



2015 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

[Open Draft]

*BEST AVAILABLE
STANDARDS AND
IMPLEMENTATION
SPECIFICATIONS*

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This 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 2015 Interoperability Standards Advisory (the 2015 Advisory) 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 toward specific health care purposes. The 2015 Advisory's scope focuses on clinical health information technology (IT) interoperability. Specifically, the scope does not include transactions governed by regulations published to implement provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The scope of future advisories may be expanded as necessary and appropriate to support the Interoperability Roadmap's evolution as well as other national priorities. The 2015 Advisory and future advisories will be published at www.healthit.gov/standards-advisory as a downloadable document and a webpage.

The 2015 Advisory is an "open draft" designed to begin an interactive process that will ultimately result in a list of standards and implementation specifications for a broad range of clinical health IT interoperability purposes. In that regard, it is important to acknowledge that this advisory is neither complete nor exhaustive and will remain that way throughout 2015. The 2015 Advisory was prepared to give stakeholders a body of work on which to react and is meant to prompt focused industry dialogue on areas where disagreement exists regarding the best available standards as well as greater certainty and clarity on areas where widespread consensus exists. In its role as a coordinator, ONC will collaborate, facilitate, and provide the mechanisms by which this dialogue will occur in order to ultimately see decisions made toward the identification of standards and implementation specifications for specific purposes.

ONC expects to annually update the Advisory through a transparent and structured process that includes advice from the HIT Standards Committee (ONC's federal advisory committee) and the public at large. To the extent possible, updates to future advisories will be done in a manner that seeks to minimize the potential for unnecessary sunk costs and to promote the entry of innovative standards. ONC will publish a new Advisory each December for the upcoming calendar year and then initiate the process to update that year's advisory for the next calendar year (e.g., the "2016 Interoperability Standards Advisory" would be published in December 2015 and the process throughout 2016 would yield the 2017 Interoperability Standards Advisory).

While the standards and implementation specifications included in an advisory may also be adopted in regulation (already or in the future), required as part of a testing or certification program, or included as procurement conditions, an advisory is non-regulatory and non-binding in nature. Overall, an advisory is intended to provide clarity, consistency, and predictability for the public regarding ONC's assessment of the "best available" standards and implementation specifications for a given clinical health IT interoperability purpose. In that regard, it is expected that stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components would first look to an advisory in order to leverage the standards and implementation specifications listed to achieve their interoperability goals.

It is ONC's intent to broadly coordinate with health IT industry stakeholders throughout 2015 to improve the 2015 Advisory's depth and breadth in order to publish a more complete 2016 Advisory. The standards and implementation specifications included in this advisory reflect ONC's initial assessment of whether the specific purpose for which a standard or implementation specification could be used is: 1) already included in an ONC regulation for that purpose; 2) used or required by a federal agency for that purpose; 3) used in production by a significant number of stakeholders for that purpose; 4) otherwise a de facto choice because there is no known or available equivalent alternative for that purpose; 5) the next version of a standard or implementation specification where its prior version is included as a best available standard for that purpose.

Purpose

Overall, an advisory is meant to serve two purposes:

- 1) ***To provide the industry with a single, public list of the standards and implementation specifications that can best be used to achieve a specific clinical health information interoperability purpose.*** With a discrete and specific purpose identified, stakeholders can have clarity regarding which standards and implementation specifications are expected to be used and, where necessary, develop migration timelines for the full adoption and implementation of a standard or implementation specification. This is especially true in situations where multiple standards exist for a given interoperability purpose and where a single standard can be used to satisfy multiple purposes.
- 2) ***To prompt dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available.*** In some cases, a single standard (and, where applicable, associated implementation specification(s)) may be necessary to achieve a specific interoperability purpose. In other cases, the industry may be able to manage the use of more than one. This advisory and its accompanying processes are designed to prompt these assessments and to reach these determinations.

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).

Introduction

This section includes additional background context to aid readers understanding of the history and actions leading up to this advisory's publication.

