The Office of the National Coordinator for Health Information Technology

2022 Interoperability Standards Advisory

Reference Edition

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Table of Contents

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Introduction to the 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) coordinates 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 2022 Reference Edition ISA reflects the numerous changes made across the ISA throughout 2021. 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 creating an account. 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. An RSS feed, capturing more granular changes to individual pages across the ISA, is also available.

For additional information about the ISA, including scope, purpose, structure, an overview of the informative characteristics attributed to each standard/implementation specification, frequently asked questions, and the annual timeline and comment process, please see pages under the site's About the ISA section.

Vocabulary/Code Set/Terminology

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	●●●●○	Yes	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 III 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; 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 is requested as to the extent the suggested value sets using SNOMED CT® parent and child codes for environmental allergens are sufficient to meet the needs for starter value set.	• Common Environmental Substances for Allergy and Intolerance documentation (2.16.840.1.113762.1.4.1186.4) • Allergic disposition (disorder) (SNOMED CT® 609328004) is parent code to: ▪ Environmental allergy (disorder) (SNOMED CT® 426232007) ▪ Allergy to substance (disorder) (SNOMED CT® 419199007) and other related 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 is requested as to the extent the suggested value sets using SNOMED CT® parent and child codes for food allergens are sufficient to meet the needs for starter value set.	• Adverse Clinical Reaction (2.16.840.1.113883.3.2074.1.1.30) (SNOMED CT® value set)
	• Propensity to adverse reactions to food (disorder) (SNOMED CT® 418471000) is parent SNOMED CT® code to:
	  ▪ Food allergy (disorder) (SNOMED CT® 414285001)
	  ▪ Food intolerance (disorder) (SNOMED CT® 235719002)
	• Food Allergen (2.16.840.1.113762.1.4.1156.1) (SNOMED CT® value set-Steward Partners Healthcare)
	• Common dietary substances for allergy and intolerance documentation (2.16.840.1.113762.1.4.1186.3) (SNOMED CT® value set-Steward HL7® Patient Care Work Group)

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	●●●○○	Yes	Free	N/A
Emerging Standard	*Medication Reference Terminology (MED-RT)*	*Final*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

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. • MED-RT replaces VA's NDF-RT, which was sunsetted in 2018. MED-RT has the capability to represent medication classes for use as an allergen category, and currently requires MeSH terms for medication classes. • 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) Representing Drug Classes for Allergy and Intolerance documentation • Pharmaceutical / biologic product (product) (SNOMED CT® 373873005) is the parent to pharmaceutical/biologic class hierarchy • Medication drug class for allergen intolerance SCT (2.16.840.1.113762.1.4.1114.14) 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

CLINICAL NOTES

Interoperability Need: Representing Clinical Notes

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
LOINC®: • A Consultation note is generated as part of a request from a clinician for an opinion or advice from another clinician. • A Discharge Summary note is a synopsis of a patient's admission and course in a hospital or post-acute care setting. • A History & Physical note documents the current and past conditions of the patient. • A Progress Note represents a patient's interval status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter. **IHE:** • See also Integrating the Healthcare Enterprise (IHE) IT Infrastructure White Paper: Enabling Document Sharing Health Information Exchange Using IHE Profiles.	**LOINC®:** • Consultation note (LOINC® code 11488-4) • Discharge Summary note (LOINC® code 18842-5) • History and Physical note (LOINC® code 34117-2) • Progress Note (LOINC® code 11506-3) **IHE:** • IHE FormatCode Vocabulary

COGNITIVE STATUS

Interoperability Need: Representing Patient Cognitive 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	N/A
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 – Cognitive Status*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*

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

• The PACIO Workgroup is developing FHIR® use cases for the exchange of functional status and cognitive status information between healthcare settings.
  ▪ Cognitive Status Implementation Guide
• The CMS Data Element Library provides the ability to download assessment data elements, including functional status, and associated health IT standards from the:
  ▪ Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)
  ▪ Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LCDS)
  ▪ Resident Assessment Instrument - Minimum Data Set (MDS)
  ▪ Outcome and Assessment Information Set (OASIS)
  ▪ Hospice Item Set (HIS)
	• Value sets were published by Regenstrief on December 15, 2017, v2.63, and continued to be updated as needed with new releases, including the most recent release v2.70. Cognitive Status data elements and their associated LOINC®s were published in the Data Element Library (DEL) in June 2018. The BIMS and CAM are included in CMS PAC assessments.
	• LOINC® Cognitive Status Codes
	  ▪ Brief interview for mental status (BIMS) 52491-8
	  ▪ Confusion Assessment Method (CAM) 52495-9
	  ▪ Montreal Cognitive Assessment (MoCA) 72133-2
	  ▪ Mini-Mental State Examination (MMSE) 72107-6

COVID-19 NOVEL CORONAVIRUS PANDEMIC

Interoperability Need: COVID-19 Novel Coronavirus Pandemic

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	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●●	Yes	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●●	Yes	$	N/A
Standard	HCPCS	Final	Production	●●●●●	Yes	Free	N/A
Standard	Clinical Vaccines Administered (CVX)	Final	Production	●●●●●	Yes	Free	N/A
Standard	Manufacturing Vaccine Formulation (MVX)	Final	Production	●●●●○	No	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●●●	Yes	Free	N/A
Standard	RxNorm	Final	Production	Feedback Requested	No	Free	N/A
Implementation Specification	HL7® Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update	Final	Feedback Requested	Feedback Requested	No	Free	Yes
Emerging Implementation Specification	*HL7® FHIR® (v4.0.1) Situational Awareness for Novel Epidemic Response (SANER) IG 0.1.0 Continuous Build*	*Balloted Draft*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*N/A*
Emerging Implementation Specification	*Logica COVID-19 (FHIR® v4.0.1) Implementation Guide CI Build*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*N/A*

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

• The following artifacts provide additional guidance on adopting codes, terminologies and coding guidance:
  ▪ CDC Official FY2022 Coding and Reporting Guidelines for ICD-10-CM
  ▪ Logica (FHIR® v4.0) Implementation Guide: COVID-19
  ▪ SNOMED CT® Coding for COVID-19 Data
  ▪ Guidance for mapping to SARS-CoV-2 LOINC® terms
  ▪ LOINC® In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests, Specimens and Results (CDC/FDA)
  ▪ COVID-19 Lab Data Reporting Implementation Specifications includes HL7® Field and HL7® V2 Message guidance
• The FHIR® profiles in the Logica IG: COVID-19 contains FHIR® profiles representing COVID-19 related data elements to support patient care, billing, research, or public reporting. The goal is to create consistent and reusable data and FHIR® profiles for different COVID-19 implementation guides.
• The emerging HL7® Situational Awareness for Novel Epidemic Response (SANER) Implementation Guide enables transmission of high level situational awareness information from inpatient facilities to centralized data repositories to support the treatment of novel influenza-like illness.
• The COVID-19 Interoperability Alliance stewards more than 600 value sets on behalf of collaborators that include SNOMED International, Regenstrief, Logica Health, the National Association of Community Health Centers, MITRE and more. These value sets support data aggregation, analytics, population cohort identification, clinical trials, and medical research.
• CDC and FDA maintain mapping of all current US approved SARS-CoV-2 invitro diagnostic lab and their corresponding specimen types and results.
• CMS Press Release on HCPCS Codes for Coronavirus Lab Testing
• CARES Act Section 18115 require laboratories to report results of SARS-CoV2 or COVID-19 testing to the Secretary of HHS in the
	• COVID-19 Related Value Sets in NLM Value Set Authority Center
	• LOINC® terms for SARS-CoV-2 and COVID-19 related concepts
	• CDC Immunization Information Systems (IIS) Code Sets
	• AMA CPT coding and guidance for COVID-19
	• AMA CPT New SARS-CoV-2 Vaccine Codes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
form and manner outlined in this memo "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 June 4, 2020" • CMS COVID-19 Vaccine Policies & Guidance • CDC COVID-19 Vaccine Data Systems	

DEMOGRAPHICS

Interoperability Need: Representing Patient Contact Information for Telecommunications

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	ITU–T E.123 (02/2001) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses and ITU–T E.164 International Telecommunication Union E.164: The international public telecommunication numbering plan	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Telecom Data Elements: ▪ Phone Number, Phone Number Type - For §170.315 (b)(1) Transitions of care and §170.315 (b)(4) Common Clinical Data Set summary record – create, patient matching data must represent phone number (home, business, cell) in accordance with the above standards. All phone numbers must be included when multiple phone numbers are present. ▪ Email Address - Per ITU–T E.123 (02/2001) above, an electronic mail address, if present, should be printed in the SMTP style below the telephone number information, and denoted by the label "E-mail" or some easily recognized variation such as "email," or the equivalent in the appropriate language.	Examples from ITU–T E.123 (02/2001) Multiple phone numbers: • Tel. (0607) 123 4567 • Fax (0607) 123 4568 • Mobile (0607) 321 9876 Phone numbers and email • Telephone: (0609) 123 4567 • International +22 609 123 4567 • Mobile (0607) 321 9876 • E-mail: jdeo@isp.com

DIETARY AND NUTRITIONAL NEEDS

Interoperability Need: Representing Nutrition Assessment, Diagnosis, Interventions and Monitoring/Evaluation

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
Standard	SNOMED CT®	Final	Production	*Feedback Requested*	No	Free	N/A
Standard	NCPT (Nutrition Care Process Terminology)	Final	Production	●●●○○	No	$	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●●	No	$	No
Emerging Implementation Specification	*HL7® FHIR® Nutrition Intake Resource*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*
Emerging Implementation Specification	*HL7® FHIR® Nutrition Product Resource*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Nutrition Care Process Terminology (NCPT) and is owned, maintained, and distributed by the Academy of Nutrition and Dietetics to support standardization of the Nutrition Care Process. Many of the terms in the NCPT have been mapped to SNOMED and/or LOINC®. • Work is currently underway to develop a food insecurity data set through the Gravity Project. • Value set: Nutrition Diagnosis Grouping (2.16.840.1.113762.1.4.1095.85)	• Food and Nutrient Delivery SNOMED CT® (2.16.840.1.113762.1.4.1095.2) • Food and Nutrition Related History LOINC® (2.16.840.1.113762.1.4.1095.78) • Food and Nutrition Related History SNOMED CT® (2.16.840.1.113762.1.4.1095.84) • CPT 97802 – 97804: identify patient assessment and intervention of medical nutrition therapy • CPT Category II 3759F and 3760F: identify assessment and screening for nutrition within the treatment of another clinical condition

EMERGENCY MEDICAL SERVICES

Interoperability Need: Representing Health Care Data for Emergency Medical Services

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	NEMSIS Version 3.4	Final	Production	Feedback Requested	No	Free	Yes
Standard	Current Procedural Terminology (CPT)	Final	Production	Feedback Requested	No	$	N/A
Standard	RxNorm	Final	Production	●●●●○	Yes	Free	N/A
Emerging Standard	*NEMSIS Version 3.5*	*Final*	*Production*	*Feedback Requested*	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The National Emergency Medical Services Information System (NEMSIS) administered by the National Highway Traffic Safety Administration's Office of Emergency Medical Services provides a universal standard for the collection and transmission of emergency medical services (EMS) operations and patient care data. Using NEMSIS-compliant electronic patient care record (ePCR) software products, data are collected by EMS practitioners at the point of care and includes information on the EMS system response, scene characteristics, patient demographics, patient condition, medical treatment provided, transport decision, patient and incident disposition and EMS system times (e.g., response time, scene time, transport time). NEMSIS includes the National EMS Database which accepts EMS data voluntarily submitted by U.S. States and Territories. Using NEMSIS-compliant ePCR software products, local EMS systems collect a national set of data elements for submission to the National EMS Database through their respective state. Local EMS systems and states have the option to collect additional NEMSIS data elements to meet local and state needs. The NEMSIS standard follows a 5-year revisioning	• CPT 99281 - 99285: patient evaluation, examination, and medical decision making for emergency department services • CPT 99288: direction of emergency care to EMS personnel by a physician or other qualified health care professional

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
cycle. The two most recent NEMSIS standard versions (V3.4.0 and 3.5.0 as of January 2021) are available for ePCR software product compliance testing and submission to the National EMS Database. NEMSIS standard version 3.5.0 was released in 2019. NEMSIS Version 3 standards (i.e., V3.4.0, and V3.5.0) include integration of several HL7® data standards, such as LOINC®, RxNorm, and ICD-10-CM. NEMSIS standard versions V3.4.0 and V3.5.0 are HL7® compliant and ANSI accredited. • NEMSIS uses Extensible Markup Language (XML) to move data. States and software companies create products that are used to send and receive EMS data in the proper XML format from agencies to states, then on to the National EMS Database. More information about NEMSIS is available at https://nemsis.org/technical-resources/. • Mapping and translation resources are available for mapping or translating older versions of the dataset to newer versions of the dataset.	

ENCOUNTER DIAGNOSIS, ASSESSMENT AND PLAN

Interoperability Need: Representing Assessment and Plan of Treatment

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)

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 Value Set(s) and Starter Set(s)
• 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.	• Vital Sign Result Value Set... ▪ OID 2.16.840.1.113883.3.3150

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	●●●●○	Yes	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. NLM has maps from ICD-9-CM diagnosis and procedure codes to SNOMED CT® to facilitate code translation and integration with newly collected SNOMED CT® data: ▪ ICD-9-CM Diagnostic Codes to SNOMED CT® ▪ ICD-9-CM Procedure Codes to SNOMED CT® • A mapping from SNOMED CT® to ICD-10-CM is available from the National Library of Medicine to support semi-automated generation of ICD-10-CM codes from clinical data encoded in SNOMED CT® for reimbursement and statistical purposes. • HIPAA mandates the use of ICD-10 for pharmacy claims using NCPDP standards, while SNOMED is optional for this use.	• 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

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	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®. • For clinical genomics purposes, the Human Phenotype Ontology (HPO) developed by Robinson, et al. and uses information from the Online Mendelian Inheritance in Man to generate its terms. It is used by some organizations to describe "phenotypic abnormalities". • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	Diagnosis and Conditions: • Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (SNOMED CT® 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

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
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 – Functional Status*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	

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 additional resources on Functional Status/Disability. ▪ American Medical Association's "Guides to the Evaluation of Permanent Impairment, Sixth Edition" ▪ The International Classification of Functioning, Disability and Health (ICF) is a World Health Organization (WHO) framework to describe and measure health and disability at both individual and population levels. • The CMS Data Element Library also provides the ability to download assessment data elements, including functional status, and associated health IT standards from the: ▪ Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) ▪ Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LCDS) ▪ Resident Assessment Instrument - Minimum Data Set (MDS) ▪ Outcome and Assessment Information Set (OASIS) ▪ Functional Assessment Standardized Items (FASI)	• Functional Status data elements were developed by CMS, and are integrated in CMS PAC assessments and CMS' Home and Community Based Services (HCBS) Functional Assessment Standardized Items (FASI). Value sets on functional status were published by Regenstrief on version 2.63 on December 15, 2017 and continue to be updated in recent versions as needed, including the most recent release v2.70. Functional Status data elements and their associated LOINC®s were published in the DEL in 2018.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The PACIO Workgroup is developing FHIR® use cases for the exchange of functional status and cognitive status information between healthcare settings. ▪ PACIO's Functional Status Implementation Guide (IG) has been officially published as Standard for Trial Use specifications by HL7®. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee. • The interoperability need is directed to cover people's functional activities at the level of the individual, including activity limitations, the ability to participate in or be involved in all areas of life, and any participation restrictions as a person or member of society.	

GOALS

Interoperability Need: Representing Patient Goals

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)
• The CMS Data Element Library also provides the ability to download assessment data elements, including various assessment of patient goals, and associated health IT standards such as LOINC® and SNOMED from the: ▪ Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) ▪ Long-Term Care Hospital Continuity Assessment Record & Evaluation Data Set (LCDS) ▪ Resident Assessment Instrument - Minimum Data Set (MDS) ▪ Outcome and Assessment Information Set (OASIS) ▪ Functional Assessment Standardized Items (FASI)	• Eating - Functional Goal 89409-7

HEALTH CARE PROVIDERS, FAMILY MEMBERS AND OTHER CAREGIVERS

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'. • The National Uniform Claim Committee (NUCC) Health Care Provider Taxonomy code set identifies health care provider groupings, classifications, and areas of specialization. It does include other providers than health care providers, which is defined by federal regulations. • The adoption of NPI for pharmacy/prescribing may be higher than for general use, however, not all prescribers (e.g., veterinarians, etc) are able to obtain an NPI.	• NUCC Provider Codes: 2.16.840.1.113883.6.101

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)
	• Pharmacy e-Health Information Technology Collaborative Occupations of Providers SNOMED CT® value set 2.16.840.1.113762.1.4.1096.129

Interoperability Need: Representing Relationship Between Patient and Another Person

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® V3 Vocabulary	Final	Production	●●○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• This value set is derived from the HL7® Vocabulary code system "RoleCode".	• Personal And Legal Relationship Role Type (VSAC OID 2.16.840.1.113883.11.20.12.1) ▪ This value set can be used to record relationships based on personal or family ties or through legal assignment of responsibility.

HEALTH CONCERNS

Interoperability Need: Representing Patient Health Concerns

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)
• A Health Concern is a health related matter that is of interest, importance or worry to someone, who may be the patient, patient's family or patient's health care provider. Health concerns are derived from a variety of sources within an EHR (such as Problem List, Family History, Social History, Social Worker Note, etc.). Health concerns can be medical, surgical, nursing, allied health or patient-reported concerns.	• Health Concern Document (LOINC® code 75310-3)

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	●●●●●	Yes	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●●	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Radiological Society of North America (Radlex) and Regenstrief Institute (LOINC®) have harmonized terms for radiology procedures. • Current Procedural Terminology (CPT®) is a code set, maintained by the American Medical Association (AMA) used to bill outpatient and office procedures. **LOINC®:** • An Imaging Narrative contains a consulting specialist's interpretation of image data.	**LOINC®:** • Diagnostic imaging study (LOINC® code 18748-4) • Radlex LOINC® Imaging Document Codes

IMMUNIZATIONS

Interoperability Need: Representing Immunizations – Administered

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Clinical Vaccines Administered (CVX)	Final	Production	●●●●●	Yes	Free	N/A
Standard	Manufacturing Vaccine Formulation (MVX)	Final	Production	●●●●○	No	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●●●	Yes	Free	N/A
Standard	RxNorm	Final	Production	Feedback Requested	No	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
General considerations: • The list above includes any vocabulary used to record immunizations in any health IT system including IIS, pharmacy, billing, etc. • RxNorm is an acceptable alternative code set for use at the local level. • RxNorm is not utilized by Pharmacy for dispensing purposes. **For Immunization Information System (IIS) consideration:** • The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains the CVX and MVX code systems, and developed and maintains the NDC vaccine tables based on information published by the FDA. • 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.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set • NDC concepts used to represent vaccines

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• 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. CDC has published guidance on NDC Unit of Use and Unit of Sale; it can be found at: https://www.cdc.gov/vaccines/programs/iis/2d-barcodes/downloads/guidance-documenting-ndc.pdf. • The lot number is used in conjunction with the NDC when reporting immunizations to state registries. There is no standard codification for lot numbers. • The IIS community does not utilize RxNorm as a code set and thus it may have limitations for interoperability across systems.	

