2017 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

Reference Edition

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The 2017 Interoperability Standards Advisory represents the Office of the National Coordinator for Health Information Technology's current assessment of the heath IT standards landscape. It 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.

Introduction to the 2017 Interoperability Standards Advisory

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

The 2017 ISA has been updated to include improvements made based on recommendations received from public comments and the Health IT Standards Committee. For historical background on the ISA please review prior ISA publications.

The most substantial changes between the 2016 and the 2017 ISA are largely related to the ISA's organization, content and framing. This includes the following:

1) Further transition of the ISA from a stand-alone document to a Web-based resource with greater interactive features, additional opportunities for engagement with stakeholders, and also providing enhanced transparency to the process of updating the ISA.
2) The discontinued use of the label "best available" as an overall concept for the ISA. This change, at the recommendation of the Health IT Standards Committee, seeks to address feedback that stakeholders may perceive varied standards and implementation specifications associated with an interoperability need as "best" despite known limitations or low adoption levels. Further, that the use of "best available" as a general label for all listings in the ISA would not provide a sufficient pathway for industry input to ultimately distinguish whether one standard or implementation specification listed in the ISA may be more "fit for purpose" and preferred for implementation over another for the same interoperability need.
3) Changing the scope of the ISA to include more specific references to research and public health.
4) Including Personal Health Device, Nursing, Research, Nutritional Health, and Social Determinant interoperability needs within the ISA.
5) Adding a new section that begins to include Functional and Data Models as well as Functional Profiles.
6) Where applicable, the addition of "Applicable Starter Set(s)" alongside appropriate code sets in Section I.
7) Links to active projects listed in ONC's Interoperability Proving Ground as a way to indicate their use of an ISA-listed standard or implementation specification to showcase ongoing implementations.
8) Better representation of the pairing of standards for observations (i.e., questions) and standards for observation values (i.e., answers).
9) A shift in the timeline and annual publication cycle from the process first established with the publication of the 2015 ISA. In December of each year, ONC will publish a static "Reference Edition" of the ISA that can be referenced in contracts, agreements, or as otherwise needed with certainty that the information will not change. For example, in December 2016, ONC will publish the 2017 ISA Reference Edition. The web-based version of the ISA, however, is expected to be updated frequently throughout the year as needed to reflect real-time updates to standards and implementation specifications from standards development organizations (SDOs) and allow dialogue and debate between stakeholders about the ISA's interoperability needs, standards, and implementation specifications on an ongoing basis. While a call for public comments is still expected to occur annually to ensure the published Reference Edition is as accurate as possible, the web-based version of the ISA

will allow for continuous feedback from stakeholders, with a more rapid ability to update the ISA to reflect changes in the standards landscape, to provide additional information that helps stakeholders better understand the limitations, preconditions, and dependencies for interoperability, and to provide corrections to any factual errors. Your continued feedback and engagement is critical to improve and refine the ISA.

The 2017 ISA includes revisions and additional descriptive text for several of the six informative characteristics.

Scope

Starting with the 2017 ISA, the ISA's focus has expanded to more explicitly include public health and health research interoperability. Thus, its scope includes electronic health information created in the context of treatment, and subsequently used to accomplish a purpose for which interoperability is needed (e.g., a referral to another care provider, public health reporting, or research). The ISA 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). CMS maintains a list of standards for this purpose that can be referenced: https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html.

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

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

It is also important to note that the ISA is designed to inform standards and implementation specification choices for all types of health IT that support interoperability needs, not solely electronic health record (EHR) systems. Furthermore, the ISA is not intended to imply that health IT systems need to support all of the listed standards and implementation specifications. Rather, in the event that a health IT developer or health care provider seeks to address a particular interoperability need, the ISA should serve as the first resource consulted to inform the selection of standards and implementation specifications. Additionally, the ISA is designed to inform the "what" that could be used to address an interoperability need in order to assure industry consistency around standards selection and is not mean to explicitly direct "how" the standards and implementation specifications would be implemented to address an interoperability need (e.g., application programming interface or conversion tools).

The ISA is designed to be a coordinated catalog of standards and implementation specifications that can be used by different stakeholders to consistently address a specific interoperability need. However, a listed interoperability need (and its associated standard(s) and implementation specifications(s)) is not meant to universally apply to all stakeholders. Rather, if a listed interoperability need is relevant to a particular clinical specialty, for example, the ISA is designed to provide a consistent foundation from which these stakeholders can agree on applicable technical requirements. Similarly, in cases where a listed interoperability need is not applicable to a given stakeholder group, the ISA in no way compels such stakeholders to consider that interoperability need.

Purpose

The Interoperability Standards Advisory 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 address specific clinical health information interoperability needs. Currently, the ISA is focused on interoperability for sharing information between entities and not on intra-organizational uses.
2) To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be used to address a specific interoperability need, discussion will take place through the ISA public comments process. The web-version of the ISA will improve upon existing processes, making comments more transparent, and allowing for threaded discussions to promote further dialogue.
3) To document known limitations, preconditions, and dependencies as well as provide suggestions for security best practices in the form of security patterns for referenced standards and implementation specifications when they are used to address a specific clinical health IT interoperability need.

The ISA is designed to provide clarity, consistency, and predictability for the public regarding the standards and implementation specifications that could be used for a given clinical health IT interoperability purpose.

Stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components are encouraged to look first to the ISA in order to more fully inform their goals. In that regard, standards and implementation specifications in the ISA and their associated informative characteristics are also available to help more fully inform policymaking. In this case, a standard or implementation specification's reference in the ISA may serve as the initial basis for industry or government consideration and action. While the ISA itself is a non-binding document, standards and implementation specifications listed in the ISA may be considered for rulemaking or other Federal requirements. However, those decisions would be made on a case-by-case basis by the administering organization.

ISA Structure

The ISA is organized and structured into five sections.

- *Section I – Vocabulary/Code Sets/Terminology* Standards and Implementation Specifications (i.e., "semantics").
- *Section II – Content/Structure* Standards and Implementation Specifications (i.e., "syntax").
- *Section III – Standards and Implementation Specifications for Services* (i.e., the infrastructure components deployed and used to address specific interoperability needs)
- *Section IV – Models and Profiles*
- *Section V – Questions and Requests for Stakeholder Feedback*

Within each section specific "interoperability need" subheadings are listed and followed by the table illustrated below. Each interoperability need may have one or more standards and/or implementation specifications associated with it. Each standard and implementation specification has six informative characteristics attributed to it in order to provide added context.

When known, an "emerging" standard or implementation specification is also listed and is shaded in a lighter color and italicized for additional emphasis. In addition, for vocabulary standards, where there may be one standard used to represent the "observation" or question being asked, and one standard used for the "observation value" or answer these are listed in distinct rows.

