AMERICAN CLINICAL LABORATORY ASSOCIATION

November 9, 2020

Dr. Don Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: ACLA Comments on 2021 ONC Interoperability Standards Advisory (ISA) [Draft for Comment]

Dear Dr. Rucker:

The American Clinical Laboratory Association (ACLA) is pleased to submit our comments in response to the *2021 ONC Interoperability Standards Advisory (ISA) [Draft for Comment]* (hereinafter the "Draft"). We thank you for your previous review of our comments on the 2019 draft ISA and we are appreciative that the ONC adopted several of our suggestions. We appreciate the opportunity to comment on the 2020 Draft.

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA members also have been a vital component of the response to the COVID-19 pandemic, having performed more than 50 million COVID-19 diagnostic and serologic tests to date. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

ACLA applauds your leadership in releasing the Draft in order to further advance health information technology (HIT) interoperability, a critical and vital goal for improving the quality of care for patients. ACLA member laboratories appreciate the opportunity to comment on the Advisory as a living document and hope these comments serve to continue to move interoperability forward.

Thank you for the consideration of ACLA's comments. If there are any questions regarding these comments, please do not hesitate to contact us by phone (202)-637-9466 or via email at jkegerize@acla.com.

Sincerely,

Joan Kegerize, MS, JD
Vice President, Reimbursement and Scientific Affairs

ATTACHMENT: ACLA COMMENTS

General comment:

Please consider adding HL7 Trademarks as defined in the Guide to Using HL7 Trademarks

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The following two items are scheduled for archive (ARCH) or subject to a different comment process (USCDI)

API Resource Collection in Health (ARCH)

https://www.healthit.gov/isa/api-resource-collection-health-arch

The API Resource Collection in Health (ARCH) was proposed in the 21st Century Cures Act NPRM as a standard, but was not included in the Final Rule. This page has been archived for historical purposes only, and will be removed from this site in January 2021.

U.S. Core Data for Interoperability (USCDI)

https://www.healthit.gov/isa/us-core-data-interoperability-uscdi

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

Representing Laboratory Tests

https://www.healthit.gov/isa/representing-laboratory-tests

2020 ISA for 2021 publication

Representing Laboratory Tests

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●○○○○	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 will have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel. ▪ 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.	▪ LOINC Top 2000+ Lab Observations - US Version OID: 1.3.6.1.4.1.12009.10.2.3

ACLA Comment:

- In the Limitations, Dependencies, and Preconditions for Consideration, second bullet, please change 'will' to 'may'. In Conformance language[1] 'may' is equivalent to 'optional'. A LOINC code may not be immediately available from or published by Regenstrief, therefore a laboratory may have to use a local code until an appropriate LOINC code is available and deployed to applicable LIS and EHR systems.
- We are aware that some EHR systems assign LOINC if not provided by the sending laboratory; these mappings should be approved in advance by the Laboratory sending the result. We suggest ONC add an EHR certification question to ascertain if the EHR system is assigning LOINC without the sending laboratory's concurrence, e.g. are you consulting with the sending laboratory regarding the assignment of LOINC.
- Some EHR systems want a 1-to-1 SNOMED CT® mapping to each laboratory result, but this not always the case, especially for microbiology. For example, e-coli and Group A Strep (GAS)/Strep pyogenes (STPY) multiple results can have a single SNOMED CT mapping (many results to one SNOMED CT)
- SNOMED CT expertise can be scarce and expensive from resource perspective; SNOMED CT is a very complicated terminology and may be beyond the expertise of a laboratory technologist.
- There is a low adoption of SNOMED CT, which is due to multiple issues. For example, managing the negation aspect, e.g. "no e-coli" could unintentionally be interpreted as "e-coli" if the negation is not interpreted correctly. We suggest ONC work with industry to provide guidance on these issues.

[1] https://tools.ietf.org/html/rfc2119

Topic: Representing Patient Sex (At Birth)

https://www.healthit.gov/isa/representing-patient-sex-birth

2020 ISA for 2021 publication

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)
▪ 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)

ACLA Comment:

This continues to be an ongoing challenge to laboratories and potentially impacts patient safety. Laboratories need the patient's chromosomal gender to be separate from a patient's identity gender as certain reference ranges are dependent on this information. We recommend ONC assess the various state laws as some states are permitting residents to legally change their birth sex. With these changes being allowed on birth certificates, we recommend ONC consider changing this section from Representing Patient's Sex (at birth) to something like Patient's Biological / Chromosomal Sex.

