



# 2016 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

*BEST AVAILABLE  
STANDARDS AND  
IMPLEMENTATION  
SPECIFICATIONS*

*[Draft for Comment]*

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

## Introduction

The Interoperability Standards Advisory (ISA) process represents the model by which the Office of the National Coordinator for Health Information Technology (ONC) will coordinate the identification, assessment, and determination of the “best available” interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs.

The Draft 2016 Interoperability Standards Advisory (Draft 2016 Advisory) remains focused on clinical health information technology (IT) interoperability and is published at <http://www.healthit.gov/standards-advisory/2016>. For detailed background on the Advisory, its purpose, and its processes please review the [2015 Advisory](#). Updates to the Draft 2016 Advisory’s substance and structure reflect input obtained from the public at large throughout 2015 and the HIT Standards Committee. A final 2016 Advisory will be published at the end of 2015.

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

- 1) Instead of referencing a general “purpose,” a section’s lead-in is framed to convey an “interoperability need” stakeholders may express to convey an outcome they would want to achieve with interoperability.
- 2) A set of six informative characteristics are now associated with each referenced standard and implementation specification to give readers an overall sense of maturity and adoptability.
- 3) Associated with each “interoperability need” are two subsections.
  - a. The first would identify any known limitations, dependencies, or preconditions associated with best available standards and implementation specifications.
  - b. The second would identify, where applicable, known “security patterns” associated with best available standards and implementation specifications. This subsection’s goal would be to identify the generally reusable security techniques applicable to interoperability need(s) without prescribing or locking-in particular security standards.
- 4) A security standards sources appendix is included to point stakeholders to the entities that maintain and curate relevant security standards information.
- 5) A revision history section has been added at the end of the document.

**This document is a draft for comment** and will continue to be refined during the public comment period. Additionally, because this draft includes both new structural and content sections please note that content for many of the new structural subsections is intentionally incomplete. Those sections that are more fully populated were done so to give the public an early opportunity to weigh in on and react to perceived value that these subsections could provide. Your feedback is critical to improve and refine these new subsections.

## Scope

The standards and implementation specifications listed in this advisory focus explicitly on clinical health IT systems’ interoperability. Thus, the advisory’s scope includes electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed (e.g., a referral to another care provider, public health reporting). The advisory does **not** include within its scope administrative/payment oriented interoperability purposes or administrative transaction requirements that are governed by HIPAA and administered by the Centers for Medicare & Medicaid Services (CMS).

## Purpose

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

- 1) To provide the industry with a single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs.

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

## **The 2016 Interoperability Standards Advisory**

The following represents an updated list of the best available standard(s) and implementation specification(s) in comparison to the 2015 Advisory. The list is not exhaustive but it is expected that future advisories will incrementally address a broader range of clinical health IT interoperability needs.

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

When one standard or implementation specification is listed as the "best available," it reflects ONC's current assessment and prioritization of that standard or implementation specification for a given interoperability need. When more than one standard or implementation specification is listed as the best available, it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry can efficiently interoperate more than one.

## **"Best Available" Characteristics**

The 2015 Advisory introduced several "characteristics" and additional factors by which standards and implementation specifications were determined to be the "best available." For example, whether a standard was in widespread use or required by regulation. Public comment and feedback from the HIT Standards Committee indicated that more explicit context for each standard and implementation specification would benefit stakeholders and clearly convey a standard's relative maturity and adoptability.<sup>1</sup>

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

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

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

## Interoperability need: [Descriptive Text]

Standard/ Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	Final	Production	●●●●○	Yes	Free	Yes
<i>Emerging Alternative Standard</i>	<i>Draft</i>	<i>Pilot</i>	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Descriptive text with “(recommended by the HIT Standards Committee)” included in cases where the HIT Standards Committee recommended the text, and on which public feedback is sought.</li> </ul>	<ul style="list-style-type: none"> <li>Descriptive text</li> </ul>

The following describes the six characteristics that were added to the Advisory in detail in order to better inform stakeholders about the maturity and adoptability of a given standard or implementation specification and provides definitions for the terms and symbols used throughout the Advisory.

### #1: Standards Process Maturity

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

- “*Final*” – when this designation is assigned, the standard or implementation specification is considered “final text” or “normative” by the organization that maintains it.
- “*Draft*” – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU) or in a “trial implementation” status by the organization that maintains it.

### #2: Implementation Maturity

This characteristic conveys a standard or implementation specification’s maturity based on its implementation state.

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

### #3: Adoption Level

This characteristic conveys a standard or implementation specification’s approximate level of adoption in health care. The following scale is used:

- “*Unknown*” – indicates no known status for the current level of adoption in health care.
- indicates 0% to 20% adoption.
- indicates 21% to 40% adoption.
- indicates 41% to 60% adoption.
- indicates 61% to 80% adoption.
- indicates 81% to 100% adoption.

#### **#4: Regulated**

This characteristic (provided as a “Yes” or “No”) conveys whether a standard or implementation specification has been adopted in regulation or required by HHS for a particular interoperability need.

#### **#5: Cost**

This characteristic conveys whether a standard or implementation specification costs money to obtain.

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

#### **#6: Test Tool Availability**

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

- “Yes” – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.
- “Yes<sup>\$</sup>” – 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.
- “No” – when this designation is assigned, it signifies that no test tool is available for a standard or implementation specification.
- “N/A” – when this designation is assigned, it signifies that a test tool for the standard or implementation would be “not applicable.”

