# 2016 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

***Best Available Standards and Implementation Specifications***

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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.

<u>"Best Available" Characteristics</u>

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

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

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

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

**Interoperability need: [Descriptive Text]**

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

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Descriptive text with "(recommended by the HIT Standards Committee)" included in cases where the HIT Standards Committee recommended the text, and on which public feedback is sought. | • Descriptive text |

The following describes the six characteristics that were added to the Advisory in detail 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.

[1] This approach uses a subset of the key attributes described in "Evaluating and classifying the readiness of technology specifications for national standardization Dixie B Baker, Jonathan B Perlin, John Halamka, Journal of

#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$"*– 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.

***HL7 - GENERAL COMMENTS:***

*Below are Health Level Seven's (HL7's) overarching and general comments on the 2016 Interoperability Standards Advisory (Advisory).*

*Overall, the Advisory is a good, progressive step forward, although some areas still need notable attention and work. Its restructuring allows for a better sense of the current state of adoption. The introduction of the six characteristics (Standards Process Maturity, Implementation Maturity, Adoption Level, Regulated, Cost, and Test Tool Availability) is helpful in understanding whether a standard is fit for regulatory endorsement, i.e., wide industry adoption. HL7 notes two important caveats however.*

> *The Standards Process Maturity characteristics in particular would need more work as they give an insufficient impression of the state of a standard than is at times reasonable. For example, C-CDA is marked as Draft, while the various Direct guides are marked as Final and one could submit that they are at least equal in terms of Standards Process Maturity. We suggest to express a neutral rating that focuses on official publication (draft if not formally published and final if published) and perhaps an indication of its expected volatility (errata, new version, etc.). This can be improved on over time.*
>
> *The second caveat is the importance of clarifying "the best standard for what". This remains a challenge with the 2016 Advisory. While the Advisory's new organization and section titles are a step in the right direction, it is still difficult to understand specific uses. This is very clear when looking at standards for Care Plan in the Advisory as an example. Depending on the use case, the suggested standard is acceptable, or insufficient. HL7 re-emphasizes that without such perspective, valuation of the Advisory remains elusive. Endorsing standards without such an understanding results in the unintended consequence of investing in the wrong solutions and even hampering innovation by focusing on the wrong problems.*

*We would like to get clarification on how use cases are being established that are in need of standards. The Advisory and its approach seem to be built around known standards rather than from critical use cases, gaps and input on user needs. Various standards were proposed for the 2015 Edition but did not get included in the final rule, and they did not make it in the Advisory either, e.g., esMD. HL7 believes that the Advisory should over time become a predictor of what will be endorsed for national adoption. Therefore, we suggest that the Advisory considers the various standards that did not make it into the 2015 Edition, or clarify that they are no longer being considered.*

*As the Advisory indicates, it is important to define the purpose or use case for a specific standard. HL7 believes it is equally important, particularly for vocabulary, to define the specific sets within a standard that are applicable for the use case at hand. For vocabulary, HL7 suggests a clarification about specific branches within a vocabulary for the use case at hand. Establishing such constraints requires consensus across clinicians and standards / implementation guide developers. HL7 welcomes participation in the development of its standards and guides, to arrive at the appropriate value sets and is ready to work with ONC and professional organizations to establish an effective process to achieve that. HL7 provides bindings to specific vocabulary / value sets in its standards and more importantly, in its implementation guides to reduce ambiguity. We suggest that ONC recognizes the introduction of these value sets as the appropriate place to have the binding at the right level of granularity.*

*Regarding testing, it is important that proposed standards must be tested sufficiently prior to inclusion in rule making. The Standards Advisory is a helpful tool to create a sketch of what direction we are heading in this area. It is important in that context to enable providers and vendors to test new versions of standards, so there is a high confidence that adoption has value and is feasible across the industry as a whole. HL7 is ready to work with ONC and other parties to address testing and pilot programs of its standards to address this critical issue and to provide a feedback loop to further improve on its standards and implementation guides before wide endorsement through regulation.*

*Lastly, if we want to achieve interoperability, it is critical that systems have required functionality to support it. To this end, HL7 has developed and consensus-approved a suite of Functional Models (FMs) and Functional Profiles for EHR and PHR systems. The FMs have also been promoted to ISO, are ISO consensus approved and are now published as International Standards which are:*

- *1) ISO/HL7 10781 EHR System Functional Model, Release 2, aka EHR-S FM (published by HL7 2014, ISO 2015)*
  *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269*
- *2) ISO/HL7 16527 PHR System Functional Model, Release 2, aka PHR-S FM (published by HL7 2014, ISO 2015)*
  *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=88*

*To enable interoperability as part of US Meaningful Use, HL7 has developed and approved via consensus:*

- *3) HL7 Meaningful Use Functional Profile for Stages 1&2, based on ISO/HL7 10781 EHR-S FM (published 2015)*
  *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=409*

*To enable interoperability for public/population health, we have development (in collaboration with the US Centers for Disease Control and Prevention (CDC)) and approved via consensus:*

- *4) HL7 Public Health Functional Profiles, suite of nine (9) FPs for specific public health services/domain areas, based on ISO/HL7 10781 EHR-S FM (published 2015)*
  *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=278*

*To enable interoperability of EHR/PHR record content when implementing HL7 Fast Health Interoperable Resources (FHIR), we have developed and approved via consensus:*

- *5) HL7 Record Lifecycle Event Implementation Guide, part of FHIR DSTU-2, based on EHR-S FM Record Infrastructure Chapter, Record Entry Lifespan and Lifecycle (published September 2015)*
  *http://hl7.org/fhir/ehrsrle/ehrsrle.html*