Interoperability Need: Representing Immunizations – Historical

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Clinical Vaccines Administered (CVX)	Final	Production	●●●●●	Yes	Free	N/A
Standard	Manufacturing Vaccine Formulation (MVX)	Final	Production	●●●●○	No	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●●●	Yes	Free	N/A
Standard	RxNorm	Final	Production	Feedback Requested	No	Free	N/A
Standard	Current Procedural Terminology (CPT)	Final	Production	●●●●○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
General considerations: • The list above includes any vocabulary used to record immunizations in any health IT system including IIS, pharmacy, billing, etc. • NDC has been used by pharmacies to report historical doses for billing purposes, so it is included here in that context. • The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains the CVX and MVX code systems, and developed and maintains the NDC vaccine tables based on information published by the FDA. • RxNorm is an acceptable alternative code set for use at the local level. • RxNorm is not utilized for reporting of previous dispensing. **For Immunization Information System (IIS) consideration:** • 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. • MVX is rarely used to record historical vaccines; however, if a provider has the information available in that standard it should be captured and messaged as part of the historical vaccination record. • The IIS community does not utilize RxNorm as a code set and thus it may have limitations for interoperability across systems.	• 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 concepts used to represent vaccines

LABORATORY

Interoperability Need: Representing Laboratory Test Ordered

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	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 laboratory 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 may have an order LOINC® code and multiple result LOINC® terms for each result in the panel. • Guidance is available for using SNOMED CT® and LOINC® together. • LOINC® code availability is contingent on assignment by Regenstrief. • For more information about representing laboratory tests as a procedure, see the Representing Medical Procedures page. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee. • Additional information beyond the test/observation code (such as LOINC®) and result value is required for correct handling and interpretation of test results. This additional information includes the result harmonization status, the reference range, and result units. See “Representing Laboratory Values/Results” for discussion of this information.	• LOINC® Mapper's Guide to the Top 2000+ Lab Observations - US Version (.pdf)

Interoperability Need: Representing Laboratory Test Performed

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	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• LOINC® code is limited to representing laboratory tests in general, no dedicated code exists solely for representing a specific laboratory test performed. • Guidance is available for using SNOMED CT® and LOINC® together. • LOINC® code availability is contingent on assignment by Regenstrief. • For more information about representing laboratory tests as a procedure, see the Representing Medical Procedures page. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee. • Additional information beyond the test/observation code (such as LOINC®) and result value is required for correct handling and interpretation of test results. This additional information includes the result harmonization status, the reference range, and result units. See “Representing Laboratory Values/Results” for discussion of this information.	• LOINC® Mapper's Guide to the Top 2000+ Lab Observations - US Version (.pdf)

Interoperability Need: Representing Laboratory Values/Results

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard for observation values	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)
• Correct handling and interpretation of laboratory test values requires information about the test instance, including the result value, the units, the reference range, and the harmonization status of the test. • Units for numeric results may be represented using UCUM, see "Representing Units of Measure." • Non-numeric results may be represented using LOINC® answer lists, SNOMED CT® codes, or standard scales or grading schemes. • Reference ranges or expected values are represented as single or dual values in the same form and with the same units as results. • Harmonization status indicates calibration equivalencies of tests and is required to verify clinical interoperability of results. Tests that are harmonized may be interpreted and trended together, and may use the same calculations, decision support rules, and machine learning models. Tests that are not harmonized should be interpreted and processed individually, not in aggregate with other tests. Standard harmonization procedures for tests with and without reference methods and materials are described in ISO 17511:2020 and 21151:2020, respectively, but corresponding data elements in results communication standards have not yet been defined. • Future uses of laboratory test results may include "real world evidence" collection for final regulatory approval and performance monitoring of specific commercial products. These tasks will require results to include device IDs, test kit IDs, kit versions, reagent lots, and calibrator lots. The messaging structure to carry this information is available in the IHE LAW and LTW profiles, but in the current version is supported only for QC specimens within the order filling system and is not reported back to the order placing system.	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
LOINC®: • A Laboratory Report Narrative contains a consulting specialist's interpretation of the laboratory report.	

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users. • RxNorm is a terminology built on and derived from other terminologies which represent various elements within RxNorm, including dose form and units of measure. RxNorm reflects and preserves the meanings, drug names, attributes, and relationships from its sources. • The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals. • Note that medications include over-the-counter, botanicals, herbal supplements need to be considered in the management of medications and conditions for which they are used. Not all of these are well-represented using the standards indicated above. • Immunizations are not considered medications for this interoperability need.	• 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)

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)
• Concepts for observation values from SNOMED-CT® 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. • Question/Answer (name/value) pairs are a valuable representation of assessments, but best practices indicate the full question with answer should be included in communication. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	• Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) - Version 2.0 [CMS Assessment]: LOINC® 88329-8 • Long-Term Care Hospital Continuity Assessment Record & Evaluation (CARE) Data Set (LCDS) v.4.0 [CMS Assessment]: LOINC® 87509-6 • Resident Assessment Instrument (RAI) Minimum Data Set (MDS) v.1.16 Nursing Home Comprehensive (NC) item set [CMS Assessment]: LOINC® 88954-3 • Outcome and Assessment Information Set (OASIS) - Version D - Start of Care [CMS Assessment]: LOINC® 88373-6

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)
• According to the Journal of Nursing Education nursing interventions can be defined as "any task that a nurse does to or for the patient" or "something that directly leads to a patient outcome." • 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)
• Reference to Standard Nursing Terminologies • 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®. • Additional information about terminology standards related to nursing is available in an ONC-funded report: Standard Nursing Terminologies (A Landscape Analysis) • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III 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®

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
Standard	ICD-10-CM	Final	Production	●●●●○	No	Free	No

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 III 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

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
Standard	LOINC®	Final	Production	Feedback Requested	No	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	• PHIN VADS PHVS_Language_ISO_639-2_Alpha3 (OID 2.16.840.1.114222.4.11.831) • The following questions are collected on CMS Assessments: ▪ What is your preferred language? LOINC® 54899-0 ▪ Do you need or want an interpreter to communicate with a doctor or health care staff? LOINC® 54588-9

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 III for an informational resource developed by the Health IT Standards Committee.	• LOINC® code: 82810-3 Pregnancy status ▪ SNOMED CT®: o Patient currently pregnant (finding), 77386006 o Not pregnant (finding), 60001007 o Possible pregnancy (finding), 102874004 • LOINC® code: 11778-8 Estimated Delivery Date or 21299-3 Gestational age method

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	●●●●○	No	$	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	●●●●○	No	Free	N/A
Standard	LOINC®	Final	Production	Feedback Requested	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 procedures. • 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. • CPT Proprietary Laboratory Analyses (PLA) codes are published quarterly (1/1, 4/1, 7/1, and 10/1) and are available on the AMA website for representing laboratory procedures. See Representing Laboratory Tests for more information about Laboratory tests. **LOINC®:** • A Procedure Note records the indications for a non-operative procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient's tolerance of the procedure.	• CPT: ▪ 80047 - 89398 - including Multianalyte Assays with Algorithmic Analyses (MAAA) codes 81490-81599 ▪ Proprietary Laboratory Analyses (PLA) U codes ▪ MAAA administrative M Codes (0002M-0013M) • LOINC®: ▪ Procedure Note (LOINC® code 28570-0)

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• A Pathology Report Narrative contains a consulting specialist's interpretation of the pathology report.	

PROVENANCE

Interoperability Need: Representing Data Provenance

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® FHIR® Provenance Resource	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Data Elements: ▪ Author Time Stamp-indicates the time the information was recorded ▪ Author Organization-the organization the author is associated with at the time they interacted with the data.	

PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE

Interoperability Need: Representing Healthcare Personnel Status

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The CDC, Center of Emergency Preparedness and Response, Situational Awareness branch, collaborating with the National Information Exchange Model (NIEM), developed -a population-level public health emergency preparedness and response information exchange requirements, which includes a minimum data set, and standardized vocabulary. Data comes directly from hospital and long-term care facility databases, not directly linked to the EHR. • *The Healthcare personnel status section of the minimum data set* provides vocabulary for a population-level reporting healthcare personnel morbidity and mortality during an emergency event.	• *Healthcare personnel status (LOINC® 95892-6 prerelease)* • *Minimum Data Set (MDS) for Public Health Emergency Operations Centers (EOC) [CDC Emergency Operations Centers] (89724-9)*

Interoperability Need: Representing Hospital/Facility Beds Utilization

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The CDC, Center of Emergency Preparedness and Response, Situational Awareness branch, collaborating with the National Information Exchange Model (NIEM), developed -a population-level public health emergency preparedness and response information exchange requirements, which includes a minimum data set, and standardized vocabulary. Data comes directly from hospital and long-term care facility databases, not directly linked to the EHR. • *The Hospital/facility beds utilization section of the minimum data set* provides vocabulary for reporting a beds utilization during an emergency event.	• *Hospital/facility beds utilization report (LOINC® 95893-4 prerelease)* • *Minimum Data Set (MDS) for Public Health Emergency Operations Centers (EOC) [CDC Emergency Operations Centers] (89724-9)*

Interoperability Need: Representing Laboratory Operations (Population Laboratory Surveillance)

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The CDC, Center of Emergency Preparedness and Response, Situational Awareness branch, collaborating with the National Information Exchange Model (NIEM), developed -a population-level public health emergency preparedness and response information exchange requirements, which includes a minimum data set, and standardized vocabulary. Data comes directly from hospital and long-term care facility databases, not directly linked to the EHR. • *The Laboratory operations section of the minimum data set* provides vocabulary for population level laboratory tests reporting (i.e., number of tests completed, positive results etc.) during an emergency event.	• *Laboratory operations report (LOINC® 89756-1)* • *Minimum Data Set (MDS) for Public Health Emergency Operations Centers (EOC) [CDC Emergency Operations Centers] (89724-9)*

Interoperability Need: Representing Mass Vaccination Status

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The CDC, Center of Emergency Preparedness and Response, Situational Awareness branch, collaborating with the National Information Exchange Model (NIEM), developed -a population-level public health emergency preparedness and response information exchange requirements, which includes a minimum data set, and standardized vocabulary. Data comes directly from hospital and long-term care facility databases, not directly linked to the EHR. • The Reporting Mass Vaccination Status panel defines the vocabulary for a population level reporting of a mass vaccination. • ICD-10 included as a value as pharmacies report mass vaccinations using ICD-10.	• Mass vaccination status (LOINC® 96987-3) • Minimum Data Set (MDS) for Public Health Emergency Operations Centers (EOC) [CDC Emergency Operations Centers] (89724-9)

Interoperability Need: Representing Population-Level Morbidity and Mortality

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The CDC, Center of Emergency Preparedness and Response, Situational Awareness branch, collaborating with the National Information Exchange Model (NIEM), developed a population-level public health emergency preparedness and response information exchange requirements, which includes a minimum data set, and standardized vocabulary. Data comes directly from hospital and long-term care facility databases, often not directly linked to the EHR. • *The Reporting event status section of the minimum data set* provides vocabulary for population-level reporting morbidity and mortality by healthcare entity (i.e., hospital, long-term care facility, regional healthcare coalition) or territorial level (county, state, national) during an emergency event.	• *Reporting event status (LOINC® 89754-6)* • *Minimum Data Set (MDS) for Public Health Emergency Operations Centers (EOC) [CDC Emergency Operations Centers] (89724-9)*

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	●●●●○	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 some statistical or epidemiologic or public health reporting purposes but may not be adequate for other uses such as 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. LOINC® is used to capture race and/or ethnicity in multiple coded panels; some of these align with the OMB race and ethnicity codes (e.g., 46463-6, 32624-9).	• Race (5 codes): PHINVADS Race Category Excluding Nulls • Race (extended set, 921 codes): PHINVADS Race Value Set • Ethnicity (2 codes) PHINVADS Ethnicity Group Value Set • Ethnicity (extended set, 43 codes): PHINVADS Detailed Ethnicity Value Set

RESEARCH

Interoperability Need: Representing Data for Biomedical and Health Services Research Purposes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Clinical Data Interchange Standards Consortium (CDISC) Controlled Terminology Standards for Data Collection through Clinical Data Acquisition Standards Harmonization (CDASH), Hosted by NCI-EVS	Final	Production	●●●○○	Yes	Free	N/A
Standard	Clinical Data Interchange Standards Consortium (CDISC) Controlled Terminology Standards for Data Aggregation through Study Data Tabulation Model (SDTM) (including QRS, Medical Device and Pharmacogenomics Data), Hosted by NCI-EVS	Final	Production	●●●●●	Yes	Free	N/A
Standard	Clinical Data Interchange Standards Consortium (CDISC) Controlled Terminology for Therapeutic Area Standards	Final	Production	●○○○○	Yes	Free	N/A
Standard	Clinical Data Interchange Standards Consortium (CDISC) Controlled Terminology for Data Collection for Protocol Hosted by NCI-EVS	Final	Production	Feedback Requested	No	Free	N/A
Standard	Clinical Data Interchange Standards Consortium (CDISC) Controlled Terminology for Analysis Dataset Model (ADaM) Hosted by NCI-EVS	Final	Production	●●●○○	Yes	Free	N/A
Standard	Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM)	Final	Production	●●●●○	No	Free	Yes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Sentinel Common Data Model	Final	Production	●●○○○	No	Free	N/A
Standard	National Cancer Institute (NCI) Enterprise Vocabulary Service (EVS)	Final	Production	●●●○○	No	Free	N/A
Standard	National Cancer Institute (NCI) cancer Data Standards Repository (caDSR)	Final	Production	●●●○○	No	Free	N/A
Standard	National Cancer Institute (NCI) Metathesaurus	Final	Production	●●●○○	No	Free	N/A
Standard	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - MedDRA	Final	Production	●●●●●	No	$	N/A
Implementation Specification	HL7® FHIR® Common Data Models Harmonization (CDMH) IG	Final	Production	●○○○○	No	Free	N/A
Emerging Implementation Specification	*HL7® FHIR® MedicationRequest Resource*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The adoption and federally required levels for using CDISC SDTM for QRS, Medical Devices and Pharmacogenomics purposes vary. • MedDRA was created to manage clinical information about pharmaceuticals, biologics, vaccines and drug-device combinations for the entire lifespan of products. It is a specific, hierarchical, medically oriented terminology designed to meet the needs of drug regulators and the pharmaceutical industry as a shared international standard. See Understanding MedDRA: The Medical Dictionary for Regulatory Activities.	• Feedback requested

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)
• An article in JAMIA provides helpful information for planning and implementing sexual orientation and gender identity data collection in electronic health records. • 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. • 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. • The Gender Harmony Project is updating the representation of several sex-related concepts, including gender identity. Their proposed value set (extensible for other use cases) for gender identity does not include the concepts of Female-to-Male (FTM)/Transgender Male/Trans Man, Male-to-Female (MTF)/Transgender Female/Trans Woman, or Additional gender category or other, please specify. HL7® Version 3 code: OTH that are included in the ONC value set which was established in regulation and incorporated by reference.	• 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® • Male-to-Female (MTF)/Transgender Female/Trans Woman. SNOMED CT® • Identifies as non-conforming gender (SNOMED CT® (US) synonyms include: Genderqueer; Identifies as neither exclusively male nor female, Non-binary gender) SNOMED CT® • 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) and Starter Set(s)
• Patient Sex (at birth), or Assigned Sex, is the sex (male or female) given to a child at birth, most often based on the child's external anatomy. • 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 III 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) • Other HL7® V3 NullFlavor codes, while not specifically required, may also be useful (1) OTH ("Other") (2) ASKU ("Asked, but Unknown") (3) NASK ("Not asked")

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	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)
• An article in JAMIA provides helpful information for planning and implementing sexual orientation and gender identity data collection in electronic health records. • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III 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 • SNOMED CT® code: Sexually attracted to neither male nor female sex 765288000 (Not required in ONC's 2015 Edition certification requirements)

SOCIAL, PSYCHOLOGICAL, AND BEHAVIORAL DATA

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
Standard	CPT-4	Final	Production	Feedback Requested	No	$	N/A
Standard	HCPCS	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.
• Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an approach to the delivery of early intervention and treatment to people with alcohol and other substance use disorders and those at risk of developing these disorders.
• For more information about observations and observation values, see Appendix III 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) (Included for reference)
	• AUDIT panel total score (LOINC® code 75624-7) (Included for reference)
	• SBIRT Service Codes (CPT 99408, 99409; HCPCS G0396, G0397, H0049, H0050)

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 meets criteria for a depressive disorder, and is best suited for this interoperability need. The LOINC® codes specified in the panel LOINC® 55757-9 are the codes required to meet the ONC certification criteria for depression screening as part of the §170.315(a)(15) Social, psychological, and behavioral data. • The full Patient Health Questionnaire 9 item (PHQ-9) incorporates DSM-IV depression criteria with other leading major depressive symptoms into a brief self-report instrument commonly used for screening and diagnosis, as well as selecting and monitoring treatment. • There are other PHQ-9 administration modalities used in other clinical settings, such as post-acute care settings, that are represented by other LOINC® panels such as LOINC® 44249-1 (PHQ-9 quick depression assessment panel) and LOINC® 54635-8 Resident mood interview (PHQ-9). Additional information regarding these panels can be found at PACIO Project (http://pacioproject.org/). • The Beck Depression Inventory Fast Screen (BDI FS) is a shorter version of the Beck Depression Inventory II (BDI II) [LOINC®:89210-9]. The BDI FS contains 7 items from the BDI II and, like the BDI II, evaluates depression symptoms in alignment with the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for depression. [PMID:19010075] • See LOINC® projects in the Interoperability Proving Ground.	• PHQ-2 panel LOINC® code 55757-9 ▪ PHQ-2 member codes o PHQ-2 Q1 LOINC® 44250-9 o PHQ-2 Q2 LOINC® 44255-8 o PHQ-2 Total Score LOINC® 55758-7 • PHQ-9 panel LOINC® code 44249-1 (Listed for reference.) • PHQ-9 panel LOINC® code 69729-2 • Beck Depression Inventory Fast Screen [BDI] LOINC® code 89211-7

Interoperability Need: Representing Drug Use

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	LOINC®	Final	Feedback Requested	Feedback Requested	No	$	No
Standard	SNOMED CT®	Final	Production	Feedback Requested	No	Free	No
Standard	CPT-4	Final	Production	Feedback Requested	No	$	N/A
Standard	HCPCS	Final	Production	Feedback Requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The Drug Abuse Screen Test (DAST-10) was designed to provide a brief, self-report instrument for population screening, clinical case finding and treatment evaluation research. It can be used with adults and older youth. • (c)1982 Harvey Skinner, PhD, Centre for Addiction and Mental Health, Toronto, Canada. • SNOMED CT® is used to represent conditions, findings and observations related to Social Determinants of Health. • Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an approach to the delivery of early intervention and treatment to people with alcohol and other substance use disorders and those at risk of developing these disorders.	• Drug Abuse Screening Test-10 [DAST-10] (LOINC® code 82666-9) • DAST-10 Total Score LOINC® code 82667-7 • SBIRT Service Codes (CPT 99408, 99409; HCPCS G0396, G0397, H0049, H0050)

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

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 Food Insecurity

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	Feedback Requested	No	Free	No
Standard	SNOMED CT®	Final	Production	Feedback Requested	No	Free	No
Standard	ICD-10-CM	Final	Production	Feedback Requested	No	Free	No
Standard	CPT-4	Final	Production	Feedback Requested	No	$	N/A
Standard	HCPCS	Final	Production	Feedback Requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The Hunger Vital Sign [HVS] is a 2-question food insecurity screening tool based on the US Household Food Security Scale developed by Children's Health Watch. Centers for Medicare & Medicaid Services uses the HVS in the Accountable Health Communities screening tool. • SNOMED CT® is used to represent conditions, observations, and non-medical interventions related to Social Determinants of Health. • ICD-10 Z55-Z65 is used to capture diagnoses related to certain Social Determinants of Health. • CPT-4 and HCPCS is used to capture medical and non-medical procedures and interventions related to Social Determinants of Health.	• LOINC® 88121-9 Hunger Vital Sign [HVS] ▪ LOINC® 88122-7 Within the past 12 months we worried whether our food would run out before we got money to buy more [U.S. FSS] ▪ LOINC® 88123-5 Within the past 12 months the food we bought just didn't last and we didn't have money to get more [U.S. FSS] ▪ LOINC® 88124-3 Food insecurity risk [HVS] • LOINC® 93025-5 Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel

Interoperability Need: Representing Housing Insecurity

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	Feedback Requested	No	Free	No
Standard	SNOMED CT®	Final	Production	Feedback Requested	No	Free	No
Standard	ICD-10-CM	Final	Production	Feedback Requested	No	Free	No
Standard	CPT-4	Final	Production	Feedback Requested	No	$	N/A
Standard	HCPCS	Final	Production	Feedback Requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Housing situation screening question is part of the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] screening instrument licensed by the National Association of Community Health Centers (NACHC). • LOINC® is used to represent screening assessments related to Social Determinants of Health. • SNOMED CT® is used to represent conditions, findings and observations related to Social Determinants of Health. • ICD-10 Z55-Z65 codes are used to capture diagnoses related to certain Social Determinants of Health. • CPT-4 and HCPCS are used to capture medical and non-medical procedures and interventions related to Social Determinants of Health.	• What is your current housing situation? (LOINC® code 71802-3) ▪ Answer list (LOINC® code LL5350-5) o I have housing o I do not have housing (staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, or in a park) o I choose not to answer that question • Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel (LOINC® code 93025-5)

