

**Best Available Standards and Implementation Specifications**

*[Open Draft – in line Comments from IHE International and IHE USA (IHE)]*

**2015 Interoperability Standards Advisory**

**Office of the National Coordinator for Health IT**

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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](http://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]](#footnote-2)

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) 13410[[2]](#footnote-3) to recognize interoperability standards for use by certain Federal 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 9339[[3]](#footnote-4), 73 FR 3973[[4]](#footnote-5), 74 FR 3599[[5]](#footnote-6), 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 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 specifications[[6]](#footnote-7):

* 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;
* 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* ***[R]*** *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.

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

| Purpose(listed alphabetically) | Standard(s) | Implementation Specification(s) |
| --- | --- | --- |
| Allergy reactions | [SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| Care team member (health care provider)  | [National Provider Identifier (NPI)](https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html?redirect=/NationalProvIdentStand/) |  |
| Ethnicity | ***[See Question #5-6]*** [**[R]** OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997](http://www.whitehouse.gov/omb/fedreg_1997standards) |  |
| Encounter diagnosis | [**[R]** SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| ***[See Question #5-7]*** [**[R]** ICD-10-CM](http://www.cms.gov/Medicare/Coding/ICD10/index.html) |  |
| Family health history | [**[R]** SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| Food allergies | ***[See Question #5-8]***  |  |
| Functioning and disability | ***[See Question #5-9]*** |  |
| Gender identity | [SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html)  |  |
| Immunizations - Historical | ***[See Question #5-10]*** * **[[R]](http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx)** [HL7 Standard Code Set CVX—Clinical Vaccines Administered](http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx)
* [MVX (Manufacturing Vaccine Formulation)](http://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx)
 |  |
| Immunizations - Administered | ***[See Question #5-11]*** [National Drug Codes (NDC)](http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm) |  |
| Industry and occupation | ***[See Question #5-12]***  |  |
| Lab tests | [**[R]** LOINC](http://loinc.org/downloads) |  |
| Medications | **[**[**R]** RxNorm](http://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormfiles.html) |  |
| Medication allergies | [**[R]** RxNorm](http://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormfiles.html)  |  |
| Numerical references and values | [The Unified Code of Units of Measure](http://unitsofmeasure.org/ucum.html) |  |
| Patient “problems” (i.e., conditions) | [**[R]** SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| Preferred language | [ISO 639-1](http://www.iso.org/iso/catalogue_detail?csnumber=22109) |  |
| [**[R]** ISO 639-2](http://www.iso.org/iso/catalogue_detail?csnumber=4767) |  |
| [ISO 639-3](http://www.iso.org/iso/catalogue_detail?csnumber=39534) |  |
| [RFC 5646](https://tools.ietf.org/html/rfc5646) |  |
| Procedures (dental) | **[**[**R]** Code on Dental Procedures and Nomenclature (CDT)](http://www.ada.org/en/publications/cdt) |  |
| Procedures (medical) | [**[R]** SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| **[R]** the combination of [CPT-4](http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page)/[HCPCS](http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/index.html) |  |
| [**[R]** ICD-10-PCS](http://www.cms.gov/Medicare/Coding/ICD10/index.html) |  |
| Race | [**[R]** OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997.](http://www.whitehouse.gov/omb/fedreg_1997standards) |  |
| Radiology(interventions and procedures) |  [RadLex](https://www.rsna.org/RadLex.aspx)  |  |
| IHE Comments | **Rationale:**RadLex provides anatomy and pathology terms for radiology reporting and imaging-specific terms, such as modality types and visual characteristics, that are not comprehensively addressed in other terminology resources. The RadLex Playbook provides a standard, comprehensive set of radiology procedure names for use in ordering, reporting, decision support, research and data analysis.**Standard(s):** Add RadLex Playbook**Implementation Specification(s) :**n/a |
| Sex | [HL7 Version 3 Value Set for Administrative Gender](http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.1.11.1) |  |
| Sexual orientation | [SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| Smoking status | [**[R]** SNOMED-CT](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) |  |
| Unique device identification | [**[R]** Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/) |  |
| Vital signs | [LOINC](http://loinc.org/downloads) |  |
| IHE Comments | IHE would like to point out that the feasibility of using LOINC for vital signs is limited today. The majority of EHRs are using LOINC for vital signs; however functionality is limited to manual entry for the most part because the increasingly large amount of vital sign data is provided by devices producing this data in nomenclatures other than LOINC:* Medical devices – IEEE 11073 10101 (10101A is now in IEEE ballot)
* Personal devices - SNOMED (specifications published by Continua)

