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ONC Standards Bulletin 2023-1

ONC Standards Bulletin 2023-1 (SB23-1) describes the background of USCDI and the development of the [Draft United States Core Data for Interoperability Version 4 \(Draft USCDI v4\)](#), which ONC released on January 12, 2023. Interested parties across the healthcare ecosystem benefit from USCDI, which sets the technical and policy foundation for the access, exchange, and use of electronic health information to support nationwide, interoperable health information exchange. This includes but is not limited to federal agencies supporting health and healthcare, hospitals, research organizations, clinicians, and software developers. The USCDI is a standard developed and adopted by ONC on behalf of the U.S. Department of Health and Human Services (HHS) to serve as a baseline set of data elements for health information exchange and to inform interoperable health IT implementations. ONC publishes new versions of USCDI annually, with a draft version in January and a final version in July, to keep pace with medical, technology, and policy changes. Draft USCDI v4 includes new data elements that advance the Biden Administration's goals of equity, diversity, and access to healthcare.

SB23-1 describes ONC's continued expansion of USCDI, including the prioritization approach applied to USCDI Version 3. SB23-1 reflects ONC's consideration of submissions for new data elements and comments on previously submitted data elements.



What is the United States Core Data for Interoperability?

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 version 1 (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 \(Cures Act Final Rule\)](#).

USCDI v1 is a required part of certain certification criteria and, as a result, certified health IT must be able to exchange USCDI data elements. The USCDI defines the data elements and, where applicable, associated vocabulary standards that must be used as part of, for example, document-based exchange and via application programming interfaces (APIs). Various other HHS programs as well as industry clinical practice guidelines may also require the capture or exchange of USCDI-defined data.

The USCDI is organized by data classes and data elements. Data elements represent concepts that can be used and exchanged as needed. USCDI data classes group data elements by a common theme. Data elements can be used not only to represent concepts common to their data class, but to describe other data elements in other data classes. For example, in the Provenance data class, the Author Organization data element is routinely used to provide additional information about other data elements, such as Clinical Notes – History and Physical. Similarly, Care Team Member Role (Provider) can be used to describe the performer of a Procedure or the ordering provider for a Medication.

A data element's use is not bound by its data class title. Furthermore, a data class title does not define the workflow where the data elements are collected and used. For example, Disability Status may be collected during initial background data collection, or it may be collected during clinical assessments.

Draft United States Core Data for Interoperability Version 4

USCDI expands over time as standards mature and requirements evolve. The public participates in the expansion by submitting data classes and data elements for future versions of the USCDI through the [ONC New Data Element and Class \(ONDEC\)](#) submission system.

During the v4 submission cycle, which ended September 30, 2022, ONC received approximately 150 submissions for new data elements and almost 350 comments on previously submitted data elements. ONC applied prioritization criteria discussed in [Standards Bulletin 2022-2](#) to develop the final list of proposed new data elements for Draft USCDI v4.

With the publication of Draft USCDI v4, ONC proposes to add 20 data elements across one new (Facility Information) and eight existing data classes, which if finalized, would result in a USCDI v4 with 112 data elements organized in 19 data classes.

Draft USCDI v4 includes data elements that focus on patient care and facilitating patient access while promoting equity, reducing disparities, supporting underserved communities, integrating behavioral health

data with primary care, and supporting public health data interoperability. The following table summarizes the data class and data elements proposed for [Draft USCDI v4](#).

New Data Classes and Data Elements Added to USCDI v4

<p>Allergies and Intolerances</p> <ul style="list-style-type: none"> • Substance (non-medication) 	<p>Encounter Information</p> <ul style="list-style-type: none"> • Encounter identifier 	<p>New Data Class</p> <p>Facility Information</p> <ul style="list-style-type: none"> • Facility identifier • Facility type • Facility name
<p>Goals</p> <ul style="list-style-type: none"> • Treatment intervention preference • Care experience preference 	<p>Health Status Assessments</p> <ul style="list-style-type: none"> • Alcohol use • Substance use • Physical activity 	<p>Laboratory</p> <ul style="list-style-type: none"> • Result unit of measure • Result reference range • Result interpretation • Specimen source site • Specimen identifier • Specimen condition and disposition
<p>Medications</p> <ul style="list-style-type: none"> • Medication instructions • Medication adherence 	<p>Procedures</p> <ul style="list-style-type: none"> • Time of procedure 	<p>Vital Signs</p> <ul style="list-style-type: none"> • Average blood pressure

What's New in Draft USCDI v4

Draft USCDI v4 includes the above 20 new data elements across one new (Facility Information) and eight existing data classes.