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 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 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. • Identification of loneliness and isolation is assessed in PAC assessments and included in the CMS Data Element Library and mapped to health IT standards.	• Social connection and isolation panel LOINC® code 76506-5 ▪ Member codes: o LOINC® code 63503-7 (with LOINC® answer list ID LL1068-7) o LOINC® code 76508-1 o LOINC® code 76509-9 o LOINC® code 76510-7 o LOINC® code 76511-5 (with LOINC® answer list ID LL963-0) o Social isolation score LOINC® code 76512-3 o LOINC® code 93159-2

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 Transportation Insecurity

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	No	Free	No
Standard	SNOMED CT®	Final	Production	Feedback Requested	No	Free	No
Standard	ICD-10-CM	Final	Production	Feedback Requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Transportation insecurity screening question is part of the screening Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] screening instrument licensed by the National Association of Community Health Centers (NACHC). • SNOMED CT® is used to represent conditions, findings and observations related to Social Determinants of Health. • ICD-10 Z55-Z65 codes are used to capture diagnoses related to certain Social Determinants of Health. • Transportation insecurity screening is collected in CMS Post-acute Care assessments, included in the CMS Data Element Library and mapped to LOINC® 93030-5.	• Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living? [PRAPARE] (LOINC® code 93030-5) • Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences [PRAPARE] Panel (LOINC® code 93025-5)

TOBACCO USE

Interoperability Need: Representing Patient Electronic Cigarette Use (Vaping)

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 2017071	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	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 2015 Edition smoking status criterion (§ 170.315(a)(11)) only applies to status of use for smoked tobacco. It does not require a terminology standard, nor does it require the ability to capture other forms of tobacco or nicotine use (e.g., smokeless tobacco, e-cigarettes, secondhand smoke) • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	• Electronic Cigarette User: SNOMED CT® 722499006 • SNOMED code for “electronic cigarette user” 785889008 |Nicotine-filled electronic cigarette user (finding)| 786063001 |Non-nicotine-filled electronic cigarette user (finding)|

Interoperability Need: Representing Patient Secondhand Tobacco Smoke Exposure

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)
• The 2015 Edition smoking status criterion (§ 170.315(a)(11)) only applies to status of use for smoked tobacco. It does not require a terminology standard, nor does it require the ability to capture other forms of tobacco or nicotine use (e.g., smokeless tobacco, e-cigarettes, secondhand smoke). • See LOINC® projects in the Interoperability Proving Ground. • For more information about observations and observation values, see Appendix III for an informational resource developed by the Health IT Standards Committee.	• Exposure to Secondhand Tobacco Smoke: SNOMED CT® 16090371000119103 • Exposed to tobacco smoke at home (current): SNOMED CT® 228524006 • Exposed to tobacco smoke at work (current): SNOMED CT® 228523000 • No known exposure to Secondhand Tobacco Smoke: SNOMED CT® 711563001

Interoperability Need: Representing Patient Tobacco Use (Smoking Status)

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
Standard for observations	LOINC®	Final	Production	● ● ● ● ●	No	Free	N/A
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	● ● ● ● ●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• The 2015 Edition smoking status criterion (§ 170.315(a)(11)) only applies to status of use for smoked tobacco. It does not require a terminology standard. • 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 III 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 • The following smoking status value set of SNOMED CT® codes, using the preferred concept term, is only required in the context of using the Common Clinical Data Set (CCDS): 1. Current every day smoker. 449868002 2. Current some day smoker. 428041000124106 3. Former smoker. 8517006 4. Never smoker. 266919005 5. Smoker, current status unknown. 77176002 6. Unknown if ever smoked. 266927001 7. Heavy tobacco smoker. 428071000124103 8. Light tobacco smoker. 428061000124105 • Additional tobacco-related codes: 1. Date quit tobacco smoking: LOINC® 74010-0 2. Date quit smokeless tobacco: LOINC® 88030-2 3. User of smokeless tobacco (finding): SNOMED CT® 713914004 4. Smokeless tobacco non-user (finding): SNOMED CT® 451381000124107 5. Former smokeless tobacco user (finding): SNOMED-CT® 456711000124105 6. Chews tobacco (finding): SNOMED-CT® 81703003 7. Snuff user (finding): SNOMED-CT® 228494002 8. User of moist powdered tobacco (finding): SNOMED-CT® 228504007 9. No known exposure to tobacco smoke (finding): SNOMED-CT® 711563001

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 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

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	Production	●●●○○	No	$	Yes Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• See Section I - Units of Measure for discussion of units of measure used with quantitative observations. • See LOINC® collaboration with IEEE for information on the Medical Device Code Mapping Table, which provides linkages between LOINC® terms and IEEE EMB/11073 standard. • ISO/IEEE 11073 is a family of standards for point-of-care medical device communication, with specific standards within the 11073 family that support collection of vital signs from medical devices, including: ▪ IEEE P11073-10404: Device Specialization - Pulse Oximeter ▪ IEEE 11073-10406: Device Specialization - Basic electrocardigraph (ECG) ▪ IEEE P11073-10407: Device Specialization - Blood Pressure Monitor ▪ IEEE 11073-10408: Device Specialization - Thermometer ▪ IEEE P11073-10415: Device Specialization - Weighing Scale ▪ IEEE 11073-10417: Device Specialization - Glucose Meter ▪ IEEE 11073-10201: Implantable Cardiac Devices • See LOINC® projects, and Continua CODE for Healthcare in the Interoperability Proving Ground.	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62 • LOINC® standard applies to USCDI required vital signs ▪ Diastolic blood pressure ▪ Systolic blood pressure ▪ Body height ▪ Body weight ▪ Heart Rate ▪ Respiratory rate ▪ Body temperature ▪ Pulse oximetry ▪ Inhaled oxygen concentration ▪ BMI Percentile (2 - 20 years) ▪ Weight-for-length Percentile (Birth - 36 Months) ▪ Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

WORK INFORMATION

Interoperability Need: Representing Job, Usual Work, and Other Work Information

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	Occupational Data for Health (ODH) Code System	Balloted Draft	Pilot	Feedback Requested	No	Free	No
Standard for observation values	CDC Census 2010 Industry and Occupation System	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7® EHRS-FM Release 2: Functional Profile; Work and Health, Release 1 – US Realm	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Self-reported, structured and standardized work history has broad applicability to healthcare as part of the medical record and is suitable for many use cases supporting patient care, population health, and public health. • An Information Model, Occupational Data for Health (ODH), supports the collection and classification of Work Information in health IT systems and has been published in JAMIA. • The ODH industry value set includes the search-friendly terms from the North American Industry Classification System (NAICS) index with the respective category. The terms in this value set are relatable to the general public. • The ODH occupation value set includes the search-friendly terms from the Occupational Information Network-Standard Occupational Classification (O*NET-SOC) system alternate titles with the respective category. The terms in this value set are relatable to the general public. • NIOSH has prepared A Guide to the Collection of Occupational Data for Health to provide tips to health IT system developers seeking to implement work concepts.	Representing Industry • Past or Present Industry Question (LOINC® code 86188-0) • Usual Industry Question (LOINC® code 21844-6) • PHVS_Industry_NAICS_Detail_ODH (urn:oid: 2.16.840.1.114222.4.11.7900) • PHVS_Industry_CDC_Census2010 codes (urn:oid:2.16.840.1.114222.4.11.7187) Representing Occupation • Past or Present Occupation Question (LOINC® 11341-5) • Usual Occupation Question (LOINC® 21843-8) • PHVS_Occupation_CDC_ONETSOC_Detail_ODH (urn: oid: 2.16.840.1.114222.4.11.7901) • PHVS_Occupation_CDC_Census2010 codes (urn:oid:2.16.840.1.114222.4.11.7186) Representing Employment Status • Employment Status Question (LOINC® 74165-2) • PHVS_EmploymentStatus_ODH (urn:oid: 2.16.840.1.114222.4.11.7129) Representing Work Schedule • Work Schedule Question (LOINC® 74159-5) • PHVS_WorkSchedule_ODH (urn:oid: 2.16.840.1.114222.4.11.7130) Representing Work Classification • Work Classification Question (LOINC® 85104-8) • PHVS_WorkClassification_ODH (urn:oid: 2.16.840.1.114222.4.11.7597) Representing Job Supervisory Level or Pay Grade • Job Supervisory Level or Pay Grade Question (LOINC®: 87707-6)

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
	• PHVS_JobSupervisoryLevelorPayGrade_ODH (unr:oid: 2.16.840.1.114222.4.11.7613)

Content/Structure

ADMISSION, DISCHARGE, AND TRANSFER

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 Specialized Standard, Implementation Guide, Version 2017071	Final	Production	●●●○○	No	$	No
Standard	NCPDP Specialized Standard, Implementation Guide, Version 10.6	Final	Production	●●●●●	No	$	No
Standard	HL7® 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	No

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

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
Implementation Specification	HL7® FHIR® DaVinci Unsolicited Notifications Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	Event Notifications via the Direct Standard™	Balloted Draft	Pilot	Feedback Requested	No	Free	No
Emerging Implementation Specification	*Carequality Subscription Implementation Guide for Push Notifications*	*In Development*	*Pilot*	*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 Exchange/Services - "Push" Exchange), has been noted as a prominent option for transport, particularly where HIE networks are not in place or not being used for this purpose. • DirectTrust Standards Implementation Guide "Event Notifications via the Direct Standard(TM)" provides a profile for the payload included in event notifications when Direct is the transport. The guide standardizes HL7® 2.5.1 usage and maps metadata	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
elements to support appropriate routing and workflow for receiving systems. Human readable text is also stipulated as a part of the specification to support uncomplicated edge systems. The Implementation Guide is expected to go to final ballot in 2021. • See HL7® V2 projects in the Interoperability Proving Ground.	• **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 Patient's Encounter to a Record Locator Service

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	IHE-PDQ (Patient Demographics Query)	Final	Production	Feedback Requested	No	Free	Yes Yes Yes
Implementation Specification	IHE-XCPD (Cross-Community Patient Discovery)	Final	Production	Feedback Requested	No	Free	Yes Yes
Implementation Specification	Carequality-QBDE (Query Based Document Exchange)	In Development	Feedback Requested	Feedback Requested	No	Free	No

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

CARE COORDINATION FOR REFERRALS

Interoperability Need: Referral from Acute Care to a Skilled Nursing Facility

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	Production	Feedback Requested	No	Free	Yes
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Emerging Implementation Specification	*360X and Long Term Care Transfers*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*

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

Interoperability Need: Referral to a Specialist - Request, Status Updates, Outcome

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	Production	●●●●●	Yes	Free	Yes
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Emerging Implementation Specification	*IHE Patient Care Coordination Technical Framework Supplement: 360 Exchange - Closed Loop Referral (360X) Rev. 1.1 – Trial Implementation*	*Balloted Draft*	*Production*	●○○○○	*No*	*Free*	*No*

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

Interoperability Need: Referral to Extra-Clinical Services - Request, Updates, Outcome

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® FHIR® R4: Observation Resource	Final	Production	●●●○○	No	Free	No
Emerging Standard	*HL7® FHIR® R4: Messaging*	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	No
Emerging Standard	*HL7® FHIR® R4: ServiceRequest Resource*	*Balloted Draft*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Standard	*HL7® FHIR® R4: Task Resource*	*Balloted Draft*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7® Bidirectional Services eReferrals (BSeR) FHIR® IG*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*360X and Social Determinants of Health (SDoH) Referrals*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The 360X Project, building on and in close coordination with the Gravity Project, is leveraging existing IHE 360X profiles to develop a profile designed to support closed-loop referrals to extra-clinical organizations in support of social determinants of health use cases. • 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.	• Feedback requested

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	Production	●●●○○	Yes	Free	Yes
Implementation Specification	HL7® FHIR® US Core R.3.0 - Care Plan Profile	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	Argonaut Data Query Implementation Guide v1.0.0 (based on FHIR® R2)	Final	Production	●●○○○	Yes	Free	
Implementation Specification	HL7® C-CDA on FHIR® Care Plan	Final	Production	●○○○○	No	Free	No
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 - Care Plan Profile*	*In Development*	*Feedback Requested*	*Feedback Requested*	*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.	• Feedback requested

• 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.	

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	$	No
Implementation Specification	HL7® CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm, Volume 1	Final	Production	●●○○○	No	Free	Yes
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	Production	●●●○○	Yes	Free	Yes
Implementation Specification	HL7® C-CDA on FHIR® Care Plan	Final	Production	●●●○○	No	Free	No
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Implementation Specification	HL7® FHIR® US Core R.3.0 - Care Plan Profile	Final	Production	●●●○○	No	Free	No
Emerging Implementation Specification	*HL7® FHIR® Pharmacist Care Plan Implementation Guide, US Realm*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 - Care Plan Profile*	*In Development*	*Production*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The Pharmacist eCarePlan 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: Documenting Care Plans for Person Centered Services

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® FHIR® Electronic Long-Term Services and Supports (eLTSS) Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The electronic Long-Term Services and Supports (eLTSS) Implementation Guide (IG) is based on FHIR® R4. The standards were developed to enable the creation, exchange and re-use of interoperable person centered service plans for use by health care, home and community based service providers, payers and the individuals they serve. These plans can help to improve the coordination of health and social services that support an individual's mental and physical health. • The eLTSS data referenced in this implementation guide refers to the eLTSS Dataset that was developed by the eLTSS Initiative, a joint project between the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS). See eLTSS Initiative website for more information.	• 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	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
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	Production	●●●○○	Yes	Free	Yes
Implementation Specification	HL7® C-CDA on FHIR® Care Plan	Final	Production	●○○○○	No	Free	
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Implementation Specification	HL7® FHIR® US Core R.3.0 - Care Plan Profile	Final	Production	●●●○○	No	Free	No
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 - Care Plan Profile*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*MCC eCare Plan Draft Implementation Guide*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The HL7® CDA R2 IG is based on C-CDA R2.1 and aligns 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
Implementation Specification	IHE Dynamic Care Planning (DCP), Rev 1.2 Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE Dynamic Care Team Management (DCTM), Rev 1.1 Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	
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	Production	●●●○○	Yes	Free	Yes
Implementation Specification	HL7® C-CDA on FHIR® Care Plan	Final	Production	●●●○○	No	Free	
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	No	Free	No
Implementation Specification	HL7® FHIR® US Core R.3.0 - Care Plan Profile	Final	Production	●●●○○	No	Free	No
Emerging Implementation Specification	*HL7® FHIR® US Core R.4.0 - Care Plan Profile*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*MCC eCare Plan Draft Implementation Guide*	*In Development*	*Feedback Requested*	*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

CLINICAL DECISION SUPPORT

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
Implementation Specification	IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• See IHE projects in the Interoperability Proving Ground. • No CDS-OAT-specific test tools.	• 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
Standard	HL7® CDS Hooks Services	Final	Production	●●●●○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The CDS Hooks specification describes the RESTful APIs and interactions between EHRs and CDS Services. • Guideline Appropriate Ordering using CDS Hooks, is a stakeholder-led initiative and part of the Argonaut project, supports Protecting Access to Medicare Act (PAMA) requirements. • Note that the maturity level of FHIR® resources may vary and is described with the specification itself. • See FHIR® projects in the Interoperability Proving Ground.	• Feedback requested

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® Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)	Final	Production	●●●●○	No	Free	Yes
Standard	HL7® FHIR® Profile: Quality (QI Core), STU 4	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Standard	HL7® FHIR® Clinical Reasoning Module, FHIR® STU Release 4	Balloted Draft	Pilot	●●●○○	No	Free	Yes
Implementation Specification	FHIR® Clinical Guidelines, STU 1	Balloted Draft	Pilot	●●○○○	No	Free	Yes

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

CLINICAL NOTES

Interoperability Need: Documentation of Clinical Notes

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	Final	Production	Feedback Requested	Yes	Free	Yes
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	Feedback Requested	Yes	Free	Yes
Implementation Specification	HL7® FHIR® US Core Implementation Guide	Balloted Draft	Feedback Requested	Feedback Requested	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• A Consultation note is generated as part of a request from a clinician for an opinion or advice from another clinician. • A Discharge Summary note is a synopsis of a patient's admission and course in a hospital or post-acute care setting. • A History & Physical note documents the current and past conditions of the patient. • An Imaging Narrative contains a consulting specialist's interpretation of image data. • A Laboratory Report Narrative contains a consulting specialist's interpretation of the laboratory report. • A Pathology Report Narrative contains a consulting specialist's interpretation of the pathology report. • A Procedure Note records the indications for a non-operative procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient's tolerance of the procedure. • A Progress Note represents a patient's interval status during a hospitalization, outpatient visit, treatment with a LTPAC provider, or other healthcare encounter.	• Feedback requested

CLINICAL QUALITY MEASUREMENT AND REPORTING

Interoperability Need: Reporting Aggregate Quality Data for 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
Standard	HL7® FHIR® R4 Clinical Reasoning Module	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA III) STU Release 2.1	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Implementation Specification	HL7® FHIR® Implementation Guide: Data Exchange for Quality Measures STU2 for FHIR® R4	Balloted Draft	Pilot	●●○○○	No	Free	Yes

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

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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture I (QRDA I) Release 1, STU Release 5.1 with Errata (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Quality Reporting Document Architecture I (QRDA I) Release 1, STU Release 5.2 with Errata (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Implementation Specification	HL7® FHIR® DaVinci Data Exchange For Quality Measures (DEQM) Implementation Guide	Balloted Draft	Pilot	●●○○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Testing tools for FHIR® and QRDA-based quality reporting are available: • https://ecqi.healthit.gov/FHIR®?qttabs_FHIR®=1 • https://ecqi.healthit.gov/qrda?qttabs_qrda=1 • The Data Exchange for Quality Measures Implementation Guide is being expanded to support communication for gaps-in-care. • 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	Final	Production	●●●●○	No	Free	Yes
Standard	HL7® CQL-based HQMF Implementation Guide STU 4 based on HQMF R1	In Development	Production	●●●●○	No	Free	Yes
Standard	HL7® Cross-Paradigm Specification: CQL Release 1 STU 4	Balloted Draft	Production	●●●●○	No	Free	Yes
Standard	HL7® Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)	Final	Production	●●●●○	No	Free	Yes
Standard	HL7® FHIR® Clinical Reasoning STU Release 3	Balloted Draft	Production	●●○○○	No	Free	Yes
Standard	HL7® FHIR® Clinical Reasoning STU Release 4	In Development	Pilot	Feedback Requested	No	Free	
Implementation Specification	HL7® CQL-based HQMF, Release 2 DSTU 3 (based on HQMF 2.1 - US Realm	Balloted Draft	Production	●●●●○	No	Free	Yes
Implementation Specification	HL7® FHIR® profile: Quality (QI Core) STU 4.0	Balloted Draft	Production	●●○○○	No	Free	Yes
Implementation Specification	HL7® FHIR® Quality Measure IG STU 2 for FHIR® R4	Balloted Draft	Production	●●○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• QI Core Profiles are used to express the data involved in a shareable measure and depend on US Core profiles. • 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

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**
Standard	HL7® FHIR® Provenance Resource	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® US Core IG Provenance Profile	Final	Production	Feedback Requested	Yes	Free	Yes
Implementation Specification	HL7® C-CDA Companion Guide: Provenance Author Participation Template	Final	Production	Feedback Requested	Yes	Free	
Implementation Specification	IHE IT Infrastructure Technical Framework	Final	Production	●●●○○	No		Yes – Open
Implementation Specification	HL7® CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes – Open
Emerging Implementation Specification	*Basic Provenance Implementation Guide*	*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.	• Feedback requested • Information about security patterns can be found in Appendix I.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The Basic Provenance IG "provides the functional and technical guidance for communicating 'Minimum Viable Provenance' in CDA and FHIR® when information is moved from the source to downstream systems." It includes a design for representing the 'last hop' only and doesn't address the potential need to share, and display full provenance (full chain of custody). • The Object Management Group (OMG) Data Governance Working Group is developing an RFP on Data Provenance & Pedigree. ONC will consider inclusion of the standard in a future version of the ISA when it is available. More information can be found at: https://www.omgwiki.org/datagovernance/doku.php. • See CDA & FHIR® projects in the Interoperability Proving Ground. • The IHE IT Infrastructure (ITI) Technical Framework defines a number of profiles for health information exchange. The document sharing profiles (e.g. XDS, XCA, XDR, XDM, MHD) define metadata elements for documents, including the full provenance of the document. The Document Digital Signature (DSG) Profile defines general purpose methods of digitally signing documents for communication and persistence. For additional information, please see the Enabling Document Sharing Health Information Exchange Using IHE Profiles whitepaper.	

