2018 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

Reference Edition

Table of Contents

Introduction to the 2018 Interoperability Standards Advisory 1

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications 2

I-A: Allergies and Intolerances 2

I-B: Encounter Diagnosis 4

I-C: Family Health History 5

I-D: Functional Status/Disability 5

I-E: Health Care Providers 6

I-F: Imaging (Diagnostics, Interventions and Procedures) 7

I-G: Immunizations 7

I-H: Industry and Occupation 8

I-I: Lab Tests 9

I-J: Medications 10

I-K: Units of Measure 11

I-L: Nursing 12

I-M: Patient Clinical "Problems" (i.e., conditions) 14

I-N: Preferred Language 14

I-O: Procedures 14

I-P: Race and Ethnicity 16

I-Q: Research 17

I-R: Sex at Birth, Sexual Orientation and Gender Identity 17

I-S: Social, Psychological, and Behavioral Data 19

I-T: Tobacco Use (Smoking Status) 23

I-U: Unique Device Identification 24

I-V: Vital Signs 25

I-W: Pregnancy Status 26

Section II: Content/Structure Standards and Implementation Specifications 26

II-A: Admission, Discharge, and Transfer 26

II-B: Care Plan 28

II-C: Clinical Decision Support 31

II-D: Clinical Quality Measurement and Reporting 33

II-E: Data Provenance 35

II-F: Diet and Nutrition 36
II-G: Drug Formulary & Benefits 36
II-H: Electronic Prescribing 37
II-I: Family Health History (Clinical Genomics) 42
II-J: Healthy Weight 43
II-K: Images 43
II-L: Laboratory 45
II-M: Medical Device Communication to Other Information Systems/Technologies 48
II-N: Patient Education Materials 49
II-O: Patient Identification Management 49
II-P: Patient Preference/Consent 50
II-Q: Public Health Reporting 52
II-R: Research 61
II-S: Segmentation of Sensitive Information 66
II-T: Summary Care Record 67
Section III: Standards and Implementation Specifications for Services/Transport/Exchange 68
III-A: "Push" Exchange 68
III-B: Clinical Decision Support Services 72
III-C: Image Exchange 73
III-D: Healthcare Directory, Provider Directory 75
III-E: Patient Identification Management 76
III-F: Public Health Exchange 76
III-G: Publish and Subscribe 77
III-H: Query 77
III-I: Resource Location 81
III-J: Consumer Access/Exchange of Health Information 81
Section IV: Models and Profiles 84
IV-A: Functional Models 84
IV-B: Functional Profiles 85
IV-C: Information Models 86
Section V: Administrative Standards and Implementation Specifications 87
V-A: Health Care Claims and Coordination of Benefits 87
V-B: Administrative Transactions - Non-Claims 93
V-C: Administrative Transactions to Financial Exchanges 96

V-D: Administrative Transactions to Support Clinical Care 99
V-E: Operating Rules to Support Administrative Transactions 102
V-F: CMS Interoperability Standards for Provider to Provider Communication 105
Appendices 108

The 2018 Interoperability Standards Advisory represents the Office of the National Coordinator for Health Information Technology's current assessment of the heath IT standards landscape. It 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.

This document contains numerous links to other federal agencies and to private organizations. You are subject to these sites' privacy policies when you access them. HHS is not responsible for Section 508 compliance (accessibility) on other federal or private sites. HHS is not responsible for the contents of any "off-site" web page referenced from this document.

Introduction to the 2018 Interoperability Standards Advisory

The Interoperability Standards Advisory (ISA) process represents the model by which the Office of the National Coordinator for Health Information Technology (ONC) will coordinate the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, research and administrative purposes. ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific interoperability needs they seek to address. Furthermore, ONC encourages further pilot testing and industry experience to be sought with respect to standards and implementation specifications identified as "emerging" in the ISA.

The 2018 Reference Edition ISA reflects the numerous changes made across the ISA throughout 2017. To learn more about what has changed, refer to the Recent ISA Updates page, which provides a summary of major changes to the ISA. In addition, registered users may subscribe to change notifications to be alerted by e-mail of all revisions to individual interoperability needs or for ISA-wide changes. Anyone may become a registered user, by submitting an account request. Once logged in, look for the blue "change notification" button at the bottom of the interoperability need page, or at the bottom of the home page to be notified of any changes across the ISA.

For additional information about the ISA, including scope, purpose, structure, and an overview of the informative characteristics attributed to each standard/implementation specification, please see the Introduction text located at www.healthit.gov/isa

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

I-A: Allergies and Intolerances

Interoperability Need: Representing Patient Allergic Reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• SNOMED CT® may not be sufficient to differentiate between an allergy or adverse reaction, or the level of severity. • For use of SNOMED CT®, codes should generally be chosen from the Clinical finding axis. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• 'Adverse Clinical Reaction' value set (OID: 2.16.840.1.113883.3.2074.1.1.30) contains SNOMED CT findings and disorders resulting from reactions to substances • 'Allergy and Intolerance Type' value set (OID: 2.16.840.1.113883.3.88.12.3221.6.2) contains SNOMED CT disorders representing classes of reactions and intolerances

Interoperability Need: Representing Patient Allergies and Intolerances; Medications

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

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

• When a medication allergy necessitates capture by medication class, SNOMED CT® should be used.
• RxNorm: Refers to the RxNorm source specifically (and not to other sources that are included with the RxNorm download).
	• Representing Medication
	  ○ Clinical Drug Ingredient (2.16.840.1.113762.1.4.1010.7) (RxNorm ingredient codes)
	  ○ Pharmaceutical / biologic product (product) (SNOMED CT 373873005) is parent to pharmaceutical/biologic classes
	• Representing Adverse Reactions/Intolerances
	  ○ Propensity to adverse reactions to drug (disorder) (SNOMED CT

	419511003) is parent to: ▪ Drug Allergy (disorder) (SNOMED CT 416098002) and child terms/codes

Interoperability Need: Representing Patient Allergies and Intolerances; Food Substances

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

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

• Feedback requested.	• Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT® substance value set)
	• Adverse Clinical Reaction (2.16.840.1.113883.3.2074.1.1.30) (SNOMED CT® disorder and finding value set)
	• Propensity to adverse reactions to food (disorder) (SNOMEDCT 418471000) is parent SNOMEDCT code to:
	  ○ Food allergy (disorder) (SNOMEDCT 414285001)
	  ○ Food intolerance (disorder) (SNOMEDCT 235719002)

Interoperability Need: Representing Patient Allergies and Intolerances; Environmental Substances

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

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

• Feedback requested.	• Allergic disposition (disorder) (SNOMEDCT 609328004) is parent code to:
	  ○ Environmental allergy (disorder) (SNOMEDCT 426232007)
	  ○ Allergy to substance (disorder) (SNOMED CT 419199007) and other related codes
	• Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT substances value set).

I-B: Encounter Diagnosis

Interoperability Need: Representing Patient Medical Encounter Diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED CT®	Final	Production	●●●●○	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Use of SNOMED CT® codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • The use of these standards may be further constrained by other standards and implementation specifications found elsewhere in the ISA. • Systems should be able to process (or at minimum display) data coded using the older ICD-9-CM standard, as this legacy content still exists and may be used for analysis/decision support/quality measurement needs, where retroactive analysis is often required, but ICD-9 should not be collected for new entries. • A mapping from SNOMED CT® to ICD-10-CM is available from the National Library of Medicine.	• Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED CT® code system) • Recommended starter set: CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

Interoperability Need: Representing Patient Dental Encounter Diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNODENT	Final	Production	●●●●○	No	$	N/A
Standard	ICD-10 Dental Diagnosis Codes	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Code System:
• SNODENT is owned, maintained and distributed by the American Dental Association (ADA). The SNODENT code set is available under license at no cost for non commercial use. The license agreement terms also permit licensees to use SNODENT in the development of non-commercial, academic, scholarly articles and presentations for publication.	• OID 2.16.840.1.113883.3.3150

I-C: Family Health History

Interoperability Need: Representing Patient Family Health History

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Some details around family genomic health history may not be captured by SNOMED CT®. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	For Diagnosis and Conditions: • Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC® code system) • Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED CT® code system) For genomic data: • Gene Identifier: HGNC Value Set (2.16.840.1.113883.4.642.2.468) • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature (2.16.840.1.113883.4.642.2.392) For family relationships and roles: • Personal Relationship Role Type urn:oid:2.16.840.1.113883.1.11.19563 • Personal And Legal Relationship Role Type urn:oid:2.16.840.1.113883.11.20.12.1

I-D: Functional Status/Disability

Interoperability Need: Representing Patient Functional Status and/or Disability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Resources for this interoperability need include: ▪ Social Security Association's Disability Determination Process ▪ American College of Occupational and Environmental Medicine	• Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) - version 3.00 (LOINC panel 85654-2) • Nursing Management Minimum Data Set panel [NMMDS] (LOINC panel 52826-5)

additional resources on Functional Status/Disability. ▪ American Medical Association's "Guides to the Evaluation of Permanent Impairment, Sixth Edition" • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• Inpatient Rehabilitation Facility - Patient Assessment Instrument (IRF-PAI) - version 1.4 [CMS Assessment] (LOINC panel 83265-9) • Outcome and assessment information set (OASIS) form - version B1 (LOINC panel 46462-8) • Outcome and assessment information set (OASIS) form - version C - Transfer to facility (LOINC panel 57193-5)

I-E: Health Care Providers

Interoperability Need: Representing Health Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	National Plan and Provider Enumeration System National Provider Identifier (NPI)	Final	Production	●●●●○	Yes	Free	N/A
Standard	National Uniform Claim Committee (NUCC) Health Care Provider Taxonomy	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• NPPES permits non-billable care team members to apply for an NPI number to capture the concept of 'person'. • NPI taxonomy does not describe all roles associated with an individual's care team, however, NUCC Health Care Provider Taxonomy codes cover concepts of other health care providers.	• NUCC Healthcare Provider Taxonomy (HIPAA) value set OID:2.16.840.1.114222.4.11.1066

Interoperability Need: Representing Provider Role in Team Care Settings

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• NUCCPT codes capture roles of direct care providers as well as other members of the care team as well as those provider supporting health services.	• NUCCPT Healthcare Provider Taxonomy : 2.16.840.1.114222.4.11.1066 • Pharmacy e-Health Information Technology Collaborative Occupations of Providers SNOMED CT value set 2.16.840.1.113762.1.4.1096.129

I-F: Imaging (Diagnostics, Interventions and Procedures)

Interoperability Need: Representing Imaging Diagnostics, Interventions and Procedures

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Radiological Society of North America (Radlex) and Regenstreif Institute (LOINC®) have harmonized terms for radiology procedures.	• Radlex LOINC Imaging Document Codes

I-G: Immunizations

Interoperability Need: Representing Immunizations – Historical

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • When an MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated providing further specificity as to the vaccines administered. • While the information is very helpful, MVX is fairly rare to have for historical vaccinations and is unrealistic to have providers collect.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set 2.16.840.1.114222.4.11.826 • RxNorm Vaccine Clinical Drug 2.16.840.1.113762.1.4.1010.8

Interoperability Need: Representing Immunizations – Administered							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Standard Code Set CVX—Clinical Vaccines Administered	Final	Production	●●●●●	Yes	Free	N/A
Standard	HL7 Standard Code Set MVX -Manufacturing Vaccine Formulation	Final	Production	●●●●○	No	Free	N/A
Standard	National Drug Code	Final	Production	Feedback requested	Yes	Free	N/A
Standard	RxNorm	Final	Production	Feedback requested	No	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●○	No	$	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • If an MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated providing further specificity as to the vaccines administered. • There is a potential issue with use of the National Drug Code regarding which code to use when there are multiple active ingredients in a single package or multiple separate ingredients that need to be mixed together. • CPT is an acceptable alternative code set for local use, but may have limitations for interoperability across systems.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set