The Federal government has provided guidance, notices, and publications on health IT standards and interoperability for well over a decade. In 2001, the Consolidated Health Informatics (CHI) initiative began as one of the e-government initiatives included in the President's Management Agenda (PMA). The CHI initiative was a collaborative effort to adopt federal government-wide health information interoperability standards to be implemented by federal agencies in order to enable the federal government to exchange electronic health information. The CHI initiative was largely active between 2001 and 2007 and was transitioned to the Federal Health Architecture in 2006. 2007 marked the last year the CHI initiative published a list of interoperability standards.¹

From 2006 through 2009, ONC, on behalf of the Secretary, had a process in place to "accept" and "recognize" health IT standards and implementation specifications. This process implemented the Secretary's assigned responsibility in Executive Order (EO) 13410² to recognize interoperability standards for use by certain Federal

¹ The Notice available at this link includes references to past CHI notices <https://www.federalregister.gov/articles/2007/12/17/07-6058/additional-consolidated-health-information-chi-health-information-technology-standards>

² <https://www.federalregister.gov/citation/71-FR-51089>

agencies. EP 13410 also directed those Federal agencies, to the extent permitted by law, to require in their contracts and agreements with certain organizations the use, where available, of health information technology systems and products that meet recognized interoperability standards. On March 1, 2007, January 23, 2008, and January 29, 2009, HHS published notices in the Federal Register (72 FR 9339³, 73 FR 3973⁴, 74 FR 3599⁵, respectively) announcing either the Secretary's acceptance or recognition of certain standards and implementation specifications.

After the Health Information Technology for Economic and Clinical Health (HITECH) Act's enactment in 2009, ONC focused its processes to adopt standards, implementation specifications, and certification criteria through regulation for the purposes of supporting the voluntary ONC Health IT Certification Program also authorized by the HITECH Act.

In 2012, ONC published a request for information (RFI) which sought comments on topics related to health information exchange governance. One such topic was how ONC could best classify technical standards and implementation specifications. ONC stated that “a formal and transparent process to classify technical standards and implementation specifications” would benefit the industry and that such a process “would be informed by the priorities set by ONC based in part on recommendations from the HIT Policy and Standards Committees through an annual review and assessment process” (77 FR 28559). To paraphrase, ONC described the three classifications as:

- “*Emerging*” – The technical standards and implementation specifications that require additional specification by the standards development community, have not been broadly tested, have no or low adoption, and/or have only been implemented within a local or controlled setting.
- “*Pilot*” – The technical standards and implementation specifications that have reached a level of maturity, specification clarity and adoption such that some entities are using them to exchange health information either in a testing or in a production.
- “*National*” – The technical standards and implementation specifications that have reached a high-level of maturity and adoption by different entities such that most entities are using or are readily able to adopt and use them to exchange health information.

ONC did not implement the approach discussed in the RFI nor publish a list of standards and implementation specifications according to the 3-part classification approach. However, it is worth noting that the HIT Standards Committee completed and recommended to the National Coordinator (in August 2012) a detailed analysis scheme by which to evaluate (maturity and adoptability) and classify standards and implementation specifications in one of those three classifications.

Despite its potential, ONC believes the 2012 classification approach has inherent limitations that stem in part from the implied meanings of the terms used for classifications (“national” and “pilot”) and such terms’ dependency on two dimensions (“maturity” and “adoptability”) at the potential exclusion of others. While the analysis scheme completed by the HIT Standards Committee is worth considering on its own, ONC does not believe it can be effectively paired with the 3-part classification approach posed in 2012. Under the 2012 classification approach, if a standard is not classified “national” it would be classified as “pilot” despite the fact that it may be used in production by a number of stakeholders in a certain geography or nationally in particular

³ <https://www.federalregister.gov/citation/72-FR-9339>

⁴ <https://www.federalregister.gov/citation/73-FR-3973>

⁵ <https://www.federalregister.gov/citation/74-FR-3599>

market segments (e.g., eHealth Exchange, CommonWell Health Alliance, etc.). Thus, a standard being classified as a “pilot” standard would inaccurately reflect its use and misrepresent its relevance in the industry.

