ONC

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The ONC Standards Bulletin is a periodically published communication for the healthcare and health IT community that includes updates about ONC health IT standards initiatives.

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ONC Standards Bulletin 2023-2

The ONC Standards Bulletin 2023-2 (SB23-2) describes the background of United States Core Data for Interoperability (USCDI) and the development of the USCDI Version 4 (USCDI v4), which ONC released on July 20, 2023. USCDI is a standard developed and adopted by ONC on behalf of the U.S. Department of Health and Human Services (HHS) that sets the technical and policy foundation for the access, exchange, and use of electronic health information to support nationwide, interoperable health information exchange. USCDI benefits a wide range of entities, individuals, and other interested parties, including federal agencies supporting health and healthcare, hospitals, research organizations, clinicians, and health IT developers. ONC publishes new versions of USCDI annually, with a draft version in January and a final version in July. This publishing cadence keeps pace with medical, technological, and policy changes. USCDI v4 includes new data elements that advance the Biden-Harris Administration's priorities of advancing equity, diversity, and access across all healthcare settings.

SB23-2 describes the ONC approach for the continued expansion of USCDI, as well as the specific priorities for adding new data elements to USCDI v4. This bulletin also includes discussion of the feedback received on the Draft USCDI v4, including recommendations received from the ONC Health IT Advisory Committee (HITAC).

United States Core Data for Interoperability Background

The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The USCDI establishes a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. USCDI v1 was adopted as a standard (at 45 CFR 170.213) in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (Cures Act Final Rule). Since the Cures Act Final Rule, ONC released two versions of USCDI, and both have now been approved through the ONC Standards Version Advancement Process (SVAP). The SVAP permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program (Certification Program) to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405). To further advance interoperability, ONC has proposed to adopt USCDI v3 in Health Data, Technology and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

USCDI v1 is included in the Certification Program as a requirement in multiple certification criteria. As a result, certified health IT must be able to exchange USCDI data elements. USCDI defines data elements and associated terminology standards, where applicable, for use in document-based exchange and through information exchange via application programming interfaces (APIs). Other HHS programs, industry guidelines, and standards may reference USCDI.[i]

The USCDI is organized by data classes and data elements. Data elements represent concepts that can be used and exchanged, in addition to representing related concepts in other data classes. For example, the *Care Team Member Role* data element can be used to describe the performer of a *Procedure* or a provider ordering a *Medication.* Similarly, the *First Name and Last Name* in the *Patient Demographics and Information* data class may be exchanged to identify a patient in a document, a laboratory result, or a diagnostic imaging report.

USCDI data classes group data elements by a common theme, but they do not define how, when, or where a data element is used. For example, *Health Status Assessments - Disability Status* may be collected during initial intake data collection, or it may be collected during clinical encounters.

United States Core Data for Interoperability Version 4

The USCDI expands annually to keep pace with clinical, technology, and policy changes. To support this expansion, ONC hosts the ONC New Data Element and Class (ONDEC) submission system which collects public submission proposals for new data classes and data elements. In addition to the ONDEC system, the public is invited to provide feedback on data classes and data elements proposed in previous USCDI cycles and whether they should be reconsidered for future versions.

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[i] CMS requires that payers share the USCDI data they maintain with patients via the Patient Access API, and with other payers via the Payer-to-Payer Data Exchange.

In January 2023, ONC published Draft USCDI v4 with 20 new data elements and one new data class that reflect the ONC's priorities for USCDI expansion that include assessment for industry-wide implementation impact. During the public comment period, ONC received nearly 600 comments from a wide range of health IT entities, individuals and interested parties, including recommendations from ONC's HITAC. ONC reviewed and considered these comments in the development of the final version of USCDI v4, and made changes to certain data elements proposed in Draft USCDI v4 and updated data elements from USCDI v3. These changes clarify the definitions, uses, and standards of the data elements.

The table below lists the data classes and elements added to USCDI v4.

Data Classes and Data Elements Added to USCDI v4

Allergies and Intolerances	**Encounter Information**	**New Data Class**
• Substance (Non-Medication)	• Encounter Identifier	**Facility Information** • Facility Identifier • Facility Type • Facility Name
Goals and Preferences • Treatment Intervention Preference • Care Experience Preference	**Health Status Assessments** • Alcohol Use • Substance Use • Physical Activity	**Laboratory** • Result Unit of Measure • Result Reference Range • Result Interpretation • Specimen Source Site • Specimen Identifier • Specimen Condition Acceptability
Medications • Medication Instructions • Medication Adherence	**Procedures** • Performance Time	**Vital Signs** • Average Blood Pressure

What's New in USCDI v4

Allergies and Intolerances

Prior versions of USCDI include data elements for *Substance (Medication)* and *Substance (Drug Class)*. Throughout the USCDI versioning cycles, ONC has received ongoing feedback that standardized data are needed to represent non-medication substances, including some of the most common allergens such as latex, peanuts, pollens, and eggs. To address this feedback, ONC added a new data element, *Substance (Non-Medication),* to the *Allergies and Intolerances* data class referencing SNOMED CT US Edition as the applicable vocabulary standard. This update will further support standardized workflows to capture and exchange this data.

