HIMSS Electronic Health Record Association

33 W. Monroe, Suite 1700
Chicago, IL 60603
swillis@himss.org
Phone: 312-915-9518
Twitter: @EHRAssociation

April 21, 2016

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

We are pleased to submit the attached comments to the Office of the National Coordinator for Health Information Technology (ONC) on its Interoperability Standards Advisory (ISA), an essential component of their effort to coordinate the identification, assessment, and determination of the "best available" interoperability standards and implementation specifications for the health IT industry to use in fulfilling our shared objectives to achieve widespread interoperability. The Electronic Health Record (EHR) Association represents more than 30 companies that design, develop, and deliver EHRs to the vast majority of healthcare organizations that are using these technologies to improve the quality and efficiency of healthcare delivery for all Americans.

In general, the Association appreciates the progress that is reflected in this version of the ISA, and submits specific and detailed comments. To highlight some of our high-level suggestions:

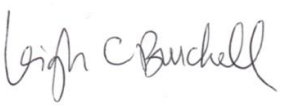
- We recommend more consistent use of terminology, a more realistic definition of the levels of standards adoption, and clarification of some use cases as well as other references and terminology.
- We suggest that, as part of the introduction, expectations are clarified that developers are not expected to implement all standards immediately. Developers should consider these standards to be a starting point, while also assessing the level of maturity and the needs of their clients when deciding whether to adopt a standard early in its lifecycle to help mature the standard, or to wait until a standard has matured and/or is included in regulatory programs.
- It is important to clarify "the best standard for what?" The EHR Association recommends that each "interoperability need" be better described. We make specific proposals, in particular in the vocabulary section, to refine the

definition of the interoperability needs as well as to make the selected vocabulary subset more specific.

- We suggest recognition of emerging efforts, even though they are not yet mature enough to recommend wide adoption, to provide FHIR-based quality measure definitions and reports.
- In Section IV: Projected Additions to the ISA, we understand that the projected additions will be in the 2017 ISA, unless there are substantial objections. We suggest that this should be the other way around, and should only be included when substantial support has been expressed. To that end, we have indicated in our detailed comments where we do or do not support inclusion in the 2017 ISA.
- We make a number of comments and have questions relative to versions and harmonization of SNOMED and LOINC. As new standards are introduced, we suggest that it is important to harmonize them into SNOMED and LOINC wherever possible to avoid mapping challenges across common concepts.

The Association looks forward to our ongoing collaboration on these important initiatives to provide guidance to all stakeholders to seamlessly and securely exchange patient information across care delivery organizations as our nation moves to more coordinated care and new payment models.

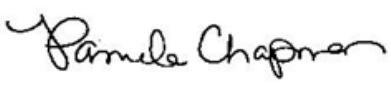
Sincerely,



Leigh Burchell
Chair, EHR Association
Allscripts

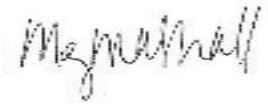
Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion



Meg Marshall, JD
Cerner Corporation

Rick Reeves, RPh
Evident

Richard Landen
QuadraMed Corporation

Sasha TerMaat
Epic

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

Attachment:
Protect Access to Medicare Act Provisions for AUC for Advanced Diagnostic Imaging [Referenced on page 48 of the ISA]

2016 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

BEST AVAILABLE STANDARDS AND IMPLEMENTATION SPECIFICATIONS

Table of Contents

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

Executive Summary

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

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

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

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

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

Per the process first established with the publication of the 2015 Advisory, this document represents the final 2016 Advisory and will now serve as the basis on which future public comments and HIT Standards Committee recommendations are sought. The comment period on this version to being the 2017 Advisory process will begin in early 2016. Your continued feedback and engagement is critical to improve and refine the Advisory.

Scope

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

Purpose

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

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

The 2016 Interoperability Standards Advisory

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

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

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

the best available, it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry can efficiently interoperate more than one.

"Best Available" Characteristics

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

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

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

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

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

The following describes the six characteristics that were added to the Advisory in detail. This detail is meant to better inform stakeholders about the maturity and adoptability of a given standard or implementation specification, and provides definition for the terms and symbols used throughout the Advisory. These definitions remain similar in nature to those presented in the Draft 2016 Advisory, but have been modified slightly to provide

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

additional clarity as requested by public comments. Stakeholders should consider all six characteristics together to gain insight into the level of maturity and adoptability of the "best available" standards provided within the Advisory.

#1: Standards Process Maturity

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

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

EHR Association Comments:

We suggest clarifying the description of the Balloted Draft category such that it does not include documents in ballot reconciliation that have not been completed or published.

There is inconsistent use of "implementation guide" vs. "implementation specification". We suggest using "implementation specification". If there is an important distinction that requires use of both terms (other than in a document title), they should be defined upfront and used accordingly, but we do not believe there is a difference.

#2: Implementation Maturity

No comments

#3: Adoption Level

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

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

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

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

EHR Association Comments:

We agree that this measure has value as we evolve the standards advisory. However, the challenge is to define the denominator that applies to this measure. As the EHR Association suggested earlier, we believe the following, less granular definitions which can be better supported by available data and provide the needed guidance to the industry to be more suitable at this stage:

1. Still being defined. Not yet being incorporated into HIT products.
2. Early adoption. Incorporated in some HIT products, preliminary pilots with healthcare organizations.
3. Some adoption. Used by a growing number of providers but not yet the majority.
4. Wide adoption. Used by most provider organizations that need to exchange this information.