The ISA also now includes links within the limitations, dependencies and preconditions to ONC's Interoperability Proving Ground (IPG) to showcase real-world implementations of standards listed within the ISA. Please note: when accessing links to the IPG, all projects for the selected standard will be listed, including those that may be demonstrating use of the standard for different interoperability needs. In addition, IPG entries are self-reported by stakeholders, so the quality and accuracy of the data may vary across entries.

In Section I, the vocabulary standards with unspecified code sets or context may be further constrained by a more explicit standard named in a subsequent section. For example, I-B Encounter Diagnoses specifies SNOMED-CT and ICD-10-CM but does not define the context of use. The Standard/Implementation Specification named for the "Interoperability Need: Ordering Labs for a Patient in Section II-K: Laboratory" further constrains the diagnosis for the patient in the context of a lab order to ICD-9CM or ICD-10CM since the lab order diagnosis is for billing/claims, not clinical diagnostics.

Interoperability need: [Descriptive Text]

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

Limitations, Dependencies, and Preconditions for Consideration:	**Section I: Applicable Value Set(s) and Starter Set(s):** **Sections II & III: Applicable Security Patterns for Consideration:**
• In the case where there is a need to reflect a conformance statement, the verbs "must" and "shall" will reflect an absolute requirement and the verbs "can" and "may" reflect optionality. • Where standards listed for an interoperability need have active projects listed on ONC's Interoperability Proving Ground, a link to that standard will be provided in this section. Please note, all projects for the standard will be listed, including those that may be demonstrating use of the standard for different interoperability needs.	• Descriptive text

The following describes the ISA's six informative characteristics in greater 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 ISA. These definitions remain similar in nature to those presented in the 2016 ISA, 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 standards and implementation specifications provided within the ISA.

#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. This also includes approved "ANSI Informative" specifications.
- ***"Balloted Draft"*** – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU), Standard for Trial Use (STU), 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".

- ***"In Development"* –** when this designation is assigned, the standard or implementation specification is currently in development. It also includes those that are in the midst of being balloted. These standards would generally benefit from lessons learned through development and pilots.

#2: Implementation Maturity

This characteristic conveys a standard or implementation specification's maturity based upon its implementation state. Where available, a link to published maturity assessments based on known published criteria about the standards is also provided. *[See Question 5, Section V]*

- ***"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 on a 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, average adoption level for that specific interoperability need in health care within the United States. The adoption level attempts to consider all implemented technology that would be used to address the identified interoperability need and is not limited to EHRs. Adoption means that the standard or implementation specification is being used in health IT in the field by end users to address the specific interoperability need. Presently, the adoption levels listed are 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 which is used only as a proxy for industry adoption; 2) feedback from subject matter experts and 3) public comments.

The adoption level also considers the variety 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. Where available, annotated references or links to publicly available documentation known about adoption levels for listed standards is also provided. *[See Question 6, Section V]*

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:

- "*Feedback requested*" Indicates that we do not have a 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. Where known, the estimated cost for access will be provided.
- "*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. Where available, a link will be provided to the publicly available test tool. *[See Question 7, Section V]*

- *"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."

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

I-A: Allergies and Intolerances

Interoperability Need: Representing Patient Allergic Reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• SNOMED CT® may not be sufficient to differentiate between an allergy or adverse reaction, or the level of severity • For use of SNOMED CT®, codes should generally be chosen from the Clinical finding axis • See LOINC projects in the Interoperability Proving Ground.	• SNOMED CT Value Set Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 • There is an 'Adverse Clinical Reaction' value set (urn:oid: 2.16.840.1.113883.3.2074.1.1.30) in Value Set Authority Center (VSAC) created by Federal Health Interoperability Modeling and Standards (FHIMS) which can be considered a candidate as a starter set.

Interoperability Need: Representing Patient Allergies and Intolerances; 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	SNOMED CT®	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• When a medication allergy necessitates capture by medication class, SNOMED CT® should be used. • RxNorm: Refers to the RxNorm source specifically (and not to other sources that are included with the RxNorm download).	• Clinical Drug Ingredient (2.16.840.1.113762.1.4.1010.7) (RxNorm ingredient codes)

Interoperability Need: Representing Patient Allergies and Intolerances; Food Substances

tType	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	UNII (Unique Ingredient Identifier)	Final	Production	●●●●○	No	Free	N/A
Standard	SNOMED CT®	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT® substance codes) • Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes)

Interoperability Need: Representing Patient Allergies and Intolerances; Environmental Substances

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT® substance codes). • Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes)

I-B: 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	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Use of SNOMED CT® codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • The use of these standards may be further constrained by other standards and implementation specifications found elsewhere in the ISA. • Systems should be able to process (or at minimum display) data coded using the older ICD-9-CM standard, as this legacy content still exists and may be used for analysis/decision support/quality measurement needs, where retroactive analysis is often required, but ICD-9 should not be collected for new entries. • A mapping from SNOMED CT® to ICD-10-CM is available from the National Library of Medicine. • The following clarification comes from the National Library of Medicine site: The purpose of the SNOMED CT to ICD-10-CM map is to support semi-automated generation of ICD-10-CM codes from clinical data encoded in SNOMED CT for reimbursement and statistical purposes.	• Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED CT® code system) • Recommended starter set: CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

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	SNODENT	Final	Production	●●●●○	No	Free	N/A
Standard	ICD-10 Dental Diagnosis Codes	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Code System:
• Feedback requested	• OID 2.16.840.1.113883.3.3150

I-C: 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 for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Some details around family genomic health history may not be captured by SNOMED CT® • See LOINC projects in the Interoperability Proving Ground.	For Diagnosis and Conditions: • Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC® code system) • 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 (2.16.840.1.113883.4.642.2.468) • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature (2.16.840.1.113883.4.642.2.392)

I-D: 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 for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The LOINC representation of the Minimum Data Set (MDS) required by CMS to document functional status of nursing home residents is a good 'starter set'. MDS is already standardized as LOINC codes. • Additional resources for this interoperability need include: ▪ Social Security Association's Disability Determination Process (https://www.ssa.gov/disability/determination.htm) ▪ American College of Occupational and Environmental Medicine	• Feedback requested

I-E: Health Care Providers

Interoperability Need: Representing Health Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	National Provider Identifier (NPI)	Final	Production	●●●●○	Yes	Free	N/A
Standard	National Uniform Claim Committee (NUCC)	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter 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'. • NPI taxonomy may not have sufficient enough detail to describe all roles associated with an individual's care team. • However, NUCC codes widely cover the concepts of health care providers beyond physicians	• No Value Set

Interoperability Need: Representing Provider Role in Team Care Settings

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) and Starter Set(s):
• Feedback requested	• Healthcare Provider Taxonomy (HIPAA): 2.16.840.1.114222.4.11.1066 • Subjects role in the care setting (SNOMED CT®)