#### **The Structure of Sections I through III**

For the purposes of the lists that follow, a specific version of the standard or implementation specification is not listed unless it makes a helpful distinction. The standards and associated implementation specifications for clinical health IT interoperability are grouped into these categories:

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

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

Section IV includes questions on which public input is requested.

Last, as noted in the 2015 Advisory, this Advisory is not intended to imply that a standard listed in one section would always be used or implemented independent of a standard in another section. To the contrary, it will often be necessary to combine the applicable standards from multiple sections to achieve interoperability for a particular clinical health information interoperability purpose.



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

### I-A: Allergies

#### Interoperability Need: Representing patient allergic reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	●●●●○	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

#### Interoperability Need: Representing patient allergens: medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">RxNorm</a>	Final	Production	●●●●○	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>When a medication allergy necessitates capture by medication class, <a href="#">NDF-RT</a> is best available (as recommended by the HIT Standards Committee)</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

#### Interoperability Need: Representing patient allergens: food substances

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Unknown	Unknown	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### Interoperability Need: Representing patient allergens: environmental substances

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">[See Question 4-5]</a>						
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>Currently, there are no vocabulary code sets considered “best available” for environmental allergens.</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

## I-B: Care Team Member

### Interoperability Need: Representing care team member (health care provider)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">National Provider Identifier (NPI)</a>	Final	Production	●●○○○	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>For the purpose of recording a care team member, it should be noted that NPI permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of ‘person’.</li> <li>There is a SNOMED-CT value set for a “subjects role in the care setting” that could also be used in addition to NPI for care team members.</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

## I-C: Encounter Diagnosis

### Interoperability Need: Documenting patient encounter diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	●●●●○	Yes	Free	N/A
Standard	<a href="#">ICD-10-CM</a>	Final	Production	●●●●○	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

## I-D: Race and Ethnicity

### Interoperability Need: Representing patient race and ethnicity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>The <a href="#">CDC Race and Ethnicity Code Set Version 1.0</a>, which expands upon the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient.</li> <li>The HIT Standards Committee noted that the high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-E: Family Health History

### Interoperability Need: Representing patient family health history

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	● ● ● ● ○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee)</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-F: Functional Status/Disability

Interoperability Need: Representing patient functional status and/or disability							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<i>[See Question 4-5]</i>						
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

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

Interoperability Need: Representing patient gender identity							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Unknown	Unknown	No	Free	N/A
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a <a href="#">report</a> by The Fenway Institute and the Institute of Medicine.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### Interoperability Need: Representing patient sex (at birth)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	For Male and Female, <a href="#">HL7 Version 3 Value Set for Administrative Gender</a>	Final	Production	● ● ● ● ○	No	Free	N/A
Standard	For Unknown, <a href="#">HL7 Version 3 Null Flavor</a>	Final	Production	● ● ● ● ○	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a <a href="#">report</a> by The Fenway Institute and the Institute of Medicine.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### Interoperability Need: Representing patient sexual orientation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Unknown	Unknown	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a <a href="#">report</a> by The Fenway Institute and the Institute of Medicine.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## I-H: Immunizations

### Interoperability Need: Representing immunizations – historical

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Standard Code Set CVX—Clinical Vaccines Administered</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A
Standard	HL7 Standard Code Set <a href="#">MVX -Manufacturing Vaccine Formulation</a>	Final	Production	● ● ● ● ○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information.</li> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Representing immunizations – administered

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Standard Code Set CVX—Clinical Vaccines Administered</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A
Standard	<a href="#">National Drug Code</a>	Final	Production	● ● ● ● ●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information.</li> <li>According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-I: Industry and Occupation

### Interoperability Need: Representing patient industry and occupation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<i>[See Question 4-5]</i>						
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## I-J: Lab tests

### Interoperability Need: Representing laboratory tests and observations

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">LOINC</a>	Final	Production	● ● ● ● ○	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>The HIT Standards Committee recommended that laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED-CT terminology.</li> <li>The HIT Standards Committee recommended that organizations not using LOINC codes should maintain and publish a mapping of their codes to the LOINC equivalent until migration to LOINC has occurred.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## I-K: Medications

### Interoperability Need: Representing patient medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">RxNorm</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## I-L: Numerical References & Values

### Interoperability Need: Representing numerical references and values

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">The Unified Code of Units of Measure</a>	Final	Production	● ● ● ○ ○	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## I-M: Patient “problems” (i.e. conditions)

### Interoperability Need: Representing patient “problems” (i.e., conditions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			



## I-N: Preferred Language

### Interoperability Need: Representing patient preferred language

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">RFC 5646</a>	Final	Production	Unknown	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language.</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

## I-O: Procedures

### Interoperability Need: Representing dental procedures performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Code on Dental Procedures and Nomenclature (CDT)</a>	Final	Production	● ● ● ● ●	Yes	\$	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>CDT is a proprietary terminology standard.</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

### Interoperability Need: Representing medical procedures performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	● ● ● ● ●	Yes	Free	N/A
Standard	the combination of <a href="#">CPT-4/HCPCS</a>	Final	Production	● ● ● ● ●	Yes	\$	N/A
Standard	<a href="#">ICD-10-PCS</a>	Final	Production	● ● ● ● ○	Yes	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