#4: Federally Required

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

EHR Association Comments:

It is unclear what a "federal program requirement" represents. Programs through regulations are clear, but it is unclear whether there may be other programs that are not tied to regulations that would introduce requirements. We are concerned that when federal procurement/contract requirements are included, such requirements get equal weight as a federal regulation, while private contracts do not have that weight. A federal contract is, in effect, no different than a private contract, where certain standards may or may not be a prerequisite for being able to qualify for that contract.

#5: Cost

No comments

#6: Test Tool Availability

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

- *"Yes"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.

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

EHR Association Comments:

The categories "Yes" and "Yes – open" give the impression that "Yes – open" is more restrictive than "Yes". We suggest renaming "Yes" to "Yes – Free". This further reinforces that tools that are not open source, yet free, are not as helpful as those that are also open.

The Structure of the Sections

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

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

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

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

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

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

EHR Association Comments:

The following general comments apply across this section:

It is important to clarify "the best standard for what?" This issue remains a challenge with this version of the Advisory. While the new organization and section titles are a step in the right direction, it remains a challenge to understand the specific use cases. This problem is very clear when looking at standards for the care plan, as an example. Depending on the use case, the suggested standard is acceptable or insufficient. We need to re-emphasize that without such perspective, the value of the Advisory remains less than it could be. Endorsing standards without such understanding of specific use cases may result in the unintended consequence of investing in the wrong solutions and even hampering innovation by focusing on the wrong problems. The EHR Association recommends that each "interoperability need" be better described. We make specific proposals, in particular in the vocabulary section, to refine the definition of the interoperability needs, as well as to make the selected vocabulary subset more specific.

We suggest that, as part of the introduction, expectations are clarified that developers are not expected to implement all standards immediately. Developers should consider these standards to be the starting point, while assessing the level of maturity and whether the needs of their clients dictate that they adopt early in the lifecycle and help mature the standard, or wait until standards have matured and/or are included in regulatory programs.

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

I-A: Allergies

EHR Association Comments:

The value set referenced represents a larger set than what is currently included in FHIR's AllergyIntolerance.reaction.manifestation. That field references SNOMED CT Clinical Findings. Unless the use case envisioned is beyond that of allergy intolerance defined in FHIR, we suggest referencing the same value set.

I-B: Health Care Provider

EHR Association Comments:

We suggest the continued use of the HL7 V3 value set, and that ONC work with HL7 on a single, harmonized value set.

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

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

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

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

I-C: Encounter Diagnosis

No comments

I-D: Race and Ethnicity

No comments

I-E: Family Health History

No comments

I-F: Functional Status/Disability

No comments

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

EHR Association Comments:

We note that SNOMED CT does not, to our knowledge, have a branch for gender identity. Consequently, if there is not such a branch, SNOMED CT should not be referenced until a suitable standard has been identified.

Interoperability Need: Representing patient gender identity

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

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

Interoperability Need: Representing patient sex (at birth)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	For Male and Female, HL7 Version 3 Value Set for Administrative Gender; For Unknown, HL7 Version 3 Null Flavor	Final	Production	●●●●○	Yes	Free	N/A

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

EHR Association Comments:

We suggest including the proper SNOMED CT branch in the value set.

Interoperability Need: Representing patient-identified sexual orientation

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

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

I-H: Immunizations

No comments

I-I: Industry and Occupation

No comments

I-J: Lab tests

EHR Association Comments:

We suggest adding a section for "Lab Results – Categorical Results", referencing SNOMED to allow for all characteristics to be asserted explicitly, as it may not be the same as for the tests using LOINC.

It is unclear to what "(questions)" in the Interoperability Need header refers. Is this meant to indicate that for "Ask At Order Entry" questions, when the response is numerical, LOINC is to be used? If so, that must be made clear. However, it also should be clarified that LOINC for "Ask At Order Entry" questions should be used for non-numerical response questions as well.

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

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

I-K: Medications

No comments

I-L: Numerical References & Values

No comments

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

No comments

I-N: Preferred Language

No comments

I-O: Procedures

No comments

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

Unless the intent is to use the older version of LOINC, this designation should be "Balloted Draft", not "Final", as the work to merge with Radlex is not completed.

LOINC for radiology procedures is only used by a few health systems (e.g., the VA), if it is the old version. It is the future version that is being merged with Radlex. Its adoption level should be "none" today, as it is being used only in a limited number of pilot sites, thus at best one bullet.

Interoperability Need: Representing imaging diagnostics, interventions and procedures

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

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

I-Q: Tobacco Use (Smoking Status)

No comments

I-R: Unique Device Identification

No comments

I-S: Vital Signs

No comments

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

II-A: Admission, Discharge, and Transfer

EHR Association Comments:

Generally, we are concerned with referencing HL7 standards rather than implementation specifications. We appreciate that, at least, this interoperability need narrowed it down substantially. However, we do suggest that there may be an opportunity with the increased interest in event notification to start to work with SDOs (HL7 and/or IHE, e.g., the PAM profile) to arrive at implementation specifications and be able to remove a reference to a standard and add more specific, less ambiguous guidance for this interoperability need. We note this applies to cross-provider interoperability only as intra-provider interoperability has already been addressed.