IEEE 11073 10101 is the only viable standard nomenclature for medical device based readings. 11073 10101 is an ISO internationally recognized standard for medical device patient vital signs and other clinical information output. However, there is not yet a standards-based mapping to convert the vital sign observations to LOINC. IHE is working with the VA and others to build a standards-based conversion of IEEE 11073 10101 data into LOINC for vital signs. Under the leadership of Clem McDonald of NLM, Swapna Abhyankar constructed the IEEE to LOINC mapping earlier this year. This mapping is being vetted and should be in the NIST RTMMS (Rosetta Terminology Mapping Management System) later in 2015. This mapping defines a use case in building the IHE Clinical Mapping (CMAP) Profile defining a mapping utility using the FHIR ConceptMap resource. This profile is being published for comment within the next month by IHE International. This utility may add more value for vital signs because LOINC codes are not used for vital signs in many countries, and, as previously mentioned US consumer devices currently use SNOMED; the utility could be used to convert from IEEE 11073 10101 to SNOMED or some other combination. IHE requests that ONC follow this work that may lead to innovation in semantic interoperability. |

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 message[[7]](#footnote-8) |  |
| **IHE Comments** | **Rationale : IHE recommends:*** Inclusion of the HL7v3 ADT standard for environments using HL7v3;
* Adding Implementation Specs for specific ADT use cases (PAM and NANI)

**Standard(s):** Add HL7 3.x ADT message**Implementation Specification(s) :**Add IHE Patient Administration Management (PAM) ProfileAdd IHE Newborn Admission Notification Information (NANI) Profile |
| **Antimicrobial use and resistance information to public health agencies** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=20)[Consolidated CDA® Release 2.0](http://www.hl7.org/documentcenter/public/wg/structure/C-CDA-R2-publication-package-20141112.zip)[[8]](#footnote-9) |
| **Care plan** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379)[Consolidated CDA® Release 2.0](http://www.hl7.org/documentcenter/public/wg/structure/C-CDA-R2-publication-package-20141112.zip)[[9]](#footnote-10) |
| **Cancer registry reporting** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [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](http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1069) |
| **IHE Comments** | **Rationale:**IHE recommends that the IHE Cancer Registry implementation specification be added; this specification has been implemented; the HL7 spec is not yet normative.**Standard(s):**n/a**Implementation Specification(s):**Add the IHE QRPH Technical Framework Supplement for Physician Reporting to a Public Health Repository - Cancer Registry (PRPH-Ca) Profile. |
| **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](http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_SDC.pdf) |   |
| **IHE Comments** | IHE notes that the current Standards document could serve as an implement specification with the addition of the definition of the specific forms to be generated. |
| **Clinical decision support knowledge artifacts** | [HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.2, Draft Standard for Trial Use.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=337) |  |
| **Clinical decision support services** | [HL7 Version 3 Standard: Decision Support Service, Release 2.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=12) | [HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use](http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=111) |
| **Clinical decision support – reference information** | [**[R]** HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208) | * [HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283)
* [HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22)
 |
| **Data element based query for clinical health information** | [Fast Healthcare Interoperability Resources (FHIR)](http://www.hl7.org/implement/standards/fhir/) |  |
| **Drug formulary checking** | **[R]** [NCPDP Formulary and Benefits v3.0](http://www.ncpdp.org/Standards/Standards-Info) |  |
| **Electronic prescribing****(e.g., new Rx, refill, cancel)**  | **[R]** [NCPDP SCRIPT Standard, Implementation Guide, Version 10.6](http://www.ncpdp.org/Standards/Standards-Info) |  |
| **Electronic transmission of lab results to public health agencies** | **[R**[**]** HL7 2.5.1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144) | [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](http://www.hl7.org/Special/committees/impl/projects.cfm?action=edit&ProjectNumber=737) |
| **Family health history (clinical genomics)** | [**[R]** HL7 Version 3 Standard: Clinical Genomics; Pedigree](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=8) | [HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=301) |
| **Health care survey information to public health agencies** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [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](https://www.hl7.org/Special/committees/structure/projects.cfm?action=edit&ProjectNumber=1002). |
| **Images** | [Digital Imaging and Communications in Medicine (DICOM)](http://medical.nema.org/standard.html) |  |
|  | **Rationale:** The DICOM standard includes a DICOM profile, effectively an implementation specification, for each specific type of medical image based on the acquisition technology (modality). **Standard(s):** n/a **Implementation Specification(s):** Add [Digital Imaging and Communications in Medicine (DICOM)](http://medical.nema.org/standard.html) which containsImage specific SOP Classes, the profiles for each type of medical image based on the acquisition technology (modality). |
| **Immunization registry reporting** | [**[R]** HL7 2.5.1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144) | [HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5](http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf) |
| **IHE Comments** | Release 1.5 is fairly recent and more tightly constrains Release 1.4.  |
| **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](http://wiki.siframework.org/file/view/V251_IG_SIF_LABRESULTS_R1_N1_v15_Pilot_Use_Only.pdf) |  |
| **IHE Comments** | **Rationale:**IHE recommends that the HL7 Implementation Guide; S&I Framework Lab Results Interface Implementation Guide be reclassified as an Implementation Specification to more appropriately reflect its content.IHE is not in a position to evaluate whether this Implementation Guide is mature enough to be considered as a best available standard; it has yet to move out of Pilot for Trial use / DSTU status to the best of our knowledge.  |
| **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](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=208). | * [HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283)
* [HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22)
 |
| **Patient preference/consent**  |  ***[See Question #5-15]*** |  |
| **IHE Comments** | **Rationale:**IHE recommends the IHE Basic Patient Privacy Consent (BPPC) profile as the current best available implementation specification for electronic patient privacy consent. It provides a solid foundation that is in use in the US and internationally. For example the Social Security Administration (SSA) uses the IHE BPPC profile for the eHealth Exchange Access Consent Policy used by the SSA’s implementation for eligibility determination for disability. Healtheway has recently completed a pilot testing program to automate testing for this profile to support SSA onboarding efforts. The open source OpenEMR product also uses IHE BPPC.  |
| **Quality reporting****(aggregate)** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [**[R]** HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DSTU Release 1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286) |
| **Quality reporting****(patient-level)** | [HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | [**[R]** HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture - Category I (QRDA) DSTU Release 2 (US Realm)](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35) |
| **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](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)  | * [Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1](http://gforge.hl7.org/gf/download/frsrelease/1021/10785/HL7_IG_DS4P_R1_CH2_DIRECT_N1_2013SEP.pdf)
 |
| **IHE Comments** | **Rationale:**The complexity of the full DS4P standard is unnecessary for behavioral health information. The only component that is necessary is the subset of DS4P that was accepted by IHE ITI into the US National Extension 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>).  This allows for the tagging of this sensitive information in a way that is appropriate to the use.  Specific guidance on exactly what tags must be used, and exactly what behaviors are expected, would be very helpful to the community to assure accurate and proper handling of this data.  The EHRA suggests **a**dopting the US Realm subset of DS4P from IHE: 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>).**Standard(s):**CDA Release 2.0**Implementation Specification(s):**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>) |
| **Summary care record**  | ***[See Question #5-17]***[HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7) | * [**[R]** Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm)](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258)
* [Consolidated CDA® Release 2.0](http://www.hl7.org/documentcenter/public/wg/structure/C-CDA-R2-publication-package-20141112.zip)[[10]](#footnote-11)
 |
| **IHE Comments** | **Rationale:**IHE is enthusiastic about the potential of the Consolidated-CDA Release 2.0. It intentionally updates and reconciles issues reported from the use of R1.1. C-CDA R1.1 includes 9 document templates and about 70 section templates. C-CDA R2.0 includes 3 new document templates and some 30 new section templates. Both are implementation specifications for use of the CDA R2.0 Standard to implement the document types included. IHE recommends that C-CDA R2.0 not be added to the Standards Advisory until backward compatibility is addressed. There needs to be a glide path. ONC should provide mechanisms to maintain interoperability between the 2.0 and 1.1 versions during the transition phase; two potential solutions include:* Extending C-CDA R2.0 with backward compatibility constraints. Current work on this is advancing in HL7 and looks promising
* Building and maintaining a proposed transformer utility

