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ONC HEALTH IT STANDARDS BULLETIN

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

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ONC Standards Bulletin 2022-1

ONC Standards Bulletin 2022-1 (SB22-1) discusses the latest draft version of the [United States Core Data for Interoperability \(USCDI\) standard](#) and how the community can provide feedback. USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. USCDI Version 1 (v1) was adopted in the [ONC Cures Act Final Rule \(May 2020\)](#). Additionally, as a Condition and Maintenance of Certification requirement established as part of the [ONC Cures Act Final Rule](#), health IT certified to specific certification criteria needs to be updated to conform to USCDI v1 by the end of December 2022.

The ONC Cures Act Final Rule also established the Standards Version Advancement Process (SVAP). SVAP provides the means for newer versions of standards adopted in regulation – such as USCDI – to be approved by the National Coordinator and subsequently made available for use and compliance under the ONC Health IT Certification Program (Certification Program).

The new Draft USCDI Version 3 (Draft USCDI v3) includes new data elements that are consistent with the Biden-Harris Administration’s Executive Orders on [Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#) and [Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats](#). Draft USCDI v3 will be open for public feedback until April 30, 2022, and ONC plans to release the final USCDI v3 in July 2022.

Draft United States Core Data for Interoperability Version 3

During the development of Draft USCDI v3, ONC received over 400 submissions through the [ONDEC](#) submission system. ONC considered these submissions and [applied established prioritization criteria](#) to select the most mature data elements, including data elements submitted during previous USCDI submission cycles. As noted in the criteria, we focused on factors that include promoting equity, reducing disparities, and supporting public health data interoperability. Based on these considerations, the following new data classes and data elements have been included as part of [Draft USCDI v3](#).


New Data Classes and Elements Added to Draft USCDI v3

New Data Class Health Insurance Information <ul style="list-style-type: none">• Coverage Status• Coverage Type• Relationship to Subscriber• Member Identifier• Subscriber Identifier• Group Number• Payer Identifier	New Data Class Health Status <ul style="list-style-type: none">• Functional Status• Disability Status• Mental Function• Pregnancy Status	Laboratory <ul style="list-style-type: none">• Specimen Type• Result Status
Patient Demographics <ul style="list-style-type: none">• Date of Death• Tribal Affiliation• Related Person's Name• Related Person's Relationship• Occupation• Occupation Industry	Procedures <ul style="list-style-type: none">• Reason for Referral	

Draft USCDI v3 Key Updates

Building upon USCDI v2, Draft USCDI v3 adds data elements in the Health Status, Procedures, Health Insurance, and Patient Demographics data classes.

Draft USCDI v3 includes four data elements in the new data class Health Status. These are: Disability Status, Mental Function (which includes the more specific Cognitive Status), Functional Status, and Pregnancy Status. The Health Status data class provides a broader context than the existing Health Concerns data class, which contains the single general data element Health Concerns. In Draft USCDI v3, the Health Status data class also includes two existing data elements Health Concerns and Smoking Status which were reclassified from their own data classes as found in USCDI v2. The ability to capture and exchange data that represent these more specific health statuses represents a significant advance for health IT to improve care and to address inequities.



Another new data class, Health Insurance Information, provides an opportunity for health IT to capture and exchange key elements of health care insurance coverage. This information can be useful in the care of patients, for price transparency, and in the identification of disparities related to insurance coverage. This data class includes seven new elements: Coverage Status and Relationship to Subscriber; Member, Subscriber, and Group Identifiers; and Coverage Type and Payer Identifier.

ONC added seven additional data elements to the Patient Demographics data class. Related Person's Name and Related Person's Relationship enable linkages between maternal and child records as well as identifying other related persons, such as caregivers, custodians, and guardians. Date of Death supports patient matching, adverse event, public health, and vital records reporting. Occupation and Occupation Industry data elements were added to support public health, equity concerns, and to capture military service. Finally, Tribal Affiliation is a new, self-reported data element extensively captured by the U.S. Indian Health Service to aid in determination of eligibility for IHS services, care-coordination with non-tribal medical facilities, and identification of disparities in health care in and across tribal populations. These data elements also support social or environmental factors that support person-centered care, enable research to advance health equity, and social determinants of health.

To address public health reporting priorities, especially considering the current COVID-19 pandemic, ONC added Specimen Type and Result Status to the Laboratory data class. Occupation, Occupation Industry, and Pregnancy Status also support public health data requirements.

ONC also added Reason for Referral in the Procedures data class, as this data element is already part of the Certification Program requirements for [Transitions of Care](#) and is broadly implemented in health IT.