We suggest adding as a separate ADT interoperability need:

- II-B Patient ID Management within a community
  - Standard: HL7 2.5.1
  - Implementation Specification: IHE PIX and PDQ

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

	• **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-B: Care Plan

EHR Association Comments:

The Advisory includes the C-CDA for exchange of care plan data. While that capability exists, in the rapidly evolving shift from fee-for-service to value-based payment models that require tight coordination across providers, static exchange of care plans may work for simple use cases, but not for those patients where tight coordination is most critical. The Advisory does not provide the context that much more work is required to develop an approach to coordinate care across providers and the standards needed for that process. This work will drive the need to have more advanced standards than what we have today. Consequently, the current line item gives a false sense of comfort in a very challenging area which should be reflected in the limitations.

To that end we suggest changing the title of this section to "Care Plan Documentation", and recognize in the Limitations section that this does not address the larger challenge of care plan coordination with the aim of maintaining a single, common care plan across providers.

Interoperability Need: Documenting patient care plans

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1	Balloted Draft	Pilot	Unknown	Yes	Free	No

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

II-C: Clinical Decision Support

No comments

II-D: Drug Formulary & Benefits

No comments

II-E: Electronic Prescribing

No comments

II-F: Family health history (clinical genomics)

No comments

II-G: Images

No comments

II-H: Laboratory

EHR Association Comments:

Per definitions, the LRI guide should be "Balloted Draft", as it is still an STU.

Interoperability Need: Receive electronic laboratory test results

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

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

• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Ordering labs for a patient

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

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

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-I: Patient Education Materials

No comments

II-J: Patient Preference/Consent

No comments

II-K: Public Health Reporting

Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●○○○○	Yes	Free	No
Emerging Alternative Implementation Specification	*HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

EHR Association Comments:

We suggest adding a Limitations, Dependencies, and Preconditions for Consideration bullet that the IHE SDC profile depends on the IHE RFD which is final text.

Interoperability Need: Reporting cancer cases to public health agencies

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

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

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

EHR Association Comments:

We suggest modifying the table below as reflected in changes highlighted.

Interoperability Need: Case reporting to public health agencies

	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

	Standard/Implementation Specification	Standard Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-~~Implementation Specification~~ Standard	IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)	~~Balloted Draft~~ *Final*	~~Pilot~~ *Production*	●○○○○ *3 bullets*	No	Free	~~No~~ *Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Informaton#IT_Infrastructure*
1- Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
2- Emerging Alternative Implementation Specification	*HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

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

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

Type	Standard/Implementation Specification	Standard Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●○	Yes	Free	No

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

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

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

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control.

	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting administered immunizations to immunization registry

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

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

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No

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

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

II-L: Quality Reporting

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

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

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

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

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

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

EHR Association Comments:

We suggest recognizing emerging efforts, although not yet mature enough to suggest wide adoption, to provide FHIR-based quality measure definitions and reports. Note that this would not be FHIR-based APIs, rather quality and document definitions using FHIR resources.

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

EHR Association Comments:

We are concerned with this use case as it does not represent a user need, but rather a technology approach. A use case should focus on the users' needs that in turn may indicate whether it is most appropriate to use a document, message, or service approach, or whether a query for data should be able to return data element-level responses. The latter is properly reflected further below by data element-based query for clinical health information, thus obviating the need for this section.

[See Question 6]

Interoperability Need: Representing clinical health information as "resource"

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

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

definition of the resource type; and, has an identified version that changes if the contents of the resource change	

II-N: Segmentation of sensitive information

EHR Association Comments:

We believe that there still remains too much variance within this subset to be recognized for use now, i.e., the vocabulary is not universally understood and, although some concepts are well-defined, others are completely unusable. There is a mix of codes that are just flags with other codes that are demands (obligations). This approach makes it unclear as to what should be done with the codes either on the publication side or the use side. Ultimately, even this subset of DS4P requires further implementation guidance or profiling. We recommend that the Advisory includes no more than the DS4P subset refined by the IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf), noting that piloting is insufficient.

As we commented on the first version of the Interoperability Standards Advisory in May 2015, we are concerned with the maturity of this standard. While DS4P is clearly used as part of C-CDA, it is ***only*** used at the document level. For section/data element level segmentation, this should be referred to as an emerging implementation specification. The terminology "Document-level segmentation of sensitive information" is confusing and ambiguous in this regard. We suggest that the limitations to document-level vs. section-level are clearly indicated in the Limitations section to avoid the perception that this may include section-level segmentation. Introducing a new section as drafted below may help clarify this further. We suggest that the adoption level be changed to no more than two bullets to appropriately reflect adoption.