The cost for the development and support of these solutions should be borne by the Federal Government and not by each vendor individually or the vendor community collectively. |
| **Syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)** | [**[R]** HL7 2.5.1](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144),  | [PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0](http://www.cdc.gov/phin/library/guides/SyndrSurvMessagGuide2_MessagingGuide_PHN.pdf) |
| **IHE Comments** | **Rationale:** n/a**Standard(s):**n/a**Implementation Specifications(s):** Add eHealth Exchange/NwHIN Document Submission, Administrative Distribution, and Health Information Event Messaging specifications |

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](https://tools.ietf.org/html/rfc5321)  |  |
| [For security, Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751](https://tools.ietf.org/html/rfc5751) |  |
| Data sharing through Service Oriented Architecture (SOA) - that enables two systems to interoperate together | [Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X](http://www.w3.org/Protocols/)  (to support RESTful transport approaches) |  |
| [Simple Object Access Protocol (SOAP) 1.2](http://www.w3.org/TR/soap12-part1/)  |  |
| **IHE Comments** **Rationale:**IHE recommends adding the implementation specification based on SOAP used by eHealth Exchange**Standard(s):**n/a**Implementation Specification(s):**eHealth Exchange Messaging Platform v3.0 |
| **IHE Comments:****Rationale:**IHE recommends adding a specific row to Data sharing through SOA to support XDR transport which is slightly different than the SOAP-based RTM**Standard(s):**Add IHE IT Infrastructure Technical Framework : IHE-XDR (Cross-Enterprise Document Reliable Interchange)**Implementation Specification(s):**n/a |
|  |
| [For security, Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246](https://datatracker.ietf.org/doc/rfc5246/) |  |
| **IHE Comments****Rationale:**IHE recommends adding a node authentication component to Data sharing through SOA**Standard(s):**n/a**Implementation Specification(s) :**[IHE ATNA (Audit Trail and Node Authentication)](http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication) |