I-H: Industry and Occupation

Interoperability Need: Representing Patient Industry and Occupation							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDC_Census 2010 Industry and Occupation System	In Development	Pilot	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The CDC_Census 2010 system is used by the National Institute for Occupational	• Representing Industry

Safety and Health (NIOSH) to classify industry and occupation entries in over 1 million records each year from health data collection systems such as health surveys, registries, and death records. They are based on the US Census' industry and occupation classification system, which is based on the North American Industry Classification System (NAICS) and Standard Occupational Classification (SOC) System. The CDC_Census system provides useful detail for the care provider and meets other federal requirements for statistical analysis. • NIOSH is developing updates to these value sets to include more detailed titles based on the Census Bureau Alphabetical Indexes for Industry and Occupation and will incorporate military service and occupation. A tool for collecting patient industry and occupation titles in electronic health records is also under development.	▪ LOINC code for Past or Present Industry: 86188-0 'History of Occupation Industry' ▪ LOINC code for Usual Industry: 21844-6 'Usual Industry' ▪ LOINC Answer List LL3925-6 contains the PHIN VADS value set: ▪ PHVS_Industry_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7187 • Representing Occupation ▪ LOINC Code for Past or Present Occupation: 11341-5 'History of Occupation' ▪ LOINC code for Usual Occupation: 21843-8 'Usual Occupation' ▪ LOINC Answer List LL3926-4 contains the PHIN VADS value set: ▪ PHVS_Occupation_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7186

I-I: Lab Tests

Interoperability Need: Representing Laboratory Tests

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED CT® terminology. • A single lab test with a single result will have the same LOINC® term for its order and result answer, but a panel order will have an order LOINC® term and multiple result LOINC® terms for each result in the panel. • A single lab test with a single result may have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• LOINC Top 2000+ Lab Observations - US Version OID: 1.3.6.1.4.1.12009.10.2.3

I-J: Medications

Interoperability Need: Representing Patient Medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●●	Yes	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●●○	Yes	Free	N/A
Standard	National Drug File – Reference Terminology (NDF-RT)	Final	Production	●●●○○	No	Free	N/A
Emerging Standard	*Medication Reference Terminology (MED-RT)*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals. • MED-RT allows for representing classes of medications when specific medications are not known. • Immunizations are not considered medications for this interoperability need. • RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users.	• Grouping Value Set: Medication Clinical Drug 2.16.840.1.113762.1.4.1010.4 ▪ Medication Clinical General Drug (2.16.840.1.113883.3.88.12.80.17) ▪ Medication Clinical Brand-specific Drug (2.16.840.1.113762.1.4.1010.5) (RxNorm). • Grouping Value Set: Clinical Substance 2.16.840.1.113762.1.4.1010.2 ▪ Medication Clinical Drug (2.16.840.1.113762.1.4.1010.4) (RxNorm) ▪ Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII)

I-K: Units of Measure

Interoperability Need: Representing Units of Measure (For Use with Numerical References and Values)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	The Unified Code for Units of Measure	Final	Production	●●●○○	Yes	Free	Yes Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• UCUM is a syntax for representing units of measure for use with numerical references and values. It is not an enumerated set of codes. • The case sensitive version is the correct unit string to be used for interoperability purposes. • Per public comments received, there may be some limitations with UCUM in the laboratory domain that remain unresolved. • The abbreviations used for a few of the units of measure listed in the UCUM standard are currently on lists of prohibited abbreviations from the Institute for Safe Medication Practice (ISMP). • Some abbreviations for units of measure include symbols which may be in conflict with other HL7 standards. • Some abbreviations for units are nonstandard for human understanding.(For example, if a result for a White Blood Cell count is 9.6 x 103/µL, the UCUM recommendation for rendering this value in a legacy character application is 9.6 x 10*3/uL. Because the "*" is a symbol for multiplication in some systems.) This recommendation may result in errors either by the information system or the human reading the result. • Some other abbreviations used in UCUM are not industry standard for the tests that use these units of measure.	• Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes) • "Table of Example UCUM Codes for Electronic Messaging" published by the Regenstrief Institute, Inc. Value set is made available at http://loinc.org/usage/units and identified by the OID 1.3.6.1.4.1.12009.10.3.1

I-L: Nursing

Interoperability Need: Representing Clinical/Nursing Assessments

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●○○○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Assessments are represented as question/answer (name/value) pairs. • Codes should generally be chosen from two axes: Clinical finding and Situation with explicit context. • When representing validated scales, LOINC should be used for the question and LOINC answers (LA Codes) should be used for the answers. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• Feedback requested.

Interoperability Need: Representing Nursing Interventions

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Coded interventions may be linked as related/dependent concepts to observations and assessments, as appropriate. • The Procedure axis of SNOMED CT is the terminology used for Nursing Interventions.	• A resource available is a map set from ICNP to SNOMED CT.

Interoperability Need: Representing Outcomes for Nursing

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Other ANA-recognized terminologies should be mapped to LOINC® for comparison across health systems and/or transmission. • Use LOINC® if the outcome is a measurement. • Use SNOMED CT® if the outcome is an observed assessment that a patient state has improved. In addition, when the outcome is recorded as an assertion (e.g., normotensive, afebrile, etc.) the terminology to be used is SNOMED CT®. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• Feedback requested.

Interoperability Need: Representing Patient Problems for Nursing

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of SNOMED CT® for this interoperability need, codes should generally be chosen from two axes: Clinical finding and Situation with explicit context. • Local and other ANA-recognized terminologies should be converted to SNOMED CT® for comparison across health systems and/or transmission.	• Starter Set: Nursing Problem List Subset of SNOMED CT

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

Interoperability Need: Representing Patient Clinical "Problems" (i.e., Conditions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of SNOMED CT® for this interoperability need, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • SNOMED CT® supports the combination of codes (post-coordination) to generate new meaning. Codes from other axes can be used in post-coordination. The need to pick multiple codes may be seen as a disadvantage. This can be avoided if post-coordination is limited to the backend, exposing a single code for users to pick. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• PHINVADS Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 • CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

I-N: Preferred Language

Interoperability Need: Representing Patient Preferred Language (Presently)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Request for Comment (RFC) 5646	Final	Production	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language.	• Language urn:oid:2.16.840.1.113883.1.11.11526 (based off RFC 4646. This will be updated to reflect RFC 5646).

I-O: Procedures

Interoperability Need: Representing Dental Procedures Performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Code on Dental Procedures and Nomenclature (CDT)	Final	Production	●●●●○	Yes	$	N/A

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

Interoperability Need: Representing Medical Procedures Performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A
Standard	CPT-4	Final	Production	●●●●●	Yes	$	N/A
Standard	HCPCS®	Final	Production	●●●●●	Yes	Free	N/A
Standard	ICD-10-PCS	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• ICD-10-PCS is primarily a billing code used only in inpatient settings. • CPT and HCPCS are codes used to report procedures and services in outpatient srocedures. • ICD-10-PCS is named in the 2015 Edition certification rules as an optional code set for procedures. • SNOMED CT procedure codes can be used to describe treatment in any clinical setting and is not tied to billing, but can be cross-mapped to corresponding ICD-10-PCS and CPT/HCPCS codes.	• Feedback requested.

I-P: Race and Ethnicity

Interoperability Need: Representing Patient Race and Ethnicity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Production	●●●●○	Yes	Free	N/A
Standard	CDC Race and Ethnicity Code Set Version 1.0	Final	Production	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon and can be rolled up to the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. • The high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic or public health reporting purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions. • LOINC® provides observation codes for use in the observation / observation value pattern for communicating race and ethnicity. • The LOINC answers for Race look similar to CDC/HL70005, but don't match; this may be confusing to implementers. • When clinically significant, the patient's "race" or "ethnicity" should be managed using an "Ask on Order Entry" question (AOE). This process is defined in the eDOS Implementation Guide developed through the ONC Standards & Interoperability Framework, and is designed work in conjunction with the LOI Implementation Guide, also developed through the ONC S&I Framework. For example, Glomerular Filtration Rate, Estimated (eGFR) results reference ranges vary based on race.	• Race (5 codes): Race Category Excluding Nulls urn:oid:2.16.840.1.113883.3.2074.1.1.3 • Race (extended set, 900+codes): Race urn:oid:2.16.840.1.113883.1.11.14914 • Ethnicity: Ethnicity urn:oid:2.16.840.1.114222.4.11.837 • Ethnicity (extended set, 43 codes): Detailed Ethnicity urn:oid:2.16.840.1.114222.4.11.877

I-Q: Research

Interoperability Need: Representing Analytic Data for Research Purposes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Clinical Data Interchange Standards (CDISC) Controlled Terminology for Regulatory Standards Hosted by NCI-EVS	Final	Feedback requested	Feedback requested	Yes	Free	N/A
Standard	CDISC) Controlled Terminology for CDISC Therapeutic Area Standards Hosted by NCI-EVS	Final	Feedback requested	Feedback requested	Yes	Free	N/A
Standard	CDISC Controlled Terminology for Medical Devices Hosted by NCI-EVS	Final	Feedback requested	Feedback requested	No	Free	N/A

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

I-R: Sex at Birth, Sexual Orientation and Gender Identity

Interoperability Need: Representing Patient Gender Identity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	HL7 Version 3 Null Flavor	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. • Even though clinicians and their patients would benefit from having these data in patient records, this does not suggest that it is the sole responsibility of clinicians and their staffs to collect these sensitive data. • When patients provide a response to this question in a patient portal, it could contradict with the information collected by providers.	• Gender identity. LOINC® code: 76691-5 • Male. SNOMED CT® code: 446151000124109 • Female. SNOMED CT® code: 446141000124107 • Female-to-Male (FTM)/Transgender Male/Trans Man. SNOMED CT® code: 407377005 • Male-to-Female (MTF)/Transgender Female/Trans Woman. SNOMED CT® code: 407376001 • Genderqueer, neither exclusively male nor female. SNOMED CT® code:

• See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	446131000124102 • Additional gender category or other, please specify. HL7 Version 3 code: OTH • Choose not to disclose. HL7 Version 3 code: ASKU

Interoperability Need: Representing Patient Sex (At Birth)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	For Male and Female, HL7 Version 3 Value Set; for Administrative Gender Unknown, HL7 Version 3 Null Flavor	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Value Set(s)**
• HL7 Version 2 and 3 need to be harmonized. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• LOINC® code: 76689-9 Sex assigned at birth • Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 • ONC's 2015 Edition certification requirements reference the following value set for birth sex that use a combination of HL7 Version 3 (V3) Standard value set for Administrative Gender and NullFlavor: (1) M ("Male") (2) F ("Female") (3) UNK ("Unknown") (HL7 V3 NullFlavor code)

Interoperability Need: Representing Patient-Identified Sexual Orientation							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard for observations	LOINC®	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A
Standard for observation values	HL7 Version 3 Null Flavor	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine of the National Academies. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• LOINC® code: 76690-7 Sexual orientation • ONC's 2015 Edition certification requirements reference the following value set for sexual orientation. Codes from (i) through (iii) are SNOMED CT® and (iv) through (vi) are from HL7 Version 3: (i) *Lesbian, gay or homosexual.* 38628009 (ii) *Straight or heterosexual.* 20430005 (iii) *Bisexual.* 42035005 (iv) *Something else, please describe.* nullFlavor OTH (v) *Don't know.* nullFlavor UNK (vi) *Choose not to disclose.* nullFlavor ASKU

