constraint of this standard and implementation specification may be required to support this interoperability need.	• Feedback requested

II-G: Images

Interoperability Need: Medical image formats for data exchange and distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Use Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes	• Feedback requested

Interoperability Need: Format of medical imaging reports for exchange and distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No
Implementation Specification	PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture.	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Ordering labs for a patient

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Support the transmission of a laboratory's directory of services to health IT.							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

II-I: Patient Education Materials

Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge form online resources							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.	Final	Production	●●●●○	Yes	Free	No
Implementation Specification	HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.	Final	Production	●●●○○	Yes	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.	Final	Production	●●●○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

II-J: Patient Preference/Consent

Interoperability Need: Recording patient preferences for electronic consent to access and/or share their health information with other care providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●○○○	No	Free	Yes – Open
2-Implementation Specification	IHE Cross Enterprise User Assertion (XUA)	Final	Production	●○○○○	No	Free	Yes - Open

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These profiles operate in conjunction with the IHE XDS, XCA, and XDR profiles • IHE BPPC may not support management of patient privacy across governmental jurisdictions which may have different regulations regarding access to patient data by providers, patients, governmental entities, and other organizations.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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. • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.

II-K: Public Health Reporting

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●○○○○	Yes	Free	No
Emerging Alternative Implementation Specification	*HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• This is a national reporting system to CDC. Stakeholders should refer to implementation guide for additional details and contract information for enrolling in the program.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting cancer cases to public health agencies							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm	Balloted Draft	Production	●●●○○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Alternative Implementation Specification	*HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm*	*Balloted Draft*	*Pilot*	●○○○○	Yes	*Free*	*No*
Emerging Alternative Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Alternative Implementation Specification	*HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements. Some jurisdictions may not support cancer case reporting at this time.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Case reporting to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
1-Implementation Specification	IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
2- Emerging Alternative Implementation Specification	*HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• Electronic case reporting is not wide spread and is determined at the state or local jurisdiction.
• Structured Data Capture Implementation Guide does not currently restrict vocabulary to standard vocabulary sets
• Some additional implementation guides related to public health reporting follow. Reporting is often captured under a specialized registry with associated standards when not specified as a separate measure. These include:
  ○ Early Hearing Detection and Intervention (EHDI)
  ○ Office of Populations Affairs (OPA) Family Planning Reporting IHE Profile
	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication.
	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
	• **Authentication Enforcer** – centralized authentication processes.
	• **Authorization Enforcer** – specified policies access control.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos).
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Electronic transmission of reportable lab results to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●○	Yes	Free	No
Implementation Specification	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1*	*Balloted Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Sending health care survey information to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting administered immunizations to immunization registry

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5*	*Final*	*Production*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements. • HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 – Addendum is also available.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0*	*Final*	*Pilot*	●○○○○	*Yes*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements. • An Erratum to the CDC PHIN 2.0 Implementation Guide was issued in August, 2015. Implementers should refer to this guide for additional information and conformance guidance.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-L: Quality Reporting

Interoperability Need: Reporting aggregate quality data to federal quality reporting initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1	Balloted Draft	Production	●●●●○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: Reporting patient-level quality data to federal quality reporting initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm)*	*Balloted Draft*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

II-M: Representing clinical health information as a "resource"

[See Question 6]

Interoperability Need: Representing clinical health information as "resource"

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 defines a "resource" as an entity that: has a known identity (a url) by which it can be addressed; identifies itself as one of the types of resource defined in the FHIR specification; contains a set of structured data items as described by the definition of the resource type; and, has an identified version that changes if the contents of the resource change	• Feedback requested

II-N: Segmentation of sensitive information

Interoperability Need: Document-level segmentation of sensitive information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Pilot	●○○○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

II-O: Summary care record

Interoperability Need: Support a transition of care or referral to another health care provider							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Balloted Draft	Production	●●●●●	Yes	Free	Yes
Emerging Alternative 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*	*Balloted Draft*	*Pilot*	*Unknown*	*Yes*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates.	• Feedback requested

Section III: Best Available Standards and Implementation Specifications for Services

III-A: "Push" Exchange

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between individuals and systems							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1- Standard	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
2 - Emerging Alternative Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*
1, 2, 3 - Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1, 2 - Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	Yes	Free	Yes
1, 2, 3 - Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
3 – Standard	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	Yes	Free	Yes
4 - Emerging Alternative Standard	*Fast Healthcare Interoperability Resources (FHIR) DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3, 4 - Emerging Alternative Implementation Specification	*IHE-MHD (Mobile Access to Health Documents*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. • The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API" • The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it to implementers in first quarter calendar year 2016.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **Recipient Encryption** - the message and health information are encrypted for the intended user • **Sender Signature** – details that are necessary to identity of the individual sending the message • **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between systems							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1- Standard	SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification	Final	Production	●●●○○	Yes	Free	Yes
2- Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●○	No	Free	Yes
1 - Implementation Specification	NwHIN Specification: Messaging Platform	Final	Production	●●●○○	No	Free	No
1- Implementation Specification	NwHIN Specification: Authorization Framework	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0 • The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

III-B: Clinical Decision Support Services

Interoperability Need: Providing patient-specific assessments and recommendations based on patient data for clinical decision support