**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”)](http://www.healthit.gov/policy-researchers-implementers/direct-project) | * [**[R]** XDR and XDM for Direct Messaging Specification](http://www.healthit.gov/policy-researchers-implementers/direct-project)
* [**[R]** IG for Direct Edge Protocols](http://www.healthit.gov/sites/default/files/implementationguidefordirectedgeprotocolsv1_1.pdf)
* [IG for Delivery Notification in Direct](http://wiki.directproject.org/file/view/Implementation%2BGuide%2Bfor%2BDelivery%2BNotification%2Bin%2BDirect%2Bv1.0.pdf)
 |
| **[**[**R]** SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification](http://modularspecs.siframework.org/SOAP%2Bbased%2BSecure%2BTransport%2BArtifacts). |  |
| **IHE Comments**IHE suggests removing the [[**R]** SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification](http://modularspecs.siframework.org/SOAP%2Bbased%2BSecure%2BTransport%2BArtifacts) row. It is already addressed in the transport Section above. |
| [IHE-XDR (Cross-Enterprise Document Reliable Interchange)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **Rationale:**IHE recommends listing the IHE-XDR again as an implementation specification as well as a base standard because the IHE-XDR can serve as an implementation specification as well. In addition, to reflect the fact that eHealth Exchange has a separate implementation specification based on IHE-XDR, IHE also recommends the inclusion of the eHealth Exchange/NwHIN Document Submission as an implementation specification**Standard(s):**no change**Implementation Specification(s):**Add[IHE-XDR (Cross-Enterprise Document Reliable Interchange)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf)Add [eHealth Exchange/NwHIN Document Submission](http://healthewayinc.org/wp-content/uploads/2014/11/nhin-document-submission-production-specification-v2-0-a.pdf) |
| [NwHIN Specification: Authorization Framework](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-authorization-framework-production-specification-v3.0.pdf) |  |
| **IHE Comments****Rationale:**IHE recommends removing this NwHIN Specification from the Standards column and adding it to the Implementation Specification column **Standard(s):**Remove[NwHIN Specification: Authorization Framework](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-authorization-framework-production-specification-v3.0.pdf)**Implementation Specification(s):**Add [NwHIN Specification: Authorization Framework](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-authorization-framework-production-specification-v3.0.pdf) |
| [NwHIN Specification: Messaging Platform](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-messaging-platform-production-specification-v3.0.pdf) |  |
| **IHE Comments** | **Rationale:**IHE recommends removing this specification from the standard column and adding it to the Implementation Specification column.**Standard(s):**Remove[NwHIN Specification: Messaging Platform](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-messaging-platform-production-specification-v3.0.pdf)**Implementation Specification(s):**AddNwHIN Specification: Messaging Platform |
| **Query for documents within a specific health information exchange domain** | [IHE-XDS (Cross-enterprise document sharing)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **IHE Comments****Rationale:**Move IHE XDS (Cross-enterprise Document Sharing) to Implementation Specification column and include underlying standards under the standards column**Standard(s):**OASIS ebRS 3.0**Implementation Specification(s):**[IHE-XDS (Cross-enterprise Document Sharing)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |
| [IHE-PIX (Patient Identity Cross-Reference)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **IHE Comments****Rationale:**To properly allocate standard(s) and implementation specification(s) and ensure that both HL7 v2.x and HL7 v2.xversions are recognized, IHE suggests the following adds and moves:* Move IHE-PIX (Patient Identity Cross Reference) to the Implementation Specification(s) column and add the IHE PIX v.3 alternative as an additional Implementation Specification.
* Add HL7 v2.x and HL7 v3.x to the standard(s) column.

**Standard(s)**Add HL7 v2.xAdd HL7 v3.xMove [IHE-PIX (Patient Identity Cross-Reference)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) to the Implementation Specifications(s) column**Implementation Specification(s)**Add[IHE-PIX (Patient Identity Cross-Reference)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf), the HL7 v.2 version by defaultAdd [IHE-PIX (Patient Identity Cross-Reference)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) HL7 v.3 |
| [IHE-PDQ (Patient Demographic Query)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **IHE Comments** | **IHE Comments****Rationale**To properly allocate standard(s) and implementation specification(s) and ensure that both HL7 v2.x and HL7 v2.x versions are recognized, IHE suggests the following adds and moves:* Move IHE-PDQ (Patient Demographic Query) to the Implementation Specification(s) column and add the IHE PDQ v3 version of IHE-PDQ as an alternative for environments using HL7 v3.
* Add HL7 v2.x and HL7 v3.x to the standard(s) column.