With all past approaches in mind, the Interoperability Standards Advisory reflects ONC’s decision to pursue a straightforward approach to advising the industry on interoperability standards and implementation specifications. This approach is designed to more clearly link standards and implementation specifications to a specific purpose and interoperable use.

The 2015 Interoperability Standards Advisory

The following represents an initial list of what ONC considers the best available standard(s) and implementation specification(s) for many clinical health data interoperability purposes as of December 2014. This list does not yet represent the full breadth and depth necessary to recognize all of the purposes for which stakeholders may seek to interoperate. The standards and implementation specifications listed in future advisories will incrementally include a broader range of clinical health information interoperability purposes.

While the standards and implementation specifications included in an advisory may also be adopted in regulation (already or in the future), required as part of a testing and certification program, or included as procurement conditions, the advisory is non-binding and serves to provide clarity, consistency, and predictability for the public regarding ONC’s assessment of the best available standards and implementation specifications for a given interoperability purpose. 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 initial assessment and prioritization of that standard or implementation specification for a given interoperability purpose. 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 and efficiently interoperate more than one.

“Best Available” Characteristics

Standards and implementation specifications in the list were included as the “best available” based on the following characteristics and in consideration of past analyses and factors for assessing standards and implementation specifications⁶:

- The standard or implementation specification is adopted for a given purpose by HHS in 45 CFR Part 170 Subpart B (entitled “Standards and Implementation Specifications for Health Information Technology”) or required for compliance by another federal agency for that purpose;
- The standard or implementation specification is used by federal agencies to electronically exchange health information with organizations participating in the eHealth Exchange (and which generally serve as the basis for electronically exchanging with such agencies);
- A “normative” or “draft standard for trial use (DSTU)” (or equivalently labeled) standard or implementation specification is published and in use by a significant number of stakeholders for a given purpose;

⁶ http://healthit.gov/sites/default/files/pdf/TransmittalMemo_HITSC_083012_NwHIN_FINAL.pdf
http://healthit.gov/sites/default/files/pdf/2012Aug30_HITSC_NWHIN_Transmittal.pdf

- A “normative” or “draft standard for trial use (DSTU)” (or equivalently labeled) standard or implementation specification is published and there is no known alternative or available equivalent to that standard or implementation specification for a given purpose; or
- The next version of a “normative” or “draft standard for trial use (DSTU)” (or equivalently labeled) standard or implementation specification is published and its prior version is included as a best available standard for a given purpose.

Overall, ONC expects some stakeholders to disagree with a standard or implementation specification listed as the “best available” in the 2015 Advisory for a specific purpose, with the omission of a standard or implementation specification, or with the inclusion of “competing” standards or implementation specifications. This disagreement is welcome and supported by the process (discussed in Section VI) through which ample time and opportunity for public comment and dialogue will be provided to improve this advisory for the future. Additionally, if stakeholders have suggestions for other characteristics, Section V includes questions related to the Interoperability Standards Advisory as a whole.

Additional Factors Affecting Best Available Determinations

The characteristics above serve as the primary basis on which a “best available” determination was made for the 2015 Advisory. However, a few additional factors contributed to the overall determination.

- **Timeliness & Availability** – The Interoperability Standards Advisory is meant to reflect the current state of available standards and implementations specifications that stakeholders could adopt, implement, and use within that calendar year for a specific purpose for which interoperability is necessary. As a counter example, next year’s 2016 Advisory would not include a standard or implementation in the process of being developed and expected to be ready during 2016. Instead the 2017 Advisory would be the next available opportunity for that standard or implementation specification to be listed.
- **Stability & Adoptability** – If a standard or implementation specification is “new” it should not be automatically excluded from consideration as a best available standard or implementation specification. The “stability” of the standard or implementation specification plays an important role in its overall adoptability. In other words, “new” standards and implementation specifications will be open for consideration and inclusion in an Interoperability Standards Advisory so long as a version of the standard or implementation specification is available and not undergoing substantive changes or corrections.

