Regenstrief Institute
Health Data Standards

May 5, 2025

Mr. Steven Posnack, MS, MHS
Acting Assistant Secretary for Technology Policy
Acting National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:

https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#comment-form

Re: ASTP's Draft United States Core Data for Interoperability (USCDI) Version 6

Dear Mr. Posnack:

The Regenstrief Institute welcomes the opportunity to submit comments on ASTP's Draft United States Core Data for Interoperability (USCDI) Version 6 and related data classes standards and elements. The Regenstrief Institute is a local, national, and global leader with a vision to provide pioneering transformative, interdisciplinary solutions for a healthier and more equitable world. A key research partner to Indiana University, Regenstrief and its research scientists are responsible for a growing number of major healthcare innovations and studies. Regenstrief is also the steward for Logical Observations Identifiers Names and Codes (LOINC®) and the Unified Code for Units of Measure (UCUM). A key part of our mission is to develop and advance the adoption of data standards that enable efficient transmission, understanding, and use of health data.

Our comments for USCDI v6 (summarized on pages 2-7), are intended to augment the USCDI with critical input and support its use in facilitating information exchange and interoperability goals.

If there are questions regarding our comments, please contact Marjorie Rallins, DPM, MS, Executive Director, Health Data Standards at mrallins@regenstrief.org or 317-274-9415.

We appreciate and look forward to continued collaboration with ASTP.

Sincerely,

Marjorie C. Rallins

Marjorie Rallins, DPM, MS
Executive Director
Regenstrief Institute Health Data Standards

Enclosure: Regenstrief Institute Health Data Standards Response Summary

Regenstrief Institute
Health Data Standards

Regenstrief Institute Response Summary

Office of the National Coordinator for Health Information Technology (ASTP)

United States Core Data for Interoperability (USCDI) Standard (Draft Version 6)

Submitted electronically to:

https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#comment-form

New USCDI V6 Data Elements

Data Class: Facility Information
Data Element: Facility Address – Physical location of available services or resources
Vocabulary: FHIR DSTU2, 3 and 4, CDA Release 2.0, HL7 V2 PL Data Type https://bit.ly/FHIRLocation
Comment: We support the use of FHIR DSTU2, 3 and 4, CDA Release 2.0, HL7 V2 PL Data Type for the Facility Address data element.

Data Class: Medical Devices
Data Element: Unique Device Identifier – Numeric or alphanumeric code that uniquely identifies a medical device. Usage note: Contains a device identifier (DI) and one or more production identifiers (PI).
Vocabulary: FDA Unique Device Identification System (UDI System) https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-rule-guidances-training-and-other-resources#rule
ASTP Question: *ASTP seeks feedback on whether Unique Device Identifier (UDI) should be one or two data elements (Unique Device Identifier—Implantable and Unique Device Identifier—Non-implantable). Is there an impact on standards development or information exchange to use one data element, Unique Device Identifier, to include both implantable and non-implantable devices?* **Comment:** We recommend a single data element to capture the UDI to facilitate data exchange across healthcare organizations. We recommend FDA Unique Device Identification (UDI) System as the vocabulary to represent the UDI data element.

Data Class: Orders
Data Element: Portable Medical Order – Provider-authored request for end-of-life or life-sustaining care for a person who has a serious life-limiting medical condition.

Usage note: These are meant to follow a person regardless of when and where such an order might be needed (e.g., hospital, care facility, community, home). There are variations in requirements and names for portable medical orders based on jurisdiction.Examples include but are not limited to POLST (Portable Medical Order for Life-Sustaining Treatment), MOLST (Medical Orders for Life-Sustaining Treatment), and out-of-hospital DNR (do-not-resuscitate).
Vocabulary: SNOMED CT ICD-10 CPT Examples: Comfort Measures SNOMED CT Value set: 1.3.6.1.4.1.33895.1.3.0.45 Hospice Care Ambulatory Value set: 2.16.840.1.113883.3.526.3.1584 ICD-10 Encounter for palliative care: Z51.5 HL7 Service Type value set: https://www.hl7.org/fhir/valueset-service-type.html, https://vsac.nlm.nih.gov/valueset/expansions?pr=ecqm
Comment: Portable Medical Orders are multi-component statements that can be computably shared using FHIR, such as described by the PACIO STU available here: https://build.fhir.org/ig/HL7/fhir-pacio-adi/index.html. Some elements of this information might be represented using the value set already identified but critical elements require the use of LOINC document codes as identified in the linked PACIO IG, for example the 100821-8 National POLST form, that includes the use of **ADIDocumentationTypeVS** (http://hl7.org/fhir/us/pacio-adi/ValueSet/ADIDocumentationTypeVS) that includes LOINC 81352-7, 81351-9, 42348-3, as well as many SNOMED CT codes. The Regenstrief Institute urges ASTP to be cautious about the alignment of the provided example value sets as sufficient representations of portable medical orders.