Additional Updates to Draft USCDI v3


To provide clarity and updates based on ongoing standards development, we made improvements and changes to existing data elements. For the data element Discharge Summary Note, we specified additional requirements, including admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization. These components are already required by the Certification Program in the [Transitions of Care](#) and [View, Download, and Transmit to 3rd Party](#) criteria, so we expect implementation burdens to be minimal.

Additionally, ONC intends to update the applicable vocabulary standards to their latest published versions when we issue the final USCDI v3. This is consistent with our approach to prior USCDI versions.

ONC REQUESTS ADDITIONAL FEEDBACK ON THE FOLLOWING DATA ELEMENTS

Sex (Assigned at Birth)

The Certification Program has long required certified health IT to be able to capture Sex Assigned at Birth (2015 Edition certification criteria that reference USCDI v1 (formerly CCDS) and the 2015 Edition Demographics certification criterion (45 CFR 170.315(a)(5))) using a defined set of standardized terminology. However, in participating in and monitoring industry activities, we have observed that changes to the concept may be in order. The [Health Level 7® \(HL7®\) Gender Harmony project \(Gender Harmony\)](#)



has been working to clarify the purpose and use of Sex Assigned at Birth, including distinguishing it from other sex and gender related concepts, such as “gender identity” and “sex for clinical use.” Gender Harmony developed the new term “Recorded Sex or Gender” to represent any recording of “sex or gender” in health records or other documents. They recognized that “Sex assigned at birth” is one example of a “Recorded Sex or Gender,” and that it preserves the historic value of sex assigned at birth as recorded in health records. ONC recently highlighted this issue on the [Health IT Buzz Blog](#). During this public feedback period, ONC seeks input on the USCDI concept of [Sex Assigned at Birth](#), its associated vocabulary standards (value set), and specifically whether the term itself and its value set should align with Gender Harmony’s definition for Recorded Sex or Gender.

Gender Identity

Gender Identity and Sexual Orientation have been a required part of the Demographics certification criterion (45 CFR 170.315(a)(5)) since its adoption in 2015, but are not currently required to be exchanged via HL7® FHIR® or C-CDA as part of certification criteria that reference USCDI v1. While Gender Identity and Sexual Orientation data elements were included in USCDI v2, USCDI v2 is not yet an option for meeting Certification Program requirements under SVAP. The [SVAP comment period](#) has been extended until May 2, 2022. If USCDI v2 is included in SVAP for certification in 2022, certified health IT would be able to voluntarily update to USCDI v2 and be capable of making Gender Identity and Sexual Orientation data elements available for access and exchange consistent with established value sets.

Gender Harmony proposed a value set to represent Gender Identity that differs from the value set adopted by ONC for the Demographics certification criterion and USCDI v2. For example, Gender Harmony does not include terms for transgender male and transgender female. ONC requests feedback on the most appropriate value set to represent [Gender Identity](#) for USCDI v3.


Patient Address

Throughout 2021, ONC worked with a broad community to improve the quality and standardization of patient address. One output of this collaborative work was the publication of the new Unified Specification for Address in Health Care (Project US@). Now that this first version has been released, ONC believes this specification can serve as the standard for patient address in health care settings. ONC seeks feedback on whether this specification should be the required standard for [Current](#) and [Previous](#) Address in USCDI v3 or a future USCDI version.

Draft USCDI v3 Public Feedback Period

As part of the predictable, transparent, and collaborative process to expand USCDI, Draft USCDI v3 has been made available to the public for feedback via the [Draft USCDI v3 website](#) or on individual data class or data element pages through April 30, 2022. You must be registered and logged in to the website to submit feedback. In addition to requesting feedback on the entire Draft USCDI v3 and the specific data elements identified above, ONC is seeking feedback on the following areas:

1. Are there any improvements needed in the data classes or elements included in Draft USCDI v3, including:
 - a. Appropriate and meaningful data class and element names and definitions?

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- b. Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?
 2. Should other data elements classified as Level 2 be added to USCDI v3 instead, or in addition to those included in Draft USCDI v3? If so, why?
 3. Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?

ONC will work with the [Health Information Technology Advisory Committee](#) to provide Draft USCDI v3 recommendations to the National Coordinator for Health Information Technology.

ONC will continue to work with the public and federal agencies to identify areas where more work is needed to inform future versions of USCDI. However, we recognize that there are specific but important use cases that require consistency and alignment on datasets that go beyond USCDI, and we also seek to be responsive to those needs. Accordingly, we launched the [USCDI+](#) initiative in 2021 to work directly with our federal partners to support the identification and establishment of domain or program-specific datasets that can be extensions to USCDI. Please see our [USCDI+ blog post](#) for more information.

ONC will consider all feedback submitted through the [Draft USCDI v3 website](#) by April 30, 2022, and is targeting release of the final USCDI v3 in July 2022.