*To enable interoperability between providers and laboratories we are developing a functional model and requirements to augment the laboratory test compendium, order, and result implementation guides, with an initial focus on the results. This should be referenced as an emerging guide that is in draft and to be published very soon.*

*HL7 suggests the inclusion of these Functional Models/Profiles and the FHIR Implementation Guide in a new category in the Advisory.*

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

***HL7 Comments***

*Overall, HL7 continues to be concerned with the adoption of UCUM for all units of measure. We suggest inclusion of this standard in this section to further the message to adopt this standard, while recognizing that some resistance remains to its full adoption in all areas.*

## I-A: Allergies

***HL7 Comments***

*The issue with interoperability of allergy information is a lack of standardization as to what is meant by an allergy or adverse reaction, or what the severity is. We suggest further clarification in this context.*

*We also note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this, it remains important to be more specific.*

| Interoperability Need: Representing patient allergic reactions | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption Level** | **Regulated** | **Cost** | **Test Tool Availability** |
| **Standard** | SNOMED-CT | Final | Production | ●●●●○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Feedback requested<br>. | • Feedback requested |

## Interoperability Need: Representing patient allergens: medications

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | RxNorm | Final | Production | ●●●●○ | Yes | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee) | • Feedback requested |

## Interoperability Need: Representing patient allergens: food substances

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |

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

## Interoperability Need: Representing patient allergens: environmental substances

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | ***[See Question 4-5]*** | | | | | | |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Currently, there are no vocabulary code sets considered "best available" for environmental allergens. | • Feedback requested |

## 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** | National Provider Identifier (NPI) | Final | Production | ●●○○○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • 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'.<br>• 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. | • Feedback requested |

## I-C: Encounter Diagnosis

***HL7 Comments***

*We note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this it remains important to be more specific.*

**Interoperability Need: Documenting patient encounter diagnosis**

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

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

## 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** | OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997 | Final | Production | ●●●●● | Yes | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The CDC Race and Ethnicity Code Set Version 1.0, which expands upon the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient.<br>• 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. | • Feedback requested |

## I-E: Family Health History

***HL7 Comments***

*We note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this it remains important to be more specific.*

**Interoperability Need: Representing patient family health history**

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

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee) | • Feedback requested |

## 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** | ***[See Question 4-5]*** | | | | | | |

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

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

***HL7 Comments***

*We note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this it remains important to be more specific.*

**Interoperability Need: Representing patient gender identity**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |

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

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

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | For Male and Female, HL7 Version 3 Value Set for Administrative Gender | Final | Production | ●●●●○ | No | Free | N/A |
| **Standard** | For Unknown, HL7 Version 3 Null Flavor | Final | Production | ●●●●○ | No | Free | N/A |

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

**Interoperability Need: Representing patient sexual orientation**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |

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

## I-H: Immunizations

**Interoperability Need: Representing immunizations – historical**

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

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

| | |
|---|---|
| • HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information.<br>• 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. | • Feedback requested |

**Interoperability Need: Representing immunizations – administered**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | HL7 Standard Code Set CVX—Clinical Vaccines Administered | Final | Production | ●●●●● | Yes | Free | N/A |
| **Standard** | National Drug Code | Final | Production | ●●●●● | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information.<br>• 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. | • Feedback requested |

## 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** | ***[See Question 4-5]*** | | | | | | |

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

## I-J: Lab tests

***HL7 Comments***

*HL7 encourages ONC to work with industry to make appropriate LOINC, UCUM, and UDI, i.e., devices, available upstream (part of the devices) for downstream use, and to work with Regenstrief to identify ways to accelerate the registration process for LOINC.*

**Interoperability Need: Representing laboratory tests and observations**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | LOINC | Final | Production | ●●●●○ | Yes | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • 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.<br>• 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. | • Feedback requested |

## 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** | RxNorm | Final | Production | ●●●●● | Yes | Free | N/A |

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

## 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** | The Unified Code of Units of Measure | Final | Production | ●●●○○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations. | • Feedback requested |

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

***HL7 Comments***

*We note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this it remains important to be more specific.*

| 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** | SNOMED-CT | Final | Production | ●●●●● | Yes | Free | N/A |

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

## 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** |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | RFC 5646 | Final | Production | Unknown | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language. | • Feedback requested |

## 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** | Code on Dental Procedures and Nomenclature (CDT) | Final | Production | ●●●●● | Yes | $ | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • CDT is a proprietary terminology standard. | • Feedback requested |

### Interoperability Need: Representing medical procedures performed

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | SNOMED-CT | Final | Production | ●●●●● | Yes | Free | N/A |
| **Standard** | the combination of CPT-4/HCPCS | Final | Production | ●●●●● | Yes | $ | N/A |
| **Standard** | ICD-10-PCS | Final | Production | ●●●●○ | Yes | Free | N/A |

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

## 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** | LOINC | Final | Production | ●●○○○ | No | Free | N/A |

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

## I-Q: Smoking Status

***HL7 Comments***

*We note that selecting "SNOMED-CT" is insufficient and requires identification of the specific branch(es) that are applicable to this use case. HL7 strives to provide that level of clarity in its implantation guides, but believes that in general references such as this it remains important to be more specific.*

| Interoperability Need: Representing patient smoking status | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption Level** | **Regulated** | **Cost** | **Test Tool Availability** |
| **Standard** | SNOMED-CT | Final | Production | ●●●●● | Yes | Free | N/A |

