AMERICAN CLINICAL LABORATORY ASSOCIATION

September 30, 2021

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: ACLA Comments: ONC Interoperability Standards Advisory (ISA) for the 2022 ISA Reference Edition

Dear Dr. Tripathi,

The American Clinical Laboratory Association (ACLA) is pleased to submit our comments in response to the *2022 ONC Interoperability Standards Advisory (ISA) [Draft for Comment]* (hereinafter the "Draft"). Thank you for the opportunity to comment on the 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. ACLA works to advance the next generation of health care delivery through policies 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 COMMENT

Comments due: September 30, 2021
Submit Comments: https://www.healthit.gov/isa/about-isa - scroll down to "Log in or register to post comments"

The following comments are submitted by the American Clinical Laboratory Association (ACLA)
Thank you for the opportunity to comment on the ISA.

General comment:
For any reference to 'lab' we suggest changing to 'laboratory' to promote usability of the guide.

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

Representing Laboratory Tests

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

2021-09-13 screen print

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 will have the same LOINC® code for the order and the result or will 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

2021 ISA for 2022 publication

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' and 'will' is not defined as a conformance verb in RFC 2119. 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.
    - Extract from RFC 2119: The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in RFC 2119.

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

Topic: Representing Patient Sex (At Birth)

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

2021-09-13 screen print

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")

ACLA Comment:

This continues to be an ongoing challenge to laboratories and potentially impacts patient safety. Laboratories need the patient's biological / chromosomal sex data to be distinct and separate from a patient's "gender identity[1]" as certain reference ranges are dependent on the patient's biological or chromosomal sex information. We recommend ONC evaluate the various state laws as some states are permitting residents to legally change their birth sex and/or enter a value other than Male or Female. 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. We are aware that HL7's Gender Harmony project has published an Informative document[2] defining "Sex for Clinical Use" (SFCU) but we do not believe this concept is semantically equivalent to the patient's biological or chromosomal sex.

Additionally, the representation of the patient's biological or chromosomal sex should be similar across all various industries including Laboratory, 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 as a patient demographic data element because they are currently supporting only HL7 V2 "Administrative Sex".

[1] *From USCDI V2 published July 2021 Gender Identity defined as "A person's internal sense of being a man, woman, both, or neither.*

[2] HL7 Standards Product Brief - HL7 Informative Document: Gender Harmony - Modeling Sex and Gender Representation, Release 1 | HL7 International

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

2021-09-13 screen print

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*
Emerging Implementation Specification	*HL7 FHIR Order Catalog Implementation Guide/Laboratory Services 0.1.0 - STU Ballot 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.

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ACLA Comment:

We support these comments submitted by HL7:

ISA eDOS comments for 2022

Additionally, we suggest that when you add Release 3.1 that you delete the older Release 3. Release 3.1 supports COVID-19 reporting requirements for DHHS and CDC.

Add:

- HL7 Version 2.5.1 Implementation Guide: Standards & Interoperability (S&I) Framework Laboratory Test Compendium Framework (eDOS) Release 2, STU Release 3.1 (US Realm)
- HL7 Version 2.5.1 Implementation Guide: Standards & Interoperability (S&I) Framework Laboratory Test Compendium Framework (eDOS) Ask at Order Entry (AOE) Release 2, STU Release 3.1 (US Realm)

Delete:

- HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework (eDOS) Release 2, STU Release 3 (US Realm)

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

2021-09-13 screen print

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-119S.	**For LAW:** The IHE/IICC Laboratory Analytical Workflow (LAW) Profile defines plug-n-play connectivity between instruments, middleware, and LIS syste laboratory. It standardizes the data flow of IVD patient and QC test work order steps and results. LAW provides the following capabilities, su 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 ; these seem like general comments

It is our understanding HL7 FHIR Implementation Guides are licensed, but there is not fee. Please confirm with HL7 and, if appropriate, remove the $ and replace with free in Cost column for the HL7® FHIR® Implementation Guide - LOINC/IVD Mapping (LIVD) R1 (STU).

Ordering Labs for a Patient

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

2021-09-13 screenprint

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.

ACLA Comment:

The quality of the data in the laboratory order from the provider may impact the laboratory result time to response and content, as we learned during the COVID-19 pandemic.

We suggest that ONC sponsor an HL7 project to develop US Core FHIR IG for laboratory order. Currently it's a "Future Candidate".

From HL7 FHIR:
Future Candidate Requirements Under Consideration
http://hl7.org/fhir/us/core/future-of-US-core.html#future-candidate-requirements-under-consideration
ServiceRequest - The CDS hooks community, and other implementers are gathering requirements for the ServiceRequest Resource.

Receive Electronic Laboratory Test Results

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

2021-09-13 screenprint

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	Production	●○○○○	Yes	$	No
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 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.	▪ **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:

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

- Please update the hyperlink in the "Federally required" column so implementers can understand the federal requirement. Most Federally Required hyperlinks are to a Federal Register posting. The NCPDP "Federally Required" hyperlink is to a NCPDP web page which does not explain the federal requirement.
- Implementers, including ACLA members, do not have access to the (National Council for Prescription Drug Programs) NCPDP link provided in the response. You must pay $750 to become a NCPDP member to download a standard. We do not have access to this standard and we do not understand why this NCPDP standard is included in content representing laboratory domain since NCPDP typically deals with medications.

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 so they are listed separately on two distinct rows. This entry 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.

- Please add US Core DiagnosticReport Profile for Laboratory Results Reporting as an "Emerging Standard"

Electronic Transmission of Reportable Lab Results to Public Health Agencies

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

2021-09-13 screenprint

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
▪ **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 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.	▪ **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:

EHRs should report required information with eCR (electronic case reporting) so ancillary information that does not pertain to laboratories does not have to be added to the ELR.

Specialty Care and Settings

Interoperability for COVID-19 Novel Coronavirus Pandemic

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

2021-09-13 screenprint

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*	*Balloted Draft*	*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 FY2021 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.
• 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 form and manner outlined in this memo "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 June 4, 2020"
	• COVID-19 Related Value Sets in NLM Value Set Authority Center
	• LOINC terms for SARS-CoV-2 and COVID-19 related concepts
	• AMA CPT coding and guidance for COVID-19
	• AMA CPT New SARS-CoV-2 Vaccine Codes

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.

The SANER specification was published by HL7. Please update the hyperlink to the published version at: HL7 FHIR® Implementation Guide: Situational Awareness for Novel Epidemic Response (SANER) STU 1. The current hyperlink is to HL7 FHIR's 'build' environment which is preparatory to balloting and publication. (build.fhir.org/ig/HL7/fhir-saner/)

Please update:

- CARES Act Section 18115 require laboratories to report results of SARS-CoV2 or COVID-19 testing to the Secretary of HHS in the form and manner outlined in this memo "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 June 4, 2020" and updated January 8, 2021

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

- 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