Allergies and Intolerances

Prior versions of USCDI include data elements for *Substance (Medication)* and *Substance (Drug Class)*. ONC received input over several USCDI update cycles that data are needed to represent non-medication substances. Food and environmental allergies such as latex, peanuts, pollens, and eggs are very common, and they are all well-represented in standard terminology. ONC added one new data element, *Substance (Non-Medication)* to this data class using SNOMED CT US Edition as the applicable vocabulary standard.



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). *Encounter Identifier* fits this need and is added to Draft USCDI v4. While there are no vocabulary standards associated with *Encounter Identifier* and each unique value is generated by the organization involved in the encounter, it is a useful reference when searching for this information.



Facility Information

Facility Information data provide details to patients and providers regarding the physical location where care was received, or services were provided (or might be provided in the future). Facility Information is valuable when care is received in multiple sites. It may also be used to identify the facility where a laboratory test is performed. Draft USCDI v4 adds three data elements: *Facility Identifier*, *Facility Type*, and *Facility Name*.



Goals

One of ONC's policy priorities is to advance the needs of underserved communities, including patients whose treatment goals and preferences are not well represented in health IT. Expression of goals, preferences, and priorities are key to determining how treatment is delivered in a person-centered way.

The advance care planning process may include expressions of interventions, religious beliefs and overall care experience preferences (e.g., a birth plan developed by the patient to express their preferences for treatment and care experience during labor and delivery). To make these types of preferences available for exchange, ONC added two data elements *Treatment Intervention Preference* and *Care Experience Preference*. This is a first step toward enabling the use and exchange of these patient perspectives.



Health Status Assessments

To advance the prioritization of data elements that address behavioral health, ONC added three data elements - *Alcohol Use*, *Substance Use*, and *Physical Activity*. We also edited the title of this data class to clarify that the focus is on assessments, rather than status, conditions, or diagnoses. *SDOH Assessment* was reclassified into this data class because it is represented by the same applicable vocabulary standards.



Laboratory

ONC added *Result Unit of Measure*, *Result Reference Range*, and *Result Interpretation* to address ongoing public health reporting needs and to provide patients and providers with more detailed information about laboratory data. Additionally, ONC added data elements that provide more information about the laboratory specimen. These are *Specimen Source Site*, *Specimen Identifier*, and *Specimen Condition and Disposition*. This data is usually contained within laboratory information systems and can be shared with and by electronic health records.



Medications

USCDI users have provided ongoing support for data elements to enable the exchange of patient medication information. In USCDI v3, ONC added *Medications* data elements to enrich the information about medication type and dosage, however these data elements did not address the extent to which a patient adheres to clinical instructions. Over several USCDI update cycles, ONC received a significant number of submissions that addressed different aspects of this need, including submissions for Medication Administration, Medication List, Reported Medication, Medication Usage, and Medication Adherence.

Exchanging medication adherence information can aid medication reconciliation and inform a provider about prescription and over-the-counter medications, supplements, herbals and other substances a patient is taking at the time of care. ONC believes that the best way to enable

use and exchange of medication reconciliation data is to add two new data elements: *Medication Instructions* and *Medication Adherence*. *Medication Adherence* includes patient-reported data, further enhancing the patient's participation in their care.



Procedures

Procedures are a significant part of health care and include functions and actions beyond surgeries and other invasive treatments. Vaccine and medication administration, and laboratory specimen collection, are all types of healthcare procedures. Capturing and exchanging the time when these are performed is critical, especially when they are repeated over time and the specific instance of a procedure is queried. For this reason, ONC added *Time of Procedure* to the *Procedures* data class. *Time of Procedure* could be used to represent the time any procedure was performed. Like the Provenance data elements *Author Time Stamp* and *Author Organization*, *Time of Procedure* is a multi-purpose data element with a commonly understood format.