Interoperability Need: Document-level segmentation and limited codification of sensitive information							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Production	●●●●●	Yes	Free	No

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

Interoperability Need: Section-level segmentation of sensitive information							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**

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

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

II-O: Summary care record

Interoperability Need: Support a transition of care or referral to another health care provider

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Balloted Draft	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1*	*Balloted Draft*	*Pilot*	*Unknown*	*Yes*	*Free*	*No*

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

Section III: Best Available Standards and Implementation Specifications for Services

III-A: "Push" Exchange

EHR Association Comments:

The reference to FHIR remains very confusing in this context, even with the explanation in the Limitations section. Is FHIR intended to be referenced for its transport or its representation of a payload? Some interpret FHIR as RESTful (although it is not limited to that), and others recognize FHIR for all its resource definitions/syntax. Perhaps the entry should just be RESTful FHIR Document Resource-based API specifications.

We suggest clarifying how to use the numbers in the first column on each row.

It is unclear why the MHD row includes both 3 and 4. Rather, it should just be 4 as it only works with RESTful FHIR Document Resource-based APIs.

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between individuals and systems							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1- Standard	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
2 - Emerging Alternative Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*
Standard (2)	*SOAP*	*Final*	*Production*	*4 bullets*	*Yes*	*Free*	*Yes*
1, 2, 3 - Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes
1, 2 - Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	Yes	Free	Yes
1, 2, 3 - Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
3 – Standard	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	Yes	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
4 - Emerging Alternative Standard	*Fast Healthcare Interoperability Resources (FHIR) DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3, 4 - Emerging Alternative Implementation Specification	*IHE-MHD (Mobile Access to Health Documents*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

Interoperability Need: An unsolicited "push" of clinical health information to a known destination between systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Standard	SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification	Final	Production	●●●○○	Yes	Free	Yes
2- Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●○	No	Free	Yes
1 - Implementation Specification	NwHIN Specification: Messaging Platform	Final	Production	●●●○○	No	Free	No

1- Implementation Specification	NwHIN Specification: Authorization Framework	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0 • The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-B: Clinical Decision Support Services

No comments

III-C: Image Exchange

EHR Association Comments:

All the purple-shaded boxes in the "Type" column should be 1.

MHD-I should be with FHIR (as above), IHE-PDQm, and IHE-PIXm. Both PDQm and PIXm should be balloted draft, pilot, and one bullet.

Interoperability Need: Exchanging imaging documents within a specific health information exchange domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE Cross Enterprise Document Sharing for Images (XDS-I.b)	Final	Pilot	●○○○○	No	Free	Yes
1~~,2~~-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	No
1~~,2~~-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
2 – Emerging Implementation Specification	RESTFul FHIR Document Reference based API specifications	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2 – Emerging Implementation Specification	PDQm	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2 – Emerging Implementation Specification	PIXm	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2-Emerging Alternative Implementation Specification	*IHE – MHD-I (Mobile Access to Health Documents for Imaging)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Exchanging imaging documents outside a specific health information exchange domain

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

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

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

III-D: Provider Directory

EHR Association Comments:

HPD is now used in several settings. We suggest that the Adoption Level be two bullets, with more than 20 Directory Servers being deployed in production.

Interoperability Need: Listing of providers for access by potential exchange partners

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

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

III-E: Publish and Subscribe

Given that the ISA should include more than go-forward standards, we should also indicate when existing standards are at end-of-life. We suggest that the NwHIN specification falls in that category and should not be promoted moving forward.

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-F: Query

EHR Association Comments:

MHD is based on the FHIR document resource. The EHR Association suggests creating a separate category for the FHIR-based requirements – i.e., Interoperability Need: Query for documents from mobile devices within a specific health information exchange domain. This approach should then include the corresponding implementation specifications for PDQm and PIXm as well.

Interoperability Need: Query for documents within a specific health information exchange domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Implementation Specification	IHE-XDS (Cross-enterprise document sharing)	Final	Production	●●●●○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1~~,2~~-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes
1~~,2~~-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
2 – Emerging Implementation Specification	RESTFul FHIR Document Reference based API specifications	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2 – Emerging Implementation Specification	PDQm	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2 – Emerging Implementation Specification	PIXm	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
2- Emerging Alternative Implementation Specification	*IHE – MHD (Mobile Access to Health Documents)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE-XCA (Cross-Community Access)	Final	Production	●●●●○	No	Free	Yes Open http://wiki.ihe.net/index.php?title-IHE_Test_tool_Information#IT_Infrastructure
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
Implementation Specification	NwHIN Specification: Patient Discovery	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:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • *NwHIN Specification: Query for Documents and NwHIN Specification: Retrieve Documents should be further constrained by eHealth Exhange Query for*	• **System Authentication** - The information and process necessary to authenticate the systems involved • **User Authentication** – The information and process necessary to authenticate the end user

Documents v3.0	• **User Details** - identifies the end user who is accessing the data • **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction for purposes of authorization. E.g., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access. • **Purpose of Use** - Identifies the purpose for the transaction, and for the purposes for which the end user intends to use the accessed objects • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed. o May be required to authorize any exchange of patient information o May be required to authorized access and use of patient information o May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply • **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: Data element based query for clinical health information

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

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

	necessary for access control by the end user. • **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

III-G: Resource Location

No comments

Section IV: Projected Additions to the ISA

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

EHR Association Comments:

From discussions, we understand that the projected additions will be in the 2017 ISA, unless there are substantial objections. We suggest that this should be the other way around, and should only be included when substantial support has been expressed. To that end, we will indicate where we do or do not support inclusion in the 2017 ISA in the "regular" section.