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
1- Implementation Specification	HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Emerging Alternative Implementation Specification	*IHE- GAO (Guideline Appropriate Ordering)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3-Emerging Alternative Implementation Specification	*IHE-CDS-OAT (Clinical Decision Support – Order Appropriateness Tracking)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: 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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Standard	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.	Final	Production	●●●○○	Yes	Free	No
1-Implementation Specification	HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.	Final	Production	●●●●○	Yes	Free	No
1-Implementation Specification	HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.	Final	Production	●●●●○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

III-C: Image Exchange

Interoperability Need: Exchanging imaging documents within a specific health information exchange domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Implementation Specification	IHE Cross Enterprise Document Sharing for Images (XDS-I.b)	Final	Pilot	●○○○○	No	Free	Yes
1,2-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	No
1,2-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
2-Emerging Alternative Implementation Specification	*IHE – MHD-I (Mobile Access to Health Documents for Imaging)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Interoperability Need: Exchanging imaging documents outside a specific health information exchange domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE Cross Community Access for Imaging (XCA-I)	Final	Pilot	●○○○○	No	Free	Yes
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos).

III-D: Provider Directory

Interoperability Need: Listing of providers for access by potential exchange partners							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes
2-Emerging Alternative Standard	*Fast Healthcare Interoperability Resources (FHIR), DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The following URL provides links to relevant FHIR Resource, Practitioner - http://www.hl7.org/implement/standards/fhir/practitioner.html • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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. • **User Details** - identifies the end user who is accessing the data.

III-E: Publish and Subscribe

Interoperability Need: Publish and subscribe message exchange

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	NwHIN Specification: Health Information Event Messaging Production Specification	Final	Production	●○○○○	No	Free	No
2-Emerging Alternative Implementation Specification	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	Balloted Draft	Pilot	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

III-F: Query

Interoperability Need: Query for documents within a specific health information exchange domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Implementation Specification	IHE-XDS (Cross-enterprise document sharing)	Final	Production	●●●●○	No	Free	Yes
1,2-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes
1,2-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
2- Emerging Alternative Implementation Specification	*IHE – MHD (Mobile Access to Health Documents)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need. • The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it to implementers in first quarter calendar year 2016.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos).**Message Interceptor Gateway** – provide a single entry point solution for centralization of security enforcement for incoming and outgoing XML WebService messages. • **System Authentication** - The information and process necessary to authenticate the systems involved • **User Authentication** – The identity information and process necessary verify the user's identity • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction. • **Patient Consent Information** - Identifies the patient consent information that: o May be required to authorize any exchange of patient information o May be required to authorized access and use of patient information o May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply • **Security Labeling** – the health information is labeled with security metadata

Interoperability Need: Query for documents outside a specific health information exchange domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE-XCA (Cross-Community Access)	Final	Production	●●●●○	No	Free	No
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
Implementation Specification	NwHIN Specification: Patient Discovery	Final	Production	●●●○○	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NwHIN Specification: Query for Documents	Final	Production	●●●○○	No	Free	No
Implementation Specification	NwHIN Specification: Retrieve Documents	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Authentication** – The information and process necessary to authenticate the end user
	• **User Details** - identifies the end user who is accessing the data
	• **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction for purposes of authorization. E.g., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access.
	• **Purpose of Use** - Identifies the purpose for the transaction, and for the purposes for which the end user intends to use the accessed objects
	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorized access and use of patient information
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: Data element based query for clinical health information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• The following URL provides links to relevant FHIR resources http://www.hl7.org/implement/standards/fhir/resourcelist.html
• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress.
	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Details** - identifies the end user who is accessing the data
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.
	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorized access and use of patient information
	  ○ May be required to be sent along with disclosed patient information to
	  ○ advise the receiver about policies to which end users must comply
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

III-G: Resource Location

Interoperability Need: Resource location within the US							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• **System Authentication** - The information and process necessary to authenticate the systems involved • **User Details** - identifies the end user who is accessing the data • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Section IV: Projected Additions to the ISA

The following tables represent projected additions to the ISA. They represent different and additional interoperability needs for which there may be "best available" standards or implementation specifications which have not yet been reviewed through the ISA's comment process. ONC seeks feedback from stakeholders as to whether the proposed interoperability needs and/or standards are accurate and would be beneficial additions to the ISA. See additional questions in Section V for specific areas where feedback is requested.

Projected Vocabulary/Code Set/Terminology Standards and Specifications:

Family Health History

Interoperability Need: Representing patient family health history observations (questions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC	Final	Production	●●●○○		Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC code system)

Gender Identity, Sex and, Sexual Orientation

Interoperability Need: Representing patient gender identity observations (questions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• LOINC code: 76691-5 Gender identity

Interoperability Need: Representing patient sex (at birth) observations (questions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• One LOINC code: 76689-9 Sex assigned at birth

Interoperability Need: Representing patient-identified sexual orientation observations (questions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• LOINC code: 76690-7 Sexual orientation.