Data Class: Patient Summary Plan
Data Element: Care Plan – Shared plan informed by members of a coordinated care team that details conditions, needs, and goals along with strategies for addressing them. Usage notes: Includes prioritized problems, health concerns, assessments, goals, and interventions from across care settings. Examples include nursing care plan, diabetic care plan, multiple chronic conditions care plan, and long-term services and support care plan.
Vocabulary: None specified
ASTP Question: *We are seeking feedback on the scope and definition of the draft Care Plan data element for USCDI. At a minimum, this data element includes the*

capability to exchange prioritized problems, health concerns, assessments, goals, and interventions. Do these minimum components reflect the common elements across different care plan types? Does the USCDI data element definition provide enough information for developers to implement the capability to exchange Care Plan? **Comment:** We support the minimum recommendations for the care plan data elements.

Data Class: Problems
Data Element: Date of Onset – Date or estimated date when signs or symptoms of a condition began. Usage note: This may be a specific day, week, month, or year, or it may be an estimate.
Vocabulary: None specified
Comment: We recommend SNOMED CT for data element Date of Onset. We recommend using the most recent version of the vocabulary available to the user.

Data Class: Problems
Data Element: Family Health History – Family member's health conditions that are relevant to a patient's care.
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2025
Comment: We recommend SNOMED CT for data element Problems. Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Updated Data Elements

Data Class: Orders
Data Element: Medication Order CHANGE: Include RxNorm as the applicable standard
Vocabulary: RxNorm
Comment: We recommend RxNorm to represent the data element Medication Order.

Data Class: Orders
Data Element: Laboratory Order CHANGE: Identifies LOINC as the standard to use - version 2.78

Vocabulary: LOINC 2.78
Comment: We recommend LOINC as the vocabulary to represent Laboratory Orders. Rather than specifying a specific version of LOINC we recommend using the most recent version of LOINC available to the user.

Data Class: Orders
Data Element: Diagnostic Imaging Order CHANGE: Include LOINC as the applicable standard
Vocabulary: LOINC 2.78
Comment: We recommend LOINC as the vocabulary to represent Diagnostic Imaging Orders. Rather than specifying a specific version of LOINC we recommend using the most recent version of LOINC available to the user.

Data Class: Orders
Data Element: Clinical Test Order CHANGE: Include LOINC as the applicable standard
Vocabulary: LOINC 2.78
Comment: We recommend LOINC as the vocabulary to represent Clinical Test Orders. Rather than specifying a specific version of LOINC we recommend using the most recent version of LOINC available to the user.

Data Class: Procedures
Data Element: Performance Time CHANGE: Revised examples to: "Examples include but are not limited to vaccine or medication administration times, surgery start time, time ultrasound performed, and laboratory specimen collection time."
Vocabulary: LOINC 2.78
Comment: We recommend LOINC as the vocabulary to represent Performance Time. Rather than specifying a specific version of LOINC we recommend using the most recent version of LOINC available to the user.

Data Class: Health Status Assessments
Data Element: SDOH Assessment CHANGE: Updated to LOINC version 2.78 CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: LOINC 2.78 SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend LOINC, SNOMED CT and ICD 10 as the vocabularies to represent Health Status Assessments. We recommend LOINC to represent screening

assessments, assessment questions, and assessment answers. We recommend SNOMED CT to represent diagnoses, goals, procedures, and service requests. We recommend ICD 10 to represent diagnoses. Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Data Class: Laboratory
Data Element: Result Unit of Measure CHANGE: UCUM updated from 2.1 to 2.2 CHANGE: Definition is now: Unit of measurement to report quantitative laboratory test results
Vocabulary: UCUM 2.2
Comment: We recommend UCUM to represent Result Unit of Measure. Rather than specifying a specific version of a standard we recommend using the most recent version of the standard available to the user.

Data Class: Allergies and Intolerances
Data Element: Reaction CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend SNOMED CT to represent Allergies and Intolerances. Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Data Class: Laboratory
Data Element: Value/Results CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend SNOMED CT to represent Laboratory Value/Results. Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Data Class: Laboratory
Data Element: Specimen Type CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend SNOMED CT to represent Specimen Type.

Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Data Class: Laboratory
Data Element: Specimen Source Type CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend SNOMED CT to represent Specimen Source Type Rather than specifying a specific version of a vocabulary we recommend using the most recent version of the vocabulary available to the user.

Data Class: Laboratory
Data Element: Result Unit of Measure CHANGE: Updated to UCUM updated from 2.1 to 2.2
Vocabulary: UCUM 2.2
Comment: We recommend UCUM to represent Result Unit of Measure Rather than specifying a specific version of a standard we recommend using the most recent version of the standard available to the user.

Data Class: Laboratory
Data Element: Result Reference Range CHANGE: Updated to UCUM updated from 2.1 to 2.2
Vocabulary: UCUM 2.2
Comment: We recommend UCUM to represent Result Reference Range Rather than specifying a specific version of a standard we recommend using the most recent version of the standard available to the user.

Data Class: Laboratory
Data Element: Specimen Condition Acceptability CHANGE: Updated to SNOMED US Edition September 2024
Vocabulary: SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release
Comment: We recommend SNOMED CT to represent Specimen Condition Acceptability. Rather than specifying a specific version of vocabulary, we recommend using the most recent version of the vocabulary available to the user.