I-F: 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) and Starter Set(s):
• Radlex and LOINC® are currently in the process of unifying terms for radiology procedures, expected in 2017. The work is at the "Balloted Draft" status in the Standards Process Maturity with no adoption level.	• Feedback requested

I-G: 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) and Starter Set(s):
• 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. • While the information is very helpful, MVX is fairly rare to have for historical vaccinations and is unrealistic to have providers collect.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set 2.16.840.1.114222.4.11.826

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	●●●●●	Yes	Free	N/A
Standard	HL7 Standard Code Set MVX -Manufacturing Vaccine Formulation	Final	Production	●●●●○	No	Free	N/A
Standard	National Drug Code	Final	Production	Feedback requested	Yes	Free	N/A
Standard	RxNorm	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s) and Starter Set(s):**
• CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • If 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. • There is a potential issue with use of the National Drug Code regarding which code to use when there are multiple active ingredients in a single package or multiple separate ingredients that need to be mixed together.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set

I-H: 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	CDC Census Coding System	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s) and Starter Set(s):**
• Feedback requested	• PHVS_Industry_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7187 • PHVS_Occupation_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7186

I-I: Lab Tests

Interoperability Need: Representing Laboratory Tests

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• 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. • 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 single lab test with a single result may have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel. • See LOINC projects in the Interoperability Proving Ground.	• The list of LOINC® Top 2000+ Lab Observations is a starter set represented by OID: 1.3.6.1.4.1.12009.10.2.3

I-J: 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
Standard	SNOMED CT®	Final	Feedback requested	Feedback requested	No	Free	N/A
Emerging Standard	*Medication Reference Terminology (MED-RT)*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter 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. • MED-RT allows for representing classes of medications when specific medications are not known. • Immunizations are not considered medications for this interoperability need. • RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users.	• 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-K: Units of Measure

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) and Starter Set(s):**
• UCUM is a syntax for representing units of measure for use with numerical references and values. It is not an enumerated set of codes. • The case sensitive version is the correct unit string to be used for interoperability purposes. • Per public comments received, there may be some limitations with UCUM in the laboratory domain that 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. • Numerical representation are uniform within healthcare entities but there is concern of the ability to transmit numerical reverences and values between healthcare entities and portal and PHR systems, in order to allow communications that include such numbers as understood by provider and patient.	• Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes) • "Table of Example UCUM Codes for Electronic Messaging" published by the Regenstrief Institute, Inc. Value set is made available at http://loinc.org/usage/units and identified by the OID 1.3.6.1.4.1.12009.10.3.1

I-L: Nursing

Interoperability Need: Representing Nursing Assessments

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Assessments are represented as question/answer (name/value) pairs. They are not represented in other terminologies. • When representing validated scales, LOINC could be used for both question/answer pair. • See LOINC projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Representing Nursing Interventions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Coded interventions may be linked as related/dependent concepts to observations and assessments, as appropriate. • See LOINC projects in the Interoperability Proving Ground.	• 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 for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Other ANA-recognized terminologies should be mapped to LOINC® for comparison across health systems and/or transmission. • Use LOINC® if the outcome is a measurement. • Use SNOMED CT® if the outcome is an observed assessment that a patient state has improved. • See LOINC® projects in the Interoperability Proving Ground.	• 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 for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

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

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 for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of SNOMED CT® for this interoperability need, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • 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) • SNOMED CT® supports the combination of codes (post-coordination) to generate new meaning. Codes from other axes can be used in post-coordination. The need to pick multiple codes may be seen as a disadvantage. This can be avoided if post-coordination is limited to the backend, exposing a single code for users to pick. • See LOINC® projects in the Interoperability Proving Ground.	• Problem 2.16.840.1.113883.3.88.12.3221.7.4 • Starter Set: CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

I-N: Preferred Language

Interoperability Need: Representing Patient Preferred Language (Presently)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Request for Comment (RFC) 5646	Final	Production	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter 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

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

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®/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) and Starter Set(s):
• ICD-10-PCS is primarily a billing code used only for Inpatient Procedures. • CPT/HCPCS are billing codes used for Outpatient Procedures. • ICD-10-PCS is named in the 2015 Edition certification rules as an optional code set for procedures. • SNOMED CT procedure codes can be used to describe treatment in any clinical setting and is not tied to billing, but can be cross-mapped to corresponding ICD-10-PCS and CPT/HCPCS codes.	• Feedback requested

I-P: 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
Standard	CDC Race and Ethnicity Code Set Version 1.0	Final	Production	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Code System ~~Value Set(s)~~:**
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon and can be rolled up to 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. • The LOINC answers for Race look similar to CDC/HL70005, but don't match; this may be confusing to implementers. • When clinically significant, the patient's "race" or "ethnicity" should be managed using an "Ask on Order Entry" question (AOE). This process is defined in the eDOS Implementation Guide developed through the ONC Standards & Interoperability Framework, and is designed work in conjunction with the LOI Implementation Guide, also developed through the ONC S&I Framework. For example, Glomerular Filtration Rate, Estimated (eGFR) results reference ranges vary based on race.	• 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 • Ethnicity (extended set, 43 codes): Detailed Ethnicity urn:oid:2.16.840.1.114222.4.11.877

I-Q: 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	Clinical Data Interchange Standards (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	●●●○○	Yes	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) and Starter Set(s):
• Feedback requested	• Feedback requested

I-R: Sex at Birth, Sexual Orientation and Gender Identity

Interoperability Need: Representing Patient Gender Identity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	HL7 Version 3 Null Flavor	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect 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. • Even though clinicians and their patients would benefit from having these data in patient records, this does not suggest that it is the sole responsibility of clinicians and their staffs to collect these sensitive data. • When patients provide a response to this question in a patient portal, it could contradict with the information collected by providers. • See LOINC projects in the Interoperability Proving Ground.	• Gender identity. LOINC® code: 76691-5 • Male. SNOMED CT® code: 446151000124109 • Female. SNOMED CT® code: 446141000124107 • Female-to-Male (FTM)/Transgender Male/Trans Man. SNOMED CT® code: 407377005 • Male-to-Female (MTF)/Transgender Female/Trans Woman. SNOMED CT® code: 407376001 • Genderqueer, neither exclusively male nor female. SNOMED CT® code: 446131000124102 • Additional gender category or other, please specify. HL7 Version 3 code: OTH • Choose not to disclose. HL7 Version 3 code: ASKU

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 observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	For Male and Female, HL7 Version 3 Value Set; for Administrative Gender Unknown , HL7 Version 3 Null Flavor	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s)
• HL7 Version 2 and 3 need to be harmonized. • See LOINC projects in the Interoperability Proving Ground.	• LOINC® code: 76689-9 Sex assigned at birth • Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 • ONC's 2015 Edition certification requirements reference the following value set for birth sex that use a combination of HL7 Version 3 (V3) Standard value set for Administrative Gender and NullFlavor: (1) M ("Male") (2) F ("Female") (3) UNK ("Unknown") (HL7 V3 NullFlavor code)

