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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 2024-1

ONC Standards Bulletin 2024-1 (SB24-1) describes the background of USCDI and the development of the Draft United States Core Data for Interoperability Version 5 (Draft USCDI v5), which ONC released on January 18, 2024. 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 federal agencies supporting health and healthcare, hospitals, research organizations, clinicians, and software developers. 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 clinical, technology, and policy changes. The draft USCDI v5 includes new data classes and elements that support improved patient care and advance the Administration's goals of equity, diversity, and access to healthcare.

SB24-1 describes ONC's continued expansion of USCDI, following the same prioritization approach applied to USCDI Version 4. SB24-1 and reflects ONC's consideration of submissions for new data elements and comments on previously submitted data elements.

United States Core Data for Interoperability Background

The United States Core Data for Interoperability (USCDI) is a standardized set of data elements for nationwide, interoperable health information exchange. 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). Since then, ONC has released three more versions of USCDI for which two have been approved under the ONC Standards Version Advancement Process (SVAP). The SVAP permits health IT developers with health IT products certified under the ONC Health IT Certification Program (Certification Program) to voluntarily update their conformance 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 raised the baseline for the Certification Program by including USCDI v3 in the recently finalized Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. The HTI-1 Final Rule established that as of January 1, 2026, the USCDI v3 will be the only USCDI version required within the Certification Program.

USCDI v1 and v3 are included in the Certification Program as a requirement in multiple certification criteria. USCDI defines data elements and associated terminology standards, where applicable, for use in document-based exchange and application programming interfaces (APIs). Some HHS programs[1] and exchange networks, such as the Trusted Exchange Framework and Common Agreement (TEFCA)[2] also require the capture or exchange of USCDI data elements.

USCDI is organized by data class and data elements. 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, *Care Team Member Role* (Provider) can be used to describe the performer of a procedure or the ordering provider for a medication. Similarly, *First Name* and *Last Name* in the Patient Demographics/Information data class may be exchanged to identify a patient in a document, a laboratory result, or a diagnostic imaging report.

Health IT Certified to USCDI-referenced certification criteria must enable the exchange of all data elements included in USCDI data elements for all patients regardless of care setting (e.g., inpatient, outpatient, or post-acute care)[3]. ONC strives to define applicable vocabulary standards for data

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[1] https://www.cms.gov/about-cms/obrhi/interoperability/implementation-guides-and-standards/application-programming-interfaces-apis-and-relevant-standards-and-implementation-guides-igs

[2] https://rce.sequoiaproject.org/

[3] https://www.healthit.gov/sites/default/files/page2/2020-03/USCDI.pdf

elements expected to be exchanged with standard code set concepts. ONC encourages health IT developers to take advantage of code sets such as SNOMED CT® U.S. Edition, LOINC®, and RxNorm® where possible.

Draft United States Core Data for Interoperability Version 5

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, ONC invites feedback on previously submitted data elements and whether they should be considered for future versions.

As part of the annual update process, ONC identifies key policy priorities that include:

- Health data needs for providing equitable care to underserved communities, public health reporting, and behavioral health integration with primary care.
- Important additions over previous USCDI versions that will broadly benefit health IT users.
- Implementation burden for: standards development organizations; developers of certified health IT products; and health care entities who will integrate these changes into clinical and other workflows.
- Outside factors such as new regulatory requirements (e.g., those included in the recently published HTI-1 final rule) are also considered.

During the USCDI v5 submission cycle, which ended September 20, 2023, ONC received more than 60 submissions recommending new data elements and over 330 comments on previously submitted data elements. Draft USCDI v5 includes data elements that focus on improving patient care and facilitating patient access, while promoting equity, reducing disparities, supporting underserved communities, and enabling public health data exchange. ONC's evaluation resulted in the following proposed data classes and data elements.