Projected Vocabulary/Code Set/Terminology Standards and Specifications:

Family Health History

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

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

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

EHR Association Comments:

We support inclusion in 2017 ISA regular section.

Gender Identity, Sex and, Sexual Orientation

Interoperability Need: Representing patient gender identity observations (questions)

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

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

EHR Association Comments:

We support inclusion in 2017 ISA regular section.

Interoperability Need: Representing patient sex (at birth) observations (questions)

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

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

EHR Association Comments:

We support inclusion in 2017 ISA regular section.

Interoperability Need: Representing patient-identified sexual orientation observations (questions)

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

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

• The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine.	• LOINC code: 76690-7 Sexual orientation.

EHR Association Comments:

We support inclusion in 2017 ISA regular section.

Health Care Provider

Interoperability Need: Provider role in care setting

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

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

EHR Association Comments:

The EHR Association suggests that further harmonization is required across the three value sets before including this requirement in an upcoming ISA rather than including only three. We note this should allow for free text roles, as it is unlikely that any set will accommodate all relevant roles at a given point (particularly considering time to approve and include new values).

Lab Tests

EHR Association Comments:

This appears already in the regular section, so it is unclear why it is repeated.

Interoperability Need: Representing numerical laboratory test order observations (questions/what will be tested)

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

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

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

Interoperability Need: Representing categorical laboratory test result observation values (answers)

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

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

Nursing

EHR Association Comments:

This appears already in the regular section, so it is unclear why it is repeated.

Interoperability Need: Representing nursing assessments

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

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

• Assessments are represented as question/answer (name/value) pairs. They are not represented in other terminologies. • LOINC should be used for the assessment/observation questions and SNOMED CT for the assessment/observation answers (value sets, choice lists).	• Feedback requested

Interoperability Need: Representing outcomes for nursing

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

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

Interoperability Need: Representing patient problems for nursing

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

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

Interoperability Need: Representing nursing interventions and observations (observations are assessment items)

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

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

EHR Association Comments:

We suggest that the vocabularies must be harmonized before introducing SNOMED-CT in an upcoming ISA.

Research

Interoperability Need: Representing analytic data for research purposes.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Controlled Terminology for Regulatory Standards Hosted by NCI-EVS	Final	Production	●●●●●	Yes	Free	N/A
Standard	CDISC Controlled Terminology for CDISC Therapeutic Area Standards Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Controlled Terminology for Medical Devices Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A

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

EHR Association Comments:

As new standards are introduced, it is important to harmonize into SNOMED and LOINC wherever possible to avoid mapping challenges across common concepts. The objective should be to capture data once and re-use them between the care setting and research wherever possible.

Tobacco Use (Smoking Status)

Interoperability Need: Representing patient tobacco use (smoking status) observations (questions)

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

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

EHR Association Comments:
We are concerned with the focus on just tobacco smoking vs. tobacco use, and suggest that this is not yet ready for inclusion in an upcoming ISA until these variances have been addressed.

Projected Content/Structure Standards and Specifications:

Admission, Discharge and Transfer

Interoperability Need: Sending a notification of a patient's admission, discharge and/or transfer status to the servicing pharmacy

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Census Message" transaction allows for long-term and post-acute care settings to notify the servicing pharmacy of a patient's admission, discharge and/or transfer status.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

EHR Association Comments:
To promote consistency of data exchange, we are concerned with the introduction of NCPDP SCRIPT for the notification of ADT events. Further review of event notification use cases must occur, considering HL7 and IHE standards and profiles, before promoting any particular specification, particularly one not commonly used for these events in the healthcare environment at large.

Care Plans

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

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

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

EHR Association Comments:

We appreciate that there is a need to communicate the existence of a care plan, and that there is a specification available specific to oncology. At the same time, there is a need for standards to coordinate the care planning process across diverse providers for which we do not yet see a solution. To avoid this confusion between individual documents vs. care plan coordination, we suggest this section be re-titled as "Care Plan Documentation" to distinguish it clearly from Care Plan Coordination.

Within the context of Care Plan Documentation, we support the inclusion of the proposed specification into the upcoming ISA as an emerging specification.

Clinical Decision Support

Interoperability Need: Provide access to appropriate use criteria

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

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

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

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

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

EHR Association Comments:

We suggest that, as also indicated in our letter to CMS on AUCs (attached), the CDS-OAT profile is not applied with a requirement to use the full underlying RAD framework and corresponding order messages, but rather that CDS-OAT can be used in combination with any other valid HL7 V2 order message. Separately, we then can focus on what the relevant implementation specification should be for communicating any imaging order to an imaging center to mature the transition from paper to electronic order management.

Images

Interoperability Need: Format of radiology reports for exchange and distribution

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

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

EHR Association Comments:

We believe the industry is not ready to support inclusion of this specification into the main ISA. Further piloting is required to provide a sufficient starting point for the industry to adopt. At a minimum, this would have to be marked an emerging implementation specification.