I-S: Social, Psychological, and Behavioral Data

Interoperability Need: Representing Financial Resource Strain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC®	Final	Production	●○○○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• A single-item question used to determine the patient's overall financial resource strain developed from the Coronary Artery Risk Development in Young Adults (CARDIA) study is best suited for this interoperability need. • See LOINC® projects in the Interoperability Proving Ground.	• Overall financial resource strain (CARDIA) LOINC® code 76513-1 • LOINC® answer list ID LL3266-5

Interoperability Need: Representing Level of Education

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• A single question, "current educational attainment" used to determine the highest grade or level of school completed or highest degree received, developed as part of the National Health and Nutrition Examination Survey (NHANES) is best suited for this interoperability need. • See LOINC® projects in the Interoperability Proving Ground.	• Current educational attainment (NHANES) LOINC® code 63504-5 • LOINC® answer list ID LL1069-5

Interoperability Need: Representing Stress

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• A single-question stress measure primarily tested in Scandinavian populations is part of the Occupational Stress Questionnaire™ (Q41) developed by the Finnish Institute of Occupational Health is best suited for this interoperability need. • See LOINC projects in the Interoperability Proving Ground.	• Occupational Stress Questionnaire™ Q41 LOINC® code 76542-0 • LOINC® answer list LL3267-3

Interoperability Need: Representing Depression

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The Patient Health Questionnaire 2 item (PHQ-2) is a 2-question initial screen for symptoms of depression in the past 2 weeks. It consists of the first 2 questions of the PHQ-9, which can determine if an individual meet criteria for a depressive disorder, and is best suited for this interoperability need.	• PHQ-2 panel LOINC® code 55757-9 ▪ PHQ-2 member codes ▪ PHQ-2 Q1 LOINC® 44250-9 ▪ PHQ-2 Q2 LOINC® 44255-8

• See LOINC projects in the Interoperability Proving Ground.	▪ PHQ-2 Total Score LOINC® 55758-7 • PHQ-9 panel LOINC® code 44249-1

Interoperability Need: Representing Physical Activity

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The Two-question screen, "moderate to strenuous activity in last 7 days" adapted by SAMHSA from the Kaiser Permanente Exercise Vital Sign screen of physical activity is best suited for this interoperability need. • See LOINC projects in the Interoperability Proving Ground.	• How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7 days? LOINC® code 68515-6 • On those days that you engaged in moderate to strenuous exercise, how many minutes, on average, did you exercise? LOINC® code 68516-4 • Responses use applicable UCUM unit of measure.

Interoperability Need: Representing Alcohol Use

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●○○○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The Alcohol Use Disorder Identification Test - Consumption [AUDIT-C] consists of the first 3 questions of the World Health Organization's 10-question AUDIT alcohol screening that can help identify patients who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence), is best suited for this interoperability need. • See LOINC projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• AUDIT-C panel (LOINC® code 72109-2) ▪ AUDIT-C member codes: ▪ LOINC® code 68518-0 (with LOINC® answer list ID LL2179-1) ▪ LOINC® code 68519-8 (with LOINC® answer list ID LL2180-9) ▪ LOINC® code 68520-6 (with LOINC® answer list ID LL2181-7) ▪ AUDIT-C total score (LOINC® code 75626-2) • AUDIT panel (LOINC code 72110-0) • AUDIT panel total score (LOINC code 75624-7)

Interoperability Need: Representing Social Connection and Isolation

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The Social connection and isolation panel is a set of five questions used to assess the number of types of social relationships on which a patient is connected and not isolated. It was developed for the National Health and Nutrition Examination Survey (NHANES), and is best suited for this interoperability need. • See LOINC projects in the Interoperability Proving Ground.	• Social connection and isolation panel LOINC® code 76506-5 ▪ Member codes: ▪ LOINC® code 63503-7 (with LOINC answer list ID LL1068-7) ▪ LOINC® code 76508-1 ▪ LOINC® code 76509-9 ▪ LOINC® code 76510-7 ▪ LOINC® code 76511-5 (with LOINC answer list ID LL963-0) ▪ Social isolation score LOINC® code 76512-3

Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The HARK (Humiliation, Afraid, Rape, Kick) is a four-question screen for identifying women who have experienced intimate partner violence (IPV) in the past year and may help women disclose IPV in general practice. It is best suited for use with this interoperability need. • See LOINC projects in the Interoperability Proving Ground.	• HARK panel LOINC® code 76499-3 ▪ HARK member codes: ▪ LOINC® code 76500-8 (with LOINC® answer list ID LL963-0) ▪ LOINC® code 76501-6 (with LOINC® answer list ID LL963-0) ▪ LOINC® code 76502-4 (with LOINC® answer list ID LL963-0) ▪ LOINC® code 76503-2 (with LOINC® answer list ID LL963-0) ▪ HARK total score LOINC® code 76504-0

I-T: Tobacco Use (Smoking Status)

Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• There are limitations in SNOMED CT® for this interoperability need, which include, but not limited to: not being able to capture severity of dependency, level of use, quit attempts, lifetime exposure, and use of e-Cigarettes. • LOINC® includes codes that support recording smoking status in the CDC's preferred (and sometimes required) responses (e.g., Tobacco smoking status NHIS[76691-5]) and other kinds of observations (e.g., Have you smoked at least 100 cigarettes in your entire life [PhenX] [63581-3] or How old were you when you first started smoking cigarettes every day [PhenX] [63609-2]. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• 'Tobacco smoking status NHIS' LOINC 72166- 2 • Current Smoking Status urn:oid:2.16.840.1.113883.11.20.9.38 ▪ ONC's 2015 Edition certification requirements reference the following value set for smoking status. Codes from SNOMED CT® : ▪ Current every day smoker. 449868002 ▪ Current some day smoker. 428041000124106 ▪ Former smoker. 8517006 ▪ Never smoker. 266919005 ▪ Smoker, current status unknown. 77176002 ▪ Unknown if ever smoked. 266927001 ▪ Heavy tobacco smoker. 428071000124103 ▪ Light tobacco smoker. 428061000124105 • Additional tobacco-related codes: ▪ User of smokeless tobacco (finding): SNOMED CT 713914004 ▪ Smokeless tobacco non-user (finding): SNOMED CT 451381000124107 ▪ Date quit tobacco smoking LOINC 74010-0

I-U: Unique Device Identification

Interoperability Need: Representing Unique Implantable Device Identifiers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	HL7 Harmonization Pattern for Unique Device Identifiers	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • The HL7 Harmonization Pattern for UDIs is currently in development, with the next revision release anticipated in February 2018. • See UDI projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Defining a Globally Unique Device Identifier

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	HL7 Harmonization Pattern for Unique Device Identifiers	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • The HL7 Harmonization Pattern for UDIs is currently in development, with the next revision release anticipated in February 2018. • See UDI projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Transmitting a Unique Device Identifier							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	HL7 Harmonization Pattern for Unique Device Identifiers	In Development	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • Compliance date for UDI of implantable, life supporting and life sustaining devices was 9/24/2015. These data are available at http://accessgudid.nlm.nih.gov • The HL7 Harmonization Pattern for UDIs is currently in development, with the next revision release anticipated in February 2018. • See UDI projects in the Interoperability Proving Ground.	• Feedback requested.

I-V: Vital Signs

Interoperability Need: Representing Patient Vital Signs							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Pilot	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC® projects in the Interoperability Proving Ground. • See Section I-K for discussion of units of measure used with quantitative observations.	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62

I-W: Pregnancy Status

Interoperability Need: Representing Patient Pregnancy Status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●○○○○	No	Free	No
Standard for observation values	SNOMED CT®	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• When patient is currently pregnant, additional data fields should be collected, including: date of pregnancy status, estimated delivery date or gestational age. See applicable value sets and Recommendations from Collaboration of the Health IT Policy and Health IT Standards Committees' Public Health Task Force (Excel File Download, 31KB) for more details. • There are ongoing deliberations within CDC and other organizations to identify the best location to capture pregnancy status in provider workflows. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix II for an informational resource developed by the Health IT Standards Committee.	• LOINC® code: 82810-3 Pregnancy status • SNOMED CT®: ▪ Patient currently pregnant (finding), 77386006 ▪ Not pregnant (finding), 60001007 ▪ Possible pregnancy (finding), 102874004 • LOINC® codes: 11778-8 Estimated Delivery Date or 21299-3 Gestational age method

Section II: Content/Structure Standards and Implementation Specifications

II-A: Admission, Discharge, and Transfer

Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	No
Implementation Specification	IHE Patient Administration Management (PAM) Integration Profile	Final	Feedback requested	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• A variety of transport protocols are available for use for ADT message delivery. Trading partners will need to determine which transport tools best meet their interoperability needs, however, Direct (referenced further in Section III-A), has been noted as a prominent option for transport, particularly where HIE networks are	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and

not in place or not being used for this purpose. • See HL7 V2 projects in the Interoperability Proving Ground.	outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** – Identifies the purpose for the transaction.

Interoperability Need: Sending a Notification of a Long Term Care Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy

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

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

II-B: Care Plan

Interoperability Need: Documenting and Sharing Care Plans for a Single Clinical Context

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1	Balloted Draft	Pilot	●●●○○	Yes	Free	Yes
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 Resource Care Plan (v1.0.2)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The care plan as expressed in the C-CDA standard does not attempt to represent the longitudinal care plan; rather it represents a "snapshot" of a care plan at a single point in time for transmission to other providers and teams to ensure continuity of care. • The Care Plan Domain Analysis Model is used as a reference model for C-CDA care plan documents in the context of the longitudinal care plan. • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See CDA and FHIR projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Domain or Disease-Specific Care Plan Standards

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan Document, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary, Release 1 – US Realm	Balloted Draft	Feedback requested	●●●○○	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Early Hearing Detection and Intervention (EHDI), Rev 2.1 Trial Implementation	Balloted Draft	Pilot	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The two HL7 CDA R2 IGs are based on C-CDA R2.1 and align with the Care Plan document specifications. The IHE Profile is based on HL7 V2.6 IG: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1. • The Personal Advance Care Plan Document is for the domain of patient-authored goals, priorities and preferences, including but not limited to Advance Directives. • See CDA and IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Sharing Patient Care Plans for Multiple Clinical Contexts

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*IHE Dynamic Care Planning (DCP), Rev 1.1 Trial Implementation*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Documenting and Sharing Medication-Related Care Plans by Pharmacists

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Pharmacist eCare Plan Version 1.0 Guidance on the Use of the HL7 CDA Consolidated Templates for Clinical Notes R2.1 Care Plan	Final	Production	●●○○○	No	$	Yes[$]
Implementation Specification	HL7 CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm, Volume 1	Final	Production	●○○○○	No	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The two implementation specifications listed for this interoperability need are a result of a joint effort between HL7 and NCPDP to create a standardized, interoperable document for exchange of consensus-driven prioritized medication-related activities, plans and goals for an individual needing care Pharmacists work in multiple environments. This project was partially funded by ONC's High Impact Pilots Cooperative Agreement Program. The Community Pharmacy Enhanced Services Network maintains a listing of vendor participants from this program. • More than 100 value sets are currently captured in VSAC in support of this interoperability need. Search for "PharmacyHIT" to view them. • See this project in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Sharing Patient Care Teams for Care Planning in Multiple Clinical Contexts

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*Sharing Patient Care Teams for Care Planning in Multiple Clinical Contexts*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-C: Clinical Decision Support

Interoperability Need: Shareable Clinical Decision Support

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 2	Balloted Draft	Production	●●○○○	No	Free	Yes
Standard	HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.	Balloted Draft	Pilot	●●○○○	No	Free	No
Implementation Specification	HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Standard	*HL7 FHIR Profiles: Quality Improvement Core (QI Core), Release 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Provide Access to Appropriate Use Criteria

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release 1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Note that the FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR) in STU 3 was incorporated into FHIR as a core implementation guide, FHIR Clinical Reasoning. • Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

II-D: Clinical Quality Measurement and Reporting

Interoperability Need: Reporting Aggregate Quality Data to Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DSTU Release 1	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA III) STU Release 2 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Reporting Patient-level Quality Data to Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3.1 (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) STU Release 4 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 V3: Representation of the Health Quality Measures Format (eMeasure), DSTU Release 2.1	Balloted Draft	Pilot	●●●●○	No	Free	Yes
Standard	HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 1.1	Balloted Draft	Production	●●○○○	No	Free	Yes
Implementation Specification	HL7 V3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF), Release 1.4 DSTU 4 (based on HQMF 2.1 – US Realm	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Implementation Specification	HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF), Release 1.1 DSTU 2 (based on HQMF 2.1 - US Realm	Balloted Draft	Production	●●○○○	No	Free	Yes
Emerging Implementation Specification	*HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF), Release 2 DSTU32 (based on HQMF 2.1 - US Realm*	*In Development*	*Pilot*	●●○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR)*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) Clinical Reasoning STU Release 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested.