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 for observations	LOINC®	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A
Standard for observation values	HL7 Version 3 Null Flavor	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect 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 of the National Academies. • See LOINC® projects in the Interoperability Proving Ground.	• LOINC® code: 76690-7 Sexual orientation • ONC's 2015 Edition certification requirements reference the following value set for sexual orientation. Codes from (i) through (iii) are SNOMED CT® and (iv) through (vi) are from HL7 Version 3: (i) *Lesbian, gay or homosexual.*38628009 (ii) *Straight or heterosexual.* 20430005 (iii) *Bisexual.* 42035005 (iv) *Something else, please describe.* nullFlavor OTH (v) *Don't know.* nullFlavor UNK (vi) *Choose not to disclose.* nullFlavor ASKU

I-S: Social Determinants (See Question 8, Section V)

Interoperability Need: Representing Financial Resource Strain							
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) and Starter Set(s):
• See LOINC® projects in the Interoperability Proving Ground.	• LOINC® code 76513-1 • LOINC® answer list ID LL3266-5

Interoperability Need: Representing Level of Education

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) and Starter Set(s):
• See LOINC® projects in the Interoperability Proving Ground.	• LOINC® code 63504-5 • LOINC® answer list ID LL1069-5

Interoperability Need: Representing Stress

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) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76542-0 • LOINC® answer list LL3267-3

Interoperability Need: Representing Depression

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) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 55757-9 • LOINC® code 44249-1

Interoperability Need: Representing Physical Activity

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) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 68515-6 • LOINC® code 68516-4 • With applicable UCUM unit of measure

Interoperability Need: Representing Alcohol Use

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
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 72109-2 • LOINC® code 68518-0 (with LOINC® answer list ID LL2179-1) • LOINC® code 68519-8 (with LOINC® answer list ID LL2180-9) • LOINC® code 68520-6 (with LOINC® answer list ID LL2181-7) • LOINC® code 75626-2 • LOINC® code 71937-7 • LOINC® code 75624-7 • LOINC® code 72110-0

Interoperability Need: Representing Social Connection and Isolation

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) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76506-5, • LOINC® code 63503-7 (with LOINC answer list ID LL1068-7) • LOINC® code 76508-1 • LOINC® code 76509-9 • LOINC® code 76510-7 • LOINC® code 76511-5 (with LOINC answer list ID LL963-0) • LOINC® code 76512-3

Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)							
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) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76499-3 • LOINC® code 76500-8 (with LOINC® answer list ID LL963-0) • LOINC® code 76501-6 (with LOINC® answer list ID LL963-0) • LOINC® code 76502-4 (with LOINC® answer list ID LL963-0) • LOINC® code 76503-2 (with LOINC® answer list ID LL963-0) • LOINC® code 76504-0

I-T: Tobacco Use (Smoking Status)

Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• There are limitations in SNOMED CT® for this interoperability need, which include, but not limited to: not being able to capture severity of dependency, level of use, quit attempts, lifetime exposure, and use of e-Cigarettes. • 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]. • See LOINC® projects in the Interoperability Proving Ground.	• LOINC® code 72166-2 "Tobacco smoking status NHIS" • Current Smoking Status urn:oid:2.16.840.1.113883.11.20.9.38 • ONC's 2015 Edition certification requirements reference the following value set for smoking status. Codes from SNOMED CT® : (1) Current every day smoker. 449868002 (2) Current some day smoker. 428041000124106 (3) Former smoker. 8517006 (4) Never smoker. 266919005 (5) Smoker, current status unknown. 77176002 (6) Unknown if ever smoked. 266927001 (7) Heavy tobacco smoker. 428071000124103 (8) Light tobacco smoker. 428061000124105

I-U: 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	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • See UDI projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Defining a Globally Unique Device Identifier

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	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • See UDI projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Transmitting a Unique Device Identifier

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	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • See UDI projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Registering and Tracking Patient Device Identifiers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Global UDI Database (GUDID)	Final	Production	●○○○○	Yes	Free	N/A

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

I-V: 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
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Pilot	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC® projects in the Interoperability Proving Ground. • See Section I-K for discussion of units of measure used with quantitative observations.	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62

Section II: 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. • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** – Identifies the purpose for the transaction.

Interoperability Need: Sending a Notification of a Long Term Care 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. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-B: Care Plan

Interoperability Need: Documenting and Sharing Care Plans for a Single Clinical Context

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	Yes
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	Feedback requested	Yes	Free	Yes
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 Resource Care Plan (v1.0.2)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The care plan as expressed in the C-CDA standard does not attempt to represent the longitudinal care plan; rather it represents a "snapshot" of a care plan at a single point in time for transmission to other providers and teams to ensure continuity of care. • The Care Plan Domain Analysis Model is used as a reference model for C-CDA care plan documents in the context of the longitudinal care plan. • See CDA and FHIR projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Domain or Disease-Specific Care Plan Standards

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan Document, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary, Release 1 – US Realm	Balloted Draft	Feedback requested	Feedback requested	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Early Hearing Detection and Intervention (EHDI), Rev 2.1 Trial Implementation	Balloted Draft	Pilot	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The two HL7 CDA R2 IGs are based on C-CDA R2.1 and align with the Care Plan document specifications. The IHE Profile is based on HL7 V2.6 IG: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1. • See CDA and IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Sharing Patient Care Plans for Multiple Clinical Contexts

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE Dynamic Care Planning (DCP), Rev 1.1 Trial Implementation*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE and FHIR projects in the Interoperability Proving Ground.	• 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
1-Standard	HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
2-Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 1.1	Balloted Draft	Production	●●○○○	No	Free	Yes
3-Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
3-Implementation Specification	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.	Balloted Draft	Pilot	●●○○○	No	Free	No
3-Implementation Specification	HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
1-Emerging Standard	*HL7 FHIR Profiles: Quality Improvement Core (QI Core), Release 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
3-Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

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 Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release 1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*IHE: Guideline Appropriate Ordering (GAO)*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE: Guideline Appropriate Ordering (GAO) specification is being incorporated into the CQF content listed above it. • See FHIR and IHE projects in the Interoperability Proving Ground. • Note that the FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR) in STU 3 was incorporated into FHIR as a core implementation guide, FHIR Clinical Reasoning.	• 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 Implementation Specification	*IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-D: Clinical Quality Measurement

Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Standard	HL7 V3: Representation of the Health Quality Measures Format (eMeasure), DSTU Release 2.1	Balloted Draft	Pilot	●●●●○	No	Free	Yes
2-Standard	HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
3-Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 1.1	Balloted Draft	Production	●●○○○	No	Free	Yes
1-Implementation Specification	HL7 V3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF), Release 1.4 DSTU 4 (based on HQMF 2.1 – US Realm	Balloted Draft	Production	●●●●○	Yes	Free	Yes
2- Implementation Specification	HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF), Release 1.1 DSTU 2 (based on HQMF 2.1 - US Realm	Balloted Draft	Production	●●○○○	No	Free	Yes
1-Emerging Implementation Specification	*HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF), Release 2 DSTU32 (based on HQMF 2.1 - US Realm*	*In Development*	*Pilot*	●●○○○	*No*	*Free*	*Yes*
2-Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR)*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*
3-Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