Health Care Provider

Interoperability Need: Provider role in care setting							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Unknown	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Healthcare Provider Taxonomy (HIPAA): 2.16.840.1.114222.4.11.1066 • HL7 Participation Function • Subjects role in the care setting (SNOMED-CT)

Lab Tests

Interoperability Need: Representing numerical laboratory test order observations (questions/what will be tested)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology. • Where LOINC codes do not exist, it is possible to request a new LOINC term be created. A number of factors may determine the length of time required for a new code to be created. • A single lab test with a single result will have the same LOINC term for its order and result answer, but a panel order will have an order LOINC term and multiple result LOINC terms for each result in the panel.	• A value Set at this granularity level (numerical) does not exist. Use Universal Lab Orders OID: 1.3.6.1.4.1.12009.10.2. (if need be, the rest of LOINC)

Interoperability Need: Representing categorical laboratory test result observation values (answers)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology.	• Feedback requested.

Nursing

Interoperability Need: Representing nursing assessments							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	Unknown	No	Free	N/A
Standard	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• Assessments are represented as question/answer (name/value) pairs. They are not represented in other terminologies. • LOINC should be used for the assessment/observation questions and SNOMED CT for the assessment/observation answers (value sets, choice lists).	• Feedback requested

Interoperability Need: Representing outcomes for nursing							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s):**
• Other ANA-recognized terminologies should be converted to LOINC for comparison across health systems and/or transmission.	• Feedback requested

Interoperability Need: Representing patient problems for nursing							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED-CT for comparison across health systems and/or transmission.	• Feedback requested

Interoperability Need: Representing nursing interventions and observations (observations are assessment items)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED-CT for comparison across health systems and/or transmission.	• Feedback requested

Research

Interoperability Need: Representing analytic data for research purposes.							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Controlled Terminology for Regulatory Standards Hosted by NCI-EVS	Final	Production	●●●●●	Yes	Free	N/A
Standard	CDISC Controlled Terminology for CDISC Therapeutic Area Standards Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Controlled Terminology for Medical Devices Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Feedback requested	• Feedback requested

Tobacco Use (Smoking Status)

Interoperability Need: Representing patient tobacco use (smoking status) observations (questions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Production	●●●●●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• LOINC includes codes that support recording smoking status in the CDC's preferred (and sometimes required) responses (e.g. Tobacco smoking status NHIS [76691-5]) and other kinds of observations (e.g. Have you smoked at least 100 cigarettes in your entire life [PhenX] [63581-3] or How old were you when you first started smoking cigarettes every day [PhenX] [63609-2].	• One LOINC code: 72166-2 "Tobacco smoking status NHIS"

Projected Content/Structure Standards and Specifications:

Admission, Discharge and Transfer

Interoperability Need: Sending a notification of a patient's admission, discharge and/or transfer status to the servicing pharmacy							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Census Message" transaction allows for long-term and post-acute care settings to notify the servicing pharmacy of a patient's admission, discharge and/or transfer status.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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.

Care Plans

Interoperability Need: Documenting, planning and summarizing care plans for patients with cancer

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary, Release 1	Balloted Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Clinical Decision Support

Interoperability Need: Provide access to appropriate use criteria

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Alternative Implementation Specification	*IHE: Guideline Appropriate Ordering (GAO)*	*Balloted Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: Communicate appropriate use criteria with the order and charge to the filling provider and billing system for inclusion on claims.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Alternative Implementation Specification	*IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)*	*Balloted Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Images

Interoperability Need: Format of radiology reports for exchange and distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Management of Radiology Report Templates (MRRT)	Balloted Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Medical Device Communication to Other Information Systems/Technologies

Interoperability Need: Transmitting patient vital signs from medical devices to other information systems/technologies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Research

Interoperability Need: Submission of analytic data to FDA for research purposes							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Production	●●●●●	Yes	Free	Yes
Standard	CDISC Analysis Dataset Model (ADaM)	Final	Production	●●●○○	Yes	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	Yes
Standard	CDISC Dataset-XML (ODM-Based)	Final	Production	●○○○○	No	Free	N/A
Standard	CDISC Define-XML (ODM-Based)	Final	Production	●●●●●	No	Free	N/A
Standard	CDISC Standard for the Exchange of Non-clinical Data (SEND)	Final	Production	●○○○○	Yes	Free	N/A
Standard	Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)	Final	Production	●○○○○	No	Free	N/A
Standard	Therapeutic Area Standards (to complement the aforementioned CDISC foundational standards that apply across all therapeutic areas)	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Feedback Requested	• Feedback requested

Interoperability Need: Pre-population of research case report forms from electronic health records							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE-CRD (Clinical Research Document)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-XUA (Cross-Enterprise User Assertion)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-ATNA (Audit Trail and Node Authentication)	Final	Production	●●○○○	No	Free	N/A
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Feedback requested	• Feedback requested

Interoperability Need: Integrate healthcare and clinical research by leveraging EHRs and other health IT systems while preserving FDA's requirements							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	IHE- RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●○○○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	N/A
Limitations, Dependencies, and Preconditions for Consideration:			**Applicable Security Patterns for Consideration:**				
• Stakeholders should review 21CFR11 for more details.			• Feedback requested				

Interoperability Need: Integrate healthcare and clinical research by leveraging EHRs and other health IT systems while preserving FDA's requirements							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes
Standard	CDISC Study/Trial Design Model (SDM)	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	IHE-RPE (Retrieve Protocol for Execution)	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Limitations, Dependencies, and Preconditions for Consideration:			**Applicable Security Patterns for Consideration:**				
• Feedback requested			• Feedback requested				