II-E: Data Provenance

Interoperability Need: Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The first implementation specification listed is focused on data provenance representation for CDA R2 implementations and the use of CDA templates. • Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • The FHIR implementation specification listed leverages the W3C Provenance specification to represent HL7® support of provenance throughout its standards. It is explicitly modeled as functional capabilities in ISO/HL7 10781 EHR System Functional Model Release 2 and ISO 21089 Trusted End-to-End Information Flows. Mappings are available within the resource. • See CDA & FHIR projects in the Interoperability Proving Ground.	• Feedback requested.

II-F: Diet and Nutrition

Interoperability Need: Exchanging Diet and Nutrition Orders Across the Continuum of Care

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Version 3 Standard: Diet and Nutrition, STU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Implementation Specification	HL7 FHIR Nutrition Order Resource	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes* *Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • In addition to the specifications listed above, work is underway to create a HL7 CDA R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Nutrition, Release 1 (US Realm), with balloting likely in January 2018. • See FHIR projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **User Details** - identifies the end user who is accessing the data • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-G: Drug Formulary & Benefits

Interoperability Need: The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• NCPDP Formulary and Benefits v3.0 does not provide real-time patient-level benefit information. • NCPDP is developing a Real Time Prescription Benefit standard that should be monitored as a potential emerging implementation specification.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-H: Electronic Prescribing

Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "New Prescription" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the Pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Refill Request" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Allows the pharmacist to request approval for additional refills of a prescription beyond those originally prescribed. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements.

	• **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The RxChange message allows a Pharmacist to request a change of a new prescription or a "fillable" prescription. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction

Interoperability Need: Cancellation of a Prescription

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Cancel" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Notifies the pharmacy that a previously sent prescription should be cancelled and not filled. • Send the prescriber the results of a prescriptions cancellation request. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g.,

	– SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Fill Status" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: (1) To notify the prescriber of a dispensed prescription, (2) to notify the prescriber of a partially dispensed prescription, and (3) to notify a prescriber of a prescription not dispensed • Opt-in functionality available in SCRIPT versions 2014+ allow prescribers to specify which prescriptions and which dispense status to receive fill notifications for. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Obtain a Patient's Medication History

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Both the "Medication History Request" and "Medication History Response" transactions need to be implemented for interoperability purposes. • Both the prescriber and the receiving pharmacy or pharmacy benefits manager (PBM) must have their systems configured for the transaction in order to facilitate successful exchange. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Obtain a Patient's Medication History from a Prescription Drug Monitoring Program

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Both the "Medication History Request" and "Medication History Response" transactions need to be implemented for interoperability purposes. • Both the prescriber and the specific Prescription Monitoring Drug Program (PDMP) must have their systems configured for the transaction in order to facilitate successful exchange. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction.

	• **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows Prescriber to Electronically Request Prior Authorization for Medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2013101	Final	Production	●●○○○	No	$	No

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

• The following transactions need to be implemented for interoperability purposes:
  ○ PAInitiationRequest and PAInitiationResponse
  ○ PARequest and PAResponse
  ○ PAAppealRequest and PAAppealResponse
  ○ PACancelRequest and PACancelResponse
• Both the prescriber and the payer/processor/pharmacy benefits manager (PBM) must have their systems configured for the transactions in order to facilitate successful exchange.
• See NCPDP projects in the Interoperability Proving Ground.
	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication.
	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
	• **Authentication Enforcer** – centralized authentication processes.
	• **Authorization Enforcer** – specifies access control policies.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).
	• **Assertion Builder** – define processing logic for identity, authorization and attribute statements.
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction

Interoperability Need: Prior Authorization Cancel Request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2013101	Final	Production	●●○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See NCPDP projects in the Interoperability Proving Ground.	• Feedback requested.

II-I: Family Health History (Clinical Genomics)

Interoperability Need: Representing Family Health History for Clinical Genomics

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Version 3 Standard: Clinical Genomics; Pedigree	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1	Balloted Draft	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*Final*	*Pilot*	*Feedback requested*	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Vocabularies and Value Sets for Consideration:

• There is no widely recognized vocabulary to capture family genomic health history, but several vocabularies/value sets are available for consideration.
• Further constraint of this standard and implementation specification may be required to support this interoperability need.
• The Office of the National Coordinator for Health Information Technology (ONC), in partnership with National Institutes of Health (NIH), created Sync for Genes to strengthen genomic data sharing, a key component of the Precision Medicine Initiative. This project is also in alignment with the recommendations made by the Precision Medicine Task Force under the Health IT Standards Committee (HITSC) to advance data standards, address relevant privacy policies, and advance innovations in health IT that support precision medicine. Sync for Genes is the first step toward integrating clinical genomics into the point-of-care by expediting the use of standards, such as Health Level 7 (HL7®) Fast Healthcare Interoperability Resource (FHIR®), to enable and improve patient's ability to seamlessly share their genomics information via point-of-care applications, such as application programming interfaces (APIs). Sync for Genes supports a critical element of sharing genomic data amplifying the ability to seamlessly share genomic information for research and commercial purposes. Below are the HL7 FHIR Clinical Genomic profiles that were tested as part of the Sync for Genes work:
  ○ **Family Health History Genetics**
  ▪ https://www.hl7.org/fhir/pushpull.html
  ○ **Sequencing Quality and Regulatory Genomics**
  ○ https://www.hl7.org/fhir/STU3/sequence.html
  ○ https://www.hl7.org/fhir/STU3/bundle.html
  ○ https://www.hl7.org/fhir/STU3/capabilitystatement.html
• The U.S. Surgeon General also offers the My Family Health Portrait, allowing individuals to enter their family health history details to share with their family
	According to HIMSS, the following vocabularies/value sets may be considered:
	• Gene Identifier: HGNC Value Set
	• Transcript Reference Sequence Identifier: NCBI vocabulary
	• DNA Sequence Variation Identifier: NCBI vocabulary
	• DNA Sequence Variation: HGVS nomenclature

members and/or healthcare providers, learn about risk for conditions that can be hereditary, and be saved as a resource that can be maintained and updated over time. • See FHIR projects in the Interoperability Proving Ground.	

II-J: Healthy Weight

Interoperability Need: Sending Health Weight Information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement – Healthy Weight (HW)	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Integrating the Healthcare Enterprise (IHE) Healthy Weight Profile Childhood obesity surveillance systems utilize either measured (e.g., NHANES) or parent/self-report height and weight to calculate BMI. The profile also includes the HL7 Occupational Data for Health (ODH) template. • Public health agencies have been studying the relationship between obesity and work factors; for example, the prevalence of obesity has been shown to vary substantially by occupation. • See IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Details** - identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-K: Images

Interoperability Need: Medical Image Formats for Data Exchange and Distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Use Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes.	• Feedback requested.

Interoperability Need: Format of Medical Imaging Reports for Exchange and Distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture.	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• DICOM defines both its own encoding of reports and templates for encoding narrative reports and machine-generated output as DICOM Structured Reports (SR) for use within imaging systems. • DICOM Part 20 is an implementation guide for HL7 CDA r2. • DICOM also defines a Diagnostic Imaging Report HL7 CDA Template, which is intended to supersede the C-CDA Diagnostic Imaging Report.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Format of Radiology Reports for Exchange and Distribution

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Format of Radiation Exposure Dose Reports for Exchange and Distribution							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	DICOM PS3.3 2017e A.35.8 X-Ray Radiation Dose SR IOD	Final	Production	●●○○○	No	Free	Yes - Open
Implementation Specification	DICOM PS3.3 2017e A.35.14 Radiopharmaceutical Radiation Dose SR IOD	Final	Production	●●○○○	No	Free	Yes - Open
Implementation Specification	DICOM PS3.3 2017e A.35.18.1 Patient Radiation Dose SR IOD	Final	Production	●●○○○	No	Free	Yes - Open

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These reports record radiation dose in three forms: ▪ The dose related information provided by an exposing device, e.g., CT, as reported by the device. ▪ The dose related information about a radiopharmaceutical administration, as reported by the administering system. ▪ The patient or organ absorbed dose based on exposure information, patient characteristics, and patient model. • See DICOM projects in the Interoperability Proving Ground.	• Feedback requested.

II-L: Laboratory

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

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

• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • The HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1 - US Realm further clarifies sender/receiver responsibilities to achieve end-to-end interoperability for this interoperability need. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Ordering Labs for a Patient

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • Note that the implementation specification has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Support the Transmission of a Laboratory's Directory of Services to Health IT

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 (also referred to as eDOS (Electronic Directory of Service)	Balloted Draft	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • Note that the current version has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Identify Linkages Between Vendor IVD Test Results and Standard Codes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	LIVD – Digital Format for Publication of LOINC to Vendor IVD Test Results	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The LIVD - Digital Format for Publication of LOINC to Vendor IVD Test results defines the digital publication of LOINC using vendor defined IVD tests associated with a set of predefined LOINC codes. LIVD assures that laboratory personnel select the appropriate LOINC codes for IVD test used by their laboratory. It also allows LIS systems to automatically map the correct IVD vendor test result to a LOINC code. LIVD was developed in collaboration with the members of the FDA IVD Semantic workgroup.	• Feedback requested.

II-M: Medical Device Communication to Other Information Systems/Technologies

Interoperability Need: Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	Continua Design Guidelines	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	ITU H.810, H.811, H.812, H.812.5, and H.813	Final	Production	●●●○○	No	Free	Yes

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

• IHE-PCD, Continua and ITU refer to the IEEE 11073-10101 standard for nomenclature.
• The following specific IHE-PCD profiles that best meet this interoperability need include:
  ▪ IHE-PCD (Patient Care Device Profiles) - Alert Communication Management (ACM)
  ▪ IHE-PCD (Patient Care Device Profiles) - Device Enterprise Communication (DEC)
  ▪ IHE-PCD (Patient Care Device Profiles) - Implantable Device – Cardiac Observation (IDCO)
  ▪ IHE-PCD (Patient Care Device Profiles) - Point-of-Care Infusion Verification (PIV)
  ▪ IHE-PCD (Patient Care Device Profiles) - Rosetta Terminology Mapping (RTM)
• The Regenstreif LOINC/IEEE Medical Device Code Mapping Table allows enterprise information systems (i.e. ""Other information Systems/Technologies") to process vital signs and combine those observations with other types of information; it bridges the semantic map between IEEE 11073 10101 conformant medical devices and certified health IT or aligned information systems that use LOINC already for laboratory reports, document taxonomies, standard forms, questionnaires, assessments, social determinants, and screeners.
• FDA cybersecurity recommendations for medical device manufacturers.
• Design Considerations and FDA Pre-Market Submission Recommendations for Interoperable Medical Devices.
• See IHE projects in the Interoperability Proving Ground.
	• Feedback requested.