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
Standard	HL7® Version 3 Standard: Diet and Nutrition, STU Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: C-CDA R2.1 Supplemental Templates for Nutrition, Release 1 (US Realm)	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*HL7® FHIR® Nutrition Order Resource*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Standard	*HL7® FHIR® Nutrition Intake Resource*	*Balloted Draft*		*Feedback Requested*	*No*	*Free*	
Emerging Standard	*HL7® FHIR® Nutrition Product Resource*	*Balloted Draft*		*Feedback Requested*	*No*	*Free*	

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

DRUG FORMULARY & BENEFITS

Interoperability Need: Allows Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescriber Systems

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	NCPDP Formulary and Benefit Standard Version 3.0	Final	Production	●●●●●	Yes	$	No
Implementation Specification	NCPDP Real Time Prescription Benefit Standard Version 12	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP Formulary and Benefit Standard, Implementation Guide, Version 53	Final	Feedback Requested	Feedback Requested	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
	• **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.

ELECTRONIC PRESCRIBING

Interoperability Need: Allows a Long Term or Post-Acute Care to Request to Send an Additional Supply of Medication

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 2017071	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up for e-mail updates to receive the latest announcements. • The NCPDP SCRIPT Standard version 2017071 Implementation Guide supports the Resupply transaction; a request from a Long Term or Post-Acute Care (LTPAC) organization to a pharmacy to send an additional supply of medication for an existing order. An example use case is when a medication supply for a resident is running low (2-3 doses) and a new supply is needed from the pharmacy, the LTPAC organization needs a way to notify the pharmacy that an additional supply for the medication is needed. • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP 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.

Interoperability Need: Allows a Pharmacy to Notify a 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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 10.6 & SCRIPT 2017071 - o RxFill: sent from a pharmacy to a prescriber or long term or post-acute care (LTPAC) facility indicating the FillStatus (dispensed, partially dispensed, not dispensed or returned to stock, transferred to another pharmacy) of the new, refill or resupply prescriptions for a patent ▪ SCRIPT 2017071 - o RxFillIndicator: Informs the pharmacy of the prescriber's intent for fill status notifications for a specific patient/medication o RxFillIndicatorChange: Sent by the prescriber to the pharmacy to indicate that the prescriber is changing the types of RxFill transactions that were previously requested, where the prescriber may modify the fill status of transactions previously selected or cancel future RxFill transactions o When transferring a prescription, the RxFillRequestIndicator should be passed to the new pharmacy as part of the prescription information. If it supports the RxFill transaction, the pharmacy to which the prescription was transferred is responsible to send the appropriate Physician RxFill Request Flag with each subsequent dispensing event.	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The prescriber must electronically send the prescription via the NCPDP SCRIPT standard in order for the prescriber's system to receive RxFill transactions and ensures the correct matching between the original prescription and the subsequent RxFill transactions. Adoption of RxFill may be improved by allowing prescribers to specify which prescriptions are to receive RxFill transactions and which RxFill message types to receive. Additionally, prescribers may choose to receive RxFill transactions for patients receiving certain medications. EMRs may also provide additional capabilities to support RxFill message handling and prescriber preferred notifications that may provide process improvements such as limiting the number of transactions received, the cost of transactions, privacy concerns and information overload. • Both the pharmacy and the prescriber must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Pharmacy to Request a Change to 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	$	Yes
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 10.6 - o RxChg, originated from the pharmacy to request a change in the original prescription. o Chgres, originated from the prescriber in response to the RxChg message. ▪ SCRIPT 2017071 - o RxChangeRequest, originated from the pharmacy to request: « a change in the original prescription (new or fillable) « validation of prescriber credentials « a prescriber to review the drug requested « obtaining a prior authorization from the payer for the prescription o FollowUpRequest, originated from the pharmacy to: « notify prescribers that this is a follow-up RxRenewalRequest or RxChangeRequest transaction, when the prescriber has not responded to the first RxRenewalRequest or first RxChangeRequest transaction in a reasonable amount of time.	• **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. • **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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
« Not sent on the original request of the RxRenewalRequest or RxChangeRequest transaction o RxChangeResponse, originated from the prescriber to respond: « to a prescription change request from a pharmacy « to a request for a prior authorization from a pharmacy « to a prescriber credential validation request from a pharmacy o Options allowed when generating an RxChangeResponse in response to an RxChangeRequest from a pharmacy: « Approved: Grant the RxChangeRequest when the prescriber concurs with the request. The prescriber must submit an RxChangeResponse equal to what the pharmacy requested. « ApprovedWithChanges: When the information submitted in the RxChangeRequest does not include all elements constituting a fillable prescription; the prescriber should include all information. « Denied: Denies the RxChangeRequest with information that explains the denial. « Validated: Sent by the prescriber system in response to an RxChangeRequest for prescriber authorization. • When drug allergies and/or drug-drug interactions initiate a prescription change request, best practice is to alert the ordering provider and the pharmacy so that they may document these events in their respective systems for future error avoidance. • The receiving pharmacy should handle Approved, ApprovedWithChanges, and Validated responses as a fillable NewRx where the original linked prescription/order is discontinued. A Denied response should be directed to a review queue where the Denial reason code is displayed. • Both the pharmacy and the prescriber must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Pharmacy to Request a New Prescription for a New Course of Therapy or to Continue Therapy

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 2017071	Final	Production	●○○○○	Yes	$	Yes
Emerging Standard	*HL7® FHIR® Medication Request*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 2017071 - o NewRxRequest: This transaction is a request from a pharmacy to a prescriber for a new prescription for a patient « NewRxResponseDenied: This transaction is a denied response to a previously sent NewRxRequest (If approved, a NewRx would be sent) A NewRxResponseDenied response may occur when the NewRxRequest cannot be processed or if information is unavailable • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP 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.

Interoperability Need: Allows a Pharmacy to Request Additional Refills

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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 10.6 - o Refreq, originated from the pharmacy to the prescriber requesting additional refills. o Refres, originated from the prescriber to the pharmacy with a Rx authorization for refills; the response to a Refreq message. ▪ SCRIPT 2017071 - o RxRenewalRequest, originated from the pharmacy to request additional refills beyond those originally prescribed « (Within the RxRenewalRequest) FollowUpRequest, originated from the pharmacy to: □ notify prescribers that this is a follow-up RxRenewalRequest or RxChangeRequest transaction, when the prescriber has not responded to the first RxRenewalRequest or first RxChangeRequest transaction in a reasonable amount of time. □ not sent on the original request of the RxRenewalRequest or RxChangeRequest transaction o RxRenewalResponse, originated from the prescriber to respond to the request	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
« Options allowed when generating an RxRenewalResponse to an RxRenewalRequest from a pharmacy: ▯ Approved: Grant the RxRenewalRequest as requested by the pharmacy, or, when the pharmacy does not request a specific number of fills (PharmacyRequestedRefills is not present) and the prescriber approves any number of fills ▯ ApprovedWithChanges: Grant the RxRenewalRequest, approving a NumberOfRefills different than the number requested by the pharmacy or when the information submitted in the RxRenewalRequest does not include all elements constituting a fillable prescription; the prescriber should include all information ▯ Denied: Deny the RxRenewalRequest as requested by the pharmacy • In a Denied response, the only new meaning that should be conveyed to the pharmacy is information that explains the denial. It is recommended that the prescribing software update the NumberOfRefills to zero and leave all other data as is in the RxRenewalResponse ▯ Replace: Data is allowed to be changed except the patient DateOfBirth. If patient DateOfBirth changes, a Denied response would be sent, and then a NewRx would follow « The receiving pharmacy might handle each of these responses differently. Approved, ApprovedWithChanges, and Replace responses might be directed to a fulfillment queue, where a Denied response might be directed to a review queue « The Replace response should be used if there are any changes beyond what is outlined in the Response Element	

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
- RxRenewalRequest should never be responded to with a NewRx, as this would result in duplicate valid prescriptions - DeniedNewPrescriptionToFollow response is not to be sent in an RxRenewalResponse for this version of SCRIPT. However, the DeniedNewPrescriptionToFollow response could be received in an RxRenewalResponse from a previous version of SCRIPT and is included for backwards compatibility. DeniedNewPrescriptionToFollow response only exists for entities that need to map this version to a previous version of SCRIPT that does not support a Replace. - Both the pharmacy and the prescriber must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. - See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer

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	$	Yes
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●○○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ RxTransferRequest: Used when the pharmacy is asking for a transfer of one or more prescriptions for a specific patient to the requesting pharmacy o The transfer is for a fillable prescription which may be: « yet to be filled « on hold « open (active) fills « current therapy (defined as drug therapy that, based upon the most recent fill date, quantity and instructions, should still be active) « allowed to be transferred by law/regulation o If multiple specific prescriptions are to be transferred, but not all prescriptions, a separate RxTransferRequest must be sent for each specific prescription ▪ RxTransferResponse: The response from the transferring pharmacy to the requesting pharmacy to the RxTransferRequest which includes the prescription(s) being transferred or a rejection of the transfer request ▪ RxTransferConfirm: Used by the pharmacy receiving (originally requesting) the transfer to confirm that the transfer prescription has been received and the transfer is complete.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The RxFill Transaction <FillStatus><Transferred> is originated by the transferring pharmacy once the <RxTransferConfirm> is received from the transfer to pharmacy. This transaction is used to notify the prescriber when a prescription has been transferred to another pharmacy and can no longer be filled at the original pharmacy. The RxTransfer transaction will identify if the receiving pharmacy supports RxFill. • Both pharmacies must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Prescriber or a Pharmacy to Request 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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ RxHistoryRequest: a request from a prescriber or a pharmacy for a list of medications that have been prescribed, dispensed, claimed or indicated (OTCs) by a patient o This patient-specific transaction supplies enough information to uniquely identify the patient ▪ RxHistoryResponse: a response to an RxHistoryRequest containing a patient's medication history; includes the medications that were dispensed or obtained within a certain timeframe, optionally including the prescriber that prescribed it o The receiver must evaluate the Consent for accurate reporting o Returns with loops of Medication, HistorySource, Prescriber, Pharmacy, and Patient elements when appropriate o HistorySource and FillNumber elements are included, when appropriate, so prescribers are able to de-duplicate records from multiple sources that reflect the same medication dispensing, and to help determine patient compliance with a prescription « Helps the prescriber determine if follow-up contact is required regarding the medication records • RxHistoryRequest and RxHistoryResponse may be sent directly or through an intermediary. • Medication history transactions may be exchanged among prescribers, pharmacies, or payers, and may include adjudicated claims and/or pharmacy dispensed/point of sale prescription information.	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• It is recommended that prescribers request Medication History from all applicable sources, whenever appropriate, to ensure the most complete view of a patient's medication history. The Medication History may be reconciled with the prescriber's patient record for improved medication management and to assist in clinical decision support. • Both the sender and receiver must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. This may also include hospitals and/or Accountable Care Organizations (ACOs). • See NCPDP projects in the Interoperability Proving Ground	

Interoperability Need: Allows a Prescriber to Cancel 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	$	Yes
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 10.6 - o CanRx: a request from a prescriber to a pharmacy to not fill a previously sent prescription. o CanRes: a response from a pharmacy to a prescriber to acknowledge a cancel request; the response to a CanRx. ▪ SCRIPT 2017071 - o CancelRx: a request from the prescriber to the pharmacy to not fill a previously sent prescription o Must contain pertinent information for the pharmacy to be able to find the prescription in their system (patient, medication (name, strength, dosage form), prescriber, prescription number if available) o Changes can be indicated in the MessageRequestCode in the CancelRx transaction ▪ CancelRxResponse: a response from the pharmacy to the prescriber to acknowledge a CancelRx o Used to denote if the cancellation is Approved or Denied o DenialReasonCode should be sent when a CancelRx is denied	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ When a Long-Term Care (LTC) prescriber has the need to modify an order and notify the pharmacy, the prescriber system will always send a CancelRx and a NewRx, regardless of the type of change • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Prescriber to Communicate Drug Administration Events

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 2017071	Final	Production	●○○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The NCPDP SCRIPT Version 2017071 Implementation Guide supports the DrugAdministration transaction communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred - for example, a medication was suspended or administration was resumed. • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP 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.

Interoperability Need: Allows a Prescriber to Communicate with a REMS Administrator

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 2017071	Final	Production	●○○○○	No	$	Yes

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

• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements.
• The NCPDP SCRIPT Version 2017071 Implementation Guide supports:
  ▪ REMSInitiationRequest and REMSInitiationResponse
  ▪ REMSRequest and REMSResponse
• Each transaction supports a particular step in the REMS process:
  ▪ The REMSInitiationRequest transaction is used by the prescriber to initiate the REMS process, by notifying the REMS Administrator of the patient and the medication for which REMS authorization is being requested, along with the prescriber's information and other related details.
  ▪ In the REMSInitiationResponse transaction, the REMS Administrator indicates the information needed from the prescriber to determine approval or denial of the authorization. In some cases, the REMS Administrator indicates to the prescriber that REMS authorization is not required for the requested medication and patient. The REMSInitiationResponse is for the medication (name, strength, dosage form) indicated in the REMSInitiationRequest. The REMS Administrator should not respond for an equivalent to the medication (e.g., generic product equivalent to brand product) indicated in the REMSInitiationRequest.
  ▪ The prescriber system gathers the requested information by presenting questions for the prescriber to answer and/or by extracting information from the patient's electronic medical record using the coded references associated to the question. The information is sent to the
	• **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
REMS Administrator in the REMSRequest transaction. This occurs in both the solicited and unsolicited models. ▪ The REMS Administrator determines whether authorization can be granted and provides the determination to the prescriber in the REMSResponse transaction. In some cases the REMSResponse transaction may indicate the REMS Administrator needs additional information in order to make a determination. • The Food and Drug Administration Amendments Act (FDAAA) of 2007 (Public Law 110-85) enables the Food and Drug Administration (FDA) to require a REMS from a pharmaceutical manufacturer if the FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks associated with the drug. The currently approved REMS programs vary in levels of complexity. Typically a Med Guide and Communication Plan is required, but some also require Elements to Assure Safe Use (ETASU). The large majority of existing REMS programs are for drugs dispensed through specialty pharmacies, clinics, and hospitals, but as REMS become more common, they may ultimately have a greater impact on retail-based products. • The impact of REMS is twofold. First, REMS with ETASU may require the pharmacist to verify prescriber, patient, and/or pharmacy enrollment in a registry and, in some cases, verify or check certain information, such as laboratory results. Second, all REMS, including those without ETASU, must fulfill FDA-approved reporting requirements. Each REMS program must also include a program assessment schedule that examines the program's effectiveness on intervals approved by the FDA as part of the overall REMS program. The results of these assessments are submitted to the FDA as part of the ongoing evaluation of REMS program effectiveness. • Both the prescriber and the REMS Administrator must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Prescriber to Prescribe Medication Using Weight-Based Dosing

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	Structured and Codified Sig Format Implementation Guide Version 2.1	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●○○	Yes	$	Yes

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

• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements.
• Included in the Structured and Codified Sig Format of electronic prescribing transactions are elements, fields and values that are directly related to the prescriber's instructions for use.
• The following elements of the Sig are required when Structured Sig is sent:
  ▪ Code system
  ▪ Dose
  ▪ Route Of Administration
• The following elements of the Sig are conditional (only required when prescriber specifies) when Structured Sig is sent:
  ▪ Vehicle
  ▪ Site of Administration
  ▪ Timing
  ▪ Duration
  ▪ Maximum Dose Restriction
  ▪ Indication
• The following elements of the Sig are required when Structured Sig is sent *and when dose is to be calculated*:
  ▪ Dose Calculation
  o Used where a body metric such as metric weight (kg) or surface area (m*2) is used to calculate a dose for a patient.
  o May often be used in conjunction with the Rate within TimingAndDuration and/or the Vehicle.
	LOINC® 2.63 codes supporting SCRIPT 2017071 <Observation> segment:
	
	• 8302-2 Body height, measured [LOINC®]
	• 3141-9 Body weight, measured [LOINC®]
	• 3140-1 Body surface area, derived [LOINC®]

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

• The SCRIPT 2017071 Observation element in the NewRx transaction supports the use of a patient's height, weight and other vital signs:
  ▪ Inclusion of VitalSign (most recent patient's height and weight) and ObservationDate (YYYY-MM-DD height and weight observed/taken) is required for patients 18 years old and younger on all new and renewal prescriptions from a prescriber to a pharmacy.
  o If the height and/or weight have changed and a prescriber is sending an approved renewal response, the response should be coded as Approved with Changes.
  ▪ ObservationDate is now mandatory when Observation Segment Measurement is sent.
  ▪ ObservationNotes may contain other pertinent information pertaining to weight-based calculations.
• It is recommended that developers adopt logic that results in a prescription that calculates a weight-based dose to suggest a measurable dose (e.g., rounded to the +/- 5-10% of the calculated dose). Measurable dose should be based on home dosing tool precision. For example, a weight-based dose calculation may result in instructions to give a child 4.7mL amoxicillin 400mg//5mL (375mg) when the measurable dose should be 5mL (400 mg is still a safe dose and easier to measure with a 5mL or 10mL oral syringe).
• Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions.
• See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Prescriber to Recertify the Continued Administration of a Medication Order

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 2017071	Final	Production	●○○○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The NCPDP SCRIPT Version 2017071 Implementation Guide supports the Recertification transaction; a notification from a facility, on behalf of a prescriber, to a pharmacy recertifying the continued administration of a medication order. An example use is when an existing medication order has been recertified by the prescriber for continued use. Long term or post-acute care use only. • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP 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.

Interoperability Need: Allows a Prescriber to Request, Cancel or Appeal Prior Authorization for Medications

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	NCPDP Formulary and Benefits, Version 3	Final	Production	Feedback Requested	No	$	No
Implementation Specification	NCPDP Formulary and Benefits Standard, Version 53	Final	Production	●○○○○	No	$	No
Standard	ASC X12	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide Version 2013101	Final	Production	●●●○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide Version 2017071	Final	Production	●●●●○	No	$	Yes

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

• Some of these standards can be used to support workflows for electronic prior authorization, but do not independently enable a prescriber to request, cancel, or appeal prior authorization for medications without the assistance of other standards and technologies.
• The prescriber system must receive timely Formulary & Benefit file updates from payers/intermediaries, giving group-level formulary and coverage information (including PA flags) for use when ordering medications.
• The following ASC X12 patient eligibility transactions enhance the PA Request transactions by supplying the prescriber system with the patient's pharmacy benefit information, and need to be implemented for interoperability purposes:
  ▪ Eligibility Request (ASC X12 270)
  ▪ Eligibility Response (ASC X12 271)
• The following SCRIPT 2017071 PA transactions need to be implemented for interoperability purposes:
  ▪ PAInitiationRequest and PAInitiationResponse
  ▪ PARequest and PAResponse
  ▪ PAAppealRequest and PAAppealResponse
  ▪ PACancelRequest and PACancelResponse
	• **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.
	• **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Both the prescriber and the payer/processor/pharmacy benefits manager (PBM) must have their systems configured for these transactions in order to facilitate successful exchange, including the ability to send or receive status or error messages. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Prescriber to Send a New Prescription 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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	Yes	$	Yes
Emerging Standard	*HL7® FHIR® Medication Request*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following transactions need to be implemented for interoperability purposes: ▪ SCRIPT 10.6 & SCRIPT 2017071 - o NewRx: This transaction is a new prescription sent from the prescriber to the pharmacy electronically so that it can be dispensed to a patient ▪ SCRIPT 2017071 - o NewRxRequest: This transaction is a request from a pharmacy to a prescriber for a new prescription for a patient « NewRxResponseDenied: This transaction is a denied response to a previously sent NewRxRequest (If approved, a NewRx would be sent) □ A NewRxResponseDenied response may occur when the NewRxRequest cannot be processed or if information is unavailable • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP 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.