**Standard(s)**Add HL7 v2.xAdd HL7 v3.xMove [IHE-PDQ (Patient Demographic Query)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) to the Implementation Specifications(s) column**Implementation Specification(s)**Add[IHE-PDQ (Patient Demographic Query)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) , the HL7 v.2 version by defaultAdd [IHE-PDQ (Patient Demographic Query)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) HL7 v.3 |
|  **Query for documents outside a specific health information exchange domain** | [IHE-XCA (Cross-Community Access)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **IHE Comments**IHE recommends moving the “eHealth Exchange Query for Documents” from its own row below to the above row with [IHE-XCA (Cross-Community Access)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) in the Standard(s) column. “eHealth Exchange Query for Documents” and “eHealth Exchange Retrieve Documents” will go in the Implementations Specification(s) column of that row. |
| [IHE-XCPD (Cross-Community Patient Discovery)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) |  |
| **IHE Comments**IHE recommends adding the “eHealth Exchange Patient Discovery” from its own row below to the above row with [IHE-XCPD (Cross-Community Patient Discovery)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) in the Standard(s) column. “eHealth Exchange Patient Discovery” will go in the Implementations Specification(s) column of that row. |
| [NwHIN Specification: Patient Discovery](http://www.healthewayinc.org/images/Content/Documents/specs/2011/nhin-patient-discovery-production-specification-v2.0.pdf) |  |
| **IHE Comments**IHE recommends removing the separate row and listing this specification as referenced above.  |
| [NwHIN Specification: Query for Documents](http://www.healthewayinc.org/images/Content/Documents/specs/2011/nhin-query-for-documents-production-specification-v3.0.pdf) |  |
| **IHE Comments**IHE recommends removing the separate row and listing this specification as referenced above. |
| [NwHIN Specification: Retrieve Documents](http://www.healthewayinc.org/images/Content/Documents/specs/2011/nhin-retrieve-documents-production-specification-v3.0.pdf) |  |
|  | **IHE Comments**IHE recommends removing the separate row and listing this specification as referenced above. |
| **IHE Comments** | **Rationale:**IHE recommends adding the following standards and specifications as separate rows under this topic category as shown below: **#1 Row to add:****Standard(s):**Oasis:* Assertions and Protocols for Security Assertion Markup Language (SAML) v2.0
* Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare v1.0
* Authentication Context for Security Assertion Markup Language (SAML) v2.0
* Web Services Security: SOAP Message Security V1.1
* Web Services Security: SAML Token Profile v1.1

WSI:* Security Profile v1.1

**Implementation Specification(s):** eHealth Exchange Specifications* Authorization Framework v3.0

**#2 Row to add:****Standard(s):**WS-I v2.0* Simple Object Access Protocol (SOAP) v1.2
* SOAP Message Encoding Style
* SOAP Faults
* Hypertext Transfer Protocol (HTTP) v1.1
* WS-Addressing v1.0
* WS-Base Notification v1.3
* Message Transmission Optimization Mechanism (MTOM) binding for SOAP v1.0
* Web Services Description Language (WSDL) v1.1
* XML Schema v1.0
* Universal Discovery and Description Interface (UDDI) v3.0.2

WS-I v1.1* Transport Layer Security v1.0
* XML Signature v1.0
* Web Services Description Language (WSDL) v1.1
* Symmetric Encryption Algorithm and Key Length AES 128-bit
* X.509 Token Profile v1.0
* Attachment Security v1.0

**Implementation Specification(s):**eHealth Exchange Specifications* Messaging Platform v3.0
 |
| **Data element based query for clinical health information** | [Fast Healthcare Interoperability Resources (FHIR)](http://www.hl7.org/implement/standards/fhir/) |  |
| **IHE Comments** | IHE acknowledges the potential use of HL7 FHIR® to enable data element query and retrieval for clinical health information. However, we recommend that the maturity of FHIR be evaluated and established prior to its being recommended in the Standards Advisory.  |
| **Image exchange** | [Digital Imaging and Communications in Medicine (DICOM)](http://medical.nema.org/standard.html) |  |
| **IHE Comments** | **Rationale:**IHE recommends expanding the above Image Exchange “Purpose” by adding the following rows:**ROW #1 addition****Standard(s):**IHE IT Infrastructure (ITI) Technical Framework * Cross Community Access (XCA)

**Implementation Specification(s):** IHE Radiology Technical Framework* Cross-Community Access for Imaging (XCA-I)

**ROW #2 addition:****Standard(s):**IHE IT Infrastructure (ITI) Technical Framework * Cross-Enterprise Document Sharing (XDS)

**Implementation Specification(s):** IHE Radiology Technical Framework* Cross-Enterprise Document Sharing for Imaging (XDS-I.b)
* Cross-Enterprise Patient Discovery (XCPD)

**ROW #3 addition:****Standard(s):*** HL7 V2.5
* HL7 V3.0
* HL7 V2.5
* HL7 V3.0

**Implementation Specification(s):** * Patient Demographic Query (PDQ)
* Patient Demographic Query v3 (PDQv3)
* Patient Cross Reference Manager (PIX)
* Patient Cross Reference Manager V3 (PIXv3)