Distinguishing between a Standard and an Implementation Specification

In general, an “implementation specification” is a set of specific constraints, instructions, or requirements that provide additional detail on how to implement a standard to achieve a specific purpose. For instance, many public health reporting purposes use the HL7 2.5.1 standard. But that standard alone is insufficient to achieve interoperability for a specific public health reporting purpose. Thus, for each purpose, an accompanying implementation guide is necessary that includes unique implementation requirements to assure interoperability can be achieved for that purpose (e.g., HL7 2.5.1 standard + immunization reporting implementation guide). In some cases, a “standard” may have “implementation guide” or “implementation specification” in its title. To the degree that there is a clear “parent” standard for an implementation specification, the “parent” standard is listed as the “standard” and all other derivatives are listed as an implementation specification.

The Structure of Sections I through IV

For the purposes of the lists that follow, a specific version of the standard or implementation specification is not listed unless it is necessary to make a distinction. The standards and associated implementation specifications for clinical health information are grouped into four categories:

- *Vocabulary/code sets/terminology* (i.e., “semantics”).
- *Content/structure* (i.e., “syntax”).
- *Transport* (i.e., the method by which information is moved from point A to point B).
- *Services* (i.e., the infrastructure components deployed and used to accomplish specific information exchange objectives)

A superscript ^{IRI} is noted before a standard or implementation specification if it meets the first “best available” characteristic – adopted in regulation by HHS or required by another federal agency. Again, some of the standards and implementation specifications listed may be “ahead” of any regulatory requirement. Additionally, if a “cell” in a table below is blank for a listed “purpose,” the blank was intentional to identify the need for standards for that purpose but for which ONC could not determine a best available standard to indicate without additional input.

An explicit stand-alone category for “security standards” was purposefully omitted because security standards for information exchange using the internet are commonplace and not unique to health care. However, specific security standards are identified with applicable transport standards in order to convey a secure approach for the use of the best available transport standards identified. Stakeholders should consult the information security resources made available by the National Institute of Standards and Technology (NIST), which provides up-to-date references to security standards (such as encryption) among other approaches to secure transmissions over the internet as well as guidance from the HHS Office for Civil Rights.

Section V includes questions related to the Advisory in general as well as specific questions for each individual section in which standards and implementation specifications are listed. In addition, the Advisory is not intended to imply that a standard listed in one section would always be used or implemented independent of a standard in another section. To the contrary, it will often be necessary to combine the applicable standards from multiple sections to achieve interoperability for a particular clinical health information interoperability purpose.

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

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Allergy reactions	SNOMED-CT	
Care team member (health care provider)	National Provider Identifier (NPI)	
Ethnicity	<i>[See Question #5-6]</i> ^{IRI}OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	
Encounter diagnosis	^{IRI}SNOMED-CT <i>[See Question #5-7]</i> ^{IRI}ICD-10-CM	
Family health history	^{IRI}SNOMED-CT	
Food allergies	<i>[See Question #5-8]</i>	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Functioning and disability	<i>[See Question #5-9]</i>	
Gender identity	SNOMED-CT	
Immunizations - Historical	<i>[See Question #5-10]</i> <ul style="list-style-type: none"> • HL7 Standard Code Set CVX—Clinical Vaccines Administered • MVX (Manufacturing Vaccine Formulation) 	
Immunizations - Administered	<i>[See Question #5-11]</i> National Drug Codes (NDC)	
Industry and occupation	<i>[See Question #5-12]</i>	
Lab tests	LOINC	
Medications	RxNorm	
Medication allergies	RxNorm	
Numerical references and values	The Unified Code of Units of Measure	
Patient “problems” (i.e., conditions)	SNOMED-CT	
Preferred language	ISO 639-1	
	ISO 639-2	
	ISO 639-3	
	RFC 5646	
Procedures (dental)	Code on Dental Procedures and Nomenclature (CDT)	
Procedures (medical)	SNOMED-CT	
	the combination of CPT-4/HCPCS	
Race	ICD-10-PCS	
	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997.	
Radiology (interventions and procedures)	RadLex	
Sex	HL7 Version 3 Value Set for Administrative Gender	
Sexual orientation	SNOMED-CT	
Smoking status	SNOMED-CT	
Unique device identification	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	
Vital signs	LOINC	