Interoperability Need: Allows a Prescriber to Send a Prescription to a Pharmacy for a Controlled Substance

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
Standard	HL7®, Version 2	Final	Production	●○○○○	No	Free	
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	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:
• 21 CFR §1311 implements US Drug Enforcement Administration's Electronic Prescription for Controlled Substance regulation.
• DEA's EPCS requires additional information satisfied by the following SCRIPT 10.6 elements:
  ▪ Digital Signature Indicator - Use Drug Coverage Status Code - "SI - Signed Prescription"
  ▪ Controlled Substance Indicator - Use DEA Schedule Field to indicate the controlled substance schedule class
  ▪ Earliest Fill Date - Use Date/Time/Period Qualifier- value= "07 - Effective Date (Begin)"
  ▪ Drug Abuse Treatment Identifier - Use DRU Segment Ø9Ø Free Text - value= “NADEAN:xxxxxxxxx” (Narcotics Addiction DEA Number)"
  ▪ Medication Indication for GHB (Gamma-Hydroxybutyric acid) - Use DRU Segment Ø9Ø Free Text - value="medical need for GHB"
• The SUPPORT for Patients and Communities Act, once implemented, will require a prescription for a Medicare part D drug be transmitted electronically using NCPDP SCRIPT 10.6, or the latest implemented version.
• Please note that the NCPDP electronic prescribing test tool currently tests the capabilities of any health IT to conform to the ONC Health IT Certification Program criterion 170.315 (b)(3), but does not test
	The DEA's EPCS regulation, 21 CFR §1311, requires additional security considerations that:
	
	• An individual practitioner must obtain an authentication credential from a credential service provider or certification authority using two of the following three factors:
	  ▪ Something only the practitioner knows, such as a password or response to a challenge question.
	  ▪ Something the practitioner is, biometric data such as a fingerprint or iris scan
	  ▪ Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.
	• The practitioner must submit identity proofing information to the credential service provider or certification authority
	• The electronic prescription application must be capable of the setting of logical access controls to limit permissions for certain functions

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
system capabilities to conform to DEA EPCS certification requirements. • Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. • See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows a Provider to Request a Patient's Medication History from a State Prescription Drug Monitoring Program (PDMP)

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	PMIX, Version 2	Final	Production	●●●●○	No	Free	No
Standard	CDS Hooks Services	Final	Production	●●○○○	No	Free	Yes
Standard	HL7®, Version 2	Final	Production	Feedback Requested	No	Free	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 2017071	Final	Production	●●○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 10.6	Final	Production	●●○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 2013101	Final	Production	Feedback Requested	No	$	No
Implementation Specification	HL7® FHIR® Implementation Guide: US Meds STU2	Balloted Draft	Pilot	Feedback Requested	No	Free	No
Emerging Standard	*SMART on FHIR®*	*Final*	*Production*	●●●○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The following NCPDP SCRIPT transactions need to be implemented for interoperability purposes: ▪ RxHistoryRequest: a request from a prescriber for a list of medications that have been prescribed, dispensed, claimed or indicated (OTCs) by a patient to a state Prescription Drug Monitoring Program (PDMP). o This patient-specific transaction supplies enough information to uniquely identify the patient	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ RxHistoryResponse: a response from a PDMP to an RxHistoryRequest containing a patient's medication history; includes the medications that were dispensed or obtained within a certain timeframe, optionally including the prescriber that prescribed it o PDMP must evaluate the Consent for accurate reporting o Returns with loops of Medication, HistorySource (pharmacy), Prescriber, Pharmacy, and Patient elements o HistorySource and FillNumber elements are included, when appropriate, so prescribers are able to de-duplicate records from multiple sources that reflect the same medication dispensing, and to help determine patient compliance with a prescription « Helps the prescriber determine if follow-up contact is required regarding the medication records • The medication history response transaction in SCRIPT Version 2017071 has been enhanced to return data from Prescription Drug Monitoring Program (PDMP) administrators. • Please note that the NCPDP electronic prescribing test tool does not currently test the capabilities of any health IT to exchange data with a state PDMP. • RxHistoryRequest and RxHistoryResponse may be sent directly or through an intermediary. • Both the prescriber and the Prescription Monitoring Drug Program (PDMP) must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive status, or error transactions. • The HL7® FHIR® Implementation Guide: US Meds STU2 includes US Meds Prescription Drug Monitoring Program (PDMP) mapping. • SMART on FHIR® defines a mechanism for interoperable "SMART Apps" that can be plugged in to EHRs and other Health IT systems. Each SMART App can expose a user interaction and can access data in the underlying system. This presents a powerful way to	• **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** –identifies the purpose for the transaction.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
extend EHR capabilities via “pluggable” app functionality. Dozens of SMART apps are available, including apps for medication management, pain management, and PDMP-EHR integration, with more expected in the future. These apps serve many different clinical needs, yet they all use the same underlying FHIR®-based API functionality. • When using the SMART on FHIR® model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply. • See NCPDP projects in the Interoperability Proving Ground	

Interoperability Need: Allows for Communication of Prescription Information Between Prescribers and Dispensers

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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements. • The NCPDP SCRIPT Version 2017071 Implementation Guide supports the following transactions: ▪ Ask the Mailbox if there are any transactions (GetMessage) o This transaction is used by the prescriber or pharmacy asking the mailbox if there are any transactions. It is at the heart of the mechanism used by a pharmacy or prescriber system to receive transactions from each other or from a payer or the Risk Evaluation and Mitigation Strategy (REMS) Administrator via a Switch, acting as a Mailbox. Please note that the adoption level of the GetMessage transaction is not reflected above. GetMessage transaction adoption is currently lower than that of the other communication transactions below (Status, Error, and Verify). ▪ Relay acceptance of a transaction back to the sender (Status) o This transaction is used to relay acceptance of a transaction back to the sender. A Status in response to any applicable transaction other than GetMessage indicates acceptance and responsibility for a request. A Status in response to GetMessage indicates that no mail is waiting for pickup. A Status cannot be mailboxed and may not contain an error. ▪ Respond that there was a problem with the transaction (Error)	• **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
- This transaction indicates an error has occurred, indicating the request was terminated. An Error can be generated when there is a communication problem or when the transaction actually had an error. An error can be mailboxed, as it may be signifying to the originator that a transaction was unable to be delivered or encountered problems in the acceptance. The Error must be a different response than a Status, since the communication between the system and the Mailbox must clearly denote the actions taking place. An Error is a response being delivered on behalf of a previous transaction, and the Status signifies no more mail. - Respond that a transaction requesting a return receipt has been received (Verify) - This transaction is a response to a pharmacy or prescriber indicating that a transaction requesting a return receipt has been received. Verifications results when a “return receipt requested” flag is set in the original request. Upon receiving a transaction with ReturnReceipt set, it is the responsibility of the receiver to either generate a Verify in response to the request (recommended) or generate a Status in response to this request, followed subsequently by a free standing Verify. This transaction notifies the originator that the transaction was received at the software system. It is not a notification of action taking place, since time may elapse before the ultimate answer to the transaction may take place. - Both the prescriber and the pharmacy must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive verify, status, or error transactions. - See NCPDP projects in the Interoperability Proving Ground.	

Interoperability Need: Allows for the Exchange of State Prescription Drug Monitoring Program (PDMP) Data

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	2015 ASAP Prescription Monitoring Program Web Service Standard 2.1A	Final	Production	●●●●●	No	Free	No
Standard	2011 ASAP Version 4.2 Standard for Prescription Monitoring Programs	Final	Production	●●●●●	No	Free	No
Standard	PMIX, Version 2	Final	Production	●●●●○	No	Free	No
Standard	2010 ASAP Prescription Monitoring Program Standards Versions 1.0 for PMP Zero Reports and Error Reports	Final	Production	●●●○○	No	Free	No
Standard	2017 ASAP Version 4.2A Standard for Prescription Monitoring Programs	Final	Production	●●●○○	No	Free	No
Standard	HL7®, Version 2	Final	Production	Feedback Requested	No	Free	No
Standard	NCPDP Telecommunication Standard,Version D	Final	Production	Feedback Requested	No	$	No
Standard	2020 ASAP Version 4.2B Standard for Prescription Monitoring Programs	Final	Pilot	Feedback Requested	No	Free	No
Implementation Specification	NIEM, Version 3.2	Final	Production	●●●●●	No	Free	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 10.6	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 2017071	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP Prescription Drug Monitoring Programs Reporting Standard, Implementation Guide, Version 12	Final	Production	Feedback Requested	No	$	No

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® FHIR® Implementation Guide: US Meds STU2	Balloted Draft	Pilot	Feedback Requested	No	Free	No

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

• National Drug Code (NDC)
  ▪ The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals.
• RxNorm
  ▪ RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users.
• RxNav
  ▪ NDC mappings are available through RxNorm via RxNav.
• Please note that many of the standards, emerging standards, and implementation specifications outlined above are specific to the in-state and interstate exchange of PDMP data. See the PDMP query ISA page for a working list of standards, emerging standards, and implementation specifications specific to a provider's ability to query a PDMP from health information technology such as an EHR.
• Data may be exchanged directly or through an intermediary. Prescribers, Dispensers, Prescription Monitoring Drug Program (PDMPs), and other intermediaries and endpoints must have their systems configured for the transaction in order to facilitate successful exchange, including the ability to send or receive status, or error transactions.
• If a state PDMP requests either ASAP 4.2, 4.2A, or 4.2B, these versions of the standard includes the Zero Reports and Error Reports standard. ASAP 4.2, 4.2A, 4.2B, and the Zero Reports and Error Reports are also available as separate standards.
• All of the ASAP standards are free to non-commercial and non-profit entities such as state PDMPs.
• The HL7® FHIR® Implementation Guide: US Meds STU2 includes US Meds Prescription Drug Monitoring Program (PDMP) standards mapping.
	• **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.
	• **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.

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® FHIR® R4 - Resource FamilyMemberHistory	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® R4 Implementation Guidance: Genomics	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR®, R4 - Genomic Pedigree	Final	Pilot	Feedback Requested	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• 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** o https://www.HL7®.org/FHIR®/pushpull.html	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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ **Sequencing Quality and Regulatory Genomics** o https://www.HL7®.org/FHIR®/STU3/sequence.html o https://www.HL7®.org/FHIR®/STU3/bundle.html o https://www.HL7®.org/FHIR®/STU3/capabilitystatement.html • The HL7® Version 2.5.1 Implementation Guide: Lab Results Interface (LRI) Version 1, STU 3 - US Realm includes a section that regards genomic information variants. It may be used as an option for meeting this interoperability need until FHIR® resources are more mature. • 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 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.	

HEALTHY WEIGHT

Interoperability Need: Sending Healthy 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
• The 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.

IMAGES

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 – Open
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 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	Pilot	●○○○○	No	Free	Yes – Open
Implementation Specification	DICOM PS3.3 2017e A.35.18.1 Patient Radiation Dose SR IOD	Final	Pilot	Feedback Requested	No	Free	Yes – Open
Implementation Specification	IHE Radiation Exposure Monitoring (REM)	Final	Production	●●○○○	No	Free	Yes – Open
Implementation Specification	IHE Radiation Exposure Monitoring for Nuclear Medicine (REM-NM)	Balloted Draft	Pilot	●○○○○	No	Free	No

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
• The DICOM PS3.3 2017e A.35.8 X-Ray Radiation Dose SR IOD has a higher adoption level for use with CT than for other x-ray modalities.
• To survey DICOM implementations, an internet search for the relevant SOP Class UID and the phrase “DICOM Conformance Statement” will typically return links to specific products. SOP Class UIDs can be found by searching for the SOP Class name (e.g. Radiation Dose) in Annex A of DICOM Part 6. For example, implementations of X-ray, Radiopharmaceutical and Patient Dose can be found with the following searches, respectively:
	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ 1.2.840.10008.5.1.4.1.1.88.67 "dicom conformance statement" ▪ 1.2.840.10008.5.1.4.1.1.88.68 "dicom conformance statement" ▪ 1.2.840.10008.5.1.4.1.1.88.75 "dicom conformance statement" • REM PixelMed DoseUtility test tool uses Gazelle EVS Client Application on the front end. • See DICOM projects in the Interoperability Proving Ground.	

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
Implementation Specification	IHE Results Distribution (RD)	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.	• Feedback requested

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 – Open

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Use Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes. • For this interoperability need, reference DICOM Parts 3, 5, and 6: Image Object Definitions, Data Structures and Encoding, Data Dictionary. The DICOM Standard - Parts 3, 5 and 6 define the required meta information, and standard encoding for storing and exchanging most types of medical "Image Objects". • The adoption level reflects DICOM's usage when exchanging data between an imaging modality and PACS. An adoption level of three would better reflect the standard's usage when exchanging medical images between organizations. • DICOM Image Object Definitions are "self describing objects" that include the meta information and image information in one object. • DICOM also specifies standard "meta objects" that can be used to reference specific images and describe other information that can be applied to those images (e.g. annotations, overlays, window/level settings, measurements, key objects, etc.) • The DICOM standard includes the specification for encapsulating standard JPEG photos and MPEG videos with DICOM-defined meta information – so the photo/video becomes a DICOM object. The original JPEG image or MPEG video is preserved inside a DICOM shell. DICOM protocols can then be used to exchange these DICOM-wrapped photos/videos – the same as any other DICOM object. • Currently machine learning output in radiology is not stored in a standard format - often it is encapsulated as a 'secondary capture' image or in a proprietary format. This means that ML output is not in a format that could be reused and that it is not portable. Algorithm output below the level of an image specified using the FHIR® ImagingStudy object should use either a DICOM SR using Template TID 1500 (for graphical annotations) or DICOM Segmentation objects for segmentations.	• **Image Encryption** – encryption of "whole object" or "specific attributes of the image" • **Digital Signatures** - to ensure the object has not been altered

LABORATORY

Interoperability Need: Exchanging InVitro Diagnostics (IVD) Test Orders & Results

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® FHIR® Implementation Guide - LOINC®/IVD Mapping (LIVD) R1 (STU)	Balloted Draft	Pilot	●○○○○	No	Free	No
Standard	CLSI AUTO 16 - Next-Generation In Vitro Diagnostic Interface, 1st Edition	Final	Pilot	●○○○○	No	$	Yes
Implementation Specification	LAW – Laboratory Analytical Workflow Profile	Final	Production	●●●○○	No	Free	Yes
Implementation Specification	LIVD – Digital Format for Publication of LOINC® to Vendor IVD Test Results	Final	Production	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
For LAW: • Laboratory test results may require additional information beyond the result value for correct handling and interpretation, including units, reference range, harmonization status of the test, and identifiers for device, test kit, kit version, reagent lot, and calibrator lot. Not all of these elements are included in current messaging standards for the full result reporting path. • Current versions of the IHE LAW and LTW profiles support communication of lot information only within an order filling system and only for QC specimens. Reporting test harmonization status is not supported in current versions of communication standards. See additional discussion in "Representing Laboratory Values/Results." • LAW – Laboratory Analytical Workflow Profile – The LAW Profile defines the physical connection, message definitions (based on	**For LAW:** The Laboratory Analytical Workflow (LAW) Profile is part of the Pathology and Laboratory Medicine (PaLM) domain and defines plug-n-play connectivity between instruments, middleware, and LIS systems in the laboratory. It standardizes the data flow of IVD patient and QC test work order steps and results. LAW is incorporated into the PaLM Volume 1 and Volume 2 Technical Framework (see link in Table above) and also can be found here. LAW provides the following capabilities, some not currently supported by LIS2 (ASTM): • Support for IA, CC, hematology, microbiology, and molecular testing

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
the HL7® Messaging Standard v2.5.1), and workflow definitions between instruments, middleware, and LIS systems in the laboratory. IICC collaborated with the IHE Pathology and Laboratory Medicine (PaLM) domain to develop the LAW Profile. See: http://ivdconnectivity.org/law-profile/ **For LIVD:** • 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 pre-defined LOINC® codes. LIVD helps assure that laboratory personnel select the appropriate LOINC® codes for IVD tests used by their laboratory. LIVD also allows LIS systems to automatically map the correct in vitro diagnostic (IVD) vendor test result to a LOINC® code. LIVD was developed by the IVD Industry Connectivity Consortium in collaboration with SHIELD. • SHIELD (*Systemic Harmonization and Interoperability Enhancement for Laboratory Data)* is a multi-agency/stakeholder public-private partnership of over 70 stakeholders across government (FDA, CDC, NIH, ONC, CMS), industry, EHR vendors, laboratories, standards developers, professional organizations and academia, focused on the development/adoption and implementation of data standards to improve laboratory data interoperability. • For additional context, please refer to the Guidance for Industry and Food and Drug Administration Staff "Logical Observations Identifiers Names and Codes (LOINC®) for In Vitro Diagnostics." • Note that the LIVD Implementation Specification (LIVD – Digital Format for Publication of LOINC® to Vendor IVD Test Results) has not been vetted through a Voluntary Consensus Standards Body (VCSB) as defined in OMB Circular A-1195.	• Unique identification of each order request at the test or test panel level • Improved query for orders • Selection of query as the default mode • Simplified order download • Ability for an analyzer to accept or reject orders • Improved device identification for test logging • Contributing substance identification for test logging • Basic and enhanced message interface to support IVD instrument rule evaluation • LOINC® identification of test requests and observations (LIVD format recommended) • Unique identification of runs • Support for hematology images, graphs, and plots • Support for transmission of raw values • Support for rerun and reflex testing • HL7® 2.5.1 based • Supports LOINC®, JLAC10, and UCUM

Interoperability Need: Ordering Laboratory Tests for a Patient

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Release 1, STU Release 3 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7® Standard for Trial Use, provides cross-implementation guide value set definitions and harmonized requirements. • 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: Receive Electronic Laboratory Test Results

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: 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: Lab Results Interface (LRI) Release 1, STU Release 3 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm, June 2018, provides cross-implementation guide value set definitions and harmonized requirements. • See HL7® V2 projects in the Interoperability Proving Ground. • Laboratory test results may require additional information beyond the result value for correct handling and interpretation, including units, reference range, harmonization status of the test, and identifiers for device, test kit, kit version, reagent lot, and calibrator lot. Not all of these elements are included in current messaging standards for the full result reporting path. See “Representing Laboratory Values/Results.”	• **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 Provider's Health IT or EHR System

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: 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
Emerging Implementation Specification	*HL7® Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS) Release 2, STU Release 3.1 (US Realm)*	*Balloted Draft*	*Production*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7® FHIR® Order Catalog Implementation Guide/Laboratory Services 0.1.1 Hyperlink to ballot*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm, June 2018, provides cross-implementation guide value set definitions and harmonized requirements. • Note that the Emerging Implementation Specification has been harmonized with the most current suite of Lab US Realm Implementation Guides, published by HL7® in June 2018 • 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.

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	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 its 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 Regenstrief 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.
	• Feedback requested

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

PATIENT EDUCATION MATERIALS

Interoperability Need: 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
Emerging Implementation Specification	*CDS Hooks Services*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

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

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 Yes Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes Yes
Emerging Implementation Specification	*IHE-PDQm (Patient Demographics Query for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes* *Yes*
Emerging Implementation Specification	*IHE-PIXm (Patient Identifier Cross-reference for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes* *Yes*
Emerging Implementation Specification	*Implementation Guide for Expressing Context in Direct Messaging*	*Balloted Draft*	*Pilot*	●○○○○	*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 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.	• **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).

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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 - Push Exchange. • 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: o (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 o (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.	• **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.

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
Implementation Specification	HL7® Implementation Guide for CDA®, Release 2: Consent Directives, Release 1	Final	Pilot	●○○○○	No	Free	N/A
Emerging Standard	*HL7® FHIR® Consent Resource*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Standard	*HL7® FHIR® Contract Resource*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
Emerging Implementation Specification	*IHE Advanced Patient Privacy and Consents (APPC)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The IHE and CDA-based specifications 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 are the critical third part of the Attribute-Based-Access-Control and SLS for this interoperability need. 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	• **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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. • The NCPDP WG18 Patient Consent task group is working on a solution for the exchange of patient consent information between providers.	Additional information about security patterns can be found in Appendix 1.