II-E: Clinical 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), DSTU Release 1	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA III) STU Release 2 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• 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 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3.1 (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) STU Release 4 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Reporting Patient-level and Aggregate Quality Data for Quality Reporting and Evaluation							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3 – (QI Core) profiles*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU 3 – FHIR Measure Report*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The FHIR-based approach to quality measurement was previously referenced in the "Clinical Quality Framework Implementation Guide". That content has been updated and renamed for STU 3 as "FHIR Clinical Reasoning". • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

II-F: 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. • See CDA projects in the Interoperability Proving Ground.	• Feedback requested

II-G: Diet and Nutrition (See Question 11, Section V)

Interoperability Need: Exchanging Diet and Nutrition Orders Across the Continuum of Care

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Version 3 Standard: Diet and Nutrition, STU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Implementation Specification	*HL7 FHIR – Nutrition Order (Request) Resource (STU 3 Sept 2016 Ballot)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See FHIR projects in the Interoperability Proving Ground.	• **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.

II-H: 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 NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging implementation specification.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-I: 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. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the 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 "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. • Allows the pharmacist to request approval for additional refills of a prescription beyond those originally prescribed. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New 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	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• The RxChange message allows a Pharmacist to request a change of a new prescription or a "fillable" prescription. • See **NCPDP projects** in the Interoperability Proving Ground.	• 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 – specifies access control policies. • Credential Tokenizer – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • Assertion Builder – define processing logic for identity, authorization and attribute statements. • User Role – identifies the role asserted by the individual initiating the transaction. • Purpose of Use - Identifies the purpose for the transaction

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	●○○○○	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. • Notifies the pharmacy that a previously sent prescription should be cancelled and not filled. • Send the prescriber the results of a prescriptions cancellation request. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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	●○○○○	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. • Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: (1) To notify the prescriber of a dispensed prescription, (2) to notify the prescriber of a partially dispensed prescription, and (3) to notify a prescriber of a prescription not dispensed • Opt-in functionality available in SCRIPT versions 2014+ allow prescribers to specify which prescriptions and which dispense status to receive fill notifications for. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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. • See NCPDP projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows Prescriber to Electronically Request Prior Authorization for Medications

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	●●●○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See NCPDP projects in the Interoperability Proving Ground.	• Feedback requested

II-J: 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	●○○○○	No	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 Vocabularies and Value Sets for Consideration:
• There is no widely recognized vocabulary to capture family genomic health history, but several vocabularies/value sets are available for consideration. • Further constraint of this standard and implementation specification may be required to support this interoperability need	According to HIMSS, the following vocabularies/value sets may be considered: • Gene Identifier: HGNC Value Set • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature

II-K: Healthy Weight (See Question 12, Section V)

Interoperability Need: Sending Health Weight Information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement – Healthy Weight (HW)	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Integrating the Healthcare Enterprise (IHE) Healthy Weight Profile Childhood obesity surveillance systems utilize either measured (e.g., NHANES) or parent/self-report height and weight to calculate BMI. • See IHE projects in the Interoperability Proving Ground.	• **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.

II-L: 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	Yes

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	Yes
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:
• DICOM defines both its own encoding of reports and templates for encoding narrative reports and machine-generated output as DICOM Structured Reports (SR) for use within imaging systems. • DICOM Part 20 is an implementation guide for HL7 CDA r2. • DICOM also defines a Diagnostic Imaging Report HL7 CDA Template, which is intended to supersede the C-CDA Diagnostic Imaging Report.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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	Feedback requested	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-M: 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	Balloted Draft	Production	●○○○○	Yes	Free	Yes
Emerging 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. • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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. • Note that the implementation specification has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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	Production	●○○○○	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. • Note that the current version has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-N: 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	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PCD refers to the IEEE 11073-10101 standard for its nomenclature. • FDA cybersecurity recommendations for medical device manufacturers: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm481968.htm • Design Considerations and FDA Pre-Market Submission Recommendations for Interoperable Medical Devices: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482649.pdf • See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-O: Patient Education Materials

Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge From 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
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-P: Patient Identification Management *(See Question 13, Section V)*

Interoperability Need: Sending a Message for Patient Identification Management Within a Community

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:
• See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-Q: 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
Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●○○○	No	Free	Yes – Open
Emerging Implementation Specification	*HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1*	*Final*	*Pilot*	●○○○○	*No*	*N/A*	*N/A*
Emerging Implementation Specification	*IHE Advanced Patient Privacy and Consents (APPC)*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

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. • Along with security tokens and consent documents, security labels that are the critical third part of the Attribute-Based-Access-Control and SLS should be mentioned as well. Security Labels are used in CDA, FHIR, as well as the IHE Document Sharing (e.g. XDS), as described on the FHIR security page at https://www.hl7.org/fhir/security-labels.html • See IHE projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **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-R: 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 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. • See CDA projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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
1-Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
2-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	●●○○○	Yes	Free	Yes
1-Emerging 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*	Yes
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Structured Data Capture (SDC) Release 1*	*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. • See CDA, IHE, and FHIR projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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
Standard	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
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)	Final	Production	●●●○○	No	Free	Yes
2-Implementation Specification	HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2 - US Realm - the Electronic Initial Case Report (eICR)	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*
2- Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Structured Data Capture (SDC) Release 1*	*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
• See FHIR and IHE projects in the Interoperability Proving Ground.
	• **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** – specifies access control policies.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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 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*	*Feedback requested*	*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. • Note the Public Health Profile as specified in the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm* is harmonized with the Lab US Realm suite of Implementation Guides and improves on the ELR emerging implementation specification. Both are scheduled for revision in the HL7 January 2017. • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.2 - US Realm	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 the National Health Care Survey Program. • See CDA projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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
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. • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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 and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance	Final	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings*	*Final*	*Pilot*	●○○○○	*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 syndromic surveillance data as there may be jurisdictional variation or requirements. • See HL7 V2 projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-S: Research