**ROW #4 addition:****Standard(s):**Digital Imaging and Communications in Medicine (DICOM)DICOM Manifest**Implementation Specification(s):** Nothing listed for this row  |
| **Resource location** | [IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_CSD.pdf) |  |
| **IHE Comments** | **Rationale:**IHE suggests reclassifying the listing for the CSD profile to Implementation Specification(s) and adding standards as follows:**Standard(s):**HTTP 1.1, XQuery 1.0, XForms 1.1SOAP 1.2, IETF RFC 4791**Implementation Specification(s):** [IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_CSD.pdf) |
| **Provider directory** | [IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf) |  |
| **IHE Comments** | **Rationale:**IHE would suggest reclassifying the listing for HPD to Implementation Specification(s) and adding standards as follows:**Standard(s):**ISO 21091, LDAP, DSML v2.0**Implementation Specification(s):** [IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_HPD.pdf) |
| **Publish and subscribe** | [NwHIN Specification: Health Information Event Messaging Production Specification](http://www.healthit.gov/sites/default/files/nhin-health-information-event-messaging-production-specification-v2.0-a.pdf) |  |
| **IHE Comments** | **Rationale:**IHE suggests removing this standard as there seem to be no known implementations-See response to question 5.5). IHE suggests adding the widely deployed IHE DSUB profile and adding the corresponding standards as follows:**Standard(s):**WS-BaseNotification 1.3 OASIS Standard 620WS-BrokeredNotification 1.3 OASIS StandardWS-Topic 1.3 OASIS Standard**Implementation Specification(s):** [IHE](http://www.healthit.gov/sites/default/files/nhin-health-information-event-messaging-production-specification-v2.0-a.pdf) IT Infrastructure Technical [Framework](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_DSUB.pdf) * Document Subscription Profile – Trial Implementation
 |

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](http://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?

**IHE Comments:**

* 1. To assist in forward planning for developers and SDOs alike, ONC should collect information from various initiatives, SDOs, and professional organizations about emerging standards and implementation guides in conformance with the Roadmap. This information should be made publicly available but through a different vehicle than the Standards Advisory to indicate its tentative nature. This information could also help ONC identify duplications and gaps that ONC could use to harmonize standards and development efforts, as well as identify innovative work that ONC can encourage and support. This information could also include projected timeframes for when these standards may be ready for wider adoption, and any standards that it might be wise to deprecate. Examples of efforts that would be included in such information are the development and testing of implementation guides which are strong candidates for 2016 Standards Advisory implementation specifications such as the:
		+ Joint S&I Framework and IHE Data Access Framework Implementation Guide soon to be released for public comment
		+ EHR | HIE I Interoperability Workgroup implementation specifications covering Direct and Community Query functionality now being used in the pilot ConCert by HIMSSTM Testing and Certification program

* 1. We suggest that versioning, where applicable, be added to the Standards Advisory to help avoid mismatches and drive harmonization industry wide. An example of where this could be helpful is in selecting specific HL7 v2.x and HL7 v3 versions. This would save time in connecting two vendor systems by providing clear direction when the vendors bring different versions to an implementation. However, this is not necessary for IHE profiles in Final Text which are not versioned.
	2. As stated in the body of the document, the present intent is that the judgment for “best” be ultimately that of (1) ONC with input from and (2) a review by the HIT Standards Committee, and (3) public consultations.  IHE proposes the establishment of a dedicated non-regulatory committee to drive the work. This committee would include appropriate representation and would add value to ONC’s decision making by providing more expertise and rigor. Members of the committee and its workgroups would be selected to be:
		+ - * Technically expert, drawing from industry
				* Experienced in the use of the standards, drawing from provider and other organizations using the standards
				* Expert in developing standards and implementation specifications, drawing on standards development organizations (SDOs) and professional societies.
	3. IHE recommends establishment of a process to measure actual adoption/use of standards and implementation specifications with links to case studies, evaluations, etc. That information should be shared publicly.
	4. The Standards Advisory is proposed as a “point-in-time” assessment that is updated yearly.  The value of a snapshot is closely linked to its predictability.  In healthcare, the deployment of connected IT solutions frequently takes several years across a wide range of distinct organizations to not only introduce the technology, but also align and update processes.  Thus IHE recommends that the annual process encourage continuity while not stifling innovation. When implementing best available standards, stability is essential to ensure that adherence to the Standards Advisory is a worthy investment.

* 1. A clear set of criteria associated with any recommendation for a standard/implementation specification is required for the recommendations to be credible. IHE recommends adherence to the following:
		+ - * Standards and implementation specifications need to be stable.  DSTUs should be avoided for inclusion in the Standards Advisory.
				* An active maintenance process must be in place.
				* Robust testing tools need to be available for software developers and provider organizations to test against the standards.
				* Some production piloting / early deployments need to have been performed for inclusion.
	2. IHE recommends mapping use cases to standards and implementation specifications. Interoperability specifications are special products of standards selection and harmonization activities for a specific business need (Use Case). This product is a meta-standard (a standard about standards)—an assembly of standards in an interoperability specification or reference standards portfolio—that defines how individual standards (e.g., those in the Advisory) have to work together to enable interoperability for a specific Use Case such as care coordination, radiology, laboratory, pharmacy, data reporting, population health, etc. The experience of the Health Information Technology Standards Panel (HITSP) showed that there is a need for additional constraints defined by the meta-standard (interoperability specification) for individual standards to work together for a specific Use Case. For example, a Personal Health Record Use Case.

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.