Interoperability Need: Submit adverse event report from an electronic health record to drug safety regulators

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE-DSC (Drug Safety Content)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE- CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: Complete disease registry forms and submit to reporting authority (ACC)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: Registering a clinical trial							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Clinical Trial Registry (CTR-XML)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Pilot	●●●●●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Feedback requested	• Feedback requested

Data Provenance

Interoperability Need: Establishing the authenticity, reliability, and trustworthiness of content between trading partners.							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• This implementation specification is focused on data provenance representation for CDA R2 implementations and the use of CDA templates.	• Feedback requested

Projected Standards and Specifications for Services:

"Push" Exchange

Interoperability Need: Push communication of vital signs from medical devices							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Pilot	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• ISO/IEEE 11073 is a suite of standards for various medical devices.	• Feedback requested

Public Health Exchange

Interoperability Need: Query/Response for Immunization Reporting and Exchange							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Version 1.2	Final	Production	●○○○○	No	Free	No
Implementation Specification	IIS Standard WSDL	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Section V: Questions and Requests for Stakeholder Feedback

As with the previous Advisory, posing questions has served as a valuable way to prompt continued dialogue with stakeholders to improve the Advisory. As stated in the Executive Summary and with the enhanced structure changes integrated via the draft 2016 Advisory, the 2016 Advisory has tried to address many of the comments received, but additional input is needed in some areas. Your feedback on the questions posed below is critical and we encourage answers to be submitted as part of the public feedback cycle that will begin in early 2016. See Appendix I for further details on the overall process.

General

1. For each standard and implementation specification there are six assessment characteristics, and with the 2016 Advisory a noteworthy amount of detail has been received and integrated. However, there are still some gaps. Please help complete any missing or "unknown" information. Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct.

2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.

Section I: Vocabulary/Code Set

3. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets.

4. Public Comments surrounding I-F: Functional Status/Disability and I-I: Industry and Occupation continue to be varied on the "best available" standards or implementation specifications in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.

Section II: Content / Structure

5. Opinions vary in the way (messaging vs. transport) the Advisory should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.

6. For the existing interoperability need, "representing clinical health information as a resource", public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.

Section IV: Projected Additions to the ISA

7. Public comments on the Draft 2016 Advisory highlighted an interest in including "interoperability needs" associated with communication between certain types of personal health devices and other information technology systems. Specifically, the health informatics standards under IEEE 11073 that have been recognized by the FDA[2] and referenced by Continua and Personal Connected Health Alliance. What particular interoperability needs would be best to include in the Advisory to reflect this work by the industry?

8. Based on comments received, some of the Interoperability Needs were split to point out where LOINC (questions) vs. SNOMED-CT (answers) applies. Please review and provide feedback on this approach. Also, provide feedback on whether the Interoperability Needs describe this separation properly.

Appendix II: Sources of Security Standards

9. Are there other authoritative sources for Security Standards that should be included in Appendix II?

[2] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/Search.cfm and use search term "11073" in the "standard designation number" search box.

Appendix I - Annual Process to Update the Interoperability Standards Advisory

ONC intends to implement the following timeline and process to update the Interoperability Standards Advisory for subsequent years. Note that timelines are approximate and may vary slightly for a variety of reasons.

- **December Preceding the Upcoming Calendar Year**
  - The new Interoperability Standards Advisory for the next calendar year is published (e.g., December 2016 for the 2017 Advisory).

- **January**
  - A first round of an approximately 90- to 120-days of public comment period will be opened on that year's Interoperability Standards Advisory.

- **April/May**
  - Sometime during late April/early May the comment period will expire.
  - ONC staff will compile all comments received during the first round comment period.
  - ONC staff will present a summary of received comments to the HIT Standards Committee (or designated Task Force) in order to prepare them to make recommendations on updates for the following year's Interoperability Standards Advisory.

- **August**
  - The HIT Standards Committee submits recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory.
  - A second round of approximately 60-days of public comment will be opened on the HIT Standards Committee's recommendations concerning the Interoperability Standards Advisory.

- **October – December**
  - Sometime during October the comment period will expire.
  - ONC will review the HIT Standards Committee recommendations as well as public comments on those recommendations.
  - ONC will prepare the next year's Interoperability Standards Advisory for publication.

If a standard or implementation is under development and expected to be completed during this process, it could be considered for inclusion in the next year's Interoperability Standards Advisory. For example, if an implementation guide is expected to be completed in October 2016 for a particular standard, this process should be able to anticipate and accommodate the potential addition of that implementation guide in the 2017 Interoperability Standards Advisory.

Appendix II – Sources of Security Standards

[See Question 9]

In this draft Advisory, a structure to capture necessary security patterns associated with interoperability needs is represented (see Section III-A and III-F for examples, and related Question 4-3). To address public comments that requested a distinct security standards section the list below provides a number of sources to which stakeholders can look in order to find the latest applicable security standards. Note that this list is not meant to be exhaustive.