II-N: Patient Education Materials

Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge From Online Resources

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

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

II-O: Patient Identification Management

Interoperability Need: Patient Demographic Record Matching

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes
Emerging Implementation Specification	*Implementation Guide for Expressing Context in Direct Messaging*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Chapter 3 of the HL7 Standard 2.5.1 named "Patient Administration" is the relevant chapter for Clinical and Administrative Domains. • NIST Special Publication 800-63, Revision 3 defines technical requirements in	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication.

each of the areas of identity proofing, registration, authenticators, management processes, authentication protocols, federation, and related assertions. These guidelines can be applied for identity proofing of any user or participant in healthcare such as clinicians, caregivers, patients and others. • The Implementation Guide for Expressing Context in Direct Messaging was designed to facilitate inter-organizational patient demographic record matching by standardizing the inclusion of patient demographic metadata in Direct messages. Direct is also listed in several Interoperability Needs in Section III-A. • Patient Identity Proofing is outside of the scope of this interoperability need but more information related to this topic is below: ▪ Identity Proofing. Each Signatory's security policy shall include the following elements to ensure appropriate identity proofing: ▪ (i) End Users (provider). Each Signatory shall identity proof participating End Users at Identity Assurance Level 2 (IAL2) prior to issuance of access credentials; and ▪ (ii) Individuals (patient). Each Signatory shall identity proof participating individuals at Identity Assurance Level 2 (IAL2) prior to issuance of access credentials; provided, however, that the Signatory may supplement identity information by allowing Participant staff to act as trusted referees and authoritative sources by using personal knowledge of the identity of the individuals (e.g., physical comparison to legal photographic identification cards such as driver's licenses or passports, or employee or school identification badges) collected during an antecedent in-person registration event. All collected personally identifiable information collected by the Signatory shall be limited to the minimum necessary to resolve a unique identity. • See HL7 V2, IHE, and Direct projects in the Interoperability Proving Ground.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-P: Patient Preference/Consent

Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●○○○	No	Free	Yes – Open
Emerging Implementation Specification	*HL7 Implementation Guide for CDA®, Release 2: Consent Directives, Release 1*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*N/A*

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*IHE Advanced Patient Privacy and Consents (APPC)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 FHIR Consent Resource*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*HL7 Contract Resource*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These profiles operate in conjunction with the IHE XDS, XCA, and XDR profiles • IHE BPPC may not support management of patient privacy across governmental jurisdictions which may have different regulations regarding access to patient data by providers, patients, governmental entities, and other organizations. • Along with security tokens and consent documents, security labels that are the critical third part of the Attribute-Based-Access-Control and SLS should be mentioned as well. Security Labels are used in CDA, FHIR, as well as the IHE Document Sharing (e.g. XDS), as described on the FHIR security page at https://www.hl7.org/fhir/security-labels.html. • Carequality is working to develop a technical method for distributing and identifying consent forms to be used as part of their Patient Consent Framework. • See IHE and FHIR projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction. • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.

II-Q: Public Health Reporting

Interoperability Need: Reporting Antimicrobial Use and Resistance Information to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●○○○○	Yes	Free	No
Emerging Implementation Specification	*HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

Interoperability Need: Reporting Cancer Cases to Public Health Agencies							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012	Balloted Draft	Production	●●○○○	Yes	Free	Yes
Implementation Specification	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm	Balloted Draft	Production	●○○○○	Yes	Free	Yes
Implementation Specification	North American Association of Central Cancer Registries, Inc. (NAACCR), Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 4.0, published April 2011	Final	Production	Feedback requested	No	Free	No
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements. Some jurisdictions may not support cancer case reporting at this time. • Note that the NAACCR specification listed has not been vetted through a Voluntary Consensus Standards Body (VSCB), however it references the HL7 V 2.5.1 standard and LOINC, and has been sponsored by a number of organizations working in the cancer registry space. • See CDA, IHE, and FHIR projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Case Reporting to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) DSTU Release 2.1 (with errata)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Implementation Specification	IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)	Final	Feedback requested	●●○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2 - US Realm - the Electronic Initial Case Report (eICR)	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Structured Data Capture (SDC) STU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 CDA R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

• Electronic case reporting involves reporting to State and/or Local jurisdictions and is not yet widespread.
• Structured Data Capture Implementation Guide does not currently restrict vocabulary to standard vocabulary sets, and may require further implementation guidance for case reporting purposes.
• The IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation Guide does not support automated initiation of sending of case reports. It can support manual entry into an electronic form as follow-up to an initial case report submission.
• Some additional implementation guides related to public health reporting follow. Reporting is often captured under a specialized registry with associated standards when not specified as a separate measure. These include:
  ○ Early Hearing Detection and Intervention (EHDI)
  ○ Office of Populations Affairs (OPA) Family Planning Reporting IHE Profile
• Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki.
	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication.
	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
	• **Authentication Enforcer** – centralized authentication processes.
	• **Authorization Enforcer** – specifies access control policies.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.

• See FHIR and IHE projects in the Interoperability Proving Ground.	

Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. • The Emerging Implementation Specification: "HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public health, Release 2 (US REALM), Draft Standard for Trial Use, Release 1.1" listed above was in a Draft Standard for Trial use status, but was not renewed or balloted as normative. However, a recommendation was received to leave it listed here until there is wider adoption/experience with other listed specifications. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Sending Health Care Survey Information to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 DSTU Release 1.2 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program for information on participation. • See CDA projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Exchanging Immunization Data with Immunization Registries

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements. • HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 – Addendum is also available. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1 and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance	Final	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings*	*Final*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements. • An Erratum to the CDC PHIN 2.0 Implementation Guide was issued in August, 2015. Implementers should refer to this guide for additional information and conformance guidance. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Data Submission for Title X Family Planning Annual Reporting

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement Family Planning Version 2 (FPv2) Rev. 1.1 – Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The HHS Office of Population Affairs (OPA) is currently engaged in an overhaul of their Family Planning Annual Reporting system, to enable the reporting of encounter level data from all of their Title X sites in a standard format and via a standard methodology. OPA is currently piloting two interoperability standards through this project and is intending to begin collecting data according to this new system in 2019. • Visit the Office of Population Affairs (OPA) website for more information about the Family Planning Annual Report, and The Family Planning Annual Report and Health Information Technology (Health IT) Initiative (FPAR 2.0).	• Feedback requested.

Interoperability Need: Reporting Birth and Fetal Death to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Version 2.5.1 Implementation Guide: Birth & Fetal Death Reporting, Release 1 (US Realm)	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement 10 Birth and Fetal Death Reporting-Enhanced (BFDR-E)	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Version 2.6 Implementation Guide: Birth and Fetal Death Reporting, Release 1 STU Release 2 (US Realm - Standard for Trial Use)	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Version 3 CDA R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1 (US Realm - Standard for Trial Use)	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Use of the listed NIST test tool **requires** digital certificates. Contact laura.rappleye@altarum.org for digital certification information.	• Feedback requested.

Interoperability Need: Reporting Newborn Screening Results to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 CDA® R2 Implementation Guide: Ambulatory Healthcare Provider Reporting to Birth Defect Registries, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: Ambulatory Healthcare Provider Reporting to Birth Defect Registries, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7 Version 2.6 Implementation Guide: Critical Congenital Heart Defects (CCHD) pulse oximetry screening results, Release 1	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Version 2.6 Implementation Guide: Early Hearing, Detection and Intervention (EHDI) Results Release 1	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Use of the listed NIST test tool **requires** digital certificates. Contact laura.rappleye@altarum.org for digital certification information. • There is current work to update the listed "ambulatory" implementation guides to include hospital reporting capabilities and Zika-related information.	• Feedback requested.

Interoperability Need: Reporting Death Records to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement Vital Records Death Reporting (VRDR) R 3.1	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Version 2.6 Implementation Guide: Vital Records Death Reporting, Release 1 (US Realm - Standard for Trial Use)	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7 CDA R2 Implementation Guide: Vital Records Death Reporting, Release 1 STU 2 - (US Realm) (Standard for Trial Use)	Balloted Draft	Pilot	●○○○○	No	Free	No

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

II-R: Research

Interoperability Need:	Submission of Clinical Research Data to FDA to Support Product Marketing Applications						
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Production	●●●●●	Yes	Free	Yes
Standard	CDISC Analysis Dataset Model (ADaM)	Final	Production	●●●○○	Yes	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	Yes
Standard	CDISC Dataset-XML (ODM-Based)	Final	Production	●○○○○	No	Free	N/A
Standard	CDISC Define-XML (ODM-Based)	Final	Production	●●●●●	Yes	Free	N/A
Standard	CDISC Standard for the Exchange of Non-clinical Data (SEND)	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)	Final	Production	●○○○○	No	Free	N/A
Standard	Therapeutic Area Standards (to complement the aforementioned CDISC foundational standards that apply across all therapeutic areas)	Final	Production	●○○○○	Yes	Free	N/A
Standard	CDISC Questionnaires, Ratings and Scales (QRS)	Final	Feedback requested	Feedback requested	No	Free	No
Emerging Implementation Specification	*CDISC Pharmacogenomics/genetics (PGx) Implementation Guide*	*Balloted Draft*	*Feedback requested*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• FDA published the draft guidance promoting use of EHRs in clinical research, in collaboration with ONC. (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm501068.pdf) • FDA CDER published a FRN focusing on Source Data Capture From Electronic Health Records: Using Standardized Clinical Research Data.	• Feedback requested.

(https://www.federalregister.gov/documents/2015/06/26/2015-15644/source-data-capture-from-electronic-health-records-using-standardized-clinical-research-data) • FDA CDER and CBER encourage the submission of study data in conformance to the data standards listed in the FDA Data Standards Catalog (DSC). Standardized study data will be required in submissions for clinical and non-clinical studies that start on or after December 17, 2016 (December 17, 2017 for INDs). See Data Standards Catalog: (http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm) and the Data Standards Strategy: (http://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm455270.pdf) • Although CDISC standards are a requirement for CDER and CBER and not for CDRH, all three Centers promote the use of Real World Data (RWD) in EHRs, registries, administrative claims and mobile health technology to generate Real World Evidence regarding the safety and effectiveness of medical products. In addition, FDA collaborates closely with other standards development organizations including but not limited to HL7, IHE, X12, and NCPDP. • FDA CDRH and CBER published the draft guidance: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. (see http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf)	

Interoperability Need: Pre-population of Research Forms from Electronic Health Records							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE-CRD (Clinical Research Document)	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-XUA (Cross-Enterprise User Assertion)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-ATNA (Audit Trail and Node Authentication)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Structured Data Capture (SDC) Release 1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	IHE- RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●○○○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	N/A
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes
Standard	CDISC Study/Trial Design Model (SDM)	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	IHE-RPE (Retrieve Protocol for Execution)	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-CRPC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Feedback requested	Feedback requested	No	Free	No
Implementation Specification	CDISC Study Data Tabulation Model Implementation Guide	Final	Feedback requested	Feedback requested	No	Free	No
Implementation Specification	CDISC Therapeutic Area User Guides	Final	Feedback requested	Feedback requested	No	Free	No
Emerging Standard	*CDISC Pharmacogenomics/genetics (PGx) Implementation Guide*	*Balloted Draft*	*Feedback requested*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should review 21CFR11 for more details. • See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE-DSC (Drug Safety Content)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE-CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

Interoperability Need: Complete Disease Registry Forms and Submit to Reporting Authority (ACC)

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested.