Additionally, the representation of the patient's biological gender should be similar across all various industries including Lab, Clinician, Pharmacy, etc.

This may require additional LOINC codes.
While the adoption level may be accurate for capturing this data since it is an EHR certification requirement, as a large commercial laboratory, we can assert we are not seeing this data reported from EHR systems, and laboratories may not be ready to accept Sex assigned at Birth because they are currently supporting only HL7 V2 "Administrative Sex".

Section II: Content/Structure Standards and Implementation Specifications

Support the Transmission of a Laboratory's Directory of Services to Provider's Health IT or EHR System

https://www.healthit.gov/isa/support-transmission-a-laboratorys-directory-services-providers-health-it-or-ehr-system

2020 ISA for 2021 publication

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 (US Realm)*	*Balloted Draft*	*Feedback requested*	*Feedback Requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ 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 current version has been harmonized with the most current suite of Lab US Realm Implementation Guides, was updated in the HL7 January 2017 Ballot Cycle, and is pending publication. ▪ 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.

ACLA Comment

- We suggest you re-title the "Applicable Value Set(s) and Starter Set(s)" section; comments do not appear to be related to the current title.
- Please remove the second bullet. The "current version" balloted in January 2017 was published in 2018, it is the "…Release 2, STU Release 3…" version you have listed under "Emerging Implementation Specification", 2nd row in the table above
    - **Or** update to: "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."
- Please add the following FHIR specification which is analogous to HL7 V2 eDOS. It has been tested in multiple FHIR Connectathons, most recently the September 2020 Connectathon, and was balloted in September 2020.

Type-Emerging Implementation Specification

2020 ISA for 2021 publication
Standard Implementation/Specification- HL7 FHIR Order Catalog Implementation Guide/Laboratory Services 0.1.0 - STU Ballot 1 Hyperlink to ballot: http://hl7.org/fhir/uv/order-catalog/2020Sep/index.html **Standards Process Maturity** – Balloted Draft **Implementation Maturity**- Pilot **Adoption Level** – 1 **Federally Required** – No **Cost** – Free **Test Tool Availability –** No

Identify Linkages Between Vendor IVD Test Results and Standard Codes

https://www.healthit.gov/isa/identify-linkages-between-vendor-ivd-test-results-and-standard-codes

2020 ISA for 2021 publication

Exchanging InVitro Diagnostics (IVD) Test Orders & Results

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
For LAW: ▪ LAW – Laboratory Analytical Workflow Profile – The LAW Profile defines the physical connection, message definitions (based on 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.	**For LAW:** The IHE/IICC Laboratory Analytical Workflow (LAW) Profile 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 provides the following capabilities, some not currently supported by LIS2 (ASTM): ▪ Support for IA, CC, hematology, microbiology, and molecular testing ▪ 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

ACLA Comment

The 2nd column 'header' is "Applicable Security Patterns for Consideration" but the comments are not related to security; Suggest you retitle as these comments to not appear to be related to the current time; rather theyseem like general comments

Ordering Labs for a Patient

https://www.healthit.gov/isa/ordering-labs-a-patient

2020 ISA for 2021 publication

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 Value Set(s) and Starter Set(s)
▪ 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.

ACLA Comment:
The 2nd column 'header' is "Applicable Value Set(s) and Starter Set(s)" section, but the comments are not related to the title; Suggest you retitle.