Encounter Information

In USCDI v3, ONC included several data elements in a new data class *Encounter Information.* Several stakeholders commented that a data element was needed to link data related to an encounter (e.g., diagnosis, medications prescribed, lab tests ordered, consultations sent). In response to these comments, *Encounter Identifier* has been added to USCDI v4. There are however no vocabulary standards associated with *Encounter Identifier, as* each unique identifier is generated by the organization involved in the encounter using its own conventions. Nonetheless, it is an important reference when searching for and requesting encounter information.

Facility Information

Within this new data class, *Facility Information* data elements provide details to patients and providers regarding the physical location of where services were or could be provided. Examples include where a laboratory test was performed, or to identify where services are available for care planning and emergency response purposes, or when care is provided or received in multiple facilities. We have clarified the definition of these new elements, including *Facility Type*, to distinguish it from other similar data elements currently exchanged by industry.

USCDI v4 adds this new data class and three new data elements: *Facility Identifier, Facility Type,* and *Facility Name.*

Goals and Preferences

An ONC policy priority is to advance the needs of underserved communities, including patients whose treatment goals and preferences are not well represented in health IT. The ability for a patient's expression of their goals and preferences to be part of their care paradigm is an essential component to person-centered care.

The care planning process may include expressions of interventions, religious beliefs, and overall care experience preferences. Examples of this include a patient's desires for whether and when lifesaving interventions like intubation or cardiopulmonary resuscitation are performed, or a patient's birth plan that expresses their preferences about their care and environment during labor and delivery. To facilitate and make these types of preferences available for exchange, ONC added two data elements to this data class: *Treatment Intervention Preference* and *Care Experience Preference.*

The data representing goals and preferences are similar in nature and, as such, warranted inclusion in a single data class. Therefore, ONC renamed the *Goals* data class to the *Goals and Preferences.*

Health Status Assessments

ONC added three data elements to the *Health Status Assessments* data class to expand the use and exchange of data elements that represent structured assessments, including those that address certain behavioral health concerns. The three new data elements include: *Alcohol Use, Substance Use,* and *Physical Activity*. These data elements are well represented in LOINC and identify critical diagnoses and interventions. In addition to these changes, *SDOH Assessment* was moved to this data class because it is represented by the same applicable vocabulary standards as the three new data elements.

Laboratory

Continuing the focus on public health reporting, ONC added six data elements to the *Laboratory* data class: *Result Unit of Measure*; *Result Reference Range*; *Result Interpretation*; *Specimen Condition Acceptability*; *Specimen Source Site*; and *Specimen Identifier*. The first three data elements above support ongoing public health reporting needs and provide patients and providers with more details for interpreting laboratory data. The latter three data elements provide more specificity for laboratory specimens. Together, these data elements provide important information for laboratory result evaluation and represent information that is typically provided by a laboratory when test results are reported, thus posing a modest implementation burden.

Medications

USCDI users have provided ongoing support for the inclusion of new data elements that represent the exchange of patient medication information. In USCDI v3, ONC added *Medications* data elements, however they did not address the extent to which a patient takes their medications according to clinical instructions.

ONC believes that the best way to represent information on whether medication is being taken by a patient according to instructions is through the addition of two data elements: *Medication Instructions* and *Medication Adherence. Medication Adherence* includes patient-reported data, further enhancing the patient's participation in their care. These two data elements can also be used to support medication reconciliation by providing a fuller picture of all prescription and over-the-counter medications, supplements, herbals, and other substances a patient is taking.

Procedures

Capturing and exchanging when procedures are performed is critical, especially when they are repeated over time. This applies to surgeries, vaccine and medication administration, laboratory specimen collection, diagnostic tests (e.g., ultrasounds) and other procedures.

For this reason, ONC added *Performance Time* to the *Procedures* data class. *Performance Time* could be used to represent the time any procedure was performed.

Vital Signs

ONC received significant input and support for *Average Blood Pressure* over several USCDI version update cycles. *Average Blood Pressure* is recognized as an independent risk factor in many diseases and health conditions. Examples include, but are not limited to, 3-day morning and evening home monitoring, clinical encounter repeat average, and 24-hour ambulatory measurement. The time period, number of readings, and specific protocols may be needed to interpret an *Average Blood Pressure* value.