New Data Classes and Data Elements Added to Draft USCDI v5

Clinical Notes
- Emergency Department Note
- Operative Note

Immunizations
- Lot Number

Laboratory
- Test Kit Unique Device Identifier

Medications
- Route

New Data Class

Observations
- Advance Directive Observation
- Sex Parameter for Clinical Use

New Data Class

Orders
- Orders

Patient Demographics/Information
- Interpreter Needed
- Pronoun
- Name to Use

Provenance
- Author
- Author Role

What's New in Draft USCDI v5

Draft USCDI v5 includes two new data classes and 13 new data elements.

Observations

Observations are a common concept in healthcare, used to support a variety of activities including diagnoses, test results, and screening assessments. *Sex Parameter for Clinical Use (SPCU)* and *Advance Directive Observation* would be added to the new *Observations* data class.

The *SPCU* data element was included as part of the HTI-1 Final Rule's update to the "patient demographics and observations" certification criterion to which certified health IT will need to be updated by no later than January 1, 2026. *SPCU* would be added to provide sex specific context to observations, tests, procedures, and results. Individuals with *SPCU* attributes of female or male can have different reference ranges for a variety of laboratory test results (e.g., hormone levels, blood counts, renal function), different expected findings on diagnostic imaging studies (e.g., genitalia, solid organ sizes, skeletal variations), different recommended preventive screening recommendations (e.g., cervical, breast, or testicular cancer screenings), and different stages of gender-affirming treatment. *SPCU* can inform clinical decision making, treatment, and/or diagnostic tests. *SPCU* also aligns with the Administration's Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals.

An *Advance Directive Observation* conveys information about an advance directive document, including its existence, location, content, and validity. Communicating and referencing advance directive information, such as a living will or a medical power of attorney, has long been an issue in healthcare. This data element does not represent any specific advance directive document, but only provides information about it.

Patient Demographics/Information

Name to Use and *Pronoun* were included as part of the HTI-1 Final Rule's update to the "patient demographics and observations" certification criterion to which certified health IT will need to be updated by no later than January 1, 2026. These two data elements would be added to advance culturally competent care for lesbian, gay, bisexual, transgender, queer, intersex, asexual, and other sexual and gender minorities (LGBTQIA+). *Name to Use* may represent a nickname or any other name preferred by the patient. *Pronoun* refers to the preferred words to be used when communicating with or about an individual. Culturally competent care is critical to reducing disparities, promoting shared decision-making between providers and patients, and in improving access to healthcare that is respectful and responsive of diverse needs. These two elements also align with President Biden's Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals

Interpreter Needed would be added to specify a patient's need for language services, regardless of their preferred language. Exchanging data on the need for interpreter services is critical to ensure all needed services are available during referrals and transfers. This promotes continuity and efficiency of care, reduces cancellation or delay of services, and enhances patient-centered care. *Interpreter Needed* also aligns with multiple Executive Orders, including Improving Access to Services for Persons with Limited English Proficiency and Advancing Racial Equity and Support for Underserved Communities, and supports the 2023 HHS Language Access Plan and Title IV of the Civil Rights Act of 1964.

Orders

The data class and element *Orders* would be added to convey a provider's intent to treat a patient. The ability to record, change, and access orders for laboratory tests, medications, or diagnostic imaging tests has been part of ONC certification since the publication of the 2015 Edition Base Electronic Health Record Definition. An order represents a provider's intent or directions to initiate care for the patient and addresses other aspects of care including planned procedures, transitions of care, consultations, and referrals. By adding the *Orders* data element to USCDI v5, orders could be exchanged to communicate intentions with other providers and support care planning and management.

Clinical Notes

Emergency Department Note and *Operative Note* would be added to convey narrative clinical content for coordination of patient care across the continuum and provide critical connections between inpatient and outpatient care settings. This is an important component of both acute and chronic disease management. These notes provide critical insight for patients into their care, and in particular, for patient populations who rely on emergency departments for primary care.