Vital Signs

ONC received significant input and support for *Average Blood Pressure*. While health IT is universally able to capture and exchange *Systolic Blood Pressure* and *Diastolic Blood Pressure* and calculate means for any set of numeric values, the concept of *Average Blood Pressure* is recognized as an independent risk factor in many diseases and health conditions. Furthermore, commenters offered that *Average Blood Pressure* may be the only blood pressure value available, such as reporting from home blood pressure monitoring devices.

Other Draft USCDI v4 Changes

ONC changed the title of three data classes to provide clarity about the uses of each data class:

1. *Health Status Assessments* changed (by removing the slash (/) between Status and Assessments) to focus on assessments of health status in certain settings, rather than the conditions or diagnoses the assessments may identify.
2. *Assessments and Plan of Treatment's* title has 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.
3. The *Unique Device Identifier(s) for a Patient's Implantable Device(s)* data class title changed to *Medical Devices* to accommodate not only implantable devices but also applied and assistive devices, which may be considered in the future.
 - a. The data element *Unique Device Identifier(s) for a Patient's Implantable Device(s)* name is also changed to *Unique Device Identifier – Implantable* for conciseness. The meaning and intent of this data element has not changed.

We simplified the definition of *Medications Indication* for clarity, and reclassified *SDOH Assessments* into the *Health Status Assessments* data class because this element more closely matches the definition of this data class.

As we have done in the past, we also updated the applicable vocabulary standards for data elements to the latest versions as of the publication of Draft USCDI v4.



ONC Requests Specific Feedback on the Following Data Elements

Treatment Intervention Preference and Care Experience Preference

ONC seeks feedback on the approach of including data elements for *Treatment Intervention Preference* and *Care Experience Preference* to represent a person's goals, preferences and priorities, and to address data that are important components of person-centered care and the advance care planning process.

Medication Adherence and Medication Instructions

ONC seeks feedback on these two *Medications* data elements to represent a patient's adherence with instructions and to facilitate medication reconciliation.

Time of Procedure

ONC received many USCDI data element submissions to add timing elements to a variety of USCDI data classes, all related to the time a procedure is performed – including but not limited to specimen collection, when a laboratory test or clinical test was performed, medication administration, and vaccine administration. Rather than add multiple data elements to USCDI, a single data element representing the time period or date, or date and time an action was performed is proposed in Draft USCDI v4. *Time of Procedure* data type is intended to follow the pattern of *Encounter Time* and includes date, or date and time.


During this public feedback period, ONC seeks input on whether a single USCDI data element *Time of Procedure*, satisfies the community submissions. ONC also seeks feedback on whether the data element name should be changed to *Procedure Time* to follow the pattern of *Encounter Time*.

Draft USCDI v4 Public Feedback Period

With its publication, [Draft USCDI v4](#) is now available for public feedback until April 17, 2023, at 11:59 pm ET. You must be registered and logged in to the website to submit feedback. Health IT expertise is not required to provide comments and ONC welcomes information that identifies the healthcare community's preferences and priorities for informing further investigation. Submitters may submit feedback on any aspect of Draft USCDI v4. In addition, ONC is seeking feedback on the following areas:

1. Suggestions for improvement in the data classes or elements in Draft USCDI v4, including:
 - a. Data class and data element definitions,
 - b. Examples of code sets used by health IT developers and implementers to communicate data element scope.
2. Should other data elements, already classified as Level 2 on the USCDI web pages, be added to USCDI v4 instead, or in addition to those in Draft USCDI v4? If so, why?
3. Are there significant barriers to development, implementation, or use for any of these data elements that warrant a change in definition, or removal from Draft USCDI v4?

ONC will also work with the Health Information Technology Advisory Committee (HITAC) to receive recommendations on Draft USCDI v4.



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, and ONC is working with governmental and industry partners through the [USCDI+ initiative](#) to support the identification and establishment of domain or program-specific datasets that can be extensions to USCDI. Please see ONC's [USCDI+ blog](#) post for more information.

ONC will consider all feedback submitted through the [Draft USCDI v4 website](#) by April 17, 2023, 11:59 pm ET and is targeting release of the final USCDI v4 in July 2023.