AMERICAN CLINICAL LABORATORY ASSOCIATION

April 17, 2023

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) v4
[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) v4 [Draft for Comment]* (hereinafter the "Draft"). We appreciate the opportunity to comment on the Draft Version 4.

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 V4 Additions for Laboratory Data Class:

I. Result Reference Range

Upper and lower limit of test values expected for a designated population of individuals. Usage note: reference range values may differ by patient characteristics, laboratory test manufacturer and laboratory test performer.

II. Result Unit of Measure

Unit of measurement to report laboratory test results so that they can be compared. Usage note: required when the test result value is numeric.

III. Specimen Condition and Disposition

Indication whether a specimen was acceptable and reason for rejection if unacceptable

I. Result Reference Range

https://www.healthit.gov/isa/taxonomy/term/7696/draft-uscdi-v4
Submitted By: CDC

Applicable Standard(s): The Unified Code for Units of Measure (UCUM) https://ucum.org/ucum.html \
Estimate of Overall Burden: Very low burden. This element should already be part of the EHR due to its laboratory regulatory requirement (CLIA)
ACLA Comments: These comments pertain to the burden of using the Unified Code for Units of Measure (UCUM). Using only the UCUM as a standard is problematic and the burden would be very high using this standard. The UCUM cannot be used when it is not supported by the analytic procedure's documentation for an FDA authorized, cleared, or approved method. Existing interfaces should not be required to update to the UCUM. (Note: the FDA approved units must be used for reporting, regardless of the standard used).

II. Result Unit of Measure

https://www.healthit.gov/isa/taxonomy/term/7706/draft-uscdi-v4#uscdi-proposal-mode-uscdi-data-element-page-display
Submitted By: CDC

Applicable Standard(s): The Unified Code for Units of Measure (UCUM) https://ucum.org/ucum.html \
Estimate of Overall Burden: Very low burden. This element should already be part of the EHR due to its laboratory regulatory requirement (CLIA)
ACLA Comments: These comments pertain to the burden using Unified Code for Units of Measure (UCUM). Using only the UCUM as a standard is problematic and the burden would be very high using this standard. The UCUM cannot be used when it is not supported by the analytic procedure's documentation for an FDA authorized, cleared, or approved method. Existing interfaces should not be required to update to UCUM. (Note: the FDA approved units must be used for reporting, regardless of the standard used).

III. Specimen Condition and Disposition

https://www.healthit.gov/isa/taxonomy/term/7691/draft-uscdi-v4#uscdi-proposal-mode-uscdi-data-element-page-display
Submitted By: College of American Pathologists

Applicable Standard(s): SNOMED CT
Estimate of Overall Burden: Very low burden. This element should already be part of the EHR due to its laboratory regulatory requirement (CLIA)
ACLA Comments: These comments pertain to the burdens using SNOMED CT. Using only SNOMED CT for specimen condition data element content is problematic as this data element has not been tested at scale. The burden would be very high using SNOMED CT values lieu of HL7 table values. We propose the use of either HL7 table or SNOMED CT as acceptable values.