Receive Electronic Laboratory Test Results

https://www.healthit.gov/isa/receive-electronic-laboratory-test-results

2020 ISA for 2021 publication

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
Implementation Specification	NCPDP Specialized Standard, Implementation Guide, Version 2017071	Final	Pilot	●○○○○	Yes	$	Yes
Emerging Standard	*HL7® Implementation Guide for C-CDA Release 2.1: Consolidated CDA for Clinical Notes and C-CDA on FHIR R4*	*Final*	*Production*	●○○○○	*No*	*$*	*No*
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 Value Set(s) and Starter Set(s)
▪ 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. ▪ The HL7® EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1 - US Realm further clarifies sender/receiver responsibilities to achieve end-to-end interoperability for this interoperability need. ▪ See HL7 V2 projects in the Interoperability Proving Ground.	▪ **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. ▪ **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. ▪ **Authentication Enforcer** – centralized authentication processes. ▪ **Authorization Enforcer** – specifies access control policies. ▪ **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). ▪ **Assertion Builder** – define processing logic for identity, authorization and attribute statements. ▪ **User Role** – identifies the role asserted by the individual initiating the transaction. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

The 2nd column 'header' is "Applicable Value Set(s) and Starter Set(s)" section, but the comments are not related to the title; Suggest you retitle.

Re: *NCPDP Specialized Standard, Implementation Guide, Version 2017071*

- Please correct the hyperlink in the Standard/Implementation Specification; it returns an error message: 404 - File or directory not found.
- Please add hyperlink in the "Federally required" column so laboratories can understand the federal requirement
- ACLA members do not have access to the NCPDP link provided in the response. We do not have access to this standard and we do not understand why this standard is here representing lab domain.

Re: *HL7® Implementation Guide for C-CDA Release 2.1: Consolidated CDA for Clinical Notes and C-CDA on FHIR R4*

- Please separate the two C-CDA references, this refers to two distinct implementation guides, one that is Clinical Document Architecture (CDA) based and one that is Fast Healthcare Interoperability Resources (FHIR) based

1. The proper title is: HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm
    - Remove $ in 'Cost' column; HL7 standards are available with no fee license.
2. The proper title is: C-CDA on FHIR Implementation Guide (IG)
    - The hyperlink for C-CDA on FHIR is: http://hl7.org/fhir/us/ccda/history.html This lists multiple versions; the latest version published in 2018 is a STU (standard for trial use)
    - Please change the Standards Maturity from 'Final' to 'Balloted Draft' (because it is a STU).
    - Remove $ in 'Cost' column; HL7 standards are available with no fee license.

Electronic Transmission of Reportable Lab Results to Public Health Agencies

https://www.healthit.gov/isa/electronic-transmission-reportable-lab-results-public-health-agencies

2020 ISA for 2021 publication

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

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. • 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 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.	• **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). • **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.

ACLA Comment:
We suggest the ONC re-clarify the title which is a mix of Value Sets and security pattern references.

Public Health Reporting/Reporting Cancer Cases to Public Health Agencies

https://www.healthit.gov/isa/reporting-cancer-cases-public-health-agencies

2020 ISA for 2021 publication

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*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Security Patterns for Consideration
▪ Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting 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 (VSCB), however it references the HL7 V 2.5.1 standard and LOINC, and has been sponsored by a number of organizations working in the cancer registry space. ▪ See CDA 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. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

ACLA Comment:

In the 2020 ISA update, the NAACCR implementation specification was changed to "Federally required" and "Yes". Please add a hyperlink indiciating the source of federal requirement which has apparently changed since the 2019 publication of the ISA (see 2019 screen print below).

2019 (referenced in 2020 comment)

Text:

Reporting Cancer Cases to Public Health Agencies

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, August 2012	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	Feedback Requested	No	Free	No
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
▪ 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 (VSCB), however it references the HL7 V 2.5.1 standard and LOINC, and has been sponsored by a number of organizations working in the cancer registry space. ▪ See CDA 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. ▪ **Purpose of Use** - Identifies the purpose for the transaction.

Specialty Care and Settings

Interoperability for COVID-19 Novel Coronavirus Pandemic

https://www.healthit.gov/isa/covid-19

2020 ISA for 2021 publication

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
Emerging Implementation Specification	*Logica COVID-19 (FHIR v4.0.1) Implementation Guide CI Build*	*In Development*	*Feedback requested*	*Feedback Requested*	*No*	*Free*	*N/A*
Emerging Implementation Specification	*HL7 FHIR (v4.0.1) Situational Awareness for Novel Epidemic Response (SANER) IG 0.1.0 Continuous 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 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) ▪ 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. ▪ 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	▪ VSAC Value Set - COVID_19 (Disorders) (ICD10CM) Contains non-specific coronavirus codes ▪ VSAC Value Set - 2019 Novel Coronavirus COVID 19 SNOMED CT Codeset ▪ VSAC Value Sets - CDC/FDA In vitro Diagnostic Tests, Specimens and Results Codes ▪ LOINC terms for SARS-CoV-2 and COVID-19 related concepts ▪ AMA CPT coding and guidance for COVID-19