Medical Device Communication to Other Information Systems/Technologies

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PCD (Patient Care Device Profiles) - Communication Management (ACM)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-PCD (Patient Care Device Profiles) - Device Enterprise Communication (DEC)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-PCD (Patient Care Device Profiles) - Implantable Device - Cardiac Observation (IDCO)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-PCD (Patient Care Device Profiles) - Point-of-Care Infusion Verification (PIV)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-PCD (Patient Care Device Profiles) - Rosetta Terminology Mapping (RTM)	Final	Production	●●○○○	No	Free	N/A

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

Research

EHR Association Comments:

As new standards to the ISA are introduced, such as CDISC, it is important to harmonize vocabularies to minimize mappings and/or additional data capture at the source. We suggest that ONC work with the respective SDOs to address these challenges.

Interoperability Need: Submission of analytic data to FDA for research purposes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Production	●●●●●	Yes	Free	Yes
Standard	CDISC Analysis Dataset Model (ADaM)	Final	Production	●●●○○	Yes	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	Yes

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

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

Interoperability Need: Pre-population of research case report forms from electronic health records

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE-CRD (Clinical Research Document)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-XUA (Cross-Enterprise User Assertion)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-ATNA (Audit Trail and Node Authentication)	Final	Production	●●○○○	No	Free	N/A
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	N/A

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

Interoperability Need: Integrate healthcare and clinical research by leveraging EHRs and other health IT systems while preserving FDA's requirements

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should review 21CFR11 for more details.	• Feedback requested

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

Interoperability Need: Submit adverse event report from an electronic health record to drug safety regulators							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE-DSC (Drug Safety Content)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE- CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes
Limitations, Dependencies, and Preconditions for Consideration:			**Applicable Security Patterns for Consideration:**				
• Feedback requested			• Feedback requested				

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

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

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

Interoperability Need: Registering a clinical trial

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

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

EHR Association Comments:

HL7 continues to provide clinical trial registration and association capabilities in HL7 V2. We suggest that ONC review with CDISC and HL7 whether these are complementary and should both be referenced, or whether HL7 should start to deprecate their registration and dynamic association capabilities.

Data Provenance

Interoperability Need: Establishing the authenticity, reliability, and trustworthiness of content between trading partners.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

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

EHR Association Comments:

The data provenance specifications should be marked as "emerging" to clarify that adoption is still in very early stages.

Projected Standards and Specifications for Services:

"Push" Exchange

Interoperability Need: Push communication of vital signs from medical devices

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Pilot	●○○○○	No	$	No

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

EHR Association Comments:

There is a need to distinguish this use case from the IHE PCD profile application of different underlying standards, where the PCD profile is more focused on device manager to EHR/other HIT, and this IEEE standard is focusing on the device to the intermediary/device manager.

We also suggest clarity on the URL of the specification, as this link arrives on a page with many choices and it is unclear which one or ones are applicable. Is the intent to focus on the home devices section in combination with the Continua implementation specification? We suggest it would be more appropriate and clear to focus on home devices. In the latter case, the adoption case would be closer to three bullets rather than one.

Public Health Exchange

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

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

EHR Association Comments:

We suggest the interoperability need should be clarified that it is the "Transport for Query/Response for Immunization Reporting", which can be used in combination with the Immunization implementation guide used for the content. Without that clarification, there is confusion about whether this replaces the Immunization implementation guide.

We support inclusion of these specifications into the main ISA sections.

Section V: Questions and Requests for Stakeholder Feedback

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

General

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

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

Section I: Vocabulary/Code Set

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

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

Section II: Content / Structure

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

   EHR Association Comments:
   For FHIR services specifically, we do believe the focus should be on service and not split between the transport and content.

   We agree that FHIR should be referenced as an emerging standard for both services (e.g., RESTful) and content (resource definitions) as it started to be done (e.g., through DAF, MHD), but want to ensure there is awareness that FHIR applies to documents (e.g., C-CDA on FHIR) and messaging as well, albeit those are still in an earlier stage. The primary focus today is on services' query/response capabilities, while write capabilities are starting to emerge as well.

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

Section IV: Projected Additions to the ISA

7. Public comments on the Draft 2016 Advisory highlighted an interest in including "interoperability needs" associated with communication between certain types of personal health devices and other information technology systems. Specifically, the health informatics standards under

IEEE 11073 that have been recognized by the FDA[2] and referenced by Continua and Personal Connected Health Alliance. What particular interoperability needs would be best to include in the Advisory to reflect this work by the industry?

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

Appendix II: Sources of Security Standards

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

EHR Association Comments:

We are not convinced that the current representation of security patterns and Appendix II provide the necessary clarity to understand how to apply specific security standards to a particular use case. We will be reviewing this further and provide suggestions in the near future that may be considered for an upcoming ISA.

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

Appendix I - Annual Process to Update the Interoperability Standards Advisory

No comments

Appendix II – Sources of Security Standards

No comments

Appendix III - Revision History

No comments

Appendix IV – Responses to Comments Requiring Additional Consideration

No comments

33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 312-915-9582
Twitter: @EHRAssociation

March 24, 2016

JoAnna Baldwin
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Baldwin,

On behalf of the Electronic Health Record (EHR) Association member companies, we want to thank you for giving us the opportunity in the listening session held on February 5, 2016 to provide our feedback to the Protect Access to Medicare Act (PAMA 218) provision for appropriate use criteria (AUC) for advanced diagnostic imaging. As discussed, we would like to offer additional comments and recommendations in this letter and the attached appendix on the implementation of AUC in health information technology (IT).