## I-P: Radiology (interventions and procedures)

### Interoperability Need: Representing radiological interventions and procedures

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">LOINC</a>	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Radlex and LOINC are currently in the process of creating a common data model to link the two standards together to promote standardized indexing of radiology terms as indicated by public comments and HIT Standards Committee recommendations.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-Q: Smoking Status

### Interoperability Need: Representing patient smoking status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SNOMED-CT</a>	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>According to the HIT Standards Committee, there are limitations in SNOMED-CT for this interoperability need, which include not being able to capture severity of dependency, quit attempts, lifetime exposure, and use of e-Cigarettes.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-R: Unique Device Identification

### Interoperability Need: Representing unique implantable device identifiers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3</a>	Final	Production	●○○○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## I-S: Vital Signs

### Interoperability Need: Recording patient vital signs

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">LOINC</a>	Final	Production	● ● ● ● ●	No	Free	N/A
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

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

### II-A: Admission, Discharge, and Transfer

#### Interoperability Need: Sending a notification of a patient's admission, discharge and/or transfer status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	HL7 2.x ADT message	Final	Production	● ● ● ● ●	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Any HL7 2.x version messaging standard associated with ADT is acceptable.</li> <li>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.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-B: Care Plan

Interoperability Need: Documenting patient care plans							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1</a>	Draft	Pilot	Unknown	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-C: Clinical Decision Support

Interoperability Need: Shareable clinical decision support							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.</a>	Draft	Pilot	Unknown	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-D: Drug Formulary & Benefits

Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP Formulary and Benefits v3.0</a>	Final	Production	● ● ● ● ●	Yes	\$	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>The HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-E: Electronic Prescribing

### Interoperability Need: A prescriber's ability to create a new prescription to electronically send to a pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</a>	Final	Production	● ● ● ● ●	Yes	\$	<a href="#">Yes</a>

<b>Limitations, Dependencies, and Preconditions for Consideration:</b>	<b>Applicable Security Patterns for Consideration:</b>
<ul style="list-style-type: none"> <li>The "New Prescription" transaction is best suited for this interoperability need.</li> <li>Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Prescription refill request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</a>	Final	Production	● ● ● ● ○	No	\$	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b>	<b>Applicable Security Patterns for Consideration:</b>
<ul style="list-style-type: none"> <li>The "Refill Request" transaction is best suited for this interoperability need.</li> <li>Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Cancellation of a prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</a>	Final	Production	Unknown	No	\$	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b>	<b>Applicable Security Patterns for Consideration:</b>
<ul style="list-style-type: none"> <li>The "Cancel" transaction is best suited for this interoperability need.</li> <li>Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Pharmacy notifies prescriber of prescription fill status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</a>	Final	Production	Unknown	No	\$	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>The “Fill Status” transaction is best suited for this interoperability need.</li> <li>Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.</li> </ul>	<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>
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### Interoperability Need: A prescriber’s ability to obtain a patient’s medication history

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">NCPDP SCRIPT Standard, Implementation Guide, Version 10.6</a>	Final	Production	●●●○○	No	\$	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>The “Medication History” transaction is best suited for this interoperability need.</li> <li>Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange.</li> </ul>	<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>
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## II-F: Family health history (clinical genomics)

### Interoperability Need: Representing family health history for clinical genomics

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Version 3 Standard: Clinical Genomics: Pedigree</a>	Final	Production	●○○○○	Yes	Free	No
Implementation Specification	<a href="#">HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1</a>	Final	Production	●○○○○	No	Free	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>According to the HIT Standards Committee, there is no available vocabulary to capture family genomic health history.</li> <li>According to the HIT Standards Committee, further constraint of this standard and implementation specification may be required to support this interoperability need.</li> </ul>	<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>
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## II-G: Images

[See Question 4-7]

Interoperability Need: Medical image formats for data exchange and distribution							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Digital Imaging and Communications in Medicine (DICOM)</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes [See Question 4-8]	Final	Production	● ○ ○ ○ ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
● Feedback requested				● Feedback requested			

Interoperability Need: Exchange of imaging reports							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Digital Imaging and Communications in Medicine (DICOM)</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture.</a>	Final	Production	● ○ ○ ○ ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
● Feedback requested				● Feedback requested			

## II-H: Laboratory

### Interoperability Need: Receive electronic laboratory test results

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012</a>	Final	Production	● ● ● ● ○	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<i>HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm</i> [no hyperlink available yet]	Draft	Pilot	● ○ ○ ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Ordering labs for a patient

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	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 [no hyperlink available yet]	Draft	Pilot	● ○ ○ ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>



### 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	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	Final	Production	●●●●●	No	Free	No
Standard	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 <i>[no hyperlink available yet]</i>	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## II-I: Patient Education Materials

### Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge form online resources

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## II-J: Patient Preference/Consent

[See Question 4-9]

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	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">IHE Basic Patient Privacy Consents (BPPC)</a>	Final	Production	● ● ● ● ○	No	Free	No
Implementation Specification	<a href="#">IHE Cross Enterprise User Authorization (XUA)</a>	Final	Production	● ● ● ● ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-K: Public Health Reporting

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.</a>	Final	Production	● ● ○ ○ ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>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.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### Interoperability Need: Reporting cancer cases to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm</a>	Draft	Production	● ● ● ○ ○	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<a href="#">HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