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

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Admission, discharge, and transfer	HL7 2.x ADT message⁷	
Antimicrobial use and resistance information to public health agencies	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.
Care plan	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2
Cancer registry reporting	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 (US Realm), Draft Standard for Trial Use
Case reporting to public health agencies	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0	
Clinical decision support knowledge artifacts	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.2, Draft Standard for Trial Use.	
Clinical decision support services	HL7 Version 3 Standard: Decision Support Service, Release 2.	HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use
Clinical decision support – reference information	^[R]HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2.	<ul style="list-style-type: none"> • HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1. • HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.
Data element based query for clinical health information	Fast Healthcare Interoperability Resources (FHIR)	
Drug formulary checking	^[R]NCPDP Formulary and Benefits v3.0	
Electronic prescribing (e.g., new Rx, refill, cancel)	^[R]NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	
Electronic transmission of lab results to public health agencies	^[R]HL7 2.5.1	HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Draft Standard for Trial Use, Release 2 (US Realm), DSTU Release 1.1

⁷ Any HL7 2.x version messaging standard associated with ADT is acceptable.

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Family health history (clinical genomics)	^[R] HL7 Version 3 Standard: Clinical Genomics: Pedigree	HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1
Health care survey information to public health agencies	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	HL7 Implementation Guide for CDA® Release 2: National Ambulatory Medical Care Survey (NAMCS), Release 1, US Realm, Volume 1- Introductory Material, Draft Standard for Trial Use.
Images	Digital Imaging and Communications in Medicine (DICOM)	
Immunization registry reporting	^[R] HL7 2.5.1	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5
Lab - results (receipt)	[See Question #5-14] ^[R] 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	
Lab - orders	[See Question #5-14]	
Lab – Directory of services	[See Question #5-14]	
Patient education materials	^[R] HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2.	<ul style="list-style-type: none"> • HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1. • HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.
Patient preference/consent	[See Question #5-15]	
Quality reporting (aggregate)	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	^[R] HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DSTU Release 1
Quality reporting (patient-level)	HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	^[R] HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture - Category I (QRDA) DSTU Release 2 (US Realm)
Segmentation of sensitive information (e.g., 42 CFR Part 2 requirements)	[See Question #5-16] HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	<ul style="list-style-type: none"> • Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
Summary care record	[See Question #5-17] HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition	<ul style="list-style-type: none"> • ^[R]Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm) • Consolidated CDA® Release 2.0^S

^S Link will be updated once publicly available.

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)	[R] HL7 2.5.1	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0

Section III: Best Available Transport Standards and Implementation Specifications

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Simple way for participants to “push” health information directly to known, trusted recipients	Simple Mail Transfer Protocol (SMTP) RFC 5321	
	For security, Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751	
Data sharing through Service Oriented Architecture (SOA) - that enables two systems to interoperate together	Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X (to support RESTful transport approaches)	
	Simple Object Access Protocol (SOAP) 1.2	
	For security, Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246	

Section IV: Best Available Standards and Implementation Specifications for Services

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
An unsolicited “push” of clinical health information to a known destination	[R] Applicability Statement for Secure Health Transport (“Direct”)	<ul style="list-style-type: none"> • [R] XDR and XDM for Direct Messaging Specification • [R] IG for Direct Edge Protocols • IG for Delivery Notification in Direct
	[R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification.	
	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	
	NwHIN Specification: Authorization Framework	
	NwHIN Specification: Messaging Platform	
Query for documents within a specific health information exchange domain	IHE-XDS (Cross-enterprise document sharing)	
	IHE-PIX (Patient Identity Cross-Reference)	
	IHE-PDQ (Patient Demographic Query)	

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
Query for documents outside a specific health information exchange domain	IHE-XCA (Cross-Community Access)	
	IHE-XCPD (Cross-Community Patient Discovery)	
	NwHIN Specification: Patient Discovery	
	NwHIN Specification: Query for Documents	
	NwHIN Specification: Retrieve Documents	
Data element based query for clinical health information	Fast Healthcare Interoperability Resources (FHIR)	
Image exchange	Digital Imaging and Communications in Medicine (DICOM)	
Resource location	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	
Provider directory	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	
Publish and subscribe	NwHIN Specification: Health Information Event Messaging Production Specification	