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

## I-R: Unique Device Identification

***HL7 Comments***

*HL7 notes that there is still work in progress on how to exactly represent the UDI in C-CDA, FHIR, and V2. To date the focus was on conveying the human readable format of the barcode only (inclusive of the UDI), while the FDA recently started to emphasize communicating the individual product identifier components as well. In essence, the standard of the UDI definition is final, but the definition on how to communicate it is not complete, thus in draft form. Specifically, C-CDA*

*does not have any formal structure to communicate anything but the human readable format of the barcode. There are options on how the UDI components can individually be communicated outside the barcoded string, but there is no final guidance yet how to consistently do so. Therefore, the impression that UDI has been fully defined (Standards Process Maturity = final) is inappropriate and the Implementation Maturity of production is premature. HL7 suggests inclusion of a separate row (sample below) in the relevant Section II sections to capture the emerging guidance clarifying on how to communicate the relevant data in either V2 messages, C-CDA documents, or FHIR.*

**Interoperability Need: Representing unique implantable device identifiers**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3 | Final | Production | ●○○○○ | Yes | Free | N/A |
| **Emerging Implementation Specification** | Harmonization Pattern for Unique Device Identifiers | Draft | Pilot | | No | Free | N/A |

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

## 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** | LOINC | Final | Production | ●●●●● | No | Free | N/A |

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

# I-T: HL7 Privacy and Security Healthcare Classification System [HCS] – HL7 PROPOSED

***HL7 Comments***

*HL7 and its Security and Community Based Collaborative Care (CBCC) Work Groups recommend that the ISA include the normative HL7 Privacy and Security Healthcare Classification System [HCS] because it encompasses vocabulary for the confidentiality Code that is required for use in:*

- *All CDA Implementation Guides at the Document Header, and may be used at the Section level because it is required in the base CDA R2 standard;*
- *The IHE XDS Soap Headers required by Meaningful Use, which must include at least the confidentialityCode and may include other HCS vocabulary for e.g., purpose of use and obligations[2];*
- *The Direct XDR/XDM option for Meaningful Use, which must include at least the confidentialityCode and may include other HCS vocabulary for e.g., purpose of use and obligations; and*

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[2] *IHE IT Infrastructure Technical Framework, Volume 3 (ITI TF-3): Cross-Transaction and Content Specifications Rev. 11.0 Final Text – 2014-09-23 p.62*

***4.2.3.2.5 DocumentEntry.confidentialityCode***
***Description:***
*The code specifying the security and privacy tags of the document. These codes are set by policy of the participants in the exchange, e.g., XDS affinity domain. confidentialityCode is part of a codification scheme.*
*The confidentialityCode can carry multiple vocabulary items. HL7 has developed an understanding of security and privacy tags that might be desirable in a Document Sharing environment, called HL7 Healthcare Privacy and Security Classification System (HCS). The following specification is recommended but not mandated by IHE, as the vocabulary bindings are an administrative domain responsibility.*
*Each confidentialityCode is coded within an ebRIM Classification object. See Section 4.2.3.1.2 for a description of coding an ebRIM Classification. There shall be zero or more ebRIM Classification containing a confidentiality code (some profiles require at least one). Multiple values of confidentialityCode are coded by specifying multiple classification objects.*

***Table 4.3.1.1-3: Sending Actor Metadata Attribute Optionality*** *page 103*

| ***Metadata Element*** | ***Metadata Attribute*** | ***XDS DS*** | ***XDS DR*** | ***XDM MC*** | ***XDR DS*** | ***XDR MS*** | ***XDS OD*** |
|---|---|---|---|---|---|---|---|
| *DocumentEntry* | *confidentialityCode* | *R* | *R* | *R2* | *R* | *R2* | *R* |

- *Data Segmentation for Privacy, which, like all CDA profiles, requires confidentialityCode at the Document Header, recommends it at the Section level, recommends inclusion of a Privacy Marking section for security labels pertaining to the entire Document, and recommends inclusion in Privacy Annotations or Security Labels at the CDA Entry Level.*

*In addition, it is used in the draft FHIM Privacy and Security Architecture Framework, which is updating the expired HL7 Security and Privacy Domain Analysis Model.*

*For these reasons, the HL7 and its Security and CBCC Work Groups support the ISA recommending increasing the adoption level to at least 61% to 80% adoption and to indicate that the specification has been adopted indirectly because DS4P, Exchange, and Direct XDR/XDM are adopted in regulation. These recommendations are captured below in an ISA table.*

| Interoperability Need: Representing privacy and security classification of healthcare information | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption Level** | **Regulated** | **Cost** | **Test Tool Availability** |
| **Standard** | HL7 Privacy and Security Healthcare Classification System [HCS] | Final (Normative) | Production | ●●●●○ | Yes since required in DS4P and optional in XD* | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Feedback requested | • ITI-3 p. 63 Use of Sensitivity tags expose the nature of the sensitivity and should be used only when the end-to-end confidentiality of the tags can be assured. |

## I-U: HL7 Role Based Access Control [RBAC] Catalog – HL7 PROPOSED

***HL7 Comments***

*HL7 and its Security and Community Based Collaborative Care (CBCC) Work Groups recommend that the ISA include the normative HL7 Role Based Access Control Catalog for purposes of enabling trading partners to exchange interoperable role information in patient consent directives and trust policies, and to enable access control systems to enforce data segmentation. This standard is based on ASTM E 1986 roles and maps these to well understood healthcare information objects to create coded RBAC permissions, which can be shared with trading partners that require recipients to comply with the sender's access control policies.*