- ASTM: http://www.astm.org/Standards/computerized-system-standards.html
- Information Organization for Standardization (ISO) Information Security Standards: http://www.27000.org/
- National Institute for Standards and Technology (NIST) Special Publications 800 Series: http://csrc.nist.gov/publications/PubsSPs.html
- NIST's Federal Information Processing Standard (FIPS): http://www.nist.gov/itl/fipscurrent.cfm
- ISO IT Security techniques – evaluation criteria for IT security, ISO/EC 15408 series: http://standards.iso.org/ittf/PubliclyAvailableStandards/index.html
- NIST Special Publication: 800-63-2. Electronic Authentication Guideline. August 2013. http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf
- FIPS PUB 202. SHA-3 Standard: Permutation-Based Hash and Extendable-Output Functions. August 2015. http://dx.doi.org/10.6028/NIST.FIPS.202
- NIST SP 1800-a-e. Securing Electronic Health Records on Mobile Devices. July 2015. https://nccoe.nist.gov/projects/use_cases/health_it/ehr_on_mobile_devices and https://nccoe.nist.gov/library/nist-sp-1800-1a-e-securing-ehrs-mobile-devices-all-volumes-plus-template-and-manifest-files
- Fair Information Practice Principles (FIPPs). http://www.nist.gov/nstic/NSTIC-FIPPs.pdf
- HIPAA Security regulations that are specific to healthcare: http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/

Appendix III - Revision History

Summary Level Description of Changes Between the 2015 Advisory and the 2016 Advisory

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Table of Contents	Enhancements made to enhance the usability	• Appreciable detail added. • In addition to the representation of each Section and/or Appendix, each of the Sections now shows the breakout areas which should assist in locating specific areas of interest
Executive Summary	With the 2015 Advisory, a great deal more 'explanatory' detail was offered to lend context and history and to spark necessary feedback. That level of information for the ISA 2016 was determined unnecessary. Any interest to access history and/or to gain context however, would be supported via link to 2015 Advisory.	• The Executive Summary has been streamlined and references a high-level description of the substantial changes introduced and referencing the ISA 2016 as baseline for future changes • Introduction section removed; explanatory / background information provided is viewed as no longer necessary • To optimize flow of information, Scope precedes Purpose • The two Purposes were mildly enhanced and one was added. The third addresses the biggest ISA 2016 change; namely, the added meta data to the table standards/implementation specification structure
The 2016 Interoperability Standards Advisory: Document Restructuring	In order to best serve the range of interests with this and subsequent ISA releases, the primary focus for the 2016 ISA was to address table restructuring -- particularly focused on finding the best way to add relevant characteristics of a standard/implementation specification thus offering added context.	• Instead of using the term "purpose," a stakeholder's need are framed by a prime focus area further specified by one or more connected "Interoperability Needs" • Meta Data describing six informative characteristics has been added to each referenced standard and implementation specification to give readers an overall sense of maturity and level of adoption: ▪ Standards Process Maturity; ▪ Implementation Maturity; ▪ Adoption Level; ▪ Federally Required; ▪ Cost; and, ▪ Test Tool Availability. • Interoperability Need has two subsections. ▪ The first would identify any known limitations, dependencies, or preconditions associated with best available standards and implementation specifications. ▪ The second dependent on the Section would either identify, where applicable, known "Security Patterns (Section II and III)" associated with best available standards and implementation specifications and/or Value Sets (Section I). • A security standards sources appendix is included to point stakeholders to the entities that maintain and curate relevant security standards information

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Projected Additions to the ISA	Because there were a number of recommended new Interoperability Needs and related Standards and Implementation Specifications that were not included in the Draft 2016 Advisory for public comment, a new section was added called "Projected Additions" that provides a means of receiving public comments on those potential changes. It is anticipated that, based on public feedback, those Projected Additions will be formally added to the next version of the ISA.	• See Section IV for the Projected Additions.
Questions and Requests for Stakeholder Feedback	The questions offered, were structured to solicit feedback on changes made to the ISA 2016 and to assist in addressing recommendations where disposition is pending. These are found within Section IV	• This approach to solicit recommendations is considered relevant and has been sustained though tailored to progress the utility of the ISA.
Revision History	In order to capture the changes the first ISA received, a Revision History has been introduced and is found in Appendix III.	• The Revision History, Appendix III, records summary & detailed levels changes and will record for the applicable ISA version, the additions, deletions and/or enhancements made as part of the annual review process.
Responses to Comments Requiring Additional Consideration	An appendix has been added to indicate those comments unable to be represented in the current Advisory released, e.g., more time and/or consideration needed.	• The current state of the ISA 2016 reflects substantive amount of the Public Comments yet several remain, e.g., more exploration required, more time to properly address; potential redirection to SDOs, etc. • **Appendix IV - Responses to Comments Requiring Additional Consideration** has been added to acknowledge and support follow on efforts.
Summarization of Content Related Changes	There have been edits (content added) that are pervasive in nature, and as a result not necessarily restated in the Revision History	• In shifting from Purpose to Interoperability Need nearly all focus areas have added Interoperability Needs • Given the new table format to offer enhanced characteristics to the standards and interoperability specifications, nearly all focus areas and associated interoperability needs content added where applicable and/or available, e.g., Characteristics; Limitations, Dependencies and Preconditions for Consideration; and Applicable Value Sets / Security Patterns unless the information was not available

Additions/Enhancements/Deletions By Sub-section Between the 2015 Advisory and the 2016 Advisory

Section	Description	Added Enhanced Deleted
I-A: Allergies	Four Interoperability Needs	Enhanced
I-A: Allergies	Allergy Reactions, Food Allergies, and Medication Allergies were combined	Enhanced
I-A: Allergies	NDF-RT (standard)	Added