### Interoperability Need: Case reporting to public health agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
(1) Implementation Specification	<a href="#">IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No
(2) Standard	<a href="#">Fast Healthcare Interoperability Resources (FHIR)</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No
(2) Implementation Specification	<a href="#">Structured Data Capture Implementation Guide</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Electronic case reporting is not wide spread and is determined at the state or local jurisdiction.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	Final	Production	● ● ● ● ●	Yes	Free	No
Implementation specification	<a href="#">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</a>	Final	Production	● ● ● ● ●	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<a href="#">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</a>	Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm [See Question 4-6]</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: <a href="http://www.cdc.gov/nchs/nhcs/how_to_participate.htm">http://www.cdc.gov/nchs/nhcs/how_to_participate.htm</a> for information on participation.</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

Interoperability Need: Reporting administered immunizations to immunization registry							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	Final	Production	● ● ● ● ●	Yes	Free	No
Implementation Specification	<a href="#">HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4</a>	Final	Production	● ● ● ● ●	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<a href="#">HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5</a>	Final	Pilot	● ○ ○ ○ ○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>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.</li> </ul>				<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

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	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 2.5.1</a>	Final	Production	● ● ● ● ●	Yes	Free	No
Implementation Specification	<a href="#">PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1</a>	Final	Production	● ● ● ● ○	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<a href="#">PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0</a>	Final	Pilot	● ○ ○ ○ ○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>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.</li> </ul>				<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-L: Quality Reporting

Interoperability Need: Reporting aggregate quality data to quality reporting initiatives							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1</a>	Draft	Production	● ● ● ● ○	Yes	Free	<a href="#">Yes</a>
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
• Feedback requested				• Feedback requested			

Interoperability Need: Reporting patient-level quality data to quality reporting initiatives							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm)</a>	Draft	Production	● ● ● ● ○	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Implementation Specification	<a href="#">HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm)</a>	Draft	Pilot	● ○ ○ ○ ○	Yes	Free	Yes
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
• Feedback requested				• Feedback requested			

## II-M: Representing clinical health information as a “resource”

Interoperability Need: Representing clinical health information as “resource”							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Fast Healthcare Interoperability Resources (FHIR)</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
• Feedback requested				• Feedback requested			

## II-N: Segmentation of sensitive information

Interoperability Need: Document-level segmentation of sensitive information							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1</a>	Final	Pilot	● ○ ○ ○ ○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## II-O: Summary care record

Interoperability Need: Support a transition of care or referral to another provider							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition</a>	Final	Production	● ● ● ● ●	No	Free	No
Implementation Specification	<a href="#">Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)</a>	Draft	Production	● ● ● ● ●	Yes	Free	<a href="#">Yes</a>
<i>Emerging Alternative Implementation Specification</i>	<a href="#">HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1</a>	<i>Draft</i>	<i>Pilot</i>	<i>Unknown</i>	<i>No</i>	<i>Free</i>	<i>No</i>
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>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.</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

## Section III: Best Available Standards and Implementation Specifications for Services

[See Question 4-10]

### III-A: An unsolicited “push” of clinical health information to a known destination

[See Question 4-3]

Interoperability Need: An unsolicited “push” of clinical health information to a known destination between individuals							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Applicability Statement for Secure Health Transport v1.1 (“Direct”)</a>	Final	Production	● ● ● ● ●	Yes	Free	<a href="#">Yes</a>
Emerging Alternative Standard	<a href="#">Applicability Statement for Secure Health Transport v1.2</a>	Final	Pilot	● ○ ○ ○ ○	No	Free	No
Implementation Specification	<a href="#">XDR and XDM for Direct Messaging Specification</a>	Final	Production	● ● ● ● ○	Yes	Free	<a href="#">Yes</a>
Implementation Specification	<a href="#">IG for Direct Edge Protocols</a>	Final	Production	● ● ○ ○ ○	Yes	Free	<a href="#">Yes</a>
Implementation Specification	<a href="#">IG for Delivery Notification in Direct</a>	Final	Production	● ● ● ○ ○	No	Free	No
Emerging Alternative Standard	<a href="#">Fast Healthcare Interoperability Resources (FHIR)</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>				<b>Applicable Security Patterns for Consideration:</b>			
<ul style="list-style-type: none"> <li>“Direct” standard is based upon the underlying standard: <a href="#">Simple Mail Transfer Protocol (SMTP) RFC 5321</a> and for security uses <a href="#">Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751</a>.</li> <li>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.</li> </ul>				<ul style="list-style-type: none"> <li><b>System Authentication</b> - The information and process necessary to authenticate the systems involved</li> <li><b>Recipient Encryption</b> - the message and health information are encrypted for the intended user</li> <li><b>Sender Signature</b> – details that are necessary to identity of the individual sending the message</li> </ul>			



### 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	Regulated	Cost	Test Tool Availability
Standard	<a href="#">SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification</a>	Final	Production	●●●○○	Yes	Free	<a href="#">Yes</a>
Implementation Specification	<a href="#">IHE-XDR (Cross-Enterprise Document Reliable Interchange)</a>	Final	Production	●●●●○	No	Free	No
Implementation Specification	<a href="#">NwHIN Specification: Authorization Framework</a>	Final	Production	●●●○○	No	Free	No
Implementation Specification	<a href="#">NwHIN Specification: Messaging Platform</a>	Final	Production	●●●○○	No	Free	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0</li> <li>The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1.</li> </ul>	<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li><b>System Authentication</b> - The information and process necessary to authenticate the systems involved</li> <li><b>Purpose of Use</b> - Identifies the purpose for the transaction</li> <li><b>Patient Consent Information</b> - Identifies the patient consent information that may be required before data can be accessed.</li> </ul>
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## 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	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Version 3 Standard: Decision Support Service, Release 2.</a>	Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use</a>	Draft	Pilot	●○○○○	No	Free	No