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The CDISC Clinical Trial Registry (CTR-XML) is used internationally, but in the US, the primary area for registering Clinical Trials is via ClinicalTrials.gov.	• Feedback requested.

II-S: Segmentation of Sensitive Information

Interoperability Need: Document-Level Segmentation of Sensitive Information							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Production	●●●○○	Yes	Free	Yes
Emerging Implementation Specification	*IHE IT Infrastructure Technical Framework Volume 4 - National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P)*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA projects in the Interoperability Proving Ground. • Per 2015 Edition Health IT Certification Criterion for DS4P (§ 170.315(b)(7) and § 170.315(b)(8)), document-level tagging is the scope required for certification. • For C-CDA transmission, document level DS4P is required in the C-CDA General Header. Therefore, adoption levels may be higher than 1/5 for document level tagging (vs. section level).	• Feedback requested.

II-T: Summary Care Record

Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	HL7 Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Balloted Draft	Production	●●●●●	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1*	*Balloted Draft*	*Pilot*	*Feedback requested*	*Yes*	*Free*	*Yes*
Emerging Implementation Specification	*IHE Patient Care Coordination Technical Framework Supplement 360 Exchange Closed Loop Referral (360X) Rev. 1.1 – Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	No	*Free*	No
Emerging Implementation Specification	*NCPDP Specialized Standard*	*Final*	*Feedback requested*	●○○○○	No	*$*	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates. • HL7 provides a C-CDA Example repository which contains a set of example C-CDA files that have undergone a review and vetting process to ensure completeness and rigor. • The IHE 360X specification listed is designed to track and manage referrals across health IT platforms. • The NCPDP Specialized Standard supports request/referral for Medication Therapy Management services. • Implementers should explore use of emerging CDA on FHIR and C-CDA on FHIR to support this interoperability need. • See CDA and CCDA projects in the Interoperability Proving Ground.	• Feedback requested.

Section III: Standards and Implementation Specifications for Services/Transport/Exchange

III-A: "Push" Exchange

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination and Information System User

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●●●○	Yes	Free	Yes
Standard	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	Yes	Free	Yes
Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes
Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	Yes	Free	Yes
Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	ITU H.810, H.811, H.812, and H.813	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	*Implementation Guide for Expressing Context in Direct Messaging v1.0*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • Direct is not currently supported by a formal SDO but is actively maintained and	• **System Authentication** – The information and process necessary to authenticate the systems involved. • **Recipient Encryption** – the message and health information are encrypted for the intended user. • **Sender Signature** – details that are necessary to identity of the individual sending the message. • **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and

updated by the Direct Community. • The ITU implementation specifications are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua-design-guidelines • See Direct and IHE projects in the Interoperability Proving Ground.	outbound messages without interruption of delivery. • **Patient Consent Information** – Identifies the patient consent information that may be required before data can be accessed. o May be required to authorize any exchange of patient information. o May be required to authorize access and use of patient information. o May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification	Final	Production	●●●○○	Yes	Free	Yes
Standard	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●○○○	Yes	Free	Yes
Standard	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	eHealth Exchange Specification: Messaging Platform	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Authorization Framework	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Document Submission	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●○	No	Free	Yes
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0. • The eHealth Exchange Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1. • "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API". • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR, Direct and IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Representing Path Traversal Expressions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Standard	*HL7Fast Healthcare Interoperability Resources (FHIR) – FluentPath, STU 1, Release 1*	Balloted Draft	*Pilot*	*N/A*	*No*	*Free*	*No*

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

Interoperability Need: Push Communication of Vital Signs from Medical Devices

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards	Final	Production	●●●○○	No	$	Yes[$]
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	Yes
Implementation Specification	ITU H.810, H.811, H.812, H812.5 and H.813	Final	Production	●●●○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• ISO/IEEE 11073 is a family of standards for various medical devices. • The IEEE1073 Nomenclature is recognized in the IHE/HL7 record set. • The ITU implementation specifications are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines.	• Feedback requested.

Interoperability Need: Medical Device Communication to Other Information Systems/Technologies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	ITU H.810, H.811, H.812, and H.813	Final	Production	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These ITU standards are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua/products/design-guidelines.	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Details** - identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Remote Patient Monitoring to Support Chronic Condition Management, Patient Education, and Patient Engagement							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	ITU H.810, H.811, H.812, H812.5, and H.813	Final	Production	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These ITU standards are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that provide several means to end-to-end interoperability between personal medical devices and health information systems. Unrestricted access to the implementation specification: http://www.pchalliance.org/continua-design-guidelines	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Details** - identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-B: Clinical Decision Support Services

Interoperability Need: Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
Standard	QICore/QuICK, Draft Standard for Trial Use HL7 FHIR Profile: Quality (QI Core), DSTU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*QICore/QuICK,, Draft Standard for Trial Use HL7 FHIR Profile: Quality (QI Core), STU Release 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language (CQL), Release 1, STU Release 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR Implementation Guide:) Clinical Reasoning STU Release 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE-GAO (Guideline Appropriate Ordering)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See FHIR & IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **Recipient Encryption** - the message and health information are encrypted for the intended user. • **Sender Signature** – details that are necessary to identity of the individual sending the message. • **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care

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

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

III-C: Image Exchange

Interoperability Need: Exchanging Imaging Documents Within a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	DICOMweb™	Final	Production	Feedback requested	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-Cross Enterprise Document Sharing for Images (XDS-I.b)	Final	Pilot	●○○○○	No	Free	Yes
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
Emerging Implementation Specification	IHE - Patient Identifier Cross-reference for Mobile (PIXm)	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE-MHD-I (Mobile Access to Health Documents for Imaging)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

Interoperability Need: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	DICOMweb™	Final	Production	Feedback requested	No	Free	No

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • See IHE projects in the Interoperability Proving Ground.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).

III-D: Healthcare Directory, Provider Directory

Interoperability Need: Listing of Providers for Access by Potential Exchange Partners

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Standard	Fast Healthcare Interoperability Resources (FHIR), US Core Implementation Guide (Release 1.0.1)	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Argonaut Provider Directory Implementation Guide Version 1.0.0	Balloted Draft	Production	●●○○○	No	Free	Yes
Emerging Standard	*HL7 Fast Healthcare Interoperability Resource (FHIR) STU3*	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation was proposed, but not adopted for CEHRT 2015. The Health IT community has recognized the value of the underlying data elements and structure of that standard. The standard has met with limited adoption due to several concerns. • The reference to FHIR for this interoperability need is in relation to the transport	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

services that are conformant to the "RESTful FHIR API". • The FHIR resources for this Interoperability Need might be limited to Service Provider Directory Resources within the Administration Module. • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. The FHIR Maturity Model and each of the levels is described on the HL7 wiki. • See IHE and FHIR projects in the Interoperability Proving Ground.	

III-E: Patient Identification Management

Interoperability Need: Exchanging Patient Identification Management Within a Community

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
Emerging Implementation Specification	*IHE - Patient Identifier Cross-reference PIX for Mobile (PIXm)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See Section II-O: Patient Identification Management for more information about the HL7 2.5.1 ADT messaging standard and information about patient identity proofing.	• Feedback requested.

III-F: Public Health Exchange

Interoperability Need: Transport for Immunization Submission and Query/Response

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	CDC-EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Version 1.2	Final	Production	●●●○○	No	Free	Yes

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

III-G: Publish and Subscribe

Interoperability Need: Publish and Subscribe Message Exchange

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	eHealth Exchange Specification: Health Information Event Messaging Production Specification	Final	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	*Balloted Draft*	*Pilot*	●●●○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The listed eHealth Exchange Specification will be deprecated in the future in favor of the emerging IHE DSUB specification and/or the equivalent FHIR profile. • See IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-H: Query

Interoperability Need: Query for Documents Within a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-XDS (Cross-enterprise document sharing)	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●●	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes
Emerging Implementation Specification	*IHE-MHD (Mobile Access to Health Documents)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE-PIXm (Patient Identifier Cross-Reference for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE-PDQm (Patient Demographics Query for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need along with IHE-XDS. • The MHD Supplement Revision 2.2 published in April 2016 is based on FHIR DSTU2. • IHE-PIXm and IHE-PDQm are used for the purposes of patient matching and to support this interoperability need along with MHD. • See IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specifies access control policies. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Message Interceptor Gateway** – provide a single entry point solution for centralization of security enforcement for incoming and outgoing XML WebService messages. • **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Authentication** – The identity information and process necessary verify the user's identity. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction. • **Security Labeling** – the health information is labeled with security metadata

Interoperability Need: Query for Documents Outside a Specific Health Information Exchange Domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE-XCA (Cross-Community Access)	Final	Production	●●●●○	No	Free	Yes
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Patient Discovery	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Messaging Platform	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Authorization Framework	Final	Production	●●●○○	No	Free	Yes
1-Implementation Specification	eHealth Exchange Specification: Query for Documents	Final	Production	●●●○○	No	Free	Yes
1-Implementation Specification	eHealth Exchange Specification: Retrieve Documents	Final	Production	●●●○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • While IHE-PIX and IHE-XCPD are best-available standards at this time, the current best-available standards may be insufficient to meet interoperability needs with sufficient accuracy. • See IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Authentication** – The information and process necessary to authenticate the end user. • **User Details** - identifies the end user who is accessing the data. • **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction for purposes of authorization. E.g., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access. • **Purpose of Use** - Identifies the purpose for the transaction, and for the purposes for which the end user intends to use the accessed objects.

	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information.
	  ○ May be required to authorized access and use of patient information.
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply.
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: Data Element Based Query for Clinical Health Information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7 Argonaut Data Query Implementation Guide Version 1.0.0	Balloted Draft	Production	●●○○○	No	Free	Yes Yes
Emerging Standard	*HL7 Fast Healthcare Interoperability Resources (FHIR), STU 3*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

• The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API".
• Note that the maturity level of FHIR resources may vary. The FHIR Maturity Model and each of the levels is described on the HL7 wiki.
• See FHIR projects in the Interoperability Proving Ground.
	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Details** - identifies the end user who is accessing the data.
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.
	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information.
	  ○ May be required to authorize access and use of patient information.
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply.
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

III-I: Resource Location

Interoperability Need: Care Service Discovery Within the US

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved. • **User Details** - identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-J: Consumer Access/Exchange of Health Information

Interoperability Need: Push Patient-Generated Health Data into Integrated EHR

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●○○○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• To learn more about Patient-Generated Health Data and its usage, see the Patient Engagement Playbook, as well as ONC's Patient-Generated Health Data webpage. • Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used, as appropriate, when pushing patient-generated health data into integrated EHRs. • A draft white paper for a Patient-Generated Health Data policy framework, created under an ONC contract, is available for review. A final version will be published in early 2018. • The SMART on FHIR Project is working in this area, and may have additional implementation guidance, as well as a list of applications supporting this interoperability need. • See FHIR, Direct, Patient Portal, API, and Open API projects in the Interoperability Proving Ground.	• **System Authentication** – The information and process necessary to authenticate the systems involved. • **User Details** – identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** – Identifies the purpose for the transaction. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user. • **Query Request ID** – Query requesting application assigns a unique identifier for each query request in order to match the response to the original query. • **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

• "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • Direct is not currently supported by a formal SDO but is actively maintained and updated by the Direct Community. • When using the SMART on FHIR model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply.	