Section	Description	Added Enhanced Deleted
I-A: Allergies	SNOMED-CT (standard)	Added
I-C: Encounter Diagnosis	Two Interoperability Needs	Enhanced
I-C: Encounter Diagnosis	SNOMED-CT (standard)	Added
I-D: Ethnicity and Race	One Interoperability Need	Enhanced
I-D: Ethnicity and Race	Separate references of Race and Ethnicity combined	Enhanced
I-E: Family Health History	One Interoperability Need	Enhanced
I-F: Functional Status/Disability	One Interoperability Need	Enhanced
I-G: Gender Identity, Sex and Sexual Orientation	Three Interoperability Needs	Enhanced
I-G: Gender Identity, Sex and Sexual Orientation	Area renamed & reorganized to address interoperability needs connected to Gender Identity, Sex & Sexual Orientation	Enhanced
I-H: Immunizations	Two Interoperability Needs	Enhanced
I-H: Immunizations	HL7 Standard Code Set CVX—Clinical Vaccines Administered (standard) was added to the Interoperability Need: Representing immunizations - administered	Added
I-I: Industry and Occupation	One Interoperability Need	Enhanced
I-J: Lab tests	One Interoperability Need	Enhanced
I-K: Medications	One Interoperability Need	Enhanced
I-K: Medications	National Drug Code (NDC) (standard)	Added
I-K: Medications	National Drug File – Reference Terminology (NDF-RT) (standard)	Added
I-L: Numerical References & Values	One Interoperability Need	Enhanced
I-M: Patient Clinical "Problems" (e.g. conditions)	One Interoperability Need	Enhanced
I-M: Patient Clinical "Problems" (e.g. conditions)	Name refined to add clarity	
I-N: Preferred Language	One Interoperability Need	Enhanced
I-N: Preferred Language	Removed ISO 639-1, ISO 639-2, ISO 639-3 because RFC 5646 encompasses them.	Deleted
I-O: Procedures	Two Interoperability Needs	Enhanced
I-O: Procedures	Procedures section represents dental and medical; uses two Interoperability Needs to show any distinction	Enhanced
I-O: Procedures	SNOMED-CT for the Interoperability Need: Representing dental procedures performed	Added
I-P: Imaging (Diagnostics, interventions and procedures	One Interoperability Need	Enhanced
I-P: Imaging (Diagnostics, interventions and procedures	Radiology (interventions and procedures changed to Imaging (Diagnostics, interventions and procedures)	Enhanced
I-P: Imaging (Diagnostics, interventions and procedures	RadLex	Deleted
I-P: Imaging (Diagnostics, interventions and procedures	LOINC	Added
I-Q: Tobacco Use (Smoking Status)	One Interoperability Need	Enhanced
I-Q: Tobacco Use (Smoking Status)	Name changed from "Smoking Status" to "Tobacco Use (Smoking Status)"	Enhanced
I-R: Unique Device Identification	One Interoperability Need	Enhanced

Section	Description	Added Enhanced Deleted
I-R: Unique Device Identification	HL7 Harmonization Pattern for Unique Device Identifiers	Added
I-S: Vital Signs	One Interoperability Need	Enhanced
II-A: Admission, Discharge, and Transfer	One Interoperability Need	Enhanced
II-A: Admission, Discharge, and Transfer	Standard changed from HL7 2.x ADT message to HL7 2.5.1 (or later) ADT message	Enhanced
II-B: Care Plan	One Interoperability Need	Enhanced
II-B: Care Plan	Changed HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2 (Implementation Specification) to HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 (Implementation Specification)	Enhanced
II-C: Clinical Decision Support	Moved two other prior "Purposes" related to Clinical Decision Support to Section III along with standards and implementation specifications.	Enhanced
II-C: Clinical Decision Support	One Interoperability Need	Enhanced
II-C: Clinical Decision Support	Changed from HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.2, Draft Standard for Trial Use (Implementation Specification) to HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use. (Implementation Specification)	Enhanced
II-D Drug Formulary & Benefits	One Interoperability Need	Enhanced
II-D Drug Formulary & Benefits	Drug Formulary Checking changed to Drug Formulary & Benefits	Enhanced
II-E: Electronic Prescribing	Five Interoperability Needs	Enhanced
II-F: Family Health History	One Interoperability Need	Enhanced
II-G: Images	Two Interoperability Needs	Enhanced
II-G: Images	PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture. (Implementation Specification)	Added
II-H: Laboratory	Three Interoperability Needs	Enhanced
II-H: Laboratory	Combined three "Purposes" under one sub-section	Enhanced
II-H: Laboratory	HL7 2.5.1 (Standard)	Added
II-H: Laboratory	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm* (Emerging Alternative Standard)	Added
II-H: Laboratory	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm (Implementation Specification)	Added
II-H: Laboratory	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 (Implementation Specification)	Added
II-I: Patient Education Materials	Three Interoperability Needs	Enhanced