PAMA requires that physicians ordering advanced diagnostic imaging consult with qualified clinical decision support (CDS) systems and provide the furnishing professional with information confirming that consult by January 1, 2017. The EHR Association appreciates the recognition by the Centers for Medicare and Medicaid Services (CMS) that this date is unrealistic, given the very short time between the detailed requirements being available in the final 2017 Physician Fee Schedule (PFS) rule (anticipated sometime before November 1, 2016) and the proposed implementation date. As CMS considers setting a revised date in the forthcoming regulation, the Association reiterates our comments to the 2016 PFS proposed rule [http://www.ehra.org/docs/EHRA%20Comments%20PFS%20NPRM.pdf]. We strongly urge CMS to consider the time needed to successfully implement the program, inclusive of finalizing the necessary interoperability standards and guidance discussed in the appendix, as well as efforts to enter into business agreements with AUC content providers. In addition, adequate time must be allowed for software developers to code, test, and deliver this new software after approved AUC mechanisms become

available, as well as for providers to implement the new software and educate their providers on the appropriate workflow requirements. While we usually suggest that 18 months is the amount of time needed between the release of final regulations (including all necessary detailed guidance) and the use of updated software versions to comply with new rules, in this case, because of negotiations that are required with content providers, we suggest that at least 24 months would be required.

Additionally, as discussed in the attached appendix, we strongly suggest that CMS and the Office of the National Coordinator for Health IT (ONC) consider whether there might be a simpler approach to the complex data flow than what is currently proposed. We would welcome participation in any discussion with the appropriate stakeholders in order to find a more optimal workflow.

Finally, the attached appendix includes our detailed comments and recommendations around the current and most optimal state of the standards that are needed to support the successful implementation for our customers.

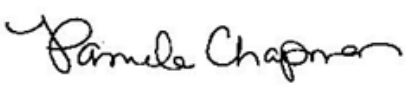
We appreciate the opportunity to provide feedback to CMS and ONC, and look forward to our ongoing collaboration towards our shared goals of more effective, efficient healthcare for all Americans.

Sincerely,

Leigh Burchell
Chair, EHR Association
Allscripts

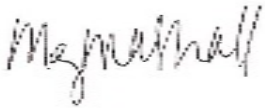
Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion



Meg Marshall, JD
Cerner Corporation

Rick Reeves, RPh
Evident

Ginny Meadows, RN
McKesson Corporation

Sasha TerMaat
Epic

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 35 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

cc: Sarah Fulton, CMS
Joseph Hutter, CMS
Kevin Larsen, ONC

Appendix 1

Suggestions for Appropriate Use Criteria (AUC) to the Centers for Medicare and Medicaid Services (CMS) for Upcoming Physician Fee Schedule (PFS) Notice of Proposed Rulemaking (NPRM)

As multiple professional societies and other organizations can offer appropriate use criteria (AUC) and supporting mechanisms, it is important to ensure that industry-accepted standards are available and supported to enable minimum, core interoperability. We note, however, that this policy approach should not preclude individual trading partners from utilizing other and/or more comprehensive interoperability capabilities, as long as the minimum, core standards remain available as a choice out-of-the-box.

While we suggest standards below for integrating decision support as part of placing orders, we do not think that standards for decision support triggered by orders should preclude or restrict other approaches. For example, in a case where an electronic health record (EHR) that integrates clinical decision support (CDS) rules has already assessed and perhaps even suggested the need for an order for advanced imaging, this would satisfy the requirement.

We note that the current proposed flow of data involves five or six integration points. These integration points include:

- Local AUC mechanism to knowledge provider;
- Order placer to AUC mechanism;
- Order placer to radiology information system (RIS);
- RIS to accounting;
- Revenue management to CMS;
- CMS to AUC mechanism to validate/audit claims.

The complex data flow as suggested would create potential challenges with scaling, considering the number of these connections. Additionally, the benefits primarily lie with the fulfilling provider at the imaging center, thus making it challenging to prompt the engagement of the ordering provider and justify their investments into the necessary technology. We suggest that there is a simpler approach that would instead require the imaging center to serve as the primary source of AUC data and, through arrangements between the imaging center and ordering provider, encourage availability of relevant clinical data that support the image request. With such an approach, further interaction with the ordering provider may only need to occur in case of failure to obtain an appropriate AUC, thus improving efficiency. Perhaps further discussions among parties such as CMS, the Office of the National Coordinator for Health IT (ONC), the American College of Radiology (ACR), the American College of Physicians (ACP), and the American Medical Association (AMA), as well as standards developers such as HL7, X12, and IHE, will help find a more optimal flow.

We note that in cases where data fields have been added or changed in claim forms, there have been substantial disruptions in health care operations, as well as substantial costs to the industry. Based on

CMS 2011 data for top procedures, this new workflow will affect some 23 million orders[1] and, if current trends were continued, would affect approximately 29 million orders in 2017. Based on prior experiences with changes like use of X12 5010 and inclusion of the national provider identifier (NPI) in claims, we would expect similar experiences with delays in processing claims, and increased rejection rates on the order of 10-40%,[2] given the fact that this proposed flow has numerous moving parts and thus the opportunity for more inefficiencies or errors.