PUBLIC HEALTH REPORTING

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
Standard	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●●○○	Yes	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Public Health Case Report, Release 2: the Electronic Initial Case Report (eICR), Release 1, STU Release 1.1	Balloted Draft	Production	●●●●○	No	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 - US Realm	Balloted Draft	Production	●●●●○	No	Free	Yes – Open
Implementation Specification	IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR) v1.0.0: STU 1 - US Realm (Balloted Draft) FHIR® electronic Case Reporting (eCR) Implementation Guide (Continuous Integration Build)*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*

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

• Electronic Initial Case Report (eICR) and the Reportability Response are paired together in pilot implementations to build a complete workflow.
• Retrieve Form for Data Capture and Structured Data Capture are paired together in pilot implementation to build a complete workflow.
• Electronic case reporting involves reporting to State and/or Local jurisdictions. It 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.
• The FHIR® electronic Case Reporting (eCR) Implementation Guide is included with both its balloted implementation guide and a link to the FHIR® continuous build. The later, as a continuous integration build, may at any point in time be unavailable, incoherent, or undergoing rapid change.
• 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.
• See FHIR® and IHE projects in the Interoperability Proving Ground.
• Direct is used as the transport for performing an unsolicited push for Case Reporting to Public Health Agencies in some jurisdictions. See An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems.
	• **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.
	• **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.
	• FHIR® Security Labels support compliance with laws, policies, and consent directives governing HIPAA PHI and specially protected information (SPI)

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 the future. • 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: Electronic Transmission of Reportable Laboratory 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® 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
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm)	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm	Balloted Draft	Production	●○○○○	No	Free	No
Emerging Standard	*FHIR® US Lab Report*	*Balloted Draft*	*Production*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• **Value Set IG -** Please also refer to the HL7® Version 2 Implementation Guide: Laboratory Value Set Companion Guide Release 1, STU Release 3 - US Realm HL7® Standard for Trial Use (June 2018). • 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. • While the names differ, please note the content in the first two Electronic Laboratory Reporting (ELR) implementation specifications listed above is now handled as a profile in the third listing, the Laboratory Results Interface (LRI) implementation	• **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. • **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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
specification, using the “LRI_PH_COMPONENT – ID: 2.16.840.1.113883.9.195.3.5” Result Profile Component. • See HL7® V2 projects in the Interoperability Proving Ground.	

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
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-server 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: Newborn Screening Results and Birth Defect Reporting 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® Version 2.6 Implementation Guide: Critical Congenital Heart Defects (CCHD) pulse oximetry screening results, Release 1	Final	Production	●○○○○	No	Free	Yes
Implementation Specification	HL7® Version 2.6 Implementation Guide: Early Hearing, Detection and Intervention (EHDI) Results Release 1	Final	Production	●○○○○	No	Free	Yes
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement Newborn Admission Notification Information (NANI) Rev. 2.1 – Trial Implementation	Final	Production	●●●○○	No	Free	No
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 3	Final	Production	●●●○○	No	Free	No
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3	Final	Production	●●●○○	No	Free	No
Emerging Implementation Specification	*HL7® v2.6 Diagnostic Audiology Reporting implementation guide*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Use of the listed test tool for "Ambulatory Healthcare Provider Reporting to Birth Defect Registries" **requires** digital certificates**.** Contact MBDR.Help@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. • The "Newborn Admission Notification Information (NANI)" is included here because its functionality directly supports other standards under this heading. • HL7® Version 2.5.1 Implementation Guide: Laboratory Orders (LOI) from EHR, Release 1, STU Release 3 and HL7® Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release contain profiles for newborn dried blood spot testing.	Feedback requested

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
Implementation Specification	HL7® Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●●○○○	Yes	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 Healthcare Safety Network (NHSN) at: https://www.cdc.gov/nhsn/cdaportal/meaningfuluse.html for information on participation. • Release 1 of the Healthcare Associated Infections IG is normative and used in ONC certification. While there are more current releases of the Healthcare Associated Infection Reports IG, they are not valid for AU or AR submissions to NHSN. These newer releases can be found at the same link as Release 1. • See CDA projects in the Interoperability Proving Ground.	• **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. • **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: 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
Implementation Specification	IHE Quality, Research and Public Health Technical Framework Supplement Birth and Fetal Death Reporting-Enhanced (BFDR-E) Rev 3.1	Balloted Draft	Pilot	●●○○○	No	Free	Yes
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	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Birth and Fetal Death Reporting, Release 1, STU Release 2 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Implementation Specification	*HL7® FHIR® Vital Records Birth and Fetal Death Reporting Implementation Guide*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• In 2019, the Division for Vital Statistics at the National Center for Health Statistics (NCHS) started focusing their standards development on FHIR®. In May 2020 the drafting of a Birth and Fetal Death Reporting FHIR® implementation guide was initiated and will be balloted in January 2021. This work is sponsored under the HL7® Public Health Work Group. • Currently, mappings to birth and fetal death reporting FHIR® resources can be found in the listed IHE profile. • The V2 test tools listed above are found under "Tool scope: Vital Records Birth and Fetal Death v 2.6 Testing Tool." • The Vital Records Common Library is a US Realm specific framework that provides common data elements between the birth and fetal death reporting and birth defects reporting FHIR® implementation guides. The purpose of this library is to avoid	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
defining the same profiles multiple times within respective implementation guides. The long-term scope of this library will include analysis and inclusion of data elements from other vital records FHIR® projects. • The IHE specification tool is supported by the CDA and V2.6 testing tools.	

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
Implementation Specification	Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012	Final	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	●●●●○	Yes	Free	Yes Yes
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Production*	●●○○○	*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 date 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 (VCSB), however	• **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. • **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).

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
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 and IHE projects in the Interoperability Proving Ground. • The NAACCR standards are used by grantees funded by CDC's National Program of Cancer Registries (NPCR). Additional detail on the NPCR standards, for both interoperability and programmatic requirements can be found here: https://www.cdc.gov/cancer/npcr/standards.htm."	• **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: 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 3.2	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7® Version 2.6 Implementation Guide: Vital Records Death Reporting, Release 1 STU R2.1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7® CDA® R2 Implementation Guide: Vital Records Death Reporting, Release 1 STU 2.1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Standard	*Vital Records Death Reporting v0.1.0 - STU Ballot #1*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The National Center for Health Statistics (NCHS) had previously developed HL7® messaging and document standards for mortality reporting. NCHS has recently made the decision to move to the FHIR® standards for exchange of data between jurisdictions and NCHS and is in the process of developing an HL7® FHIR® IG for Death Reporting which should be published by January 2020. This will be tested at the IHE Connectathon in January 2020 and piloted at NCHS during that same year. • HL7® balloted HL7® Version 2.6 Implementation Guide: Vital Records Death Reporting, Release 2 (US Realm - Standard for Trial Use) in May 2019. Publication is expected by December 2019. • The V2 test tools above are found under "Tool scope: Vital Records"	• Feedback requested

Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)							
Type	**Standard / Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally required**	**Cost**	**Test Tool Availability**
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0	Final	Production	●●●○○	Yes	Free	Yes
Implementation Specification	Erratum to the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings Release 2.0 (April 21, 2015)	Final	Production	●●●○○	Yes	Free	
Implementation Specification	HL7® Version 2.5.1 PHIN Messaging Guide For Syndromic Surveillance, Release 2.0 - NIST Clarifications and Validation Guidelines (Version 1.6)			*Feedback Requested*	No	Free	
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	Testing Clarification for PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1) Release 1.2 (February 15th, 2013)	Final	Production	●●●●○	Yes	Free	
Implementation Specification	HL7® Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 - US Realm	Balloted Draft	Pilot	Feedback Requested	No	Free	

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Stakeholders must 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. • The PHIN Messaging Guide for Syndromic Surveillance Release 2.0 and its errata are referenced in the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition and are currently used for certification. In addition see the "NIST Clarifications and Validation Guidelines (Version 1.6)" listed above. • The PHIN Messaging Guide for Syndromic Surveillance Release 1.1 and its "testing clarification" document are referenced in the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition and were previously used for certification. • Additional information can be found at the NSSP Resource Center.	• **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. • **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 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
Implementation Specification	HL7® Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm	Balloted Draft	Pilot	●●○○○	Yes	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	●●○○○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Stakeholders should refer to the National Health Care Survey Registry at: https://www.cdc.gov/nchs/dhcs/nhcs_registry_landing.htm for information on participation. • See CDA projects in the Interoperability Proving Ground.	• **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. • **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.

RESEARCH

Interoperability Need: Data Collection for Submission to Registries and Reporting Authorities

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	●●●●●	Yes	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: 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
Standard	HL7® FHIR® Resource Observation-Content	Final	Production	Feedback Requested	No	Free	No
Standard	HL7® FHIR® Resource Medication-Content	Balloted Draft	Pilot	Feedback Requested	No	Free	No
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-RFD (Retrieve Form for Data Capture)	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	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	HL7® FHIR® Implementation Guide: Structured Data Capture (SDC) Release 1	Final	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE-CRD (Clinical Research Document)	Balloted Draft	Production	●●○○○	No	Free	N/A
Emerging Standard	*HL7® FHIR® Audit Event*	*Balloted Draft*	*Production*	●●●○○	*No*	*Free*	*N/A*

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Emerging Standard	*HL7® FHIR® Questionnaire/Questionnaire Response*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*
Emerging Standard	*HL7® FHIR® Resource Research Study - Content*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Standard	*HL7® FHIR® Resource Research Subject - Content*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Standard	*HL7® FHIR® Resource Questionnaire Response - Content*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Standard	*HL7® FHIR® AdverseEvent*	*In Development*	*Feedback Requested*	*Feedback Requested*	*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 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)	Final	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE-CPRC (Clinical Research Process Content)	Balloted Draft	Pilot	●●○○○	No	Free	No
Implementation Specification	IHE-RPE (Retrieve Protocol for Execution)	Balloted Draft	Production	●●●●○	No	Free	No
Emerging Standard	*HL7® FHIR® Resource Research Study - Content*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

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. • CTR-XML standard is based on CDISC ODM. It is an extension of the ODM standard.	• Feedback requested

Interoperability Need: Submission of Clinical Research Data Contained in EHRs and Other Health IT Systems for General Purpose or Preserving Specific FDA 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
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Feedback Requested	Feedback Requested	No	Free	No
Implementation Specification	IHE-CRPC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-RPE (Retrieve Protocol for Execution)	Balloted Draft	Production	●●●●○	No	Free	N/A
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: 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	Feedback Requested	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
Standard	CDISC Questionnaires, Ratings and Scales (QRS)	Final	Feedback Requested	Feedback Requested	No	Free	No
Standard	Therapeutic Area Standards (to complement the aforementioned CDISC foundational standards that apply across various therapeutic areas)	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
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 guidance: Use of EHR Data in Clinical Investigations, in collaboration with ONC. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry) • FDA CDER published a FRN focusing on Source Data Capture From Electronic Health Records: Using Standardized Clinical Research Data. (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 but 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) • Therapeutic Area Standards, that apply across a number of therapeutic areas, include a series of IGs at different level of maturity, from development to final.	• 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	Feedback Requested	No	Free	N/A
Implementation Specification	IHE-DSC (Drug Safety Content)	Balloted Draft	Pilot	Feedback Requested	No	Free	N/A
Implementation Specification	IHE-CPRC (Clinical Research Process Content)	Balloted Draft	Pilot	Feedback Requested	No	Free	N/A
Emerging Standard	*HL7® FHIR® Adverse Event Resource*	*In Development*	*Feedback Requested*	*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

SECURITY TAGS FOR SENSITIVE INFORMATION

Interoperability Need: Security Tags for Sensitive Information

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7® Healthcare Privacy and Security Classification System (HCS), Release 1	Final	Production	●○○○○	No	Free	No
Standard	HL7® v2.9	Final	Production	●○○○○	No	Free	
Standard	HL7® FHIR® R4 - Security Labels	Final	Production	●○○○○	No	Free	
Implementation Specification	HL7® Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Production	●○○○○	No	Free	Yes
Implementation Specification	IHE IT Infrastructure Technical Framework Volume 4 - National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P)	Final	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® Data Segmentation for Privacy	In Development	Pilot	●○○○○	No	Free	No
Standard	HL7® Version 3 Standard: Privacy, Access and Security Services (PASS); Access Control, Release 1	Final	Feedback Requested	Feedback Requested	No	Free	

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The 2015 Edition Cures Update Health IT Certification Criteria includes two optional criteria for Security Tags - Summary of Care (§ 170.315(b)(7) and § 170.315(b)(8)). Health IT certified to these criteria use the HL7® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1. • HL7® FHIR® v3 Implementation Guide for DS4P provides CDA templates to enable privacy and segmentation markings at the document, section and entry (data element) levels:	• Feedback requested • Additional information about security patterns can be found in Appendix 1.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ CDA Privacy Markings Section- specifies how a document, section, or entry may be constrained to specify privacy and security markings. ▪ CDA Privacy Segmented Section-may apply to any section of a C-CDA document if that section metadata (sensitivity, confidentiality) is different than the document's overall ▪ Privacy Metadata Templates-support the exchange of protected information by annotating specific entries with several observations, policies and constraints. Examples include: o CDA Privacy Annotation-a set of security observations that allow for specific privacy metadata for an entry that overrides that of a document or section o CDA Protected Problem-combines a mandatory provenance and privacy annotations with the default constraints applied to a ProblemObservation o CDA Security Observation-a class of abstract templates to indicate a security classification, control, category, or integrity criterion « Subclasses include Obligation, Confidentiality, Refrain Policy, and Purpose of Use Security Observations • US Realm CDA documents are required to include a Confidentiality code in the document header, taken from the HL7® BasicConfidentialityKind value set defined by the DS4P standard. Therefore, adoption levels may be higher for document level tagging (vs. section level). • HL7® v2.9 adopted HL7® Healthcare Privacy and Security Classification System syntax for assigning security labels in the ARV (Access Restrictions), BHS (Batch Header), FHS (File Header), and MSH (Message Header) segments. • See CDA and DS4P in the Interoperability Proving Ground.	

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
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	Final	Production	●●●●●	Yes	Free	Yes
Implementation Specification	HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm	Balloted Draft	Production	*Feedback Requested*	No	Free	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2020101	Final	Production	●○○○○	No	$	No
Implementation Specification	HL7® FHIR® DaVinci Payer Coverage Decision Exchange (PCDE) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
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*

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

UNIQUE DEVICE IDENTIFICATION

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® Cross-Paradigm Implementation Guide: UDI Pattern, Release 1	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Per the FDA, Unique Device Identification system will be phased in over several years, with the initial final compliance date of September 24, 2020. In an update published on June 30, 2020, FDA announced a Immediately in Effect Guidance for Industry and Food and Drug Administration Staff, updating its policy regarding compliance dates for class I and unclassified devices that are not implantable, life-supporting, or life-sustaining. The guidance explains that, at this time, the FDA does not intend to enforce UDI labeling (21 CFR 801.20 & 801.50), Direct Mark (21 CFR 801.45), GUDID Data Submission (21 CFR 830.300), and Standard Date Format (21 CFR 801.18) requirements before September 24, 2022. • 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: 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
Standard	NCPDP Telecommunication Standard Implementation Guide, Version F2	Final	Production	Feedback Requested	No	$	
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	Feedback Requested	No	$	Yes
Implementation Specification	HL7® Cross-Paradigm Implementation Guide: UDI Pattern, Release 1	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	NCPDP Product Identifiers Standard Implementation Guide Version 1.4	Final	Production	Feedback Requested	No	$	No
Emerging Implementation Specification	*HL7® FHIR® US Core Implantable Device Profile*	*In Development*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7® CDA® R2 Implementation Guide: C-CDA Supplemental Templates for Unique Device Identifier (UDI) for Implantable Medical Devices, Release 1 - US Realm*	*Balloted Draft*	*Production*	*Feedback Requested*	*No*	*Free*	

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Per the FDA, Unique Device Identification system will be phased in over several years, with the initial final compliance date of September 24, 2020. In an update published on June 30, 2020, FDA announced a Immediately in Effect Guidance for Industry and Food and Drug Administration Staff, updating its policy regarding	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
compliance dates for class I and unclassified devices that are not implantable, life-supporting, or life-sustaining. The guidance explains that, at this time, the FDA does not intend to enforce UDI labeling (21 CFR 801.20 & 801.50), Direct Mark (21 CFR 801.45), GUDID Data Submission (21 CFR 830.300), and Standard Date Format (21 CFR 801.18) requirements before September 24, 2022. • 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. • See UDI projects in the Interoperability Proving Ground. • HL7® Cross-Paradigm Implementation Guide: UDI Pattern, Release 1 - will be updated with HL7® FHIR® Releases.	

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® Cross-Paradigm Implementation Guide: UDI Pattern, Release 1	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	NCPDP Telecommunication Standard, Implementation Guide, Version F6	Final	Pilot	Feedback Requested	No	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Per the FDA, Unique Device Identification system will be phased in over several years, with the initial final compliance date of September 24, 2020. In an update published on June 30, 2020, FDA announced a Immediately in Effect Guidance for Industry and Food and Drug Administration Staff, updating its policy regarding compliance dates for class I and unclassified devices that are not implantable, life-supporting, or life-sustaining. The guidance explains that, at this time, the FDA does not intend to enforce UDI labeling (21 CFR 801.20 & 801.50), Direct Mark (21 CFR 801.45), GUDID Data Submission (21 CFR 830.300), and Standard Date Format (21 CFR 801.18) requirements before September 24, 2022. • 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.	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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. • Support of the full length of the UDI-DI will be available in the NCPDP SCRIPT Standard Implementation Guide, Version 2017071, and the NCPDP Telecommunication Standard Implementation Guide, Version F6. Today, these numbers are reformatted to support the field size limitations.	

WORK INFORMATION

Interoperability Need: Work Information Templates

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Occupational Data for Health, Release 1.1 – US Realm (STU)	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	IHE Patient Care Coordination (PCC) Technical Framework Supplement: CDA Content Modules, Revision 2.7 – Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	
Implementation Specification	HL7® FHIR® Release 4.0.1 Implementation Guide: Occupational Data for Health (ODH), Release 1.1 (STU)	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Implementation Specification	HL7® Version 2.9 Messaging Standard – An Application Protocol for Electronic Data Exchange in Healthcare Environments, Normative. Chapter 3, Patient Administration	Final	Production	Feedback Requested	No	Free	
Emerging Implementation Specification	*HL7® FHIR® Profile: Occupational Data for Health (ODH), Release 1.1 (Standard for Trial Use)*	*Final*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*N/A*
Emerging Implementation Specification	*HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Occupational Data for Health (ODH) Release 1.1 - US Realm*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*

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

• An information model of Patient Work, called Occupational Data for Health (ODH), has been published in JAMIA.
• Any or all of the Occupational Data for Health (ODH) CDA sections, FHIR® profiles, or V2 segments can be incorporated as a non-breaking addition to interoperability specifications.
• All ODH sections/profiles are an option in these implementation specifications:
  ▪ IHE Patient Care Coordination (PCC) Technical Framework Supplement to Volume 1, CDA Occupational Data Options (XDS-MS, XHPR, EDR), Revision 1.1 – Trial Implementation
  ▪ IHE Patient Care Coordination (PCC) Technical Framework Supplement: Query for Existing Data for Mobile (QEDm), Revision 2.2 – Trial Implementation
  ▪ IHE PCC TF Supplement: International Patient Summary (IPS), Revision 1.1 – Trial Implementation
  ▪ IHE Quality, Research and Public Health Technical Framework Supplement: Healthy Weight (HW), Revision 2.4 – Trial Implementation
• The ODH Usual Work section/profile is required in these implementation specifications:
  ▪ HL7® CDA R2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 – US Realm; HL7® STU R1.1
  ▪ HL7® CDA R2 Implementation Guide: Vital Records Death Reporting (EDRS to National Agency), Release 1, STU 2.1 – US Realm; HL7® STU
  ▪ HL7® FHIR® Release 4.0.1 Implementation Guide: Vital Records Mortality and Morbidity Reporting, R1, Version 1.0 (STU)
• The ODH Job and Usual Work sections/profiles are options in these implementation specifications:
  ▪ HL7® CDA R2 Implementation Guide: Public Health Case Report – the Electronic Initial Case Report (eICR), Release 1.0 – US Realm; STU 2.0
	• These standards are intended to transmit data that are part of the medical record and must be protected accordingly.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ HL7® FHIR® Release 4.0.1 Implementation Guide: Electronic Case Reporting (eCR) – US Realm. Version 1.0.0 (STU) • NIOSH has prepared A Guide to the Collection of Occupational Data for Health to provide tips to health IT system developers seeking to implement work concepts.	

