

Issue 2021-1

ONC HEALTH IT STANDARDS BULLETIN

JANUARY 2021

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



ONC Standards Bulletin 2021-1

The inaugural ONC Standards Bulletin 2021-1 (SB21-1) discusses the United States Core Data for Interoperability (USCDI) and the Standards Version Advancement Process (SVAP). It provides additional background and context associated with these two important initiatives, including information synthesized from the Health Information Technology Advisory Committee (HITAC) and the ONC Cures Act Final Rule and Interim Final Rule.

The **USCDI** is an ONC-stewarded standard comprised of a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

The **SVAP** enables health IT developers to voluntarily incorporate newer versions of specific ONC-regulated standards and implementation specifications into their products under the ONC Health IT Certification Program, including future final versions of the USCDI.

SB21-1 reflects ONC's implementation of the HITAC's recommendation to develop a periodic publication to communicate updates related to standards initiatives and priorities. Within this bulletin, additional information is provided about the USCDI and SVAP policy and technical considerations, public comment analyses, and subsequent opportunities for stakeholder engagement. Examples of projects that health IT stakeholders may wish to build and expand upon their efforts related to the USCDI and SVAP are also described.



USCDI Background and Development of USCDI Version 1

The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. It establishes a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. ONC published a Draft USCDI version 1 (USCDI v1) and the associated data classes and data elements for public comment as part of the ONC Cures Act notice of proposed rulemaking. ONC also charged the HITAC to create a taskforce to consider the Draft USCDI v1 and the related update timeline and expansion process. In consideration of the input received from public comment in response to ONC's proposed rule and from the HITAC task force, the [USCDI v1](#) was adopted as a standard in the [ONC Cures Act Final Rule](#) published May 1, 2020.

The USCDI's impact is not limited to health IT products certified under the ONC Health IT Certification Program. The ONC Cures Act Final Rule provisions related to "information blocking" also reference the USCDI as the initial scope of electronic health information (EHI) healthcare providers, health information networks and exchanges, and developers of certified health IT need to consider when it comes to the access, exchange, and use of EHI. Please see the USCDI v1 and the [USCDI Fact Sheet](#) for more information.

SVAP Background and Approved Standards for 2020

The SVAP enables health IT developers to voluntarily incorporate newer versions of specific ONC-regulated standards and implementation specifications into their products under the ONC Health IT Certification Program, including future versions of the USCDI. The SVAP will advance interoperability by permitting developers of certified health IT to implement newer versions of standards and specifications than currently adopted in regulation. ONC established an annual public comment process for SVAP-eligible standards and implementation specifications. For example, the final USCDI v2 would be included as part of the SVAP-eligible standards and implementation specifications considered for 2021.

During the comment period for 2020 SVAP-eligible standards and implementation specifications (September – November 2020), a total of 34 comments were