Section	Description	Added Enhanced Deleted
II-J: Patient Preference/Consent	One Interoperability Need	Enhanced
II-J: Patient Preference/Consent	IHE Basic Patient Privacy Consents (BPPC) (Implementation Specification)	Added
II-J: Patient Preference/Consent	IHE Cross Enterprise User Assertion (XUA) (Implementation Specification)	Added
II-K: Public Health Reporting	Seven Interoperability Needs	Enhanced
II-K: Public Health Reporting	Combined the seven "Purposes" into one Sub-section	Enhanced
II-K: Public Health Reporting	Updated HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition (Standard) to HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition (Standard)	Enhanced
II-K: Public Health Reporting	HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1 (Emerging Alternative Implementation Specification)	Added
II-K: Public Health Reporting	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm (Implementation Specification)	Added
II-K: Public Health Reporting	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide (Emerging Alternative Implementation Specification)	Added
II-K: Public Health Reporting	IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD) (Implementation Specification)	Added
II-K: Public Health Reporting	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide (Emerging Alternative Implementation Specification)	Added
II-K: Public Health Reporting	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification (Implementation Specification)	Added
II-K: Public Health Reporting	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 (Implementation Specification)	Added
II-K: Public Health Reporting	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1 (Implementation Specification)	Added
II-L: Quality Reporting	Two Interoperability Needs	Enhanced
II-L: Quality Reporting	Combined two "Purposes" into one sub-section	Enhanced
II-L: Quality Reporting	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm) (Emerging Alternative Implementation Specification)	Added
II-M: Representing clinical health information as a "resource"	One Interoperability Need	Enhanced
II-M: Representing clinical health information as a "resource"	Data element based query for clinical health information changed to Representing clinical health information as a "resource"	Enhanced
II-M: Representing clinical health information as a "resource"	Changed Fast Healthcare Interoperability Resources (FHIR) (standard) to Fast Healthcare Interoperability Resources (FHIR), DSTU 2 (standard)	Enhanced

Section	Description	Added Enhanced Deleted
II-N: Segmentation of sensitive information	One Interoperability Need	Enhanced
II-O: Summary care record	One Interoperability Need	Enhanced
II-O: Summary care record	Consolidated CDA Release 2.0 (Implementation Specification)	Deleted
II-O: Summary care record	*HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1* (Emerging Alternative Implementation Specification)	Added
III-A: "Push" Exchange	Section III changed from "Best Available Transport Standards and Implementation Specifications" to "Best Available Standards and Implementation Specifications for Services" and added seven subsections (from eight original "Purposes")	Enhanced
III-A: "Push" Exchange	Two Interoperability Needs	Enhanced
III-A: "Push" Exchange	Applicability Statement for Secure Health Transport v1.2 (Emerging Alternative Standard)	Added
III-A: "Push" Exchange	XDR and XDM for Direct Messaging Specification (Implementation Specification)	Added
III-A: "Push" Exchange	IHE-XDR (Cross-Enterprise Document Reliable Interchange) (Standard)	Added
III-A: "Push" Exchange	Fast Healthcare Interoperability Resources (FHIR) DSTU 2 (Emerging Alternative Standard)	Added
III-A: "Push" Exchange	IHE-MHD (Mobile Access to Health Documents (Emerging Alternative Implementation Specification)	Added
III-B: Clinical Decision Support Services	Two Interoperability Needs	Enhanced
III-B: Clinical Decision Support Services	HL7 Version 3 Standard: Decision Support Service, Release 2. (Standard)	Added
III-B: Clinical Decision Support Services	HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use (Implementation Specification)	Added
III-B: Clinical Decision Support Services	IHE- GAO (Guideline Appropriate Ordering) (Emerging Alternative Implementation Specification)	Added
III-B: Clinical Decision Support Services	IHE-CDS-OAT (Clinical Decision Support – Order Appropriateness Tracking) (Emerging Alternative Implementation Specification)	Added
III-B: Clinical Decision Support Services	Moved the "Infobutton" standards and implementation specifications from Section II to this sub-section.	Enhanced
III-C: Image Exchange	Two Interoperability Needs	Enhanced
III-C: Image Exchange	IHE Cross Enterprise Document Sharing for Images (XDS-I.b) (Implementation Specification)	Added
III-C: Image Exchange	IHE-PDQ (Patient Demographic Query) (Implementation Specification)	Added
III-C: Image Exchange	IHE-PIX (Patient Identifier Cross-Reference) (Implementation Specification)	Added
III-C: Image Exchange	IHE – MHD-I (Mobile Access to Health Documents for Imaging) (Emerging Alternative Implementation Specification)	Added
III-C: Image Exchange	IHE Cross Community Access for Imaging (XCA-I) (Implementation Specification)	Added
III-C: Image Exchange	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference) (Implementation Specification)	Added
III-D: Provider Directory	One Interoperability Need	Enhanced

Section	Description	Added Enhanced Deleted
III-D: Provider Directory	Fast Healthcare Interoperability Resources (FHIR), DSTU 2 (Emerging Alternative Standard)	Added
III-E: Publish and Subscribe	One Interoperability Need	Enhanced
III-E: Publish and Subscribe	IHE Document Metadata Subscription (DSUB), Trial Implementation (Emerging Alternative Implementation Specification)	Added
III-F: Query	Three Interoperability Needs	Enhanced
III-F: Query	IHE – MHD (Mobile Access to Health Documents) (Emerging Alternative Implementation Specification)	Added
III-F: Query	Changed from Fast Healthcare Interoperability Resources (FHIR), DSTU 2 (Standard) to Fast Healthcare Interoperability Resources (FHIR), DSTU 2 (standard)	Added
III-G: Resource Location	One Interoperability Need	Enhanced
IV: Projected Additions to ISA	All new content added for public comment	Added
V: Questions and Requests for Stakeholder Feedback	N/A	
Appendix I	Section 6 in the original ISA was moved to Appendix I – Annual Process to Update the Interoperability Standard Advisory	Added
Appendix II	Sources of Security Standards	Added
Appendix III	Revision History	Added
Appendix IV	Responses to Comments Regarding Additional Considerations	Added