**IHE Comments:**

IHE has identified the following “purposes” for addition to the specified sections or reclassification to those sections:

1. II. Content/Structure
* Research Protocols – Standard is CDISC and HL7 v3 and the IG is IHE QRPH CRPC (Clinical Research Process Content)
1. IV. Services

Expansion of Services into a Foundational Service Components category. This will include the “security” components discussed in “The Structure of Sections I through IV”. This expanded category would include basic component standards and implementation specifications necessary as building blocks for the Services infrastructure components. Purposes to be folded into the Foundational Services Category could include:

Audit logging of transactional activity – Standard is IHE ATNA (Audit Trail and Node Authentication)

Ensuring of consistent date and time stamps throughout a sequence of health events- Standard is IHE CT (Consistent Time)

User access authorizations and assertions – IHE standards include:

IHE XUA ([Cross-Enterprise User Assertion](http://wiki.ihe.net/index.php?title=Cross-Enterprise_User_Assertion))

IHE EUA ([Enterprise User Authentication](http://wiki.ihe.net/index.php?title=Enterprise_User_Authentication))

IHE IUA (Internet User Authorization)

IHE ATNA (Audit Trail and Node Authentication)

Terminology/nomenclature mapping services as well as workflows required to bring non-EHR data into EHRs – Standards to be determined. Related implementation specification soon to be published for comment include IHE Clinical Mapping (CMAP) and IHE Remote Patient Monitoring (RPM)

Simple way for known, trusted participants to “pull” health information directly from other known trusted participants (existing) – Standards to be determined

Purposes to be moved to the IV. Foundational Services Category from II. Content/Structure Standards could include:

Segmentation of sensitive information

Patient preference/consent

Research – Standard is BPEL and HL7 v3 and the implementation specifications include:

IHE QRPH RPE (Retrieve Protocol for Execution)

IHE CRD (Clinical Research Document)

IHE DSC (Drug Safety Content)

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?

**IHE Comments**

1. For Section I:  Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications, the column “Implementation Specification” should contain the value set (and a specific version, if desired), while the standard is the terminology standard from which the value set is derived.  For example:

|  |  |  |
| --- | --- | --- |
| Allergy reactions | [**SNOMED-CT**](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html) | **Value set is all entries from the Concept “Allergy Reaction”** |

Or if the value set is fixed:

|  |  |  |
| --- | --- | --- |
| Allergy reactions | [**SNOMED-CT**](http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html)**version/date.** | **Value set is all entries from the Concept “Allergy Reaction”** |

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?

**IHE Comments:**

* 1. In Category IV, Publish and subscribe: the Standards Advisory proposed the NwHIN Specification: Health Information Event Messaging Production Specification. There is little deployment of the NWHIN Implementation Specification.  This specification was written by a very small group and never gathered acceptance.  We suggest to replace the NWHIN Implementation Specification with the much more widely used IHE DSUB Profile: (<http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_DSUB.pdf>) and the following underlying base standards from the OASIS Web Services Notification Family of Standards:

(<http://www.oasis-(open.org/committees/tc_home.php?wg_abbrev=wsn)>

• WS-BaseNotification 1.3 OASIS Standard

(<http://docs.oasis-open.org/wsn/wsn-ws_base_notification-1.3-spec-os.pdf>)

• WS-BrokeredNotification 1.3 OASIS Standard

(<http://docs.oasis-open.org/wsn/wsn-ws_brokered_notification-1.3-spec-os.pdf>)

• WS-Topics 1.3 OASIS Standard

(<http://docs.oasis-open.org/wsn/wsn-ws_topics-1.3-spec-os.pdf>)

|  |  |  |
| --- | --- | --- |
| **Publish and subscribe** | **WS-BaseNotification 1.3 OASIS Standard 620****WS-BrokeredNotification 1.3 OASIS Standard****WS-Topics 1.3 OASIS Standard** | [**IHE**](http://www.healthit.gov/sites/default/files/nhin-health-information-event-messaging-production-specification-v2.0-a.pdf) **IT Infrastructure Technical** [**Framework**](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_DSUB.pdf) **- Document Subscription Profile – Trial Implementation** |

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?

**IHE Comments:**

1. Providers do not considered diagnosis codes as administrative codes. Administrative codes sets that have to do with demographics do have clinical relevance. From a provider standpoint these should not be removed. Not considering the administrative codes would result in loss of the historical data. There is a need to mine data for analytics; the administrative data will be a part of that as it relates to the clinical data. Analytics is in part based on Dx codes. Administrative standards are relevant to value based care. In part as recognition of this need the IHE Patient Care Coordination Domain is developing the IHE Clinical Mapping (CMAP) profile that includes a use case for mapping from SNOMED-CT to ICD-10.

5-10. ***[Section I]*** Should the MVX code set be included and listed in tandem with CVX codes?

**IHE Comments:**

1. IHE supports the American Immunization Registry Association (AIRA) position on this question:

“AIRA supports the inclusion of CVX as the primary method for reporting historical doses, and MVX as an additional data element when it is available, noting that MVX is not always known for a historical dose. When it is known, however, it provides helpful additional data to infer the brand of vaccine administered.