Services/Exchange

“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
Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	No	Free	Yes Yes Yes
Standard	HL7® FHIR® RESTful API	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	Final	Production	●○○○○	No	Free	Yes
Implementation Specification	Implementation Guide for Expressing Context in Direct Messaging v1.1	Final	Production	●○○○○	No	Free	No
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	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2019071	Final	Production	●●○○○	No	$	No

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 2017071	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	IHE-MHD (Mobile access to Health Documents)	Final	Production	Feedback Requested	No	Free	Yes Yes
Implementation Specification	IG for Direct Edge Protocols	Final	Feedback Requested	●●●●●	Yes	Free	Yes
Emerging Standard	*Specialty Medication Enrollment HL7® FHIR®*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Standard	*DirectTrust Trusted Instant Messaging Plus (TIM+)*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

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

• This interoperability need also includes transport for the following purposes, primarily using the Direct Standard: The Direct Standard (TM) 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.
  ▪ Transport for Transition of Care or Referral to Another Health Care Provider
  ▪ Transport for a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers
• 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).
• DirectTrust Standards announced that the Direct Standard (TM) has been approved as American National Standard ANSI/DS 2019-01-100-2021-Applicability Statement for Secure Health
	• **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.
	• **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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
TransportVersion 1.3. The new version has been submitted to the SVAP process in 2021 and is under consideration. • 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 • The DirectTrust Trusted Instant Messaging Plus standard provides secure instantaneous communication via the XMPP standard between servers allowing forfederated trust communities and cross-platform communication. The draft standard supports text-based communication, file transfers, group messaging, and "presence". Future versions of the Standard are expected to support audio and video communications. • See Direct and IHE projects in the Interoperability Proving Ground. • IHE-MHD is very similar to IHE-XDR, but uses FHIR®. The typical use case for MHD in this mode is when documents are known to be needed by a recipient. Such as a patient referral in the use case given in XDR. In addition the MHD can be used as an push API to a system that ultimately delivers the content. For example diagrammed below is MHD initiating a push to an Intermediary. In this use case the MHD push request could be handled by the intermediary that further pushes the content using XDR or an e-mail carrying XDM (e.g., the Direct Project). • On the recipient side the MHD could be used by an intermediary to forward a XDR or XDM push content. MHD could also be used on the recipient side as a query/retrieve where the intermediary has cached content addressed to that recipient. This Intermediary is an example of a Direct Project HISP with the added functionality provided by MHD, enabling FHIR® based push with end-to-end interoperability between three different transport stacks in MHD, XDR, and e-mail XDM.	• **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	HL7® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Standard	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●●●●	Yes	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
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
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2019071	Final	Production	●●○○○	No	$	No
Emerging Standard	*DirectTrust Trusted Instant Messaging Plus (TIM+)*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Standard	*Specialty Transaction HL7® FHIR®*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*$*	*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. • "The Direct Standard"(TM) 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" • The DirectTrust Trusted Instant Messaging Plus standard provides secure instantaneous communication via the XMPP standard between servers allowing for federated trust communities and cross-platform communication. The draft standard supports text-based communication, file transfers, group messaging, and "presence". Future versions of the Standard are expected to support audio and video communications. • See Direct, FHIR®, and IHE projects in the Interoperability Proving Ground.	• **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. • **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. • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user. • **Purpose of Use** – identifies the purpose for the transaction.

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
Implementation Specification	Continua Design Guidelines	Balloted Draft	Production	Feedback Requested	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.

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	IEEE 11073-10101-2004 - Health informatics -- Point-of-care medical device communication -- Part 10101: Nomenclature	Final	Production	●●●○○	No	$	Yes[$]
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	Yes 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
• 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-design-guidelines	• Feedback requested

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, H.812.5, 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.

Interoperability Need: Representing Path Traversal Expressions

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• See FHIR® Projects in the Interoperability Proving Ground.	• Feedback requested

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® FHIR® Profile: Quality Improvement Core (QI Core), Release 1, STU 3	Balloted Draft	Pilot	●●○○○	No	Free	No
Standard	HL7® Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU 4(1.4)	Balloted Draft	Pilot	●●●○○	No	Free	Yes
Standard	HL7® Standard: Clinical Quality Language Specification, Release 1, R5 (CQL 1.5)	Final	Pilot	●●●○○	No	Free	Yes
Standard	HL7® CDS Hooks Services, Version 1.0 STU	Balloted Draft	Production	●●●○○	No	Free	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. • 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**
Standard	HL7® Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2.	Final	Production	●●●●○	Yes	Free	No
Standard	CDS Hooks Services Version 1.0	Balloted Draft	Pilot	●○○○○	No	Free	Yes
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
Implementation Specification	HL7® FHIR® Implementation Guide Clinical Reasoning Module, FHIR® R4 STU	Balloted Draft	Pilot	●●○○○	No	Free	No

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

CONSUMER ACCESS/EXCHANGE OF HEALTH INFORMATION

Interoperability Need: Collection and Exchange of Patient Reported Outcomes

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® FHIR® Patient Reported Outcomes Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® Patient Reported Outcomes Implementation Guide (Continuous Integration Build)	In Development	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® Argonaut Questionnaire Implementation Guide	Final	Feedback Requested	Feedback Requested	No	Free	No
Implementation Specification	IHE Mobile Access to Health Documents (MHD) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	Yes Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The FHIR® Patient Reported Outcomes (PRO) Implementation Guide is included with the balloted, standard for trial use (STU) implementation guide and a link to the continuous build of the same. The latter, as a continuous integration build, may at any point in time be unavailable or undergoing change. • The creation/generation and scoring of PRO measure instruments and interpretation of the PRO data is dictated by the organizations/institutions that created, tested, and validated them. • The HL7® FHIR® PRO IG is not intended to be used to define or generate PRO measure instruments, or interpret PRO data. • The FHIR® PRO IG leverages the Structured Data Capture Implementation Specification and the profiles listed below to capture and exchange patient reported outcome data: ▪ SDC Questionnaire ▪ SDC QuestionnaireResponse ▪ SDC Adaptive Questionnaire	• PROM Instrument and Meta Data Security Conformance ▪ **SHALL** support the Communication security mechanisms outlined in FHIR® Security Specification ▪ **SHALL** support the Authentication security mechanisms outlined in FHIR® Security Specification ▪ **SHOULD** support other security recommendations outlined in FHIR® Security as appropriate. • EHR or Care Delivery IT System Security Conformance ▪ **SHALL** support the Communication security mechanisms outlined in FHIR® Security Specification ▪ **SHALL** support the Authentication security mechanisms outlined in FHIR® Security Specification ▪ **SHOULD** support other security recommendations outlined in FHIR® Security as appropriate. • External Pro Administration System Security Conformance

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ SDC Adaptive QuestionnaireResponse • See the PRO project in the: ▪ Interoperability Proving Ground ▪ ONC Health IT Scientific Initiatives Realm • The IHE-MHD profile can include data in the form of CDA, FHIR®-Documents, or FHIR® Bundles.	▪ **SHALL** support the Communication security mechanisms outlined in FHIR® Security Specification ▪ **SHALL** support the Authentication security mechanisms outlined in FHIR® Security Specification ▪ **SHOULD** support other security recommendations outlined in FHIR® Security as appropriate. • Patient Facing Administration App System Security Conformance ▪ **SHALL** support the Communication security mechanisms outlined in FHIR® Security Specification ▪ **SHALL** support the Authentication security mechanisms outlined in FHIR® Security Specification ▪ **SHOULD** support other security recommendations outlined in FHIR® Security as appropriate. ▪ **MAY** have to comply with other security requirements to interact with the External Assessment Center. • External Assessment Center Security Conformance ▪ **SHALL** support the Communication security mechanisms outlined in FHIR® Security Specification ▪ **SHALL** support the Authenitication security mechanisms outlined in FHIR® Security Specification ▪ **SHOULD** support other security recommendations outlined in FHIR® Security as appropriate. ▪ **MAY** have to comply with other security requirements to interact with the External Assessment Center. • Feedback Requested, as security is at the discretion of the implementing organization based on the ecosystem and operational considerations within each organization.

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
Standard	HL7® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Standard	Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs)	Final	Production	●●●●●	Yes	$	N/A
Implementation Specification	Applicability Statement for Secure Health Transport v1.2 (Direct)	Final	Production	●●●●○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• To learn more about Secure Messaging, 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). • As of March 2019, DirectTrust received accreditation as an ANSI SDO. A new division of the organization, DirectTrust Standards has convened a consensus body to update and maintain the Direct Standard (TM) going forward and to seek ANSI approval for the Standard.	• **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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used when data is being exchanged between patients and providers. • 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. • 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: 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
Standard	HL7® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Standard	Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs)	Final	Production	●○○○○	Yes	$	N/A
Implementation Specification	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●○○○○	Yes	Free	Yes
Implementation Specification	IHE Mobile Access to Health Documents (MHD) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	Yes Yes
Emerging Implementation Specification	*HL7® FHIR® Patient Reported Outcomes Implementation Guide*	*Balloted Draft*	*Feedback Requested*	*Feedback Requested*	*No*	*Free*	*No*

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. • ONC published a White Paper and a Practical Guide to better understand and illustrate the opportunities, challenges, and best practices for using patient generated health data. • Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used, as appropriate, when pushing patient-generated health data into integrated EHRs. • 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. • When using the SMART on FHIR® model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply. • 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

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). • As of March 2019, DirectTrust received accreditation as an ANSI SDO. A new division of the organization, DirectTrust Standards has convened a consensus body to update and maintain the Direct Standard (TM) going forward and to seek ANSI approval for the Standard. • The MHD profile provides methods of expressing the medical data (document), the Provenance of that document (metadata), and the reason for submitting (submission Set).	

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
Standard	HL7® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	IHE Basic Patient Privacy Consents (BPPC) Profile	Final	Production	●○○○○	No	Free	Yes
Implementation Specification	IHE Advanced Patient Privacy Consents (APPC) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	Yes
Emerging Implementation Specification	*HL7® FHIR® Patient Reported Outcomes Implementation Guide*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*$*	
Emerging Implementation Specification	*Health Relationship Trust (HEART) Specification*	*In Development*	*Pilot*	*Feedback Requested*	*No*		

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.
• To learn more about how APIs can help patients participate in research, see the Patient Engagement Playbook.
• 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.
• 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.
• 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.
	• **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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• When using the SMART on FHIR® model, the authentication model is OAuth2. The other security patterns listed do not apply. • The IHE Basic Patient Privacy Consents (BPPC) profile provides a means for recording the ceremony of patient consenting to a policy. The BPPC profile will use terms consistent with ISO 22600 - Privilege Management and Access Control (PMAC), but is not restricted to systems that implement PMAC. See the IHE white paper Enabling Document Sharing Health Information Exchange Using IHE Profiles (http://profiles.ihe.net/ITI/HIE-Whitepaper/index.html. • The IHE Advanced Patient Privacy Consents (APPC) profile is used when additions or deviations from a "Basic" consent policy are needed. The APPC mechanism provides for deeper coded consents beyond what BPPC supports. BPPC continues to be used to capture the ceremony and overall policy, where APPC provides the specific additions or deviations.	• **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

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
Standard	HL7® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Standard	Direct (Applicability Statement for Secure Health Transport v1.2)	Final	Production	●●●●○	Yes	Free	Yes
Standard	Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs)	Final	Production	●●●●●	Yes	$	N/A
Implementation Specification	UDAP Implementation Guide for Registration and Authorization of Consumer Facing Health Apps	In Development	Production	*Feedback Requested*	No	Free	Yes
Implementation Specification	IHE Mobile Access to Health Documents (MHD) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	Yes Yes
Implementation Specification	IHE Query for Existing Data for mobile (QEDm) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	No

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.
• For a consumer-facing resource on this interoperability need, see ONC's Guide to Getting & Using Your Health Records.
• 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-
	• **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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
mediated exchange) and NATE (for consumer-mediated exchange). • As of March 2019, DirectTrust received accreditation as an ANSI SDO. A new division of the organization, DirectTrust Standards has convened a consensus body to update and maintain the Direct Standard (TM) going forward and to seek ANSI approval for the Standard. • Current Procedural Terminology (CPT) Consumer Friendly Descriptors (CFDs) may be used when data is being exchanged between patients and providers. • 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. • When using the SMART on FHIR® model, the authentication model uses OAuth2. Except for "Secure Communication", the security patterns listed do not apply. • The IHE Mobile Access to Health Documents (MHD) profile provides a simple API for document discovery and download. This API may be used in many settings including by Patient managed applications. See -- https://profiles.ihe.net/ITI/HIE-Whitepaper/index.html • The IHE Query for Existing Data for mobile (QEDm) profile provides for a simple query for a subset of clinical FHIR® Resources. This subset is consistent with USCDI.	▪ 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 • **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

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	HL7® FHIR® Validated Healthcare Directory Implementation Guide Home	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Implementation Specification	HL7® FHIR® DaVinci Provider Data Exchange (PDex: Plan Network Directory) Implementation Guide	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® Argonaut Provider Directory Implementation Guide Version 1.0.0	Balloted Draft	Production	●●○○○	No	Free	Yes
Implementation Specification	IHE Mobile Care Services Discovery (mCSD)	Balloted Draft	Pilot	Feedback Requested	No	Free	No
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes Yes Yes

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. However, this implementation specification has met with limited adoption due to several concerns. • 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	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• See IHE White Paper for use-case analysis and recommendations on how to use mCSD	

IMAGE EXCHANGE

Interoperability Need: Exchanging Images 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	Digital Imaging and Communication in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No
Implementation Specification	IHE Cross Community Access for Imaging (XCA-I)	Final	Pilot	●○○○○	No	Free	Yes
Implementation Specification	The combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes Yes Yes
Implementation Specification	IHE Portable Data for Imaging (PDI)	Final	Production	●●●●○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The IHE XCA-I profile can be found in Section 2.1.27 of the IHE Radiology (RAD) linked above. • IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • For IHE-PDI, network transfers are preferable to digital media transfers, though the latter may be used when network solutions are not in place • 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).

Interoperability Need: Exchanging Images 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	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No
Standard	DICOMweb Store (STOW) and Query/Retrieve (WADO) - PS3.18 DICOM Standard – Part 18: Web Services	Final	Production	●●●○○	No	Free	No
Implementation Specification	IHE Cross Enterprise Document Sharing for Images (XDS-I.b)	Final	Production	●○○○○	No	Free	Yes Yes
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes Yes Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes Yes Yes
Implementation Specification	RESTful HL7® FHIR® Document Reference-based API Specifications	Final	Feedback Requested	●○○○○	No		
Emerging Implementation Specification	*IHE - Patient Identifier Cross-reference for Mobile (PIXm)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE – WIA (Web-based Image Access)*	*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-server 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.

PATIENT IDENTIFICATION MANAGEMENT

Interoperability Need: Exchanging Patient Identification Within and Between Communities

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 Yes Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes Yes Yes
Implementation Specification	IHE - XCPD (Cross Community Patient Discovery)	Final	Production	●●●●●	No	Free	Yes Yes
Implementation Specification	IHE-Patient Identifier Cross-reference PIX for Mobile (PIXm)	Balloted Draft	Production	Feedback Requested	No	Free	Yes Yes
Implementation Specification	IHE-Patient Demographics Query for Mobile (PDQm) Profile	Balloted Draft	Production	Feedback Requested	No	Free	Yes Yes
Implementation Specification	IHE-Patient Master Identity Registry (PMIR) Profile	Balloted Draft	Feedback Requested	Feedback Requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• See Section II: Patient Identification Management for more information about the HL7® 2.5.1 ADT messaging standard and information about patient identity proofing. • Consider use of HL7® FHIR® Patient $match operation for MPI-based query. • The Patient Master Identity Registry PMIR Profile is a collaborative community based system of cooperating patient identity sources maintaining a master identity for each patient. PMIR leverages the FHIR® standard.	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• See the IHE IT Infrastructure White Paper covering the PMIR Profile - https://profiles.ihe.net/ITI/HIE-Whitepaper/index.html#54-patient-master-identity-registry-pmir. • The Patient Demographics Query for Mobile (PDQm) Profile provides similar functionality as PDQ but uses the FHIR® standard. PDQm can be a FHIR® API backed by a PDQ query or a Cross-Enterprise Patient Discovery (XCPD) query. • The PMIR, PDQm, and PIXm Profiles are used within the MHDS Profile to manage and find the patient's identifier in that community as part of the Centralized Discovery and Retrieve environment. • MHD, PDQm and PIXm also have test plan pages: MHD test plan page; PDQm test plan page; PIXm test plan page. • See the IHE IT Infrastructure White Paper covering the methods of managing Patient Identities - https://profiles.ihe.net/ITI/HIE-Whitepaper/index.html#5-patient-identity-management.	

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
• The IHE Document Sharing infrastructure is ready to support Public Health Exchanges. See IHE publication. This includes both Push and Query/Retrieve. The Document Sharing enables any kind of content including CDA and FHIR®-Documents; but can also carry documents that don't meet the HL7® definition of document such as a FHIR® Bundle of measures. Document Sharing can also support legacy documents, such as PDF.	• Feedback requested

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	Yes
Implementation Specification	HL7® FHIR® R4® Subscription resource	In Development	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	*Balloted Draft*	*Pilot*	●●○○○	*No*	*Free*	*Yes* *Yes*
Emerging Implementation Specification	*Carequality Subscription Implementation Guide for Push Notifications*	*In Development*	*Pilot*	*Feedback Requested*	*No*	*Free*	*N/A*

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-server 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.

QUERY

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® FHIR® RESTful API	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification	FHIR® Bulk Data Access Implementation Guide	Final	Production	Feedback Requested	Yes	Free	Yes – Open
Implementation Specification	HL7® FHIR® DaVinci Payer Data Exchange (PDex) Implementation Guide	Balloted Draft	Production	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® DaVinci Clinical Data Exchange (CDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® DaVinci Payer Health Record Exchange (HRex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE Mobile Cross-Enterprise Document Data Element Extraction (mXDE) Profile*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE Query for Existing Data for Mobile (QEDm)*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The combination of mXDE and QEDm provide for Provenance evidence between the FHIR® Resources made available via QEDm and the documents from which that data was decomposed. In this way the client application using FHIR® Resource data can ask for Provenance. For each Provenance record given there is a unique document that contained that information. Thus the client can know how many documents stated the medical information, and can navigate to those documents. See IHE whitepaper section consuming data as FHIR® resources.	▪ May be required to authorize any exchange of patient information ▪ May be required to authorized access and use of patient information ▪ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply • **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user. • **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

Interoperability Need: 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 Specification	IHE-XCPD (Cross-Community Patient Discovery)	Final	Production	●●●●●	No	Free	Yes Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●○○○○	No	Free	Yes Yes 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
Implementation Specification	eHealth Exchange Specification: Query for Documents	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	eHealth Exchange Specification: Retrieve Documents	Final	Production	●●●●●	No	Free	Yes
Implementation Specification	HL7® FHIR® DocumentReference resource	Final	Production	●●○○○	No	Free	No
Implementation Specification	Carequality Query-Based Document Exchange Implementation Guide	Final	Production	●●●●●	No	Free	N/A
Implementation Specification	CommonWell Health Alliance Specification Services	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	HL7® FHIR® DaVinci Clinical Data Exchange (CDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	HL7® FHIR® DaVinci Provider Data Exchange (PDex) Implementation Guide	Balloted Draft	Production	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE - MHDS (Mobile Health Document Sharing)*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • 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. • The FHIR® DocumentReference reference includes the Patient/$match operation, which allows for patient matching using MPI-based logic. • The Document Sharing exchange family of specifications from IHE fit this use-case well. This includes FHIR® based exchanges as specified in the Mobile access to Health Documents (MHD) and Mobile Health Documents Sharing (MHDS)	• **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: 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 Yes
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●●	No	Free	Yes Yes Yes
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●●	No	Free	Yes Yes Yes
Implementation Specification	HL7® FHIR® DaVinci Clinical Data Exchange (CDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	HL7® FHIR® DaVinci Provider Data Exchange (PDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Implementation Specification	*IHE – MHD (Mobile Access to Health Documents*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*Yes*
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-Reference for Mobile)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*IHE - MHDS (Mobile Health Document Sharing)*	*Balloted Draft*	*Pilot*	*Feedback Requested*	*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. • The Document Sharing exchange infrastructure is a family of implementation guides specifically designed to support this setting. This includes the FHIR® based Mobile Health Document Sharing (MHDS) comprehensive community exchange. Both XDS and MHDS enable the automation of discovery and retrieve of document content by more advanced health information systems.	• **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. • **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.

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
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement 10 Mobile Care Services Discovery (mCSD) 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. • See Human Services Data Specification and API Protocols	• **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.

Administrative

ADMINISTRATIVE TRANSACTIONS - NON-CLAIMS

Interoperability Need: Administrative Transaction Acknowledgements

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	ASC X12C/005010X231 Implementation Acknowledgment for Health Care Insurance (999), June 2007 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12C/005010X231A1 Type 1 Errata to Implementation Acknowledgment for Health Care Insurance (999), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●●●○	No	$	No
Implementation Specification	ASC X12N/006020X290 Implementation Acknowledgment for Health Care Insurance (999), September 2013 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Pilot	●○○○○	No	$	No

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. 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	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
information about requirements for covered entities and their business associates and enforcement from this link. • The acknowledgement transactions have not been adopted under HIPAA but may be used voluntarily between willing trading partners. Similarly, the operating rules available for use with these transactions may be used on a voluntary basis.	

