AMERICAN CLINICAL LABORATORY ASSOCIATION

April 12, 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: United States Core Data for Interoperability (USCDI) v2
[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) v2 [Draft for Comment]* (hereinafter the "Draft"). We appreciate the opportunity to comment on the Draft Version 2.

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 ACLA:
Thank you for the opportunity to comment on the USCDI.

General comment:

Please consider adding HL7 Trademarks as specified in the Guide to Using HL7 Trademarks.
It would be helpful to have a definition for each data class and data element.

Care Team Member(s)

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Text:

Provider Identifier - APPLICABLE STANDARD(S)

DATA ELEMENT	APPLICABLE STANDARD(S)
Provider Identifier DRAFT v2	

ACLA Comment:
We suggest individual NPI as the applicable standard (not group NPI).

Encounter Information

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Text:

Encounter Type - APPLICABLE STANDARD(S)

DATA ELEMENT	APPLICABLE STANDARD(S)
Encounter Type DRAFT v2	

ACLA Comment:
This must be defined in order to be useful because there are varied interpretations. Episode and encounter are often challenging in industry and we recommend definitions for each. Please consider referencing existing HL7 standards if possible.

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Text:

Encounter Time – DATA ELEMENT and APPLICABLE STANDARD(S)

DATA ELEMENT	APPLICABLE STANDARD(S)
Encounter Time DRAFT v2	

ACLA Comment:
This must be defined in order to be useful because there are varied interpretations. For example, is this the time of the encounter, the time expended, elapsed time of the encounter (as suggested by AMA for CPT encoding) etc. If this is the start/stop time of the encounter, then suggest using an established time format (e.g. HL7 format) including time zone.

Laboratory

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Text:

Values/Results - APPLICABLE STANDARD(S)

DATA ELEMENT	APPLICABLE STANDARD(S)
Values/Results *Outcome of the examination of a tested specimen.*	

ACLA Comment:

When reporting values and results for applicable tests USCDI should use an established, previously adopted standard. For example, when representing microbiology we recommend using SNOMED CT. This is consistent with the HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI) Release 1 that ONC previously adopted for Meaningful Use Stage 2.

Patient Demographics

As different groups are beginning to tackle patient sex and gender identity, there may be competing and/or duplicative efforts that need to be harmonized with patient demographics. For example, social determinants of health (SDOH) is driving many initiatives within the ONC, HL7, FHIR and federal and state regulations. We encourage harmonization across different standards bodies so there is a unified approached of how things should be messaged. There is still much confusion in the industry whether attributes such as race and sex, are demographics or observations.

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Text:

Birth Sex - APPLICABLE STANDARD(S)

DATA ELEMENT	APPLICABLE STANDARD(S)
Birth Sex	• Birth sex must be coded in accordance with HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor (https://www.healthit.gov/sites/default/files/170299_f_29_hl7_v3_agender_and_nullflavor.pdf) attributed as follows: 1. Male. M 2. Female. F 3. Unknown. nullFlavor UNK

ACLA Comment:

Please clarify that only the three above values must be supported and not all the nullFlavors in the spreadsheet.

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There are growing concerns with demands for laboratories to report additional data related to sex/gender. For example, California requires reporting of Sexual Orientation and Gender Identity (SOGI) for public health reportable results. ONC required EHRs to collect SO and GI for 2015 certification per Demographics certification requirements: Paragraphs (a)(5)(i)(D) and (E), but not to exchange the data. We note that ONC has proposed SO and GI elements for future adoption, currently in USCDI Level 2. Additionally, HL7 has recently balloted a Gender Harmony Informative Document that suggests additional terms.

ONC announced Project US@ – a Unified Specification for Address in Health Care. While we agree that harmonizing address is an important endeavor, the landscape for gender identity has gained significant traction where we believe harmonizing terminology and requirements for "Gender Harmony" is equally important. We suggest that ONC expand the scope of the standards harmonization to not only include Project US@, but also drive the interoperability needs for sex/gender orientation, identity and concepts within the healthcare industry. We believe the clinical and technical community would participate and appreciate guidance in this area and even participate in summits, surveys, town halls and any other workgroup setting ONC prefers.

Race

Page 10

Text: Race

DATA ELEMENT	APPLICABLE STANDARD(S)
Race	• The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (https://obamawhitehouse.archives.gov/omb/fedreg_1997standards) • CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (https://www.cdc.gov/phin/resources/vocabulary/index.html)

ACLA Comment:

From a laboratory perspective it is only a single race and single ethnicity that is populated.

We suggest that ONC include the rolled up CDC tabular view below which is easier to read.

Code	Description
1002-5	American Indian or Alaska Native
2028-9	Asian
2054-5	Black or African American
2076-8	Native Hawaiian or Other Pacific Islander
2131-1	Other Race
2106-3	White

Ethnicity

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Text: Ethnicity

DATA ELEMENT	APPLICABLE STANDARD(S)
Ethnicity	• The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (https://obamawhitehouse.archives.gov/omb/fedreg_1997standards) • CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (https://www.cdc.gov/phin/resources/vocabulary/index.html)

ACLA Comment:

We suggest that ONC include the rolled up CDC tabular view below which is easier to read.

Code	Description
2135-2	Hispanic or Latino
2186-5	Not Hispanic or Latino
	Unknown[1]

Additionally, while 'Unknown' is not in the CDC table, it is in HL7 V2 Table 0189 Ethnic Group."

[1] We are suggesting 'Unknown' as an additional code not in the CDC definition. For example: 'Unknown' is not in the CDC table, it is in HL7 V2 Table 0189 Ethnic Group.