Interoperability Need: Submission of Clinical Research Data to FDA to Support Product Marketing Applications							
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	●●●●●	Yes	Free	N/A
Standard	CDISC Standard for the Exchange of Non-clinical Data (SEND)	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	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	●○○○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• FDA published the draft guidance promoting use of EHRs in clinical research, in collaboration with ONC. (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm501068.pdf) • FDA CDER published a FRN focusing on Source Data Capture From Electronic Health Records: Using Standardized Clinical Research Data. (https://www.federalregister.gov/documents/2015/06/26/2015-15644/source-data-capture-from-electronic-health-records-using-standardized-clinical-research-data) • FDA CDER and CBER encourage the submission of study data in conformance to the data standards listed in the FDA Data Standards Catalog (DSC). Standardized study data will be required in submissions for clinical and non-clinical studies that start on or after December 17, 2016 (December 17, 2017 for INDs). See Data Standards Catalog: (http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm) and the Data Standards Strategy: (http://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm455270.pdf) • Although CDISC standards are a requirement for CDER and CBER and not for CDRH, all three Centers promote the use of Real World Data (RWD) in EHRs, registries, administrative claims and mobile health technology to generate Real World Evidence regarding the safety and effectiveness of medical products. In addition, FDA collaborates closely with other standards development organizations including but not limited to HL7, IHE, X12, and NCPDP. • FDA CDRH and CBER published the draft guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. (see http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf	• Feedback requested

Interoperability Need: Pre-population of Research Forms from Electronic Health Records							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	Final	Production	●●●○○	No	Free	N/A
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-CRD (Clinical Research Document)	Balloted Draft	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
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Structured Data Capture (SDC) Release 1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• See IHE projects in the Interoperability Proving Ground.	• 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
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-CRPC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Stakeholders should review 21CFR11 for more details. • See IHE projects in the Interoperability Proving Ground.	• 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:
• See IHE projects in the Interoperability Proving Ground.	• 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
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• 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:
• The CDISC Clinical Trial Registry (CTR-XML) is used internationally, but in the US, the primary area for registering Clinical Trials is via ClinicalTrials.gov.	• Feedback requested

II-T: 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	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA projects in the Interoperability Proving Ground. • Per 2015 Edition Health IT Certification Criterion for DS4P (§ 170.315(b)(7) and § 170.315(b)(8)), document-level tagging is the scope required for certification. • For C-CDA transmission, document level DS4P is required in the C-CDA General Header. Therefore, adoption levels may be higher than 1/5 for document level tagging (vs. section level)	• Feedback requested

II-U: 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	Yes Yes
Implementation Specification	HL7 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 Yes
Emerging 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*	*Feedback requested*	*Yes*	*Free*	*Yes* *Yes*

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. • See CDA and CCDA projects in the Interoperability Proving Ground.	• Feedback requested

Section III: Standards and Implementation Specifications for Services/Transport/Exchange

III-A: "Push" Exchange

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination and Information System User							
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 v1.2 ("Direct")	Final	Production	●●●●○	Yes	Free	Yes
2 – Standard	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	Yes	Free	Yes
1, 2 - Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes
1, 2 - Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	Yes	Free	Yes
1, 2 - Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
3-Implementation Specification	ITU H.810, H.811, H.812, and H.813	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 leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange).
• Direct is not currently supported by a formal SDO but is actively maintained and updated by the Direct Community.
• The ITU implementation specifications are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines
• See Direct and IHE projects in the Interoperability Proving Ground.
	• **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.
	• **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 authorize 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

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- Standard	Applicability Statement for Secure Health Transport v1.2 ("Direct")	Final	Production	●○○○○	Yes	Free	Yes
3- Standard	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
1 - Implementation Specification	eHealth Exchange Specification: Messaging Platform	Final	Production	●●●○○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Implementation Specification	eHealth Exchange Specification: Authorization Framework	Final	Production	●●●○○	No	Free	Yes
1 – Implementation Specification	eHealth Exchange Specification: Document Submission	Final	Production	●●●○○	No	Free	Yes
2- Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●○	No	Free	Yes
3 - Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU3*	*In Development*	*Pilot*	●○○○○	*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 eHealth Exchange Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1. • "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 leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API" • The FHIR resources for this Interoperability Need might be limited to Patient, Clinical Categorization Resources in the Administration Module, and resources in the Clinical Summary, Diagnostics, and Medication Modules. • See FHIR, Direct and IHE projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Representing Path Traversal Expressions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Standard	*HL7Fast Healthcare Interoperability Resources (FHIR) – FluentPath, STU 1, Release 1*	Balloted Draft	*Pilot*	*N/A*	*No*	*Free*	*No*

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

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	Production	●●●○○	No	$	Yes
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	Yes
Implementation Specification	ITU H.810, H.811, H.812, and H.813	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• ISO/IEEE 11073 is a family of standards for various medical devices. • The IEEE1073 Nomenclature is recognized in the IHE/HL7 record set • The ITU implementation specifications are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines	• Feedback requested

Interoperability Need: Medical Device Communication to Other Information Systems/Technologies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	ITU H.810, H.811, H.812, and H.813	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These ITU standards are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines	• **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.

Interoperability Need: Remote Patient Monitoring to Support Chronic Condition Management, Patient Education, and Patient Engagement

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	ITU H.810, H.811, H.812, and H.813	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These ITU standards are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines	• **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.

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- Standard	QICore/QuICK, Draft Standard for Trial Use HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	No
3- Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 1.1	Balloted Draft	Pilot	●○○○○	No	Free	No
4-Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR Implementation Guide:) Clinical Reasoning STU Release 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
5-Emerging Implementation Specification	*IHE-GAO (Guideline Appropriate Ordering)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• 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 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 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. • See IHE projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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 Yes
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes Yes

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. • See IHE projects in the Interoperability Proving Ground.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos)..

III-D: Healthcare Directory, 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**
Implementation Specification	IHE-IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes Yes
Standard	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*HL7 Fast Healthcare Interoperability Resource (FHIR) STU3*	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation was proposed, but not adopted for CEHRT 2015. The Health IT community has recognized the value of the underlying data elements and structure of that standard. The standard has met with limited adoption due to other concerns with the API. Work is underway in FHIR workgroups to reconcile FHIR resources with the data requirements of Provider/Healthcare Directories in order to offer a Healthcare Directory resource as part of FHIR. http://argonautwiki.hl7.org/index.php?title=Implementation_Guide • The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API" • The FHIR resources for this Interoperability Need might be limited to Service Provider Directory Resources within the Administration Module. • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. • See IHE and FHIR projects in the Interoperability Proving Ground	• Feedback requested

III-E: Patient Identification Management *(See Question 14, Section V)*

Interoperability Need: Exchanging Patient Identification Management Within a Community

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Production	Final	●●●●○	No	Free	Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Production	Final	●●●●○	No	Free	Yes

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

III-F: Public Health Exchange

Interoperability Need: Transport for Immunization Submission, Reporting

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	CDC-EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Version 1.2	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	CDC- IIS Standard WSDL	Final	Production	●○○○○	No	Free	No