*This approach is used in the Authorization Framework used for Exchange where roles of recipients are matched to determine permission of the resources requested/disclose.*

**Interoperability Need: Representing role based access control**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | *HL7 Role Based Access Control Catalog* | Final | Production | ●●●●○ | to the extent used in MU Exchange | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • *Near term enhancement: HL7 Security and CBCC WGs are balloting an update to the RBAC Catalog to include Attribute Based Access Control codes for clearances, which leverage the HL7 Healthcare Classification System security labels, to enable data segmentation.* | • *Conveyance of role and clearances in attribute and authorization certificates must be encrypted.* |

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

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

***HL7 Comments***

*HL7 notes that there are many successful implementations of ADT using V2.3.1, V2.4, V2.5, etc. with various pre-adoptions of specific capabilities in more current versions. The Advisory suggests that best available is V2.x rather than being specific. There is no mention of its use within or across providers. While for intra-provider use the current variations are manageable, for inter-provider interoperability, narrowing of the best available would be appropriate. HL7 suggests for inter-provider interoperability and other purposes, promoting V2.5.1 as best available as most other V2.x based implementation guides using ADT componentry are V2.5.1 based (e.g., immunizations, laboratory, etc.). We also emphasize a need to establish implementation guides when communication of ADT events becomes a requirement, to ensure consistency.*

**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 |
|---|---|---|---|---|---|---|---|

| 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 |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Any HL7 2.x version messaging standard associated with ADT is acceptable.<br>• 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. | • Feedback requested |

## II-B: Care Plan

***HL7 Comments***

*This is an example where the use of "draft" is done inconsistently in this section. If "draft" is meant to reflect the DSTU, then it is done right, but a couple of others in subsequent sections are not. However, we point to our general comments that this approach is creating an inconsistent perspective across standards as not all use the same process steps and designations. See our general comments for further considerations.*

*We are concerned that the level of granularity for the use case may give the wrong impression on available standards. While the C-CDA has the ability communicate care plans data, in the rapidly evolving shift from FFS to value based payment models that require tight coordination across providers, static exchange of such care plans can work for simple use cases, but not for those patients where tight coordination is most critical. The ISA does not reflect the understanding that much more work is required to get to an approach to address the more complex virtual coordination across providers and the standards needed for that process. This will drive the need to have more advanced standards than what we have today. In summary, the current line item gives a false sense of comfort in a very challenging area which should be reflected in the limitations, or by adjusting the title.*

**Interoperability Need: Documenting patient care plans**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 | Draft | Pilot | Unknown | No | Free | No |

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

## II-C: Clinical Decision Support

***HL7 Comments***

*There is considerable work in progress to harmonize standards for CDS and Quality Measures with a focus on moving towards FHIR. HL7 notes that it is not clear from the Advisory that this work in progress and that some of the standards referenced as a result would change soon. HL7 recommends that an additional row be included to highlight the emerging standards.*

The Physician Fee Schedule final rule indicated a likely delay in the implementation of Appropriate Use Criteria (AUC) given the challenges to name the mechanisms in time for a January 1, 2017 roll-out. As this effort involves the need to endorse standards for HIT to interact with AUC service providers and communicate such data along with the order and likely the claim, we suggest that it is very timely to identify the emerging standards that are being developed and tested and that are likely candidates for approved mechanisms to be based on. We suggest to recognize these current efforts, based primarily on HL7 V2 and FHIR, as emerging implementation specifications to provide an early indication how these requirements can be consistently supported. Note that GAO profile is currently slated to go through the HL7 January 2016 ballot cycle (opening December 2015) to adopt as a FHIR profile.

**Interoperability Need: Shareable clinical decision support**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use. | Draft | Pilot | Unknown | No | Free | No |

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

## Interoperability Need: Provide access to appropriate use criteria

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ●○○○○ | No | Free | |
| Emerging Implementation Specification | IHE/HL7 Guideline Appropriate Ordering (GAO) | Draft | Pilot | None | No | Free | No |

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

## Interoperability Need: Communicate AUCs with the order and charge to the filling provider and billing system for inclusion on claims.

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | HL7 V2.5.1 | Final | Production | ●●●●● | No | Free | |
| Emerging Implementation Specification | IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT) | Draft | Pilot | None | No | Free | No |

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

## II-D: Drug Formulary & Benefits

**Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | NCPDP Formulary and Benefits v3.0 | Final | Production | ●●●●● | Yes | $ | No |

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

## 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** | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | ●●●●● | Yes | $ | Yes |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The "New Prescription" transaction is best suited for this interoperability need.<br>• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | • Feedback requested |

**Interoperability Need: Prescription refill request**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | ●●●●○ | No | $ | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The "Refill Request" transaction is best suited for this interoperability need.<br>• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | • Feedback requested |

**Interoperability Need: Cancellation of a prescription**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | Unknown | No | $ | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The "Cancel" transaction is best suited for this interoperability need.<br>• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | • Feedback requested |

## 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** | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | Unknown | No | $ | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The "Fill Status" transaction is best suited for this interoperability need.<br>• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | • Feedback requested |

## 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** | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | ●●●○○ | No | $ | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The "Medication History" transaction is best suited for this interoperability need.<br>• Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | • Feedback requested |

## II-F: Family health history (clinical genomics)

***HL7 Comments***

*This represents another example where the use of "final" vs. "draft" causes confusion. The implementation guide is an informative document, but marked final. That is correct from a publication perspective, but when comparing it to a DSTU that is marked "draft" it creates the potentially wrong impression that one is more mature than the other.*