<b>Limitations, Dependencies, and Preconditions for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>	<b>Applicable Security Patterns for Consideration:</b> <ul style="list-style-type: none"> <li>Feedback requested</li> </ul>
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### 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	Regulated	Cost	Test Tool Availability
Standard	<a href="#">HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.</a>	Final	Production	●●●○○	Yes	Free	No
Implementation Specification	<a href="#">HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.</a>	Final	Production	●●●●○	No	Free	No
Implementation Specification	<a href="#">HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.</a>	Final	Production	●●●●○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>		<b>Applicable Security Patterns for Consideration:</b>					
● Feedback requested		● Feedback requested					

### III-C: Image Exchange

#### Interoperability Need: Exchanging imaging documents among a group of affiliated entities

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">IHE Cross Enterprise Document Sharing for Images (XDS-I)</a>	Draft	Pilot	●○○○○	No	Free	No
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>		<b>Applicable Security Patterns for Consideration:</b>					
● Feedback requested		● Feedback requested					

### III-D: Provider Directory

Interoperability Need: Listing of providers for access by potential exchange partners							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	<a href="#">Yes</a>
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### III-E: Publish and Subscribe

Interoperability Need: Publish and subscribe message exchange							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">NwHIN Specification: Health Information Event Messaging Production Specification</a>	Final	Production	● ● ● ○ ○	No	Free	No
Emerging Alternative Implementation Specification	<a href="#">IHE Document Metadata Subscription (DSUB), Trial Implementation</a>	Draft	Pilot	● ○ ○ ○ ○	No	Free	No
Limitations, Dependencies, and Preconditions for Consideration:				Applicable Security Patterns for Consideration:			
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>			

### III-F: Query

Interoperability Need: Query for documents within a specific health information exchange domain							
Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">IHE-XDS (Cross-enterprise document sharing)</a>	Final	Production	● ● ● ● ○	No	Free	No
Implementation Specification	<a href="#">IHE-PDQ (Patient Demographic Query)</a>	Final	Production	● ● ● ● ○	No	Free	No
Implementation Specification	<a href="#">IHE-PIX (Patient Identifier Cross-Reference)</a>	Final	Production	● ● ● ● ○	No	Free	No
Emerging Alternative Implementation Specification	<i><a href="#">IHE – MHD (Mobile Access to Health Documents)</a></i>	<i>Draft</i>	<i>Pilot</i>	● ○ ○ ○ ○	<i>No</i>	<i>Free</i>	<i>No</i>
<b>Limitations, Dependencies, and Preconditions for Consideration:</b>			<b>Applicable Security Patterns for Consideration:</b>				
<ul style="list-style-type: none"> <li>IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.</li> </ul>			<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>				

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specifications	the combination of <a href="#">IHE-XCPD (Cross-Community Patient Discovery)</a> and <a href="#">IHE-PIX (Patient Identifier Cross-Reference)</a>	Final	Production	● ● ● ● ○	No	Free	No
Implementation Specification	<a href="#">NwHIN Specification: Patient Discovery</a>	Final	Production	● ● ● ○ ○	No	Free	No
Implementation Specifications	<a href="#">IHE-XCA (Cross-Community Access)</a> further constrained by <a href="#">eHealth Exchange Query for Documents v 3.0</a>	Final	Production	● ● ● ● ○	No	Free	No
Implementation Specification	<a href="#">NwHIN Specification: Query for Documents</a>	Final	Production	● ● ● ○ ○	No	Free	No
Implementation Specification	<a href="#">NwHIN Specification: Retrieve Documents</a>	Final	Production	● ● ● ○ ○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.</li> </ul>	<ul style="list-style-type: none"> <li><b>System Authentication</b> - The information and process necessary to authenticate the systems involved</li> <li><b>User Details</b> - identifies the end user who is accessing the data</li> <li><b>User Role</b> - identifies the role asserted by the individual initiating the transaction</li> <li><b>Purpose of Use</b> - Identifies the purpose for the transaction</li> <li><b>Patient Consent Information</b> - Identifies the patient consent information that may be required before data can be accessed.</li> <li><b>Query Request ID</b> - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.</li> </ul>

### Interoperability Need: Data element based query for clinical health information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	<a href="#">Fast Healthcare Interoperability Resources (FHIR)</a>	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>	<ul style="list-style-type: none"> <li><b>System Authentication</b> - The information and process necessary to authenticate the systems involved</li> <li><b>User Details</b> - identifies the end user who is accessing the data</li> <li><b>User Role</b> - identifies the role asserted by the individual initiating the transaction</li> <li><b>Purpose of Use</b> - Identifies the purpose for the transaction</li> <li><b>Patient Consent Information</b> - Identifies the patient consent information that may be required before data can be accessed.</li> <li><b>Query Request ID</b> - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.</li> </ul>

## III-G: Resource Location

### Interoperability Need: Resource location within the US

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Implementation Specification	<a href="#">IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation</a>	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>	<ul style="list-style-type: none"> <li>Feedback requested</li> </ul>

## Section IV: Questions and Requests for Stakeholder Feedback

Similar to the 2015 Advisory, this draft gives stakeholders a body of work from which to react in order to prompt continued dialogue to improve the Advisory. As stated in the Introduction, this draft 2016 Advisory will continue to be refined during the public comment period. Additionally, because this draft includes both new structural and content sections please note that content for many of the new structural subsections is intentionally incomplete. Those sections that are more fully populated were done so to give the public an early opportunity to weigh in on and react to perceived value that these subsections could provide. Your feedback is critical to improve and refine these new subsections. Please visit <http://www.healthit.gov/standards-advisory> to provide your comments and suggestions.