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

III-G: 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
Implementation Specification	eHealth Exchange Specification: Health Information Event Messaging Production Specification	Final	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	*Balloted Draft*	*Pilot*	●●●○○	*No*	*Free*	*Yes* *Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• **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** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-H: 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 Yes Yes
1-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●●	No	Free	Yes Yes
1-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes Yes
2- Emerging Implementation Specification	*IHE-MHD (Mobile Access to Health Documents)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
2 – Emerging Implementation Specification	*IHE-PIXm (Patient Identifier Cross-Reference for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
2 – Emerging Implementation Specification	*IHE-PDQm (Patient Demographics Query for Mobile)*	*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 along with IHE-XDS. • The MHD Supplement Revision 2.2 published in April 2016 is based on FHIR DSTU2. • IHE-PIXm and IHE-PDQm are used for the purposes of patient matching and to support this interoperability need along with MHD. • See IHE projects in the Interoperability Proving Ground.	• **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** – specifies access control policiesspecifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – 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 authorize 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	Yes Yes
1-Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
1-Implementation Specification	eHealth Exchange Specification: Patient Discovery	Final	Production	●●●○○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1 - Implementation Specification	eHealth Exchange Specification: Messaging Platform	Final	Production	●●●○○	No	Free	Yes
1- Implementation Specification	eHealth Exchange Specification: Authorization Framework	Final	Production	●●●○○	No	Free	Yes
1-Implementation Specification	eHealth Exchange Specification: Query for Documents	Final	Production	●●●○○	No	Free	Yes
1-Implementation Specification	eHealth Exchange Specification: Retrieve Documents	Final	Production	●●●○○	No	Free	Yes

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.
• While IHE-PIX and IHE-XCPD are best-available standards at this time, the current best-available standards may be insufficient to meet interoperability needs with sufficient accuracy.
• See IHE projects in the Interoperability Proving Ground.
	• **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	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*In Development*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

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

• The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API"
• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress.
• See FHIR projects in the Interoperability Proving Ground.
	• **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 authorize 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-I: 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:
• See IHE projects in the Interoperability Proving Ground.	• **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: Models and Profiles *(See Question 15, Section V)*

IV-A: Functional Models

Interoperability Need: EHR Interoperability with the HIT Ecosystem

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	ISO/HL7 10781 EHR System Functional Model, Release 2, aka EHR-S FM (published by HL7 2014, ISO 2015)	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: PHR Interoperability with the HIT Ecosystem

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	ISO/HL7 16527 PHR System Functional Model, Release 2, aka PHR-S FM (published by HL7 2014, ISO 2015)	Final	Production	Feedback requested	No	Free	N/A

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

IV-B: Functional Profiles

Interoperability Need: Interoperability for Public Health Services

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Public Health Functional Profiles (published 2015), suite of nine (9) FPs for specific public health services/domain areas, based on ISO/HL7 10781 EHR-S FM	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: Enable Interoperability for Nutrition Care							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 EHR-System Electronic Nutrition Care Process Record System (ENCPRS) Functional Profile, Release 1	Final	Production	Feedback requested	No	Free	N/A

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

IV-C: Information Models

Interoperability Need: Information model for the interoperability of Diet and Nutrition Orders							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 V3 Domain Analysis Model: Diet and Nutrition Orders, Release 2	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: Information Model for the Interoperability of Behavioral Health							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 Version 3 Domain Analysis Model: Behavioral Health Record, Release 2	Final	Production	Feedback requested	No	Free	N/A

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

Section V: Questions and Requests for Stakeholder Feedback

As with the previous Interoperability Standards Advisories (ISA), posing questions has served as a valuable way to prompt continued dialogue with stakeholders to improve the ISA. Your feedback on the questions posed below is critical and we encourage answers to be submitted as part of the current public comment process.

General

1. Based on public comment and Health Information Technology Standards Committee recommendations, the ISA is now an interactive web application. What additional functionalities would make the ISA more useful as a resource?

2. In what ways has the ISA been helpful? What are ways in which the ISA could be improved to add value to nationwide standards adoption and use?

3. For each standard and implementation specification there are six assessment characteristics, for which detailed information has been received and integrated. However, some gaps remain. Please help complete information that is missing or noted "feedback requested." 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.

4. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Please comment on accuracy and completeness; where information gaps remain, forward applicable content.

5. For the Implementation Maturity characteristic for the standards and implementation specifications, ONC plans to publish a link, where available, to published maturity assessments based on known published criteria. Please help identify any publications that are publically available and provide the hypertext links to those resources.

6. For the Adoption Level characteristic for the standards and implementation specifications, ONC plans to include reference annotations or links to publicly available documentation known about adoption levels for listed standards. Please help identify any publications that are publicly available and provide the hypertext links to those resources.

7. For the Test Tool Availability characteristic for the standards and implementation specifications, ONC plans to publish references, where available, a to the publicly available test tool. Please help identify any publicly available test tools.

Section I: Vocabulary/Code Set

8. Are there additional Social Determinant Interoperability Needs with corresponding standards that should be included in the ISA?

9. For consideration of a new subsection Representing Birth and Newborn Data Sets-Please comment on the feasibility and maturity of birth and newborn datasets, including the IHE Newborn Discharge Summary, that can be transferred between mother, newborn and pediatric medical home records.

Section II: Content / Structure

10. The way FHIR is represented has changed in the ISA based on public feedback. Please provide feedback on whether this is a better way to reference FHIR within Interoperability Needs.

11. Subsection II-G: Diet and Nutrition was added. Please review and provide comment about the accuracy of the attributes.

12. Subsection II-K: Healthy Weight was added. Please review and provide comment about the accuracy of the attributes.

13. Subsection II-P: Patient Identification Management was added. Please review and provide comment about the accuracy of the attributes.

Section III: Standards and Implementation Specifications for Services

14. Subsection III-E: Patient Identification Management was added. Please review and provide comment about the accuracy of the attributes.

Section IV: Models and Profiles

15. Is the traditional ISA format used for listing standards and implementation specifications applicable for listing Models and Profiles? Are there additional or different attributes that should be collected for them? Are there additional models and profiles that should be listed?

Appendix I: Sources of Security Standards

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

Appendix I – Sources of Security and Privacy Standards and Security Patterns

[See Question 16, Section V]

In the Interoperability Standards Advisory, a structure to capture necessary security patterns associated with interoperability needs is represented (see Section III-A and III-F for examples). 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, and while every effort is made to ensure links are current, links may become outdated as organizations make changes to their websites.