Appendix IV – Responses to Comments Requiring Additional Consideration

ONC has reviewed all of the comments that were submitted as part of the public comments process and has incorporated many of the recommendations into this current version. In some cases, feedback provided may have been out of scope of the ISA or where additional exploration may be needed for consideration in future ISA drafts. To acknowledge these areas, and recognize the time and effort required for stakeholders to submit thoughtful public comments, ONC has attempted to address as many of these recommendations as possible in the statements below.

Overarching

- Several comments were received around inclusion of EHR Functional Model elements within the ISA. ONC will explore, with stakeholder and HIT Standards Committee feedback whether or not this is feasible and if these should be included in future updates
- As described in the executive summary, the scope of the ISA has been limited to clinical health IT interoperability needs. As we work to update the ISA, we will explore adding various purposes to its scope. At this time, payment and administrative standards will not be included. CMS maintains a list of standards for this purpose that can be referenced: https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/TransactionCodeSetsStands/TransactionsandCodeSetsRegulations.html
- Further, the ISA does not attempt to represent how these standards can help support providers in meeting legal requirements for maintaining patient health records for their business needs.
- Several commenters suggested addition of use case development and management of information flows. Doing so would not be in alignment with the purpose of the ISA and is not addressed.
- We received requests to include standards related to transfer on pregnancy, birth information, newborn nursery, newborn screening, etc. ONC will continue to explore inclusion of these standards for future ISA updates.
- We also received requests to include standards for preventive health schedules. ONC may need additional information in this area, but will explore inclusion of these in future ISA updates.
- Requests were made to distinguish between "eligible providers" for Meaningful Use and "non-eligible providers". The ISA focuses on the representation of standards and implementation specifications that can be used to achieve interoperability needs.
- Specific requests were received regarding variance in adoption level for specific settings. While ONC recognizes adoption level may vary by setting type, this information is difficult to convey in the current ISA structure. We will work with these organizations to identify the best way to ensure health IT stakeholders understand limitations on adoption level. However, the adoption level was revised to attempt to accommodate some of these concerns.
- Several commenters asked for clarification regarding "draft" standards. Note that ONC does not plan to include standards that are in early development in the ISA, but will include as "emerging alternative" or as "best available" after formally receiving a "DSTU" or equivalent designation.
- The ISA does not directly address primary and secondary use but is beginning to add standards related to research interoperability needs.
- The ISA does not currently address "end-to-end chain of trust", health record capture, retention, auditing, or other standards associated with this concept. Similar to functional models, ONC will explore inclusion in future ISA updates.
- ONC does not plan to provide more granularity on implementation maturity levels at this time. Nor does ONC intend to provide a direct assessment as to the "readiness" of standards to be used within the ISA. Instead, the current characteristics are provided to allow for stakeholders to make their own informed decisions as to whether a standard or implementation specification will meet their needs.
- ONC does not currently have the capacity to publish testing results surrounding how well standards support interoperability needs identified in the ISA. ONC encourages other organizations to build upon the information provided in the ISA to provide additional value such as this.
- ONC does not intend to provide contact information for each of the SDOs with standards referenced within the ISA. However, a URL for each standard or implementation specification is provided, which may provide contact information or at least a link to the SDO home page whereby stakeholders could contact the SDO if needed.

Section I

- Requests to add standards related to social determinants of health could not immediately be addressed, due in large part to the sheer volume of comments and the Interoperability Roadmap's priority of send, receive, find and use core data set for care and patient access. ONC will continue to explore means by which social determinants can be addressed in future ISA updates.
- ONC will continue to monitor areas where a best available standard has not yet become evident (i.e., industry and occupation, functioning status/disability, etc.) and will attempt to include a best available standard in future ISA updates.

Section II

- ONC will consider adding implementation guides, such a best practices for documenting referrals to community resources, if deemed appropriate, in future ISA updates.
- ONC will follow progress on projects related to care planning, and include resulting standards and implementation specifications in future ISA updates.
- ONC will continue to monitor industry activities surrounding genomic standards and current developments in FHIR profiles in this area. We will include them in future ISA updates as appropriate.
- ONC received comments around the IHE Radiology Domain's Suite of Profiles, but at this time did not have enough information to warrant inclusion for many of them. ONC will continue to explore inclusion for future ISA updates.
- A request was received regarding adding Nutrition/Diet Orders and other related dietary implementation information. ONC will analyze for inclusion in future ISA updates.
- A request was received regarding inclusion of "legacy data standards". ONC will continue to explore inclusion of this for future ISA updates.
- ONC will consider, for future ISA updates, adding "Privacy Patterns for Consideration", but do not have sufficient information to provide these at this time.

Section III:

- N/A