### General

- 4-1. In the 2015 Advisory, each standard and implementation specification was listed under a “purpose.” Prior public comments and HIT Standards Committee [recommendations](#) suggested that the Advisory should convey a clearer link to the ways in which standards need to support business and functional requirements. This draft attempts to do so and lists standards and implementation specifications under more descriptive “interoperability needs.” Please provide feedback on whether revision from “purpose” to “interoperability need” provides the additional requested context and suggestions for how to continue to improve this portion.
- 4-2. For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or “unknown” information.
- 4-3. For each standard and implementation specifications, there is a table that lists security patterns. This draft only includes select examples for how this section would be populated in the future. Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.
- 4-4. For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.

### Section I: Vocabulary/Code Set

- 4-5. Based on public feedback and HIT Standards Committee review, there does not appear to be a best available standard for several “interoperability needs” expressed in this section of the draft Advisory. Please provide feedback on whether this is correct or recommend a standard (and your accompanying rationale).

### Section II: Content / Structure

- 4-6. Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

- 4-7. In addition to the two interoperability needs already listed, are there others that should be included related to imaging? If so, what would the best available standard and/or implementation specifications be?
- 4-8. Should a more specific/precise aspect of DICOM be referenced for the implementation specification for this interoperability need?
- 4-9. The HIT Standards Committee recommended to ONC that clearer implementation guidance is required. Are there additional implementation specifications that should be considered for this interoperability need?

### **Section III: Services**

- 4-10. The 2015 Advisory's Section III, Transport has since been removed with content representation migrated as applicable within Section IV Services. What is your view of this approach?

### **Appendix II: Sources of Security Standards**

- 4-11. Are there other authoritative sources for Security Standards that should be included in Appendix II?



## Appendix I - Annual Process to Update the Interoperability Standards Advisory

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

- **December Preceding the Upcoming Calendar Year**
  - The new Interoperability Standards Advisory for the next calendar year is published (e.g., December 2016 for the 2017 Advisory).
  - A first round of an approximately 90- to 120-days of public comment period will be opened on that year's Interoperability Standards Advisory.
- **April/May**
  - Sometime during late April/early May the comment period will expire.
  - ONC staff will compile all comments received during the first round comment period.
  - ONC staff will present a summary of received comments to the HIT Standards Committee (or designated Task Force) in order to prepare them to make recommendations on updates for the following year's Interoperability Standards Advisory.
- **August**
  - The HIT Standards Committee submits recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory.
  - A second round of approximately 60-days of public comment will be opened on the HIT Standards Committee's recommendations concerning the Interoperability Standards Advisory.
- **October – December**
  - Sometime during October the comment period will expire.
  - ONC will review the HIT Standards Committee recommendations as well as public comments on those recommendations.
  - ONC will prepare the next year's Interoperability Standards Advisory for publication.

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

## Appendix II – Sources of Security Standards

*[See Question 4-11]*

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

- ASTM: <http://www.astm.org/Standards/computerized-system-standards.html>
- Information Organization for Standardization (ISO) Information Security Standards: <http://www.27000.org/>
- National Institute for Standards and Technology (NIST) Special Publications 800 Series: <http://csrc.nist.gov/publications/PubsSPs.html>
- NIST's Federal Information Processing Standard (FIPS): <http://www.nist.gov/itl/fipscurrent.cfm>