**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** | HL7 Version 3 Standard: Clinical Genomics; Pedigree | Final | Production | ●○○○○ | Yes | Free | No |
| **Implementation Specification** | HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1 | Final | Production | ●○○○○ | No | Free | No |

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

## II-G: Images

***[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** | Digital Imaging and Communications in Medicine (DICOM) | 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** | Digital Imaging and Communications in Medicine (DICOM) | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture. | Final | Production | ●○○○○ | No | Free | No |

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

## II-H: Laboratory

***HL7 Comments***

*The three guides are listed as pilot. HL7 suggests that this family of implementation guides provides a good example where active promotion for early adoption is essential to drive towards consistent exchange of lab orders, results, and compendium. HL7 looks forward to work with ONC to identify opportunities to promote such implementations.*

*Considering the publication of this Advisory being in the timeline of publishing newer versions of the respective guides, HL7 offers the following status at time of our feedback:*

- *LRI IG Release 1 DSTU 2 is published and available at this link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279*
- *LOI IG Release 1 DSTU 2 is not yet published, but is expected to be out shortly.*
- *eDOS IG Release 2 DSTU 2 is published and available at this link: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=151*
- *The EHR-S Functional Requirements for Lab Results is in draft and will be available shortly.*

*HL7 notes that the LOI IG R1 DSTU 2 should be marked as an emerging standard as there is no piloting nor wide adoption yet.*

*HL7 also suggests that the EHR-S Functional Requirements document is already listed in the Limitations, Dependencies, and Preconditions for Consideration section of the laboratory results as it provides further guidance how to process results received using the LRI IG.*

## Interoperability Need: Receive electronic laboratory test results

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

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. | • Feedback requested |

## Interoperability Need: Ordering labs for a patient

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | HL7 2.5.1 | Final | Production | ●●●●● | No | Free | No |
| **Implementation specification** | HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm *[no hyperlink available yet]* | Draft | Pilot | ●○○○○ | No | Free | No |

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

| | |
|---|---|
| • HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. | • Feedback requested |

**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** | HL7 2.5.1 | 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 *[no hyperlink available yet]* | Draft | Pilot | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. | • Feedback requested |

## 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** | HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2. | Final | Production | ●●●●○ | Yes | Free | No |
| **Implementation Specification** | HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1. | Final | Production | ●●●○○ | No | Free | No |

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

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

## II-J: Patient Preference/Consent

***[See Question 4-9]***

***HL7 Comments***

*HL7 supports this Advisory appraisal as stated in the table below.*

*We note that implementers of DS4P depend on the standards used to capture patient preferences as noted above in addition to their adoption of BPPC. However, HL7 is not clear on the relationship that ONC perceives between XUA and BPPC and asks that this be clarified. The appearance is that somehow XUA depends on or adds to BCPP. XUA is a well-established authentication IHE profile, and is a precondition of any authorization protocol that would determine whether the requester's claims [e.g., Oasis XSPA SAML assertion as to the requestor's role, clearance [aka HCS clearances], context [e.g., HCS Compartment] meet or exceed the Custodian's security labels on the requested content. The source of the Custodian's security labels, i.e., the XD* confidentialityCodes, cannot be derived from the unstructured patient preferences conveyed by BPCC. So there is a disconnect between enforcement of BPCC instance.*

**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** | IHE Basic Patient Privacy Consents (BPPC) | Final | Production | ●●●●○ | No | Free | No |
| **Implementation Specification** | IHE Cross Enterprise User Authorization (XUA) | Final | Production | ●●●●○ | No | Free | No |

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

| • Feedback requested | • *Control access as with all patient consent directive information.* |
|---|---|

## II-: HL7 Privacy Consent Directive CDA IG – HL7 PROPOSED

***HL7 Comments***

*HL7 reccommends that the ISA include the normative HL7 Privacy Consent Directive CDA IG to enable interoperable and computable consents expressed as structured HL7 privacy and security vocabulary, BPPC, and as XACML policies. This standard is the only specification available for encoding consent rules that can be enforced by data segmentation. The BPPC cannot meet these criteria, and yet is also able to be encapsulated in the Consent Directive CDA as unstructured content, as a Consent URI, as an XACML rule, or as an externally reference document. The HL7 Consent Directive IG enables an interoperable "glide path", as coined by John Halamka, for trading partners at various levels of maturity to support patient preferences as end user develop capabilities to consume and computably enforce these consent directives.*

*The HL7 Security and CBCC WGs recommend that ONC consider that by including the DS4P in 2015 Edition Health IT Certification Criterion they make it incumbent on § 170.315(b)(7) outbound implementers to be capable of manually or computably transforming patient preferences into security labeling on the outbound CDAs and make it incumbent on § 170.315(b)(8) inbound implementers to parse these preferences into enforcing access control decisions. If the inbound implementer receives unstructured consent directives or references to external location of patient agreed to BPPC consent directive templates, then these implementers have an additional discovery, retrieve, and manually parse these unstructured patient preferences. This does not scale. The only available means for automating the generation and consumption of patient consent directives in CDA based exchanges is to use the HL7 Consent Directive CDA IG.*

*Our recommendations are captured in the table below.*

**Interoperability Need:**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release | Final *Note in process of being published as Normative* | Production | ●○○○○ *Implemented in Prince George's County and in other SAMHSA Consent2Share Operational installations.* | No | Free | Yes, SAMHSA Consent2Share has conformance testing tools |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Feedback requested | • As with any transaction related to contracts, policies, consent directives, access control mechanisms need to be in place to enforce sender's security, privacy, and trust policies. |