Interoperability Need: Patient Exchanging Secure Messages with Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●○○○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• To learn more about Patient Portals and their usage, see the Patient Engagement Playbook. • See FHIR, Direct, Patient Portal, API, and Open API projects in the Interoperability Proving Ground. • "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • Direct is not currently supported by a formal SDO but is actively maintained and updated by the Direct Community. • Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used when data is being exchanged between patients and providers. • When using the SMART on FHIR model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply.	• **System Authentication** – The information and process necessary to authenticate the systems involved. • **User Details** – identifies the end user who is accessing the data. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** – Identifies the purpose for the transaction. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user. • **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

Interoperability Need: View, Download, and Transmit Data from EHR

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●○○○	Yes	Free	Yes
Implementation Specification	HL7 Fast Healthcare Interoperability Resources (FHIR) STU 2, Argonaut Data Query Implementation Guide	Balloted Draft	Production	●●●○○	No	Free	Yes Yes Yes
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:

- To learn more about Patient Portals and their usage, see the Patient Engagement Playbook.
- See FHIR, Direct, Patient Portal, API, and Open API projects in the Interoperability Proving Ground.
- "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751.
- For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange).
- Direct is not currently supported by a formal SDO but is actively maintained and updated by the Direct Community.
- Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used when data is being exchanged between patients and providers.
- The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the RESTful FHIR API.
- When using the SMART on FHIR model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply.

Applicable Security Patterns for Consideration:

- **System Authentication** – The information and process necessary to authenticate the systems involved.
- **User Details** – identifies the end user who is accessing the data.
- **User Role** – identifies the role asserted by the individual initiating the transaction.
- **Purpose of Use** – Identifies the purpose for the transaction.
- **Patient Consent Information** – Identifies the patient consent information that may be required before data can be accessed.
    - May be required to authorize any exchange of patient information.
    - May be required to authorize access and use of patient information.
    - May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply.
- **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.
- **Secure Communication** – create a secure channel for client-to-server and server-to-server communication.
- **Query Request ID** – Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.
- **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

Interoperability Need: Remote Patient Authorization and Submission of EHR Data for Research							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Emerging Implementation Specification	*HL7 Fast Healthcare Interoperability Resources (FHIR) STU Release 3*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

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

• See Sync for Science and Sync for Genes for more details about the research project use case that pertains to this interoperability need.
• The Kantara Initiative's UMA (User Managed Access) Work Group project's use case is designed to develop specifications that allow individual control of authorized data sharing and service access to promote interoperability in support of this interoperability need.
• The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the RESTful FHIR API.
• See FHIR , API, and Open API projects in the Interoperability Proving Ground.
• Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used when data is being exchanged between patients and providers.
• When using the SMART on FHIR model, the authentication model uses OAuth2. The other security patterns listed do not apply.
	• **System Authentication** – The information and process necessary to authenticate the systems involved.
	• **User Details** – identifies the end user who is accessing the data.
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Patient Consent Information** – Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorize access and use of patient information.
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply.
	• **Purpose of Use** – Identifies the purpose for the transaction.
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Section IV: Models and Profiles

IV-A: Functional Models

Interoperability Need: EHR Interoperability with the HIT Ecosystem							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	ISO/HL7 10781 EHR System Functional Model, Release 2, aka EHR-S FM (published by HL7 2014, ISO 2015)	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: PHR Interoperability with the HIT Ecosystem							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	ISO/HL7 16527 PHR System Functional Model, Release 2, aka PHR-S FM (published by HL7 2014, ISO 2015)	Final	Production	Feedback requested	No	Free	N/A

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

IV-B: Functional Profiles

Interoperability Need: Interoperability for Public Health Services							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 Public Health Functional Profiles (published 2015), suite of nine (9) FPs for specific public health services/domain areas, based on ISO/HL7 10781 EHR-S FM	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: Enable Interoperability for Nutrition Care							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	HL7 EHR-System Electronic Nutrition Care Process Record System (ENCPRS) Functional Profile, Release 1	Final	Production	Feedback requested	No	Free	N/A

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

IV-C: Information Models

Interoperability Need: Information model for the interoperability of Diet and Nutrition Orders

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 V3 Domain Analysis Model: Diet and Nutrition Orders, Release 2	Final	Production	Feedback requested	No	Free	N/A

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

Interoperability Need: Information Model for the Interoperability of Behavioral Health

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Version 3 Domain Analysis Model: Behavioral Health Record, Release 2	Final	Production	Feedback requested	No	Free	N/A

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

Section V: Administrative Standards and Implementation Specifications

V-A: Health Care Claims and Coordination of Benefits

Interoperability Need: Health Care Claims or Equivalent Encounter Information for Professional Claims

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Interoperability Need: Health Care Claims or Equivalent Encounter Information for Institutional Claims							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	X12 Version 5010	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • This transaction is also used to conduct coordination of benefits between entities that agree to use it between their two organizations. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions. • For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

that transaction set.	

Interoperability Need: Health Care Claims or Equivalent Encounter Information for Dental Claims

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • This transaction is also used to conduct coordination of benefits (COB) between entities that agree to do so. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions. • For a description of the functionality of each transaction, visit the X12 website.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

Interoperability Need: Health Care Claims or Equivalent Encounter Information for Retail Pharmacy Claims

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2010; and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2)	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The pharmacy telecommunication standard provides a standard format for the electronic submission of third party drug claims and other transactions between pharmacy providers, health plans (payers, insurance companies), third-party administrators, and others with financial responsibility. • Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all covered entities – health plans, clearinghouses and covered health care providers are required to use the telecommunication standard for claim and service billing, as well as eligibility verification, predetermination of benefits, and prior authorization. The standard can perform a variety of other functions as well. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Costs for access to the NCPDP standards are based on membership. NCPDP's Standards Matrix is available as a reference providing a high-level overview of the latest version/release and/or the most commonly used of NCPDP standards and implementation guides, as well as NCPDP's Data Dictionary and External Code List.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Interoperability Need: Health Care Claims or Equivalent Encounter Information for Retail Pharmacy Supplies and Professional Services

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●●●	Yes	$	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2010; and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2)	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • The pharmacy telecommunication standard provides a standard format for the electronic submission of third party drug claims and other transactions between pharmacy providers, health plans (payers, insurance companies), third-party administrators, and others with financial responsibility. • Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all covered entities – health plans, clearinghouses and covered health care providers are required to use the telecommunication standard for eligibility verification as well as claim and service billing, predetermination of benefits, and prior authorization. The standard can perform a variety of other functions as well. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Costs to access the NCPDP standards is based on membership. NCPDP's Standards Matrix is available as a reference providing a high-level overview of the latest version/release and/or the most commonly used of NCPDP standards and implementation guides, as well as NCPDP's Data Dictionary and External Code List. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions. • For a description of the functionality of each transaction, visit the X12 website.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

Interoperability Need: Health Care Claim Status Request and Response

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●○○	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. • For a description of the functionality of each transaction, visit the X12 website.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

V-B: Administrative Transactions - Non-Claims

Interoperability Need: Enrollment and Disenrollment in a Health Plan

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●○○	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • There are two versions of the enrollment transaction in use by industry today. One is the adopted transaction exchanged between a covered health plan and the employer, which is not a covered entity. The adoption rate is unknown. The other version, referred to as the HIX, has not been adopted by the federal government, but is used by the issuers participating in the federal marketplace or health insurance exchanges created by the Affordable Care Act. It includes data elements necessary to complete that enrollment process.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

• Additional information is available on testing, and the full cost on any of the X12 transactions. • For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set. ASETT is the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions.	

Interoperability Need: Health Care Eligibility Benefit Inquiry and Response

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • This transaction is used for dental, professional and institutional services. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT is the HHS compliance tool to enable testing and complaint	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

filing for all X12 and NCPDP transactions. • For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

Interoperability Need: Health Care Eligibility Benefit Inquiry and Response for Retail Pharmacy Coverage

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2010; and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2)	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Costs to access the NCPDP standards are based on membership status. NCPDP's Standards Matrix is available as a reference providing a high-level overview of the latest version/release and/or the most commonly used of NCPDP standards and implementation guides, as well as NCPDP's Data Dictionary and External Code List.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

V-C: Administrative Transactions to Financial Exchanges

Interoperability Need: Health Plan Premium Payments for Covered Members

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●○○○	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218	Final	Production	●●○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT is the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions • For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

Interoperability Need: Electronic Funds Transfer for Payments to Health Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NACHA Operating Rules, Appendix One and Three ACH File Exchange Specifications; ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries; and Data content in CCD Addenda Record: ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), April 2006: Section 2.4: 835 Segment Detail: "TRN"	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Widespread implementation of the Electronic Funds Transfer (EFT) transaction by providers may be somewhat constrained by unanticipated transaction fees and costs associated with new payment technologies (e.g. virtual credit cards) imposed or used by third parties, vendors, clearinghouses, and health plans. • File testing is done between the banks and their originators of the ACH files, between the banks and the ACH Operators and for the software vendors with the ACH Operators. Testing for a new originator is done with the bank before they originate their first file. Testing between the banks and the ACH Operators is done when there is a new application – currently a lot of testing is being done between the banks and the ACH Operators for Same Day ACH Debits (to be implemented in September 2017). If a bank changes ACH processing software or hires a third-party vendor, testing will be done between the bank and the ACH Operator. • Because only the current version of an ACH file format is allowed through the ACH Network, the originating bank reviews all files to make sure that the formatting is correct before they send the files to the ACH Operators. The ACH Operators also review all files to make sure that the mandatory fields within the ACH file are formatted correctly – if they are not the files are returned to the originating bank. Both the originating bank and the ACH Operators are looks at the files to make sure that the files are syntactically correct. • ACH Network is an electronic funds transfer system governed by the NACHA Operating Rules, which provides for interbank clearing of electronic entries for participating financial institutions.	• All covered entities are required to meet HIPAA security and privacy requirements in order for Electronic Data Interchange (EDI) to occur. • For Automated Clearing House (ACH) Network risks and enforcement, one can refer to NACHA's ACH Network Risk and Enforcement Topics and 2017 NACHA Operating Rules & Guidelines.

Interoperability Need: Health Care Payment and Remittance Advice

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●●●○○	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • Adoption of standards to increase the efficiency of the health care system was required by the Health Insurance Portability Act of 1996 (HIPAA). This version of the standard was adopted in 2009, and compliance was required by January 2012. The purpose of the electronic standard transactions was to improve efficiency in the health care system by reducing the use of paper and increasing the electronic exchange of health care information. • Challenges with this transaction may occur when the remittance information does not match the claim or the payment. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT is the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions. • For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set. • Pharmacy providers will receive the X12 835 remittance advice transaction with their payments, and NCPDP offers specific guidance on how the X12 835 remittance advice should be mapped in response to the NCPDP D.0 claim transaction to maximize reconciliation.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

V-D: Administrative Transactions to Support Clinical Care

Interoperability Need: Referral Certification and Authorization Request and Response for Dental, Professional and Institutional Services

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 5010	Final	Production	●○○○○	Yes	$	Yes
Implementation Specification	ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1	Final	Production	●○○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The Administrative Simplification provisions of HIPAA apply to the adoption of electronic transaction standards and operating rules for use in the health care industry. HIPAA has some different requirements for information exchange than EHRs, but there is hope for convergence in the future. Information about the HIPAA regulations regarding standards and operating rules can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. Readers can find information about requirements for covered entities and their business associates and enforcement from this link. • This standard and the transaction were adopted under the Health Insurance Portability Act of 1996 (HIPAA) to increase efficiency in the health care system by reducing the use of paper and increasing the exchange of health care information electronically. The current version was adopted in 2009, and required for use in 2012. Content from the transactions is often maintained in provider practice management and billing systems but duplicates information in electronic health records. • Low utilization of this transaction is likely due to reported business process issues. • Before implementation of a new version of a standard, end to end testing should be conducted with vendor systems and between trading partners to ensure changes have been accommodated. • Additional information is available on testing, and the full cost on any of the X12 transactions. ASETT is the HHS compliance tool to enable testing and complaint filing for all X12 and NCPDP transactions.	• All covered entities and their business associates are required to comply with the HIPAA Privacy and Security Rules. Health and Human Services has partnered with the Office of the National Coordinator and the National Institutes of Standards and Technology to publish comprehensive guidance for Security specific to electronic protected health information. A self-assessment tool kit is available to support integrating privacy and security into practices.