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
Implementation Specification	ASC X12N/005010X220 Benefit Enrollment and Maintenance (834), August 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X220A1 Type 1 Errata to Benefit Enrollment and Maintenance (834), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●●○○	Yes	$	Yes
Implementation Specification	ASC X12N/005010X307 Health Insurance Exchange: Enrollment (834), January 2013, as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	Feedback Requested	No	$	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. This information is often maintained in provider practice management and billing systems but duplicates information in electronic health records.	• 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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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. • 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. • Operating rules have not been adopted for the enrollment transaction standard. • *NCPDP operating rules are in the NCPDP Telecommunication Standard, Implementation Guide, Version D.0. Additional operating rules are not developed by any entity outside of NCPDP for the pharmacy standards.*	

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
Implementation Specification	ASC X12N/005010X279 Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X279A1 Type 1 Errata to Health Care Eligibility Inquiry and Response (270/271), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	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. 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. This version was adopted in 2009 and mandatory use was required in January 2012. • 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.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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 transactions. • The HL7® FHIR® Implementation Specifications are for use building APIs to support interoperability to support ONC, HHS and CMS priorities.	

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 1.2	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	NCPDP Telecommunication Standard, Implementation Guide, Version F6, April 2020 and Equivalent Batch Standard Implementation Guide, Version 15	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP Real-Time Prescription Benefit Standard Version 12	Final	Production	●○○○○	No	$	No

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 covered entities, which includes health plans, health care clearinghouses and certain health care providers. Information about the HIPAA regulations and enforcement can be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. • 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. • NCVHS made a recommendation to HHS to adopt the Telecommunication Standard Implementation Guide Version F6 and Subrogation Version 15 in 2019, requesting adoption through rulemaking in CY 2020. Find the history for this recommendation information on the NCVHS 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.

ADMINISTRATIVE TRANSACTIONS TO FINANCIAL EXCHANGES

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
• 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	• 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 2019 NACHA Operating Rules & Guidelines.

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

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
Implementation Specification	ASC X12N/005010X221 Health Care Claim Payment/Advice (835), April 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X221A1 Type 1 Errata to Health Care Claim Payment/Advice (835), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	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.	• 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.

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

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
Implementation Specification	ASC X12N/005010X218 Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●○○○	Yes	$	Yes
Implementation Specification	ASC X12N/005010X306 Health Insurance Exchange Related Payments (820), January 2013 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	Feedback Requested	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. This information 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.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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 transactions. • For a description of the functionality of each transaction, visit the website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

ADMINISTRATIVE TRANSACTIONS TO SUPPORT CLINICAL CARE

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
Implementation Specification	ASC X12N/006020X315 Health Care Services Request for Review and Response (278), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	ASC X12N/006020X313 Health Care Claim Request for Additional Information (277), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	ASC X12N/006020X316 Additional Information to Support a Health Care Services Review (275), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	HL7® CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 - US Realm	Final	Production	●○○○○	No	Free	No
Implementation Specification	HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1	Final	Production	●○○○○	No	Free	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide Version 2020101	Final	Production	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The HIPAA legislation requires adoption of a standard for health care attachments; the Affordable Care Act of 2010 reiterated this requirement. HHS has not proposed adoption of a standard for attachments to support claims and other administrative transactions to date (11/2021). Willing trading partners may exchange attachments through methods agreed upon by those organizations, including through different means of electronic exchange, and the use of standards. • Pilots to test new standards for consideration to be adopted under HIPAA is permissible using the exception process under 162.940. • CMS provides additional information about the HIPAA administrative simplification provisions on its website. • Pharmacy referral transactions have been published in the NCPDP SCRIPT Standard Version 2020101. These transactions are currently available for use by trading partner agreement. Authorizations are also available in NCPDP SCRIPT Standard Version 2017071. The SCRIPT transactions can handle a single attachment that can contain multiple documents.	• 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 Telecommunication Standard, Implementation Guide, Version F6, April 2020	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●●	No	$	No
Implementation Specification	NCPDP SCRIPT Standard Implementation Guide, Version 2020101	Final	Production	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Referral transactions published in the NCPDP SCRIPT Standard Version 2020101. These transactions are currently available for use by trading partner agreement. • In 2019, NCVHS recommended that HHS adopt the Telecommunication Standard Implementation Guide Version F6 and Subrogation (as HIPAA Standards). Pending HHS rulemaking. • NCPDP requested that HHS adopt NCPDP SCRIPT 2017071 for prior authorization under HIPAA. This standard has been adopted under the Medicare Part D program. • 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 operating rules are incorporated as part of the NCPDP standards and separate operating rules are not adopted for pharmacy standards; including for the NCPDP SCRIPT standard. • 12/4/2020: NCPDP is requesting feedback on the Emerging Transaction(s) within NCPDP SCRIPT Standard:	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ Patient Care Service Referral (ServiceReferral) ▪ Patient Care Service Documentation (ServiceDocumentation) ▪ Response to Request for Patient Care Service Referral (ResponseToReferralRequest) ▪ Request for Patient Care Service Referral (RequestForReferral) ▪ Response to Patient Care Service Referral (ServiceReferralResponse)	

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
Implementation Specification	ASC X12N/005010X217 Health Care Services Review—Request for Review and Response (278), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	● ○ ○ ○ ○	Yes	$	Yes
Implementation Specification	HL7® FHIR® Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide	Balloted Draft	Production	● ● ○ ○ ○	No	Free	Yes
Implementation Specification	HL7® FHIR® Da Vinci Documentation Templates and Payer Rules (DTR) Implementation Guide	Balloted Draft	Production	● ● ○ ○ ○	No	Free	Yes
Implementation Specification	HL7® FHIR® Da Vinci Prior Authorization Support (PAS) Implementation Guide	Balloted Draft	Pilot	● ● ○ ○ ○	No	Free	Yes
Implementation Specification	HL7® CDA R2 Implementation Guide: Dental Data Exchange	Balloted Draft	Production	● ○ ○ ○ ○	No	Free	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. Information about the HIPAA regulations and enforcement may be found at https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html. • Adoption of standards to increase the efficiency of the health care system was required by the Health Insurance Portability Act of 1996 (HIPAA). The most recent versions of the medical and pharmacy standards were adopted in 2009, with a January 2012 compliance date. The purpose of the electronic standard transactions is to improve efficiency in the health care system by reducing the use of paper and increasing the electronic exchange of health care information.	• 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.

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

• 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.
• ASETT is the HHS compliance tool to enable testing and complaint filing for 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.
• HL7® Da Vinci Use Cases:
  ▪ Coverage Requirements Discovery (CRD). The goal of the CRD use case is to give providers real-time access to payer approval requirements, documentation, and rules at point of service to reduce provider burden and support treatment planning.
  ▪ Documentation Templates and Payer Rules (DTR). The goal of the DTR use case is to reduce provider burden and simplify process by establishing electronic versions of administrative and clinical requirements that can become part of the providers workflow
  ▪ Prior Authorization Support (PAS). The goal of the PA use case is to define FHIR® based services to enable provider, at the point of service, to request authorization (including all necessary clinical information to support the request) and receive immediate authorization
  ▪ Note: all Da Vinci use cases are piloted and tested during regular connectathons hosted by HL7® and approved professional affiliates throughout the year. To learn more about connectathons and other Da Vinci use cases or FHIR® accelerator programs, visit www.HL7®.org or http://www.HL7®.org/about/davinci/use-cases.cfm
• The HL7® Dental Data Exchange STU Implementation Guide provides an HL7® CDA-based set of templates defining the Dental Referral Note and Dental Consultation Note. These standardized documents are intended to support bi-directional information exchange between a medical and a dental provider or between dental providers. This publication provides the data model, defined data items, and their corresponding code and value sets, specific to a dental referral note and dental consultation note intended for exchange.	

HEALTH CARE CLAIMS AND COORDINATION OF BENEFITS

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
Implementation Specification	X12N/005010X212 Health Care Claim Status Request and Response (276/277), August 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	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. This information 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 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: 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
Implementation Specification	ASC X12N/005010X224 ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X224A2 Type 1 Errata to Health Care Claim: Dental (837), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	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. This information is often maintained in provider practice management and billing systems but duplicates information in electronic health records.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• This transaction is also used to conduct coordination of benefits (COB) between organizations 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 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.	

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
Implementation Specification	ASC X12/N005010X223 Health Care Claim: Institutional (837), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X223A2 Type 1 Errata to Health Care Claim: Institutional (837), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●●●●	Yes	$	Yes
Emerging Implementation Specification	*HL7® FHIR® CARIN for Blue Button Implementation Guide*	*In Development*	*Feedback Requested*	*Feedback Requested*	*Yes*	*Free*	*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. 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. • 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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. • The HL7® FHIR® Carin for BlueButton Implementation Guide was recommended for use in the May 2020 CMS Interoperability and Patient Access final rule to enable the Patient Access API policy, specifically to support patients access to data held by their payers, enabling them to request data to be sent to a third party app.	

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
Implementation Specification	ASC X12N/005010X222 Health Care Claim: Professional (837), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X222A1 Type 1 Errata to Health Care Claim: Professional (837), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●●●●	Yes	$	Yes
Emerging Implementation Specification	*HL7® FHIR® CARIN Blue Button Implementation Guide*	*In Development*	*Feedback Requested*	*Feedback Requested*	*Yes*	*Free*	*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. 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	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
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. • Information about the CMS May 2020 Interoperability and Patient Access final rule and the HL7® FHIR® APIs included in that rule may be found on the CMS Interoperability website.	

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	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	NCPDP Telecommunication Standard, Implementation Guide, Version F2, March 2018 and Equivalent Batch Standard Implementation Guide, Version 15	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007	Final	Production	●●●●●	Yes	$	
Implementation Specification	NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 10	Final	Production	●○○○○	No	$	
Implementation Specification	HL7® FHIR® DaVinci Provider Data Exchange (PDex: Formulary) Implementation Guide	Balloted Draft	Production	●●●○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• NCPDP submitted request in February 2018 to have updated standards adopted under HIPAA: NCPDP Telecommunication Standard Implementation Guide Version F2 and Subrogation standard Version 10. Pending rulemaking 10/2021. • 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.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• 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. • The Medicare Part D program may require use of different NCPDP standards per statute. • 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. • Information about the CMS May 2020 Interoperability and Patient Access final rule and the HL7® FHIR® APIs included in that rule may be found on the CMS Interoperability website. This rule includes use of the HL7® FHIR® DaVinci Provider Data Exchange (PDex: Formulary) Implementation Guide.	

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
Implementation Specification	NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2010	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	ASC X12N/005010X222 Health Care Claim: Professional (837), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and ASC X12N/005010X222A1 Type 1 Errata to Health Care Claim: Professional (837), June 2010 as Type 1 Errata to an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●●●●●	Yes	$	Yes
Implementation Specification	NCPDP Uniform Healthcare Payer Date Standard Implementation Guide V24	Final	Production	●○○○○	No	$	No
Implementation Specification	NCPDP Telecommunication Standard, Implementation Guide, Version F2, March 2018 and Equivalent Batch Standard Implementation Guide, Version 15	Final	Production	●○○○○	No	$	Yes
Implementation Specification	NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007	Final	Production	●●●●●	Yes	$	
Implementation Specification	NCPDP Uniform Healthcare Payer Data Standard Implementation Guide V28	Final	Production	●○○○○	No	$	No

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Emerging Implementation Specification	*NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 10*	*Final*	*Production*	*Feedback Requested*	*No*	*$*	*No*

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 by covered health care organizations - all health plans, covered health care providers and clearinghouses. 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. • The NCPDP 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), covered entities are required to use the telecommunication standard for eligibility verification, claim and service billing, predetermination of benefits, and prior authorization for retail pharmacy transactions. • 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 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. • For issues related to enforcement of the HIPAA standards and operating rules, ASETT is the HHS compliance tool to enable testing and complaint filing.	• 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.

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• The NCPDP Telecommunication Standard Implementation Guide Version F2 and subrogation Version 10 have been requested for adoption under HIPAA by NCVHS. NCVHS recommendation letters to HHS may be viewed on the NCVHS website. • For a description of the functionality of each X12 transaction, visit the X12 website. Click on a transaction set name to toggle the display of the purpose and scope of that transaction set.	

OPERATING RULES TO SUPPORT ADMINISTRATIVE TRANSACTIONS

Interoperability Need: Operating Rules for Benefit Enrollment

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH Core Operating Rules for Benefit Enrollment	Final	Production	● ○ ○ ○ ○	No	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules were included as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. The purpose of operating rules is to support the use of an adopted standard transaction and ensure the consistent and uniform use of those adopted standards. • Operating rules for the benefit enrollment and disenrollment have not yet been recommended for adoption by NCVHS but are available for *voluntary use by covered entities.* • In Spring 2020, CAQH CORE restructured its operating rules from phase-based rule sets to rule sets based on the business processes supported by the rules. • 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. CAQH CORE maintains free implementation tools to support operating rule implementation. Additionally, CAQH CORE offers educational webinars which are archived on its website.	• Feedback requested

Interoperability Need: Operating Rules for Premium Payments

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH CORE Operating Rules for Premium Payments	Final	Production	●○○○○	No	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules were included as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. The purpose of operating rules is to support the use of an adopted standard transaction and ensure the consistent and uniform use of those adopted standards. • *NCPDP operating rules are in the NCPDP Telecommunication Standard, Implementation Guide, Version D.0. Additional operating rules are not developed by any entity outside of NCPDP for the pharmacy standards.* • Operating rules for the premium payments have not yet been recommended for adoption by NCVHS but are available for *voluntary use by covered entities.* • In Spring 2020, CAQH CORE restructured its operating rules from phase-based rule sets to rule sets based on the business processes supported by the rules. • 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. CAQH CORE maintains free implementation tools to support operating rule implementation. Additionally, CAQH CORE offers educational webinars which are archived on its website.	• Feedback requested

Interoperability Need: Operating Rules for Prior Authorization and Referrals

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH CORE Operating Rules for Prior Authorization	Final	Production	● ○ ○ ○ ○	No	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules for prior authorization and referrals have not been proposed for adoption by NCVHS and have not been adopted by HHS. • NCVHS recommendation letters to HHS may be found on the NCVHS website • Operating rules are intended to support the use of adopted standard transactions under the Health Insurance and Portability Act of 1996 (HIPAA). They include additional requirements to help health plans and providers implement each transaction in a more uniform way and ensure more consistent use of the transactions. • In Spring 2020, CAQH CORE restructured its operating rules from phase-based rule sets to rule sets based on the business processes supported by the rules. • Testing, or certification for operating rules - adopted and voluntary - is available for a fee. • Certification is voluntary and not required by regulation. • CAQH CORE maintains free implementation tools to support operating rule implementation. Additionally, CAQH CORE offers regular educational webinars which are archived on its website to support implementation.	• Feedback requested

Interoperability Need: Operating Rules to Support Claim Status Transactions

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH, Committee on Operating Rules for Information Exchange Claim Status Operating Rules	Final	Production	●●●●○	Yes	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules were included 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 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. • In 2012, HHS adopted operating rules for claim status, and incorporated the Phase I and II rules by reference in 162.920 • In 2020 CAQH CORE updated its phase-based operating rule structure to align with the business processes supported by the rules. Prior versions of the CAQH CORE Claim Status Operating Rules are incorporated by reference in § 162.920 and available on the CAQH CORE Mandated Operating Rules website along with a crosswalk to the new operating rule naming and versioning conventions • Testing, or certification with the operating rules is voluntary and available for a fee through a vendor contracted to the authoring entity. The checklist is available on the website. Certification for operating rules is voluntary and not required by federal regulation. • CAQH CORE maintains free implementation tools on its website to support operating rule implementation. Additionally, CAQH CORE offers educational webinars which are archived on its website.	• Feedback requested

Interoperability Need: Operating Rules for Claims

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH CORE Operating Rules for Claims	Final	Production	● ○ ○ ○ ○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules were included as a requirement of the Patient Protection and Affordable Care Act of 2010, under section 1104, Administrative Simplification. The purpose of operating rules is to support the use of an adopted standard transaction and ensure the consistent and uniform use of those adopted standards. • Operating rules for the claims transaction have not yet been recommended for adoption by NCVHS but are available for *voluntary use by covered entities.* • *NCPDP operating rules are in the NCPDP Telecommunication Standard, Implementation Guide, Version D.0. Additional operating rules are not developed by any entity outside of NCPDP for the pharmacy standards.* • In Spring 2020, CAQH CORE restructured its operating rules from phase-based rule sets to rule sets based on the business processes supported by the rules. • 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. • CAQH CORE maintains free implementation tools to support operating rule implementation. Additionally, CAQH CORE offers educational webinars which are archived on its website.	• Feedback requested

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

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH, Committee on Operating Rules for Information Exchange Operating Rules for Electronic Remittance Advice (ERA) and Electronic Funds Transfer (EFT)	Final	Production	●●●○○	Yes	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• Operating rules were included as a requirement of the Patient Protection and Affordable Care Act of 2010 (ACA), under section 1104, Administrative Simplification. • Operating rules are intended to support and enhance the use of the standard transactions. They may include additional requirements to help implement the transaction in a more uniform way between health plans and providers and ensure a more complete set of information in the response. For the process of electronic funds transfer transactions, the operating rules require a standard enrollment data set for all health plans to use with providers. • In 2020 CAQH CORE updated its phase-based operating rule structure to align with the business processes supported by the rules. Prior versions of the CAQH CORE ERA/EFT Operating Rules are incorporated by reference in § 162.920 and available on the CAQH CORE Mandated Operating Rules website along with a crosswalk to the new operating rule naming and versioning conventions • The ERA/EFT rules support the uniform use of combinations for certain Claim and Remark Codes (CARCs and RARCs), as well as use of certain standard data elements for enrolling providers electronically for EFT or ERA transactions. • Testing, or certification with the operating rules is available for a fee and is voluntary. CAQH works with a vendor to conduct the certification process. The checklist is available on the website.	• Feedback requested

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
• CAQH CORE maintains free implementation tools to support operating rule adoption on its website. Additionally, CAQH CORE offers regular educational webinars which are archived on its website to drive greater industry awareness of the value of operating rules in collaboration with leading healthcare organizations	

Interoperability Need: Operating Rules to Support Electronic Prescribing Transactions

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	NCPDP Operating Rules for the Formulary and Benefit Standard v10	Final	Pilot	● ○ ○ ○ ○	No	$	No
Operating Rules	NCPDP Operating Rules to Support Electronic Prescribing Transactions	Final	Production	● ● ● ● ●	No	$	Yes

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rule for formulary corresponds with NCPDP Formulary and Benefit Standard v50 and later which has not been named in regulation. • These operating rules are not related to the HIPAA standards, but rather to electronic prescription standards adopted under a different statutory authority.	• Feedback requested

Interoperability Need: Eligibility and Benefits Operating Rules for Standard Transactions

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Operating Rules	CAQH, Committee on Operating Rules for Information Exchange, Eligibility & Benefits Operating Rules	Final	Production	●●●●○	Yes	Free	Yes[$]

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Operating rules were added 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 may include certain 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. • *NCPDP operating rules are in the NCPDP Telecommunication Standard, Implementation Guide, Version D.0. Additional operating rules are not developed by any entity outside of NCPDP for the pharmacy standards.* • In 2012 HHS adopted Phase 1 operating rules for Eligibility and Claim Status, which were incorporated by reference at 162.920. • In 2020 CAQH CORE updated its phase-based operating rule structure to align with the business processes of covered entities, that is, eligibility verification, claim status requests, claims processing. The phase structure was retired. HHS has not released new policies or guidance to officially adopt the documents or the revisions. Prior versions of the CAQH CORE Eligibility & Benefits Operating Rules are incorporated by reference in § 162.920 and available on the CAQH CORE Mandated Operating Rules website along with a crosswalk to the new operating rule naming and versioning conventions. • Testing, or certification with the operating rules is available for a fee, and is voluntary and available through a vendor contracted to the authoring entity. • CAQH CORE offers free implementation tools to support implementation.	• Feedback requested

Appendices

Appendices, including Sources for Security Standards/Security Patterns, Models and Profiles, Educational/Informational Resources, and State and Local Public Health Readiness for Interoperability are available for viewing online at www.healthit.gov/isa.