AIRA believes it is important to define the concepts of “administered” and “historical”, however. Per AIRA’s Modeling of Immunization Registry Operations Workgroup (MIROW) Manual, Chapter 7 on Data Quality, administered and historical are differentiated as follows:

“Administered” value for the Administered/Historical Indicator points out that the Immunization Information System Authorized Organization (IIS-AO) submits its own Vaccination Event, i.e., attests that it conducted the Vaccination Event (“I am the Vaccinator IIS-AO”).

•          In this case, an expanded set of data items for a Vaccination Event Submission would be expected (this is the Best Practice -- see BR105R1, chapter 5).

•          In some cases, IIS-AO submits its own Vaccination Event (“administered”), but does not have all expected information for the expanded set of data items. Following are three situations when a reduced set of data items for an “administered” Vaccination Event submission may be allowed (see BR105R2, chapter.

o   Legacy immunizations. Example is an IIS-AO that begins reporting to (comes onboard) IIS and wants to submit information about Vaccination Events it conducted some time ago, before entering into an agreement with IIS.

o   Limited EHR capacity. In some cases, EHR that IIS-AO uses does not support expanded set of data elements, so IIS-AO is not able to send them. IIS still wants the data and cannot mandate upgrade to EHR.

 This situation would be for a limited time period, as established by the IIS.

o   Birth Doses. HepB and other hospital birth doses may not have all required data elements available.

o   Notes:

 Rules for accepting or rejecting "Administered" Vaccination Event Submissions with less than the expanded data set should be the same for Electronic Data Exchange and Direct User Interface submissions.

 When reduced set of data items is reported for the “Administered” Vaccination Event, an error message should always be sent or displayed in the UI. Also, other methods of communicating data quality problems should be employed, i.e., monthly reports.

“Historical” value for the Administered/Historical Indicator points out that the IIS-AO originates a Vaccination Event Submission for a Vaccination Event that was administered (and therefore, owned) by some other entity (“I am NOT Vaccinator IIS-AO; I am just Recorder IIS-AO”).

In this case, a reduced set of data items for a Vaccination Event Submission would be expected.”

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?

**IHE Comments:**

1. IHE supports the American Immunization Registry Association (AIRA) position on this question:

“It is important to recognize that NDC codes change and are added more frequently than CVX and MVX codes so relying on those as the sole source for vaccine administration records would require changes by some IIS (**Immunization Information Systems)**, and may also necessitate additional maintenance to the IIS as the codes are changed and updated. There are also continued challenges with dual NDC codes on external packaging and on unit of use, so additional mapping functionality would be essential. Finally, NDC is not a commonly leveraged data element currently in EHRs. Using NDC would require a significant development effort for the EHR community, as well as potential unnecessary burden to maintain and update the NDC codeset at each provider practice.

It is also unclear whether NDC codes would be appropriate for use with bidirectional (patient history/forecast) message exchanges. The Standards Advisory does not address this use case directly, but recognizing that this is a current practice in IIS-EHR exchange, primary use of NDC over CVX/MVX brings up significant concerns.

Finally, see comments above regarding the importance of common definitions regarding differentiating historical and administered immunizations.

For these reasons, AIRA would support CVX and MVX as the preferred codesets for administered immunizations, while NDC continues to be used in 2D barcoding and some inventory decrementing. We (AIRA) would also like to collaborate in evaluating the benefits and costs of transitioning to NDC as a potential replacement codeset for administered immunizations in the future.

5-15. ***[Section II]*** Are there best available standards for the purpose of “Patient preference/consent?” Should the [NHIN Access Consent Specification v1.0](http://healthewayinc.org/images/Content/Documents/specs/2010/nhin-access-consent-policies-production-specification-v1.0.pdf) and/or IHE BPPC be considered?

**IHE Comments:**

1. See the IHE response to the “**Patient preference/consent**” purpose row in Section II.

5-16. ***[Section II]*** For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?

**IHE Comments:**

1. See the IHE response to the “**Segmentation of sensitive information”** purpose row in Section II.

5.17***. [Section II]*** 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?

**IHE Comments:**

1. See the IHE response to the “**Summary care record”** purpose row in Section II**.**

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.

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> [↑](#footnote-ref-2)
2. <https://www.federalregister.gov/citation/71-FR-51089> [↑](#footnote-ref-3)
3. <https://www.federalregister.gov/citation/72-FR-9339> [↑](#footnote-ref-4)
4. <https://www.federalregister.gov/citation/73-FR-3973> [↑](#footnote-ref-5)
5. <https://www.federalregister.gov/citation/74-FR-3599> [↑](#footnote-ref-6)
6. [*http://healthit.gov/sites/default/files/pdf/TransmittalMemo\_HITSC\_083012\_NwHIN\_FINAL.pdf*](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*](http://healthit.gov/sites/default/files/pdf/2012Aug30_HITSC_NWHIN_Transmittal.pdf) [↑](#footnote-ref-7)
7. Any HL7 2.x version messaging standard associated with ADT is acceptable. [↑](#footnote-ref-8)
8. Link will be updated once publicly available. [↑](#footnote-ref-9)
9. Link will be updated once publicly available. [↑](#footnote-ref-10)
10. Link will be updated once publicly available. [↑](#footnote-ref-11)