## Appendix III - Revision History

### Summary Level Description of Changes

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Abbreviated Introduction	With the 2015 Advisory, a great deal more 'explanatory' detail was offered to lend context and history and to spark necessary feedback. That level of information for the ISA 2016 within the Introduction was determined unnecessary. Any interest to access history and/or to gain context however, would be supported via link to 2015 Advisory.	<ul style="list-style-type: none"> <li>The ISA 2016 bypassed the need of an Executive Summary. The introduction sustained content deemed most relevant</li> <li>Scope precedes Purpose</li> <li>The two Purposes were mildly enhanced and one was added. The third addresses the biggest ISA 2016 change; namely, the added meta data to the table standards/implementation specification structure</li> </ul>
Document Restructuring	<p>The Public Comments and ISA Task Force received appreciable comments and direction from the Health IT Standards Committee (HITSC). In order to best serve the range of interests with this and subsequent ISA releases, the primary focus for the 2016 ISA was to address table restructuring -- particularly focused on finding the best way to add relevant characteristics of a standard/implementation specification thus offering added context.</p> <p>The breadth of changes to document structure has introduced noteworthy content which did extend the volume of the ISA, e.g., greater than 40 pages as compared to the 13 with the original ISA 2015.</p>	<ul style="list-style-type: none"> <li>Instead of using the term “purpose,” a section’s lead-in is framed to convey an “interoperability need” stakeholders may express to convey an outcome they would want to achieve with interoperability.</li> <li>Meta Data describing six informative characteristics has been added to each referenced standard and implementation specification to give readers an overall sense of maturity and level of adoption: Standards Process Maturity; Implementation Maturity; Adoption Level; Regulated; Cost &amp; Testing Tool Availability</li> <li>Interoperability Need has two subsections. <ul style="list-style-type: none"> <li>The first would identify any known limitations, dependencies, or preconditions associated with best available standards and implementation specifications.</li> <li>The second would identify, where applicable, known “security patterns” associated with best available standards and implementation specifications. This subsection’s goal would be to identify the generally reusable security techniques applicable to interoperability need(s) without prescribing or locking-in particular security standards.</li> </ul> </li> <li>Transport Section (previously ISA 2015 Section III)), has been removed: 1) it was deemed to not provide additional clarity/value to stakeholders; and 2) the standards and implementation specifications in the “services” section included them as applicable.</li> <li>A security standards sources appendix is included to point stakeholders to the entities that maintain and curate relevant security standards information</li> </ul>
Revised Questions	The questions offered, were structured to solicit feedback on changes made to the ISA 2016 and to assist in addressing recommendations where disposition is pending. These are found within Section IV	
Revision History	In order to capture the changes the first ISA received, a Revision History has been introduced and is found in Appendix III.	<ul style="list-style-type: none"> <li>The Revision History, Appendix III, records summary &amp; detailed levels changes and will record for the applicable ISA version, the additions, deletions and/or enhancements made as part of the annual review process.</li> <li>Given changes will continue during the Public Comment period and beyond, the Revision History will likewise be updated as changes occur and be cumulative in nature offering traceability.</li> </ul>

## Additions/Enhancements

Section / Interoperability Need	Standard Added	Description
<b>Overarching</b>		The Interoperability Needs reflected have received edits to expand the context and support the consolidation of like interoperability needs
<b>I-A: Allergies</b>	SNOMED-CT (Food Allergy) NDF-RT (Medication Allergen)	<ul style="list-style-type: none"> <li>Per HITSC recommendation, allergies were organized to add distinction between the reaction, the allergen causing the reaction and types of allergen</li> <li>HITSC recommendation were added via Limitations, Dependencies &amp; Preconditions supporting medications and environmental substances allergens</li> </ul>
<b>I-B: Care Team Member</b>		HITSC views/recommendations added via Limitations, Dependencies & Preconditions
<b>I-D: Race and Ethnicity</b>	CDC Race and Ethnicity Code Set Version 1.0	HITSC views/recommendation added via Limitations, Dependencies & Preconditions
<b>I-E: Family Health History</b>		HITSC views (around family genomic health history) added via Limitations, Dependencies & Preconditions
<b>I-G: Gender Identity, Sex and Sexual Orientation</b>	Reference/link to Fenway Institute of Medicine report offered For Male and Female patient sex (at birth), HL7 Version 3 Value Set for Administrative Gender For Unknown patient sex (at birth), HL7 Version 3 Null Flavor	<ul style="list-style-type: none"> <li>Area renamed &amp; reorganized to address interoperability needs connected to Gender Identity, Sex &amp; Sexual Orientation</li> <li>HITSC recommendation added via Limitations, Dependencies &amp; Preconditions</li> </ul>
<b>I-H: Immunizations</b>	For administered: HL7 Standard Code Set CVX—Clinical Vaccines Administered	Historical & Administered: HITSC views / recommendations (surrounding use of CVX and MVX codes) added via Limitations, Dependencies & Preconditions
<b>I-P: Radiology (interventions and procedures)</b>	LOINC	Replaced RadLex; per HITSC recommendation added via Limitations, Dependencies & Preconditions
<b>I-Q: Smoking Status</b>		HITSC recommendation describing the limitations in what SNOMED-CT captures added via Limitations, Dependencies & Preconditions
<b>II-A: Admission, Discharge, and Transfer</b>		<ul style="list-style-type: none"> <li>HITSC recommendation added via Limitations, Dependencies &amp; Preconditions citing acceptability of any HL7 2.x version messaging standard</li> <li>HITSC recommendation added via Limitations, Dependencies &amp; Preconditions surrounding available transport protocols</li> </ul>
<b>II-B: Care Plan</b>		HITSC recommendation added via Limitations, Dependencies & Preconditions citing availability of transport protocols
<b>II-C: Clinical Decision Support</b>		The standards and specifications supporting what were 3 areas have been combined under interoperability need of “Shareable clinical decision support
<b>II-D Drug Formulary &amp; Benefits</b>		HITSC recommendation added via Limitations, Dependencies & Preconditions related to monitoring NCPDP Real Time Prescription Benefit inquiry (RTPBI)