ACLA Comment:

Please add hyperlinks in the "Federally Required" column when Federally Required is 'Yes'

Please revise both hyperlinks for Logica (https://covid-19-ig.logicahealth.org/index.html) to reference the official HL7 Logica webpage: http://hl7.org/standards/hsp-marketplace/index.html. The current ISA LOGICA hyperlink is to a non-HL7 website; HL7 projects must be hosted on an HL7 website per HL7 policy.

Please add more links to the information provided on COVID-19.

The SANER specification is being balloted by HL7 for the early January 2021 ballot cycle; it is an official HL7 project. Please change the status to "Balloted Draft".

Please add reference to additional HHS artifacts which ultimately reference HL7, LOINC, and SNOMED standards:

- June 4, 2020 HHS mandate: COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
- COVID-19 Lab Data Reporting Implementation Specifications: https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf
    - This document (last column) references HL7 Field and HL7 V2 Guidance: https://confluence.hl7.org/display/OO/Proposed+HHS+ELR+Submission+Guidance+using+HL7+v2+Messages

Appendix I – Sources of Security Standards and Security Patterns

https://www.healthit.gov/isa/appendix-i-sources-security-standards-and-security-patterns

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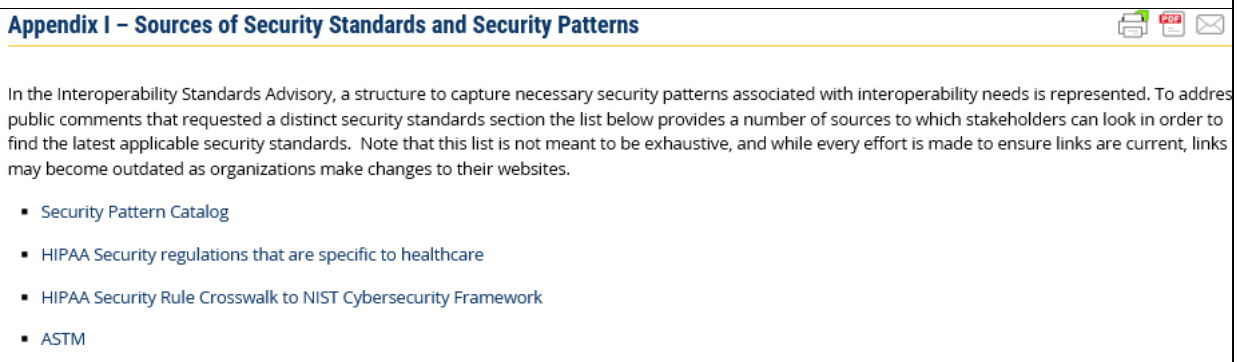

Appendix I – Sources of Security Standards and Security Patterns

In the Interoperability Standards Advisory, a structure to capture necessary security patterns associated with interoperability needs is represented. To addres public comments that requested a distinct security standards section the list below provides a number of sources to which stakeholders can look in order to find the latest applicable security standards. Note that this list is not meant to be exhaustive, and while every effort is made to ensure links are current, links may become outdated as organizations make changes to their websites.

- Security Pattern Catalog
- HIPAA Security regulations that are specific to healthcare
- HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework
- ASTM

Appendix II - Models and Profiles

https://www.healthit.gov/isa/appendix-ii-models-and-profiles

HL7 Standards - Section 1: Primary Standards

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HL7 Standards - Section 1: Primary Standards

Section 1 Primary standards are the most popular standards integral for system integrations, and interoperability. Most frequently used and in-demand standards are in this category. (This section also includes the Version 2 and Version 3 solution sets, which encompass all standards relative to that version. HL7's primary standards and other select products are licensed at no cos. Additional information can be found at HL7's licensing cost update.)

ACLA Comment:

Please correct typo, 'cos' to 'cost'

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

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ACLA Comment: **No suggested comment, but note that some items were changed, but new entries added used 'lab' instead of 'laboratory'.**