- Security Pattern Catalog: https://people.cs.kuleuven.be/~koen.yskout/icse15/catalog.pdf
- HIPAA Security regulations that are specific to healthcare: http://www.hhs.gov/hipaa/for-professionals/security/index.html
- HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework: http://www.hhs.gov/sites/default/files/nist-csf-to-hipaa-security-rule-crosswalk-02-22-2016-final.pdf
- ASTM: http://www.astm.org/Standards/computerized-system-standards.html
- ASTM E1384-07 (2013) Standard Practice for Content and Structure of the Electronic Health Record (EHR): http://www.astm.org/Standards/E1384.htm
- ASTM E1714-07 (2013) Standard Guide for Properties of a Universal Healthcare Identifier (UHID): http://www.astm.org/Standards/E1714.htm
- ASTM E1762-95 (2013) Standard Guide for Electronic Authentication of Health Care: http://www.astm.org/Standards/E1762.htm
- ASTM E1985-98 (2013) Standard Guide for User Authentication and Authorization: http://www.astm.org/Standards/E1985.htm
- ASTM E1986-09 (2013) Standard Guide for Information Access Privileges to Health: http://www.astm.org/Standards/E1986.htm
- ASTM E2017-99 (2010) Standard Guide for Amendments to Health Information: http://www.astm.org/Standards/E2017.htm
- ASTM E2147-01 (2013) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: http://www.astm.org/Standards/E2147.htm
- ASTM E2212-02a (2010) Standard Practice for Healthcare Certificate Policy: http://www.astm.org/Standards/E2212.htm
- ASTM E2595-07 (2013) Standard Guide for Privilege Management Infrastructure: https://www.astm.org/Standards/E2595.htm
- Information Organization for Standardization (ISO) Information Security Standards: http://www.27000.org/
- ISO/TS 14265:2011 Health informatics - Classification of purposes for processing personal health information: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=54547
- ISO IT Security techniques – evaluation criteria for IT security, ISO/EC 15408 series: http://standards.iso.org/ittf/PubliclyAvailableStandards/index.html
- ISO 17090-1:2013 Health informatics - Public Key Infrastructure - Part 1: Overview of digital certificate services: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=63019

- ISO 17090-2:2015 Health informatics - Public key infrastructure -- Part 2: Certificate profile: http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=35&ics2=240&ics3=80&csnumber=63020
- ISO 17090-3:2008 Health informatics - Public key infrastructure - Part 3: Policy management of certification authority: http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=35&ics2=240&ics3=80&csnumber=39847
- ISO/IS 17090-4 Health informatics - Public key infrastructure-Part 4: Digital signatures for healthcare documents: http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=35&ics2=240&ics3=80&csnumber=61185
- ISO/TS 17975:2015 Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=61186
- ISO/TR 21089:2004(en) -Health informatics — Trusted end-to-end information flows: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=35645
- ISO 21091: 2013 Health informatics - Directory services for healthcare providers, subjects of care and other entities: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=51432
- ISO/TS 21298:2008 Health informatics -- Functional and structural roles: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=40133
- National Institute for Standards and Technology (NIST) Special Publications 800 Series: http://csrc.nist.gov/publications/PubsSPs.html
- NIST's Federal Information Processing Standards (FIPS): http://www.nist.gov/itl/fipscurrent.cfm
- NIST Special Publication 800-53. Security and Privacy Controls for Federal Information Systems and Organizations Revision 4. April 2013: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf
- NIST Privacy Risk Management for Federal Information Systems. NISTIR 8062 Draft. May 2015: http://csrc.nist.gov/publications/drafts/nistir-8062/nistir_8062_draft.pdf
- NIST Special Publication: 800-63-2. Electronic Authentication Guideline. August 2013: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf
- NIST Digital Authentication Guideline, Special Publication 800-63-3, Public Draft, Q4 2016: https://www.nist.gov/itl/nstic/special-publication-800-63-3
- NIST 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/sites/default/files/library/sp1800/hit-ehr-nist-sp1800-1a-draft.pdf and https://nccoe.nist.gov/library/nist-sp-1800-1a-e-securing-ehrs-mobile-devices-all-volumes-plus-template-and-manifest-files
- NIST Fair Information Practice Principles (FIPPs): https://www.whitehouse.gov/sites/default/files/rss_viewer/NSTICstrategy_041511.pdf
- NIST Guide for Conducting Risk Assessments, Special Publication 800-30 Revision 1: http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-30r1.pdf

- NIST Framework for Improving Critical Infrastructure Cybersecurity, V1, February 2014: https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf
- NIST 800-53 Rev 4: Security & Privacy controls: http://csrc.nist.gov/publications/nistpubs/800-53-rev4/sp800-53r4_summary.pdf
- NIST SP 800-183: Network of 'Things': http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-183.pdf
- NIST SP 800-160: Systems Security Engineering: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-160.pdf
- NIST CSP 500-291: Cloud Computing: https://www.nist.gov/sites/default/files/documents/itl/cloud/NIST_SP-500-291_Version-2_2013_June18_FINAL.pdf
- NIST SP 1500-1: Big Data Interoperability: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1500-1.pdf
- OpenID Connect 1.0: http://openid.net/specs/openid-connect-core-1_0.html
- OAUTH 2.0: https://tools.ietf.org/html/rfc6749
- User-Managed Access (UMA) Profile of OAuth 2.0: https://docs.kantarainitiative.org/uma/rec-uma-core.html
- IHE – Cybersecurity Standards: https://www.us-cert.gov/Information-Sharing-Specifications-Cybersecurity
- IHE – Consistent Time: http://wiki.ihe.net/index.php/Consistent_Time
- IHE – Audit Trail and Node Authentication: http://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication
- IHE – Enterprise User Authentication: http://wiki.ihe.net/index.php/Enterprise_User_Authentication
- IHE – Cross-Enterprise User Assertion (XUA): http://wiki.ihe.net/index.php/Cross-Enterprise_User_Assertion_(XUA)
- IHE – Document Digital Signature: http://wiki.ihe.net/index.php/Document_Digital_Signature
- IHE – Basic Patient Privacy Consents -- http://wiki.ihe.net/index.php/Basic_Patient_Privacy_Consents
- IHE – Document Encryption: http://wiki.ihe.net/index.php/Document_Encryption
- IHE – Access Control: http://wiki.ihe.net/index.php/ITI_Access_Control_White_Paper
- HL7 CDA® R2 Implementation Guide: Patient-Friendly Language for Consumer User-Interfaces, Release 1: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=412
- HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=354
- HL7 Healthcare Privacy and Security Classification System (HCS), Release 1: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=345
- HL7 Implementation Guide for CDA®, Release 2: Privacy Consent Directives, Release 2: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=280
- HL7 Version 3 Standard: Security and Privacy Ontology, Release 1Category: Privacy and Consent: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=348
- HL7 Version 3 Standard: Healthcare (Security and Privacy) Access Control Catalog, Release 3: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=72
- HL7 Version 3 Standard: Privacy, Access and Security Services (PASS) Access Control Services Conceptual Model, Release 1: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=73

- HL7 Version 3 Standard: Privacy, Access and Security Services; Security Labeling Service, Release 1 (SLS): http://www.hl7.org/implement/standards/product_brief.cfm?product_id=360
- Structured Threat Information Expression (STIX): http://stixproject.github.io/about/
- Trusted Automated Exchange of Indicator Information (TAXI): http://taxiiproject.github.io/