Immunizations

Lot Number would be added to provide important information for patient care and public health reporting. *Lot Number* is a required component in the immunization messaging process and is critical for Vaccine Adverse Event Reporting System (VAERS) tracking, as well as in the event of a recall. The inclusion and availability of *Lot Number* will also support immunization inventory tracking.

Medications

Route was originally submitted as a combined data element with *Medication-Dose*. ONC subsequently received numerous comments that it is separate and independently valuable. *Route* would be added to represent details for prescribing, administering, and taking medication.

Provenance

Author and *Author Role* would be added to provide insight into the source of data, which is especially important as data increasingly comes from multiple sources. Including the source of data can help inform interpretation and validity of the data which leads to better clinical decision making.

Tracing data back to the original author and being able to identify the original source (who or what created the data) supports patient safety.

Laboratory

Test Kit Unique Device Identifier would be added to provide additional information about laboratory and other diagnostic test results to help interpret and compare test results. It can be used along with *Result Reference Range* to compare results of tests with the same LOINC codes that may use different test methods.

Other Draft USCDI v5 Changes

The following updates would be made to existing data classes and elements:

1. *Encounter Location* would include National Healthcare Safety Network (NHSN) Healthcare Facility Patient Care Location (HSLOC); this standard has been identified as being applicable to multiple care settings.

2. *Procedures* would include a clarification that Code on Dental Procedures and Nomenclature (CDT) may be exchanged.

3. *Immunizations* would update two applicable vocabulary standard citations:

    - IIS: Current HL7 Standard Code Set, CVX – Vaccines Administered to CVX – Vaccines Administered

    - Vaccine National Drug Code (NDC) Directory – Vaccine NDC Linker Table to National Drug Code (NDC).

4. In order to provide clarity to implementers we would update definitions, usage notes, or examples for the following data elements: *Current Address, Previous Address*, *Diagnostic Imaging Test*, *Discharge Summary Note*, *Procedure Note, Encounter Disposition*, *Result Unit of Measure, Mental/Cognitive Status, Functional Status, and Disability Status.* ONC also updated the definition of the *Care Team Members* data class.

For more detail, see the Draft USCDI v5 change log.

As we have done in the past, we updated the applicable vocabulary standards for data elements to the latest versions as of the publication of Draft USCDI v5.

ONC Requests Specific Feedback on the Following Data Elements

Author and Author Role

ONC seeks feedback on the new *Author* and *Author Role* data elements that would be added to the Provenance data class, specifically, whether there is sufficient implementation across health IT developers.

Lot Number

ONC seeks feedback on the new *Lot Number* data element that would be added and its placement in the *Immunizations* data class. Specifically, we are interested in feedback on whether *Lot Number* may apply more broadly to medications.

Test Kit Unique Device Identifier

ONC seeks feedback on the new *Test Kit Unique Device Identifier* data element that would be added to the *Laboratory* data class, including in what scenarios this data element would be useful and what experience health IT developers have exchanging this element.

Draft USCDI v5 Public Feedback Period

With its publication, Draft USCDI v5 is now available for public feedback until **April 15, 2024, at 11:59 pm ET**. You must be registered and logged in to the website to submit feedback. Anyone may submit feedback on any aspect of Draft USCDI v5. In addition to such general feedback and the specific feedback requested above, ONC is seeking feedback on the following areas:

1. Suggestions for improvement in the data classes or elements in Draft USCDI v5, including:
    a. Data class and element definitions, usage notes, and examples; and
    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 v5 instead of, or in addition to, those in Draft USCDI v5? If so, why?
3. Are there significant barriers to development, implementation, or use of any of these data elements that warrant a change in definition or removal from Draft USCDI v5?

ONC will also work with the Health Information Technology Advisory Committee (HITAC) to receive recommendations on Draft USCDI v5.

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. 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.

ONC is targeting release of the final USCDI v5 in July 2024.