JULY 2024
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability **PROPOSED RULE**

USCDI Version 4

ONC
Office of the National Coordinator for Health Information Technology

A New Baseline Version of USCDI

The United States Core Data for Interoperability (USCDI) standard in § 170.213 is a baseline set of data that can be commonly exchanged across care settings for a wide range of uses and is a required part of ONC Health IT Certification Program (Program) criteria. ONC proposes to update the USCDI standard in § 170.213 by adding USCDI v4 and establishing an expiration date of January 1, 2028 for USCDI v3 for purposes of the Program.

What's Being Proposed?

- Update the USCDI standard in § 170.213 by adding USCDI v4 and establishing an expiration date of January 1, 2028 for USCDI v3 for purposes of the Program.
- Add USCDI v4 in § 170.213(c) and incorporate it by reference in § 170.299.
- Health IT Modules to accommodate USCDI v4 data elements using the Fast Health Interoperability Resources (FHIR®) US Core Implementation Guide Version 7.0 in § 170.215(b)(1)(iii) and the HL7 Consolidated CDA (C-CDA), Version 3.0.0 – STU3 in § 170.205(a)(1).

Background

Based on feedback ONC received through the ONC New Data Element and Class submission system and other public feedback, ONC released Draft USCDI v4 in January 2023. Draft USCDI v4 included 20 new data elements and one new data class as well as updated minimum standard code set versions. ONC then finalized and released USCDI v4 in July 2023 with four additional data elements in the Medications data class.

ONC uses a predictable, transparent, and collaborative process to expand USCDI, including providing the opportunity for public comment. Additionally, health IT developers can use the Standards Version Advancement Process (SVAP) to voluntarily implement and use the most recent National Coordinator-approved version of USCDI without waiting for ONC to require that newer version via rulemaking. ONC uses a public comment process to identify newer versions of standards for approval by the National Coordinator as part of SVAP. As of September 2023, USCDI v3 became available for voluntary certification through SVAP, and in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, USCDI v3 was adopted as the baseline standard within the Program beginning January 1, 2026.

Benefits

The adoption of USCDI v4 would enable more accurate and complete patient-centered data capture and exchange, as well as standardize more data supporting behavioral health and marginalized and underserved communities. The use of USCDI v4 would also support data users' abilities to identify, assess, and analyze gaps in care, which could in turn be used to inform and address the quality of healthcare through interventions and strategies.

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Certification Criteria That Reference USCDI

The USCDI standard is currently cross-referenced in certain certification criteria. A Health IT Module can be certified to any of these criteria by ensuring that it complies with any of the USCDI versions included in § 170.213 that have not expired and have been made available for update through SVAP. The criteria cross-referencing to USCDI are:

- "Care coordination - Transitions of care - Create" (§ 170.315(b)(1)(iii)(A)(*1*) and (*2*));
- "Care coordination - Clinical information reconciliation and incorporation - Reconciliation" (§ 170.315(b)(2)(iii)(D)(*1*)-(*3*));
- "Decision support interventions – Decision support configuration" (§ 170.315(b)(11)(ii)(A) and (B) and (iv)(A)(*5*)-(*13*));
- "Patient engagement - View, download, and transmit to 3rd party - View" (§ 170.315(e)(1)(i)(A)(*1*) and (*2*), and (iii));
- "Transmission to public health agencies – electronic case reporting" (§ 170.315(f)(5)(i)(C)(*2*)(*i*));
- "Design and performance - Consolidated CDA creation performance" (§ 170.315(g)(6)(i)(A) and (B));
- "Design and performance - Application access – all data request – Functional requirements" (§ 170.315(g)(9)(i)(A)(*1*) and (*2*)); and
- "Design and performance - Standardized API for patient and population services – Data response" (§ 170.315(g)(10)(i)(A) and (B)).

New Data Classes and Elements in USCDI v4

Facility Information – new data class and data elements: Facility Identifier, Facility Type, and Facility Name.

Allergies and Intolerances – new data element: Substance (Non-Medication).

Encounter Information – new data element: Encounter Identifier.

Goals – updated data class and new data elements: Goals is renamed to Goals and Preferences and adds Treatment Intervention Preference and Care Experience Preference.

Health Status Assessments – new data elements: Alcohol Use, Substance Use, and Physical Activity. One data element, SDOH Assessments, has been moved to Health Status Assessments.

Laboratory – new data elements: Result Unit of Measure, Result Reference Range, Result Interpretation, Specimen Source Site, Specimen Identifier, and Specimen Condition Acceptability.

Medications – new data elements: Medication Instructions and Medication Adherence.

Procedures – new data element: Performance Time.

Vital Signs – new data element: Average Blood Pressure.

Medical Devices – updated data class and data element name: Unique Patient Identifier(s) for a Patient's Implantable Device(s) is renamed to Medical Devices to broaden the data class definition to accommodate more than just implantable devices. Unique Patient Identifier(s) for a Patient's Implantable Devices(s) is renamed to Unique Device Identifier – Implantable.

Visit Healthit.gov/proposedrule for more information.