Assuming the currently proposed flow and associated interoperability, while standards and implementation guidance are emerging, further efforts are required to solidify these guides. Specifically:

- ***Local AUC mechanism to knowledge provider***
  To support communication of appropriate use criteria definitions/knowledge, HL7's Clinical Decision Support Knowledge Artifact Implementation Guide should be considered. However, we also note that given the anticipated volume of content and change, the presence of such standards is not critical, nor should support of such standards by developers be required. Either way, to further spur innovation, we do suggest that appropriate use criteria knowledge/definitions/algorithms be available in an open, no-cost, computable format.
- ***Order Placer to AUC mechanism***
  To support access to a remote AUC mechanism at time of order placement, HL7's Guidelines on Appropriate Ordering should be considered. This FHIR-based implementation guide has gone to both an IHE and HL7 ballot. The materials have been through initial testing at IHE Connectathon and were demonstrated at RSNA in November of 2015 and at HIMSS in February 2016. However, further refinement will still be necessary once there is clarity on exactly what information is to be communicated from the AUC mechanism to the ordering provider, on to the filling provider, and finally included on a claim. The HL7 ballot is still undergoing reconciliation, which is conservatively expected to be completed in late summer, with subsequent publication in the second half of the year.
- ***Order Placer to RIS, RIS to Accounting***
  To support the communication of the AUC data with the order and charge to the fulfilling provider and revenue management system respectively, where multiple systems are involved, IHE's CDS-OAT profile is emerging as the relevant implementation guide. We note that in this space a variety of HL7 V2-based implementations are in production, not necessarily using the IHE Radiology Technical Framework. For communication of AUC data, we believe it only necessary to indicate that orders for advanced imaging use any version of HL7 Version 2, and comply with requirements for the OBR and OBX segments specified in the Placer Order Management transaction (RAD-2). Such a statement would not require complete conformance with RAD-2, nor with the CDS-OAT profile, enabling systems which do not use that specification for imaging ordering to continue to use whatever HL7 Version they presently use, but would require that the CDS information be communicated consistently in all systems. Please note that the CDS-OAT profile is also considered to be in trial implementation, and is expected to change based upon feedback from the IHE Connectathon, as well as the HIMSS and RSNA

[1] See Part B Physician/Supplier National Data - CY - 2011 Top 200 Level 1 Current Terminology (HCPCS/CPT) Codes. http://bit.ly/Top200-Level1-2011

[2] 5010 Payment Claims Rejected? Clearinghouse Official Reveals Possible Reasons Why. 15-Feb-2012. AAFP News; Conn J. Up to 37% of Medicaid claims rejected after NPI. 30-May-2008. Modern Healthcare

demonstrations that took place in Q4 2015 and Q1 2016. We expect revisions of this profile with more readily citable requirements to be available in the second half of 2016.

- ***Revenue Management to CMS***
  To support the inclusion of the AUC data on the claim, updates to the X12 guidance must be provided. We understand that this work has not yet started, while X12 is preparing the 7030 version to be finalized this summer for consideration for inclusion in the next HIPAA version. We suggest that the next HIPAA version includes the necessary guidance on how to communicate the necessary AUC data.
- ***CMS to AUC mechanism to validate/audit claims.***
  Once the claim has arrived at CMS, we anticipate that some form of validation and/or audit is required. Depending on the format of the AUC data (e.g., some form of token vs. individual data), CMS may need to access the original AUC data generated by the AUC mechanism. We suggest that such a process does not involve the need for ongoing validation access to the ordering provider's health IT, but rather involves a separate registry populated by the AUC mechanism provider, direct access to the AUC mechanism provider, or achievement through an immutable token that contains all the information necessary to perform a comparison with the claim.

We strongly suggest that the AUC information be streamlined so that both the ordering and imaging provider workflow is simpler, more readily accomplished, and less prone to failure due to the many sequential steps described under the current requirements. We believe that section (q)(4)(B) of the legislation pertaining to information about the evaluation could be satisfied by providing a token that could be verified and queried via the certified AUC mechanism provider.

To further support these enhancements to finalize guidance, it is critical that CMS clarify exactly what AUC data is to be communicated from the AUC mechanism to the ordering provider, on to the filling provider, and finally included on a claim. We strongly suggest that the AUC information requirements be streamlined so that both the ordering and imaging provider workflow is simpler, more readily accomplished, and less prone to failure due to the many sequential steps described under the current requirements. As previously stated, we believe that this work should be done in consultation with relevant SDOs (e.g., HL7 and IHE) in order to ensure optimal workflow. To that end, we also suggest that AUC should be based on industry standard vocabularies such as SNOMED and ICD-10, rather than any development of separate, appropriate use criteria vocabulary that may not fit in the ordering providers' workflows or add additional translation steps. The more components that are added to a provider's workflow, the less likely it will be successfully adopted.

Adequate time must be available to complete these standards and implementation guides, including initial testing and pilots, as well as time for relevant HIT to incorporate such support and roll it out to their clients, who in turn must implement these. ***Again, we reiterate given the additional work that will need to be done should this work proceed, at least 24 months would be required from the time that final regulations and supporting materials are available before providers are required to comply.***