Section V: Questions Regarding the Interoperability Standards Advisory

The 2015 Advisory was prepared to give stakeholders a body of work on which to react and is meant to prompt a focused industry dialogue for health IT on areas where disagreement exists as well as greater certainty and clarity on areas where widespread consensus exists to ultimately see decisions made toward the identification of standards and implementation specifications for specific purposes. Therefore, ONC poses questions in this section as a means to help begin this dialogue and feedback. Please visit www.healthit.gov/policy-researchers-implementers/2015-interoperability-standards-advisory-public-comments for instructions of the overall input process.

- 5-1. **[General]** What other characteristics should be considered for including best available standards and implementation specifications in this list?
- 5-2. **[General]** Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?
- 5-3. **[General]** For sections I through IV, what “purposes” are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.
- 5-4. **[General]** For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?
- 5-5. **[General]** For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available? If so, why?

- 5-6. **[Section I]** Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?
- 5-7. **[Section I]** Should more traditionally considered “administrative” standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?
- 5-8. **[Section I]** Should “Food allergies” be included as a purpose in this document or is there another approach for allergies that should be represented instead? Are there standards that can be called “best available” for this purpose?
- 5-9. **[Section I]** Should this purpose category be in this document? Should the International Classification of Functioning, Disability and Health (ICF) be included as a standard? Are there similar standards that should be considered for inclusion?
- 5-10. **[Section I]** Should the MVX code set be included and listed in tandem with CVX codes?
- 5-11. **[Section I]** Public health stakeholders have noted the utility of NDC codes for inventory management as well as public health reporting when such information is known/recorded during the administration of a vaccine. Should vaccines administered be listed as a separate purpose with NDC as the code set?
- 5-12. **[Section I]** Is there a best available standard to represent industry and occupation that should be considered for inclusion in the 2016 Advisory?
- 5-13. **[Section I]** If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the “implementation specification” column or should a new column be added for value sets?
- 5-14. **[Section III]** Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year’s 2016 Advisory once finalized?
- 5-15. **[Section III]** Are there best available standards for the purpose of “Patient preference/consent?” Should the NHIN Access Consent Specification v1.0 and/or IHE BPPC be considered?
- 5-16. **[Section III]** For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?
- 5-17. **[Section III]** For the 2015 list, should both Consolidated CDA® Release 1.1 and 2.0 be included for the “summary care record” purpose or just Release 2.0?
- 5-18. **[Section IV]** Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?

Section VI: Annual Process to Update the Interoperability Standards Advisory

ONC intends to implement the following timeline and process to update the Interoperability Standards Advisory for subsequent years. The process for the open draft 2015 Advisory will roughly follow this same process despite its later publication date in 2015.

- **December Preceding the Upcoming Calendar Year**
 - The new Interoperability Standards Advisory for the next calendar year is published (e.g., December 2015 for the 2016 Advisory).
 - A first round 90 to 120-day public comment period will be opened on that year's Interoperability Standards Advisory.
- **April/May**
 - Sometime during late April/early May the comment period will expire.
 - ONC staff will compile all comments received during the first round comment period.
 - ONC staff will present a summary of received comments to the HIT Standards Committee (or designated Task Force) in order to prepare them to make recommendations on updates for the following year's Interoperability Standards Advisory.
- **August**
 - The HIT Standards Committee submits recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory.
 - A second round 60-day public comment will be opened on the HIT Standards Committee's recommendations concerning the Interoperability Standards Advisory.
- **October – December**
 - Sometime during October the comment period will expire.
 - ONC will review the HIT Standards Committee recommendations as well as public comments on those recommendations.
 - ONC will prepare the next year's Interoperability Standards Advisory for publication.

If a standard or implementation is under development and expected to be completed during this process, it could be considered for inclusion in the next year's Interoperability Standards Advisory. For example, if an implementation guide is expected to be completed in October 2015 for a particular standard, this process should be able to anticipate and accommodate the potential addition of that implementation guide in the 2016 Interoperability Standards Advisory.