• For a description of the functionality of each transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

Interoperability Need: Health Care Attachments to Support Claims, Referrals and Authorizations

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	X12 Version 6020	Final	Pilot	●○○○○	No	$	No
Implementation Specification	X12N 278 - Health Care Services Request for Review and Response (006020X315)	Final	Pilot	●○○○○	No	$	No
Implementation Specification	X12N 277 - Health Care Claim Request for Additional Information (006020X313)	Final	Pilot	●○○○○	No	$	No
Implementation Specification	X12N 275 - Additional Information to Support a Health Care Services Review (006020X316)	Final	Pilot	●○○○○	No	$	No
Implementation Specification	X12C 999 - Implementation Acknowledgment for Health Care Insurance (005010X231), and X12C 999 - Errata for Implementation Acknowledgment for Health Care Insurance (005010X231)	Final	Production	●●●●○	No	$	No
Implementation Specification	X12N 999 - Implementation Acknowledgment for Health Care Insurance (006020X290)	Final	Pilot	●○○○○	No	$	No
Implementation Specification	HL7 Implementation Guide for CDA®, Release 2: Unstructured Documents	Final	Production	●●●○○	No	$	No
Implementation Specification	HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	$	No
Implementation Specification	HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1	Balloted Draft	Pilot	●○○○○	No	$	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Additional CDA R2 Templates - Clinical Documents for Payers – Set 1, Release 1.1 (US Realm)	Final	Pilot	●○○○○	No	$	No
Implementation Specification	HL7 Implementation Guide: LOINC Clinical Document Ontology, Release 1	Final	Pilot	●○○○○	No	$	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1	Final	Pilot	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The standards for attachments to support claims and other administrative transactions have not been adopted for use, though the original HIPAA legislation required their adoption, and the Affordable Care Act reiterated the requirement. • A proposed rule was published in 2005, and a final rule was released in 2006, and then withdrawn. • There are at least two provider/payer partners who have implemented the attachment standards successfully, on a voluntary basis, following a pilot project in 2004. • CMS provides additional information about the HIPAA administrative simplification provisions.	• Feedback requested.

Interoperability Need: Referral Certification and Authorization for Pharmacy Transactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2010	Final	Production	●●●○○	Yes	$	Yes
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide, Version 2013101	Final	Production	●●○○○	Yes	$	No

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

V-E: Operating Rules to Support Administrative Transactions

Interoperability Need: Operating Rules to Support Eligibility Transactions (Phase I)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CAQH, Committee on Operating Rules for Information Exchange	Final	Production	●●●○○	Yes	Free	No
Implementation Specification	CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011	Final	Production	●●●○○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Operating rules were adopted as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. • Operating rules are intended to support and enhance the use of the standard transactions. They include additional requirements to help implement the transaction in a more uniform way across health plans, and ensure a more complete set of information in the response. For example, rather than just "yes or no" for eligibility information, the operating rule requires health plans to return patient eligibility and financial responsibility for a list of service types such as emergency care, inpatient hospitalization, and dental and vision services. • Operating rules include other business rules to support the eligibility transaction as it moves between the provider and the health plan, such as the format of the health plan's companion guide (see CORE Rule 152), as well as response time for real time and batch transactions (see CORE Rules 155 and 156). • Operating rules are developed through workgroups which are consensus driven, based on the members who participate. Greater participation from more diverse members will result in more robust content and utility to enable to the rules to support the transactions and serve the users effectively. This is where the convergence of administrative and clinical systems will take place with respect to patient benefit information in the electronic health record. • Phase I eligibility operating rules include: ▪ (1) Phase I CORE 150: Batch Acknowledgement (not adopted) version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (2) Phase I CORE 151 Real Time Acknowledgement (not adopted) version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ Although Phase I CORE 150 & 151 operating rules are not part of the federal mandate for adoption of Phase I CAQH CORE Operating Rules, they are required for voluntary CORE Certification. ▪ (3) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master	• Feedback requested.

Companion Guide Template. (Incorporated by reference in § 162.920). ▪ (4) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (5) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (6) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (7) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (8) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). • Testing or certification with the operating rules is voluntary and available through a vendor contracted to the authoring entity. The checklist is available on the website.	

Interoperability Need: Operating Rules to Support Eligibility and Claim Status Transactions (Phase II)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CAQH, Committee on Operating Rules for Information Exchange	Final	Production	●●●○○	Yes	Free	No
Implementation Specification	CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010, Update March 2011	Final	Production	●●●○○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Operating rules were adopted as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. • Operating rules are intended to support and enhance the use of the standard transactions. They include additional requirements to help implement the transaction in a more uniform way across health plans, and ensure a more complete set of information in the response. For example, rather than just "yes or no" for eligibility information, the operating rule requires health plans to return patient eligibility and financial responsibility for a list of service types such as emergency care, inpatient hospitalization, and dental and vision services. • Operating rules include other business rules to support the eligibility transaction as it moves between the provider and the health plan, such as the format of the health plan's companion guide (see CORE Rule 152), as well as response time for real time and batch transactions (see CORE Rules 155 and 156). • Operating rules are developed through workgroups which are consensus driven, based on the members who participate. Greater participation from more diverse members will result in more robust content and utility to enable to the rules to	• Feedback requested.

support the transactions and serve the users effectively. This is where the convergence of administrative and clinical systems will take place with respect to patient benefit information in the electronic health record. • Phase II eligibility and claim status operating rules include: ▪ (1) Phase II CORE 250: Claim Status Rule, version 2.1.0 March 2011 (Incorporated by reference in § 162.920). ▪ (2) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (3) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920). ▪ (4) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920). ▪ (5) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).(b). • Testing or certification with the operating rules is voluntary and available through a vendor contracted to the authoring entity. The checklist is available on the website.	

Interoperability Need: Operating Rules for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA) for Payments and Reconciliation (Phase III)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CAQH, Committee on Operating Rules for Information Exchange	Final	Production	●●●○○	Yes	Free	No
Implementation Specification	CAQH, Committee on Operating Rules for Information Exchange, Phase III CORE EFT & ERA Operating Rule Set Approved June 2012	Final	Production	●●●○○	Yes	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Operating rules were adopted as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. • Operating rules are intended to support and enhance the use of the standard transactions. They include additional requirements to help implement the transaction in a more uniform way across health plans, and ensure a more complete set of information in the response. For example, rather than just "yes or no" for eligibility information, the operating rule requires health plans to return patient eligibility and financial responsibility for a list of service types such as emergency care, inpatient hospitalization, and dental and vision services. • Operating rules include other business rules to support the eligibility transaction as it moves between the provider and the health plan, such as the format of the health	• Feedback requested.

plan's companion guide (see CORE Rule 152), as well as response time for real time and batch transactions (see CORE Rules 155 and 156). • Operating rules are developed through workgroups which are consensus driven, based on the members who participate. Greater participation from more diverse members will result in more robust content and utility to enable to the rules to support the transactions and serve the users effectively. This is where the convergence of administrative and clinical systems will take place with respect to patient benefit information in the electronic health record. • These operating rules include CAQH CORE policies for voluntary testing and certification, which are not mandatory. The other rules support the EFT and ERA through a range of requirements, from the companion guide template, to the uniform use of combinations for certain Claim and Remark Codes (CARCs and RARCsWeb Site Disclaimers), to certain standard data elements for enrollingWeb Site Disclaimers providers electronically for EFT or ERAWeb Site Disclaimers transactions. • Phase III Operating Rules for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA) for Payments and Reconciliation include: ▪ (1) Phase III CORE 350: Healthcare Claim Payment/Advice (835) Infrastructure Rule ▪ (2) Phase III CORE 360: Uniform Use of CARCs and RARCs (835) Rule ▪ (3) Phase III CORE 370: EFT and ERA Reassociation (CCD+/835) Rule ▪ (4) Phase III CORE 380: EFT Enrollment Data Rule ▪ (5) Phase III CORE 382: ERA Enrollment Data Rule • Testing or certification with the operating rules is voluntary and available through a vendor contracted to the authoring entity. The checklist is available on the website.	

V-F: CMS Interoperability Standards for Provider to Provider Communication

Interoperability Need: Durable Medical Equipment/Home Health Agency Order Submission

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	CMS EMDI Implementation Guide Section 4.1.1 and Appendix B	In Development	Pilot	Feedback requested	No	Free	No
Implementation Specification	CMS EMDI Implementation Guide Section 5.1.5.1	In Development	Pilot	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Organizations may use an internal (native) or external EHR/document management system that provides the following capabilities: • Send and receive patient records to providers with electronic referrals. • Send and receive documents related to the use cases using secure messaging.	• Feedback requested.

• Integrate information from other systems, as required, to provide complete documentation. • Send multiple documents, as necessary, to meet the use cases. • Create metadata where appropriate. • Ensure that all documents clearly indicate the patient and provider responsible for each item of documentation created or signed off by a different provider. • Clearly indicate the document type (e.g. Mime type) for each document. • Provide electronic or digital signature capabilities for all clinical documents. • Consume the associated clinical data and integrate it into the patient's medical record.	

Interoperability Need: Durable Medical Equipment/Home Health Agency Document Request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	CMS EMDI Implementation Guide Section 4.1.2 and Appendix B	In Development	Pilot	Feedback requested	No	Free	No
Implementation Specification	CMS EMDI Implementation Guide Section 5.1.5.4	In Development	Pilot	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Organizations may use an internal (native) or external EHR/document management system that provides the following capabilities: • Send and receive patient records to providers with electronic referrals. • Send and receive documents related to the use cases using secure messaging. • Integrate information from other systems, as required, to provide complete documentation. • Send multiple documents, as necessary, to meet the use cases. • Create metadata where appropriate. • Ensure that all documents clearly indicate the patient and provider responsible for each item of documentation created or signed off by a different provider. • Clearly indicate the document type (e.g. Mime type) for each document. • Provide electronic or digital signature capabilities for all clinical documents. • Consume the associated clinical data and integrate it into the patient's medical record.	• Feedback requested.

Interoperability Need: Durable Medical Equipment/Home Health Agency Signature Request

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*CMS EMDI Implementation Guide Section 4.1.3 and Appendix B*	*In Development*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*CMS EMDI Implementation Guide Section 5.1.5.7*	*In Development*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

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

• Organizations may use an internal (native) or external EHR/document management system that provides the following capabilities:
  • Send and receive patient records to providers with electronic referrals.
  • Send and receive documents related to the use cases using secure messaging.
  • Integrate information from other systems, as required, to provide complete documentation.
  • Send multiple documents, as necessary, to meet the use cases.
  • Create metadata where appropriate.
  • Ensure that all documents clearly indicate the patient and provider responsible for each item of documentation created or signed off by a different provider.
  • Clearly indicate the document type (e.g. Mime type) for each document.
  • Provide electronic or digital signature capabilities for all clinical documents.
  • Consume the associated clinical data and integrate it into the patient's medical record.
	• Feedback requested.

Appendices

Appendices, including Sources for Security Standards/Security Patterns, and Educational/Informational Resources are available for viewing online at www.healthit.gov/isa.