Section / Interoperability Need	Standard Added	Description
<b>II-E: Electronic Prescribing</b> <ul style="list-style-type: none"> <li>A prescriber's ability to create a new prescription to electronically send to a pharmacy</li> <li>Prescription refill request</li> <li>Cancellation of a prescription</li> <li>Pharmacy notifies prescriber of prescription fill status</li> <li>A prescriber's ability to obtain a patient's medication history</li> </ul>		Area reorganized to address five connected interoperability needs each with recommendations via Limitations, Dependencies and Preconditions to leverage their area's particular transaction and of necessity to have prescriber and receiving pharmacy systems configured to facilitate the exchange
<b>II-F: Family Health History</b>		HITSC recommendation added via Limitations, Dependencies & Preconditions related to lack of vocabulary for family genomic health history and a reference to transport of this data
<b>II-G: Images</b>	Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes	HITSC recommendation added via Limitations, Dependencies & Preconditions related to need for feedback on new SOP
<b>II-H: Laboratory</b>		
<ul style="list-style-type: none"> <li>Receive Lab test results</li> </ul>	<ul style="list-style-type: none"> <li>HL7 2.5.1 as Standard</li> <li>HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012 from Standard to Implementation Specification</li> <li>HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2</li> <li>US Realm as Emerging Alternative Implementation Specification</li> </ul>	Area reorganized to address the three connected interoperability needs and also notes the HL7 Laboratory US Realm Value Set Companion Guide, Release 1, Sep 2015 as a resource for each
<ul style="list-style-type: none"> <li>Ordering labs for a patient</li> </ul>	<ul style="list-style-type: none"> <li>HL7 2.5.1 as Standard</li> <li>HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm as Implementation Specification</li> </ul>	
<ul style="list-style-type: none"> <li>Support the transmission of a laboratory's directory of services to health IT</li> </ul>	<ul style="list-style-type: none"> <li>HL7 2.5.1 as Standard</li> <li>HL7 Version 2.5.1 Implementation Guide: S&amp;I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 as Standard</li> </ul>	
<b>II-J: Patient Preference/Consent</b>	IHE Basic Patient Privacy Consents (BPPC) IHE Cross Enterprise User Authorization (XUA)	Per HITSC recommendations, two implementation specifications added

Section / Interoperability Need	Standard Added	Description
<b>II-K: Public Health Reporting</b>		
<ul style="list-style-type: none"> <li>Reporting antimicrobial use and resistance information to PH agencies</li> </ul>		<ul style="list-style-type: none"> <li>Area reorganized to consolidate seven applicable PH Reporting interoperability needs</li> <li>HITSC recommendation added via Limitations, Dependencies &amp; Preconditions for stakeholders to refer to health departments in their jurisdiction for added information when transmitting information</li> </ul>
<ul style="list-style-type: none"> <li>Reporting cancer cases to PH agencies</li> </ul>	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm as Emerging Alternative Implementation Specification	
<ul style="list-style-type: none"> <li>Case reporting to PH agencies</li> </ul>	<ul style="list-style-type: none"> <li>Fast Healthcare Interoperability Resources (FHIR) &amp; Structured Data Capture Implementation Guide as Standard</li> <li><a href="#">Structured Data Capture Implementation Guide as Implementation Specification</a></li> </ul>	
<ul style="list-style-type: none"> <li>Electronic transmission of reportable lab results to PH agencies</li> </ul>	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 as Implementation Specification	
<ul style="list-style-type: none"> <li>Sending health care survey information to PH agencies</li> </ul>	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm inserted as replacement	
<ul style="list-style-type: none"> <li>Reporting administered immunizations to immunization registry</li> </ul>	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 added as an implementation specification  HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 reflected an emerging alternative as Emerging Alternative IS	
<ul style="list-style-type: none"> <li>Reporting syndromic surveillance to PH (ED, inpatient, and urgent settings)</li> </ul>	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent CareData Release 1.1 as Implementation Specification	
<b>II-L: Quality Reporting</b>	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 3 (US Realm)	
<b>II-O: Summary care record</b> <ul style="list-style-type: none"> <li>Support a transition of care or referral to another provider</li> </ul>	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 as emerging alternative Implementation Specification	HITSC recommendation added via Limitations, Dependencies & Preconditions regarding specific document templates within the C-CDA Implementation Specification and need for trading partners to have systems supporting the document templates

Section / Interoperability Need	Standard Added	Description
<b>III-A: An unsolicited ‘push’ of clinical health information to a known destination</b> <ul style="list-style-type: none"> <li>between providers</li> <li>between systems</li> </ul>	Fast Healthcare Interoperability Resources (FHIR) as an emerging alternative standard	<ul style="list-style-type: none"> <li>HITSC recommendation added via Limitations, Dependencies &amp; Preconditions regarding Direct standard and its basis standard (SMTP) and for security uses; Direct dependencies also relayed.</li> <li>Approximate nine Applicable Security Patterns were also listed for both interoperability needs</li> <li>The alignment of standards / implementations specifications received minor updates</li> </ul>
<b>III-E: Resource Location</b>	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation reflected from standard to an Implementation Specification	
<b>III-F: Provider Directory</b>	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation reflected from standard to an Implementation Specification	
<b>III-G: Publish and Subscribe</b>	NwHIN Specification: Health Information Event Messaging Production Specification reflected from standard to an Implementation Specification IHE Document Metadata Subscription (DSUB), Trial Implementation as an Emerging Alternative Implementation Specification	

#### Deletions / Refinements

Section / Interoperability Need	Standard Removed	Description
<b>I-N: Preferred Language</b>	Refined from 4 to 1: RFC 5646	HITSC recommendation added via Limitations, Dependencies & Preconditions citing the fact RFC 5646 contains the others originally listed
<b>I-P: Radiology (interventions and procedures)</b>	RadLex	Replaced by LOINC
<b>II-K Public Health Reporting</b>  Sending health care survey information to PH agencies	HL7 Implementation Guide for CDA® Release 2: National Ambulatory Medical Care Survey (NAMCS), Release 1, US Realm, Volume 1- Introductory Material, Draft Standard for Trial Use replaced	