## II- Data Provenance CDA IG – HL7 PROPOSED

***HL7 Comments***

*HL7 recommends that the ISA include the HL7 Data Provenance CDA IG Draft Standard for Trial Use at the pilot and lowest adoption level as this is the only available specification that constrains the CDA, C-CDA, and DS4P to ensure that trading partners can establish Provenance policies as to the key metadata needed to establish the authenticity, reliability, and trustworthiness of the CDA content they exchange.*

*HL7 views this as a current and steadily increasing business need as healthcare "consumer" systems deal with the proliferation of copies, extracts, and aggregation of CDA content the WGs anticipate them receiving, and these systems' need to develop automated "integration" rules such that, e.g., trusted content can be automatically integrated while less reliable content can be manually reviewed or sequestered.*

*Our recommendations are captured in the Advisory table below.*

**Interoperability Need:**

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | HL7 Data Provenance CDA IG Draft Standard for Trial Use<br><br>(official link is challenged, this link can be used internally while we get the right link) | Final DSTU | Pilots – ONC DPROV | ●○○○○ | no | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Feedback requested | • Application of the DPROV IG constraints may enforce inclusion of sensitive information such |

| | |
|---|---|
| | as the provide type, id, and role, which may disclose protected information. In addition, since the DPROV IG inherits both the C-CDA General Header and the DS4P CDA constraints, the same precautions recommended for DS4P and XD* regarding protected security labels pertains. |

## II-K: Public Health Reporting

***HL7 Comments***

*HL7 suggests that the references to FHIR and Structured Data Capture need the versions (DSTU 2 and Release 1 DSTU respectively).*
*HL7 notes that the Electronic Laboratory Reporting to Public Health (ELR) Release 2 DSTU 1.1 is available. Therefore, if other DSTUs are marked as final, this one should be as well. However, note the general comments on the use of "draft" vs. "final".*

**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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm. | Final | Production | ●●○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • This is a national reporting system to CDC. Stakeholders should refer to implementation guide for additional details and contract information for enrolling in the program. | • Feedback requested |

**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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm | Draft | Production | ●●●○○ | Yes | Free | Yes |
| ***Emerging Alternative Implementation Specification*** | *HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm* | *Draft* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements. | • Feedback requested |

## 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** | IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0 | Draft | Pilot | ●○○○○ | No | Free | No |
| **(2) Standard** | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ●○○○○ | No | Free | No |
| **(2) Implementation Specification** | Structured Data Capture Implementation Guide | Draft | Pilot | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Electronic case reporting is not wide spread and is determined at the state or local jurisdiction. | • Feedback requested` |

## 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** | HL7 2.5.1 | Final | Production | ●●●●● | Yes | Free | No |
| **Implementation specification** | HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification | Final | Production | ●●●●● | Yes | Free | Yes |
| ***Emerging Alternative Implementation Specification*** | *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1* | *Draft* | *Pilot* | *Unknown* | *No* | *Free* | *No* |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. | • Feedback requested |

## 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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm ***[See Question 4-6]*** | Draft | Pilot | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation. | • Feedback requested |

## 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** | HL7 2.5.1 | Final | Production | ●●●●● | Yes | Free | No |
| **Implementation Specification** | HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 | Final | Production | ●●●●● | Yes | Free | Yes |
| ***Emerging Alternative Implementation Specification*** | *HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5* | *Final* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements. | • Feedback requested |

## 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** | HL7 2.5.1 | Final | Production | ●●●●● | Yes | Free | No |
| **Implementation Specification** | PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1 | Final | Production | ●●●●○ | Yes | Free | Yes |
| ***Emerging Alternative Implementation Specification*** | *PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0* | *Final* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements. | • Feedback requested |

## 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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1 | Draft | Production | ●●●●○ | Yes | Free | Yes |

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

| Interoperability Need: Reporting patient-level quality data to quality reporting initiatives | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption Level** | **Regulated** | **Cost** | **Test Tool Availability** |
| **Standard** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm) | Draft | Production | ●●●●○ | Yes | Free | Yes |
| **Emerging Alternative Implementation Specification** | HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm) | 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"

***HL7 Comments***

*HL7 is not clear on the use case this is attempting to reflect. What is the use case that requires clinical health information to be represented as a resource? The ability to, e.g., query more granular data or enable RESTful service access to individual data elements within the Common Clinical Data Set (where "data element" effectively equates to individual concepts represented in the CCDS) seem to be the real underlying use cases and as such should be recognized.*

*HL7 notes that the version of FHIR should be referenced (DSTU 2) and also suggests that the FHIR specification includes maturity statements for each resource that can inform the implementer whether the definition is sufficiently mature for their need. Since FHIR DSTU 2 is officially published, this is another example where the Standards Process Maturity is not consistently applied.*

| 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** | Fast Healthcare Interoperability Resources (FHIR) | 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

***HL7 Comments***

*HL7 recommends that the Advisory increase the maturity measures for the normative Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 to:*

*Implementation Maturity = Production*
*Adoption Level = 61% to 80% adoption*
*Regulated = yes, as it is named in the 2015 Edition Health IT Certification Criterion at § 170.315(b)(7) and § 170.315(b)(8)*

*In addition, HL7 recommends that the Advisory include DS4P Part 2: NwHIN Direct and Part 3: NwHIN Exchange Transport Profiles for use with the DS4P Part 1: CDA R2 and Privacy Metadata Reusable Content Profile when using those transport protocols.*

*We also recommend that the ISA include Applicable Security Patterns for Consideration that ensure that only authorized users access the DS4P Privacy Marking Section or any Privacy Annotations that could reveal protected information.*