Additional USCDI v4 Changes

In addition to renaming the *Goals* data class to *Goals and Preferences* as noted above, ONC changed the title of two other data classes to provide additional clarity:

1. The *Assessments and Plan of Treatment* data class title has been changed to *Patient Summary and Plan* to support the variety of data that may be exchanged regarding the overall state of the patient and recommendations for further care.

2. The *Unique Device Identifier(s) for a Patient's Implantable Device(s)* data class title has been changed to *Medical Devices* to accommodate more than just implantable devices. This change will support the expansion of this data class for future data elements related to applied and assistive devices. In addition, the data element *Unique Device Identifier(s) for a Patient's Implantable Device(s)* name has been changed to *Unique Device Identifier – Implantable* to align to the data class name change. The meaning and intent of this data element has not changed.

ONC also made several minor changes to the definitions, examples, usage notes, and applicable vocabulary standards for several data elements. These changes are included in the USCDI v4 Change Log.

As in previous versions of USCDI, ONC updated the applicable vocabulary standards to the most recent versions and updated data elements to add applicable vocabulary standards where they are referenced in specifications. ONC does not specify which values or codes within these standards must be used. In some cases, the implementation guides for Health Level Seven (HL7®) Fast Health Interoperability Resources (FHIR®) US Core and Consolidated Clinical Document Architecture (C-CDA®) specify value sets for use when exchanging these data. Additional information about these and other available value sets can be found in the ONC Interoperability Standards Advisory (ISA). We encourage entities, individuals, and interested parties to use the ISA to identify other relevant value sets to represent data elements in USCDI.

USCDI v5 Submission Period

With the publication of USCDI v4, ONC now kicks off the beginning of the next cycle to update USCDI to version 5. The ONDEC submission system is open and ready to collect recommendations for data elements to be considered for Version 5.

ONC made several improvements to ONDEC to gather more targeted information about submissions and to provide detailed information about how ONC evaluates and considers updates for future versions. ONC renamed Comment Level to Level Zero to better reflect the progression of data element maturity and breadth of applicability. Additionally, leveling criteria have been updated to clarify requirements for each level.

ONC encourages the community to engage and collaborate to submit feedback for data elements previously submitted that are not included in USCDI v4. **All submissions for new data elements and** feedback on existing data elements **must be received by Monday, September 20, 2023, at 11:59 pm ET.**

To guide and support this process, ONC established the following prioritization criteria to signal to the community which types of data ONC will focus on in future versions:

USCDI Prioritization Criteria

- Represent important additions to previous USCDI versions
- Address and mitigate health and healthcare inequities and disparities
- Address the needs of underserved communities
- Address behavioral health integration with primary care and other physical care
- Address public health interoperability needs of reporting, investigation, and emergency response
- Require modest standards or implementation guide development
- Require modest developmental burden on health IT products
- Create modest implementation burden on providers and health systems
- Result in modest cumulative lift for all new data elements combined

ONC Areas of Interest

ONC is engaged in ongoing community feedback on areas of interest related to health data. These topics include the interoperability of diagnostic imaging data and the ability to identify and track unique health concerns of veterans of military service.

Over the last year, ONC has heard from a variety of entities, individuals, and interested parties including the Healthcare Information Technology Advisory Committee (HITAC) that providing shareable links or detailed information about individual diagnostic imaging studies, series, and images offers great potential to improve access to images. ONC believes additional work is needed in this space to advance the meaningful, secure, and shareable access to images. We look forward to working with the health IT community on the best way to approach this issue to make progress.

Our military veterans experience a unique set of circumstances that can significantly impact their health and healthcare. ONC worked with the National Institute for Occupational Safety & Health (NIOSH) as they developed the data model Occupational Data for Health (ODH), which can communicate many aspects of military service. By adding *Occupation* and *Occupation Industry* to the *Patient Demographics/Information* data class in USCDI v3 in 2022 – which was proposed for adoption in HTI-1 – military service could become a required data element for exchange if such proposal is finalized. ONC encourages the community to suggest data elements to improve exchange of health information to better serve the needs of veterans.

Next Steps for USCDI

ONC continues to work with the public and federal agencies to identify areas where more work is needed to inform future versions of USCDI. ONC recognizes there are specific but important use cases that require consistency and alignment on datasets that go beyond USCDI. For example, ONC has worked with federal partners to release a draft USCDI+ Quality data element list to support quality measurement and improvement activities.

For more information about ONC's USCDI+ program please read ONC's USCDI+ blog post and check out the USCDI+ website.

After the submission and comment period ends for USCDI v5, ONC will evaluate public feedback to determine which new data elements to include in Draft USCDI v5, which ONC expects to publish in early 2024. We look forward to working with the public to continue to improve USCDI for broader use.

ONC will consider all submissions from ONDEC and all feedback submitted through the USCDI website by September 20, 2023, 11:59 pm ET.