AMERICAN CLINICAL LABORATORY ASSOCIATION

April 18, 2022

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: United States Core Data for Interoperability (USCDI) v3
[Draft for Comment]

Dear Dr. Tripathi,

The American Clinical Laboratory Association (ACLA) is pleased to submit our comments in response to the *United States Core Data for Interoperability (USCDI) v3 [Draft for Comment]* (hereinafter the "Draft"). We appreciate the opportunity to comment on the Draft Version 3.

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 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 Draft and hope these comments serve to continue to move interoperability forward.

We thank ONC for its consideration of our comments. Please contact me at 202-637-9466 or jkegerize@acla.com with any questions.

Sincerely,

Joan Kegerize
Vice President for Reimbursement & Scientific Affairs

ATTACHMENT: ACLA COMMENTS

The following comments are submitted by the American Clinical Laboratory Association:
Thank you for the opportunity to comment on the USCDI.

Proposed USCDI V3 Additions for Laboratory Data Class:

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Specimen Type *Type of specimen (e.g., nasopharyngeal swab, whole blood, serum, urine, wound swab) on which a lab test is performed.*	
Result Status *Representing the stage of completeness of a result of a laboratory test.*	

Laboratory/Specimen Type

https://www.healthit.gov/isa/taxonomy/term/2491/draft-uscdi-v3

Data Element:
Specimen Type
Type of specimen (e.g., nasopharyngeal swab, whole blood, serum, urine, wound swab) on which a lab test is performed.

Original Submission:
From CDC: | Interoperability Standards Advisory (ISA) (healthit.gov)

ACLA Comment:
These comments pertain to the "Applicable Vocabulary Standard(s)" which might be named in future USCDI versions.

The original submission from CDC specifies LOINC as an applicable standard, however the hyperlink is to PHINVADs vocabulary "hot topics" page: If you search for "Specimen Type" there are at least 13 different value sets for Specimen Type. If/when ONC cites vocabulary standard(s), please provide a hyperlink which is a direct link to the applicable vocabulary.

The CDC submission also references Supporting Artifacts which "…are standard elements in HL7 laboratory messaging: https://www.cdc.gov/elr/index.html".

HL7's electronic laboratory reporting (ELR) Implementation Guide that was cited for Meaningful Use Stage 1: "HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)". The ELR requires V2.5.1 HL7 Table 0487 for Specimen Type table, which is obviously not LOINC codes. This inconsistent reference to multiple terminologies in the original submission may impede interoperability without clarifying the contextual definition. Specimen type may not be populated (although SPM-4 is required in ELR) but some PHAs prefer specimen source (OBR-15), which has been deprecated in HL7, to be reported instead.

When ONC cites vocabulary standards for this data element, we suggest the HL7 V2 terminology referenced in the ELR be cited since the ELR IG is referenced in Meaningful Use (as of Stage 1) and deployed in all US Public Health Agencies. Some PHAs prefer SNOMED CT for specimen type, however the SNOMED terminology is not totally in synch with HL7 Table 0487 values referenced in the ELR. There is a mapping

from HL7 Table 0487 to SNOMED CT which might be referenced as a resource; it is available here: Conceptmap-example-specimen-type - FHIR v4.0.1 (hl7.org).

ELR: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98

Laboratory/Result Status

https://www.healthit.gov/isa/taxonomy/term/2441/draft-uscdi-v3

Data Element:
Representing the stage of completeness of a result of a laboratory test.

Original Submission:
From CDC: | Interoperability Standards Advisory (ISA) (healthit.gov)

ACLA Comment:
Please clarify the result status element and whether it is for the panel or each individual test. For example, a Complete Blood Count (CBC) is the panel, and the White Blood Count (WBC) is one individual test within the panel.

The standards referenced in the original submission do not include HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI); Release 1 (US Realm) which was required by Meaningful Use Stage 2 and the HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) required for Meaningful Use Stage 1 and currently used for COVID-19 and other STLT health department reporting.

When ONC cites vocabulary standards, we suggest the HL7 V2 terminology referenced in the LRI and ELR be cited as a required terminology since these terminologies are currently used for laboratory result reporting.

LRI: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279

ELR: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98