*This caution would not pertain to implementers of the 2015 Edition Health IT Certification Criterion at § 170.315(b)(7) and § 170.315(b)(8) criteria as those do not require inclusion of these components of the DS4P. However, for Meaningful Use implementers of DS4P wishing to convey information governed by 42 CFR Part 2, Title 38 Section 7332, or more stringent state laws or organizational policies in a manner that permits more fine grain segmentation, this access control consideration should be heeded. Our recommendations are captured in the Advisory table below.*

| 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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | In process of Normative 2 ballot | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 | Final | Production at header and XD* | ●●●●○ | Yes | Free | Yes |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Suite of conformance tests developed by ONC DS4P project | • Access Control systems must ensure that only authorized users are able to access the DS4P Privacy Marking section or any Privacy Annotations that include HCS |

## II-O: Summary care record

***HL7 Comments***

*HL7 recognizes that many stakeholders have indicated it is important to send the right amount of data to the right recipient at the right time. To date, too frequently the recipient has been overwhelmed with too much data. The 2015 Edition has provided more flexibility to tailor the data to the recipient's needs through additional document types and provider flexibility. HL7 suggests that further inclusion of other targeted document types and the imminent availability of improved query capabilities will enable improved scoping of data for a specific ToC at hand. Furthermore a project is in progress to address pertinent and relevant data that is aimed to address scoping the right data set as well. HL7 suggests that these efforts are recognized as emerging implementation specifications and that it is considered as another critical area to focus pilot projects.*

| 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** | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| **Implementation Specification** | Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm) | Draft | Production | ●●●●● | Yes | Free | Yes |
| ***Emerging Alternative Implementation Specification*** | *HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1* | *Draft* | *Pilot* | *Unknown* | *No* | *Free* | *No* |

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

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

***[See Question 4-10]***

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

***[See Question 4-3]***

***HL7 Comments***

*HL7 believes, based on implementer feedback, that XDR/XDM are at least, if not more widely adopted, than Applicability Statement for Secure Health Transport v1.1 ("Direct"). XDR andt hat XDM for Direct Messaging Specification provides far greater privacy, security, and provenance capabilities than "Direct". Given that most MU conformant EHRS and their partnering HIE and HISP business associates already use XD* for Exchange and have in place the governance and trust policies to support those exchanges, HL7 believes that the adoption level should be listed as equivalent to that of "Direct" in the ISA. In addition, we recommend that ONC accept their edits on the Applicable Security Patterns for Consideration.*

*This and other suggestions are in the Advisory table below.*

| 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 |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Standard** | Applicability Statement for Secure Health Transport v1.1 ("Direct") | Final | Production | ●●●●● | Yes | Free | Yes |
| ***Emerging Alternative Standard*** | *Applicability Statement for Secure Health Transport v1.2* | *Final* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |
| **Implementation Specification** | XDR and XDM for Direct Messaging Specification | Final | Production | ●●●●● | Yes | Free | Yes |
| **Implementation Specification** | IG for Direct Edge Protocols | Final | Production | ●●○○○ | Yes | Free | Yes |
| **Implementation Specification** | IG for Delivery Notification in Direct | Final | Production | ●●●○○ | No | Free | No |
| ***Emerging Alternative Standard*** | *Fast Healthcare Interoperability Resources (FHIR)* | *Draft* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |

| **Limitations, Dependencies, and Preconditions for Consideration:** | **Applicable Security Patterns for Consideration:** |
|---|---|
| • "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751.<br>• 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. | • **System Authentication** - The information and process necessary to authenticate the systems involved<br>• **Recipient Encryption** - the message and health information are encrypted for the intended user<br>• **Sender Signature** – details that are necessary to identity of the individual sending the message<br>• **Patient Consent Information** - Identifies the patient consent information that:<br>  ○ May be required to authorize any exchange of patient information<br>  ○ May be required to authorized access and use of patient information<br>  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply<br>• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user. |

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

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0<br>• The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1. | • **System Authentication** - The information and process necessary to authenticate the systems involved<br>• **Purpose of Use -** Identifies the purpose for the transaction<br>• **Patient Consent Information** - Identifies the patient consent information that ~~- may be required before data can be accessed.~~:<br>  ○ May be required to authorize any exchange of patient information<br>  ○ May be required to authorized access and use of patient information<br>  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply<br>• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user |

## 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 | HL7 Version 3 Standard: Decision Support Service, Release 2. | Draft | Pilot | ●○○○○ | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Implementation Specification | HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use | Draft | Pilot | ●○○○○ | No | Free | No |

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

**Interoperability Need: Retrieval of contextually relevant, patient-specific knowledge resources from within clinical information systems to answer clinical questions raised by patients in the course of care**

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

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

## III-C: Image Exchange

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

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| **Implementation Specification** | IHE Cross Enterprise Document Sharing for Images (XDS-I) | Draft | Pilot | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • 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** | IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation | Draft | Pilot | ●○○○○ | No | Free | Yes |

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

## 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** | NwHIN Specification: Health Information Event Messaging Production Specification | Final | Production | ●●●○○ | No | Free | No |
| ***Emerging Alternative Implementation Specification*** | *IHE Document Metadata Subscription (DSUB), Trial Implementation* | Draft | Pilot | ●○○○○ | No | Free | No |

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

## III-F: Query

***HL7 Comments***

*HL7* recommend**s that ONC accept the following** edits on the Applicable Security Patterns for Consideration.

**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** | IHE-XDS (Cross-enterprise document sharing) | Final | Production | ●●●●○ | No | Free | No |
| **Implementation Specification** | IHE-PDQ (Patient Demographic Query) | Final | Production | ●●●●○ | No | Free | No |
| **Implementation Specification** | IHE-PIX (Patient Identifier Cross-Reference) | Final | Production | ●●●●○ | No | Free | No |
| ***Emerging Alternative Implementation Specification*** | *IHE – MHD (Mobile Access to Health Documents)* | *Draft* | *Pilot* | ●○○○○ | *No* | *Free* | *No* |

| **Limitations, Dependencies, and Preconditions for Consideration:** | **Applicable Security Patterns for Consideration:** |
|---|---|
| • IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need. | • **System Authentication** - The information and process necessary to authenticate the systems involved<br>• **User Authentication –** The identity information and process necessary verify the user's identity<br>• **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction *for purposes of authorization. I.e., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access.*<br>• **Purpose of Use** - Identifies the purpose for the transaction, *and for the purposes for which the end user intends to use the accessed objects.*<br>• **Patient Consent Information** - Identifies the patient consent information that:<br>  ○ May be required to authorize any exchange of patient information<br>  ○ May be required to authorized access and use of patient information<br>  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply<br>• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.<br>• |

## 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 IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference) | Final | Production | ●●●●○ | No | Free | No |
| **Implementation Specification** | NwHIN Specification: Patient Discovery | Final | Production | ●●●○○ | No | Free | No |
| **Implementation Specifications** | IHE-XCA (Cross-Community Access) further constrained by eHealth Exchange Query for Documents v 3.0 | Final | Production | ●●●●○ | No | Free | No |
| **Implementation Specification** | NwHIN Specification: Query for Documents | Final | Production | ●●●○○ | No | Free | No |
| **Implementation Specification** | NwHIN Specification: Retrieve Documents | Final | Production | ●●●○○ | No | Free | No |

**Limitations, Dependencies, and Preconditions for Consideration:**

- IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.

**Applicable Security Patterns for Consideration:**

- **System Authentication** - The information and process necessary to authenticate the systems involved
- **User Authentication –** The information and process necessary to authenticate the end user
- ~~**User Details** – identifies the end user who is accessing the data~~
- **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction *for purposes of authorization. I.e., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access.*
- **Purpose of Use** - Identifies the purpose for the transaction*, and for the purposes for which the end user intends to use the accessed objects.*
- **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
  - May be required to authorize any exchange of patient information
  - May be required to authorized access and use of patient information
  - May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
- **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

| | |
|---|---|
| | • **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query. |

## 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** | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|---|
| • Feedback requested | • **System Authentication** - The information and process necessary to authenticate the systems involved<br>• **User Authentication** – The information and process necessary to authenticate the end user<br>• **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction *for purposes of authorization. I.e., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access.*<br>• **Purpose of Use** - Identifies the purpose for the transaction, *and for the purposes for which the end user intends to use the accessed objects.*<br>• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.<br>  ○ May be required to authorize any exchange of patient information<br>  ○ May be required to authorized access and use of patient information<br>  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply<br>• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.<br>• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.<br>• ~~**System Authentication** - The information and process necessary to authenticate the systems involved~~<br>• ~~**User Details** - identifies the end user who is accessing the data~~<br>• ~~**User Role** - identifies the role asserted by the individual initiating the transaction~~<br>• ~~**Purpose of Use** - Identifies the purpose for the transaction~~<br>• ~~**Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.~~<br>• ~~**Query Request ID** - Query requesting application assigns a unique identifier for~~ |

| | |
|---|---|
| | ~~each query request in order to match the response to the original query.~~ |

## III-G: Resource Location

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

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

## IV-A: HL7 PASS Access Control Service Functional Model*HL7 Comments*

*HL7 recommends that the ISA include the HL7 PASS Access Control Service Functional Model, which past the October 2015 normative ballot after a 2 year DSTU period and is now undergoing ballot reconciliation and expected to pass. This standard specifies the access control functionalities required for interoperable exchange of health information including conveyance of Obligations to which end users much comply, e.g., to support data segmentation.*

*Our recommendations are captured in the Advisory table below.*

| **Type** | **Standard/Implementation Specification** | **Standards Process Maturity** | **Implementation Maturity** | **Adoption Level** | **Regulated** | **Cost** | **Test Tool Availability** |
|---|---|---|---|---|---|---|---|
| **Standard** | | Final | Pilot | ●○○○○ | No | Free | N/A |

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

## IV-B: HL7 PASS Security Labeling Service Functional Model [SLS]

***HL7 Comments***

*HL7 recommends that the Advisory include the normative HL7 PASS Security Labeling Service Functional Model, which specifies the technology agnostic services required to implement an Access Control System capable of segmenting health information both for access and use by users within the trust domain and for disclosure to end users outside of a trust domain. HL7 considers SLS to be widely adopted because it describes current Access Control processes that have a long history of use. Currently many Access Control Systems apply Confidentiality and Purpose of Use security labels in XD* metadata for Exchange and Direct XDR/XDM or as values for the Confidentiality attributes on all CDA Headers and Sections. Where Confidentiality or Purpose of Use security labels are used to enforce the policies represented by these labels, especially jurisdictional laws such as 42 CFR Part 2, HITECH Self-pay, and Title 38 Section 7332 or state laws more stringent than HIPAA.*

*Our recommendations are captured in the ISA table below.*

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|---|---|---|---|---|---|
| Standard | *HL7 PASS Security Labeling Service Functional Model* | Final | Production | ●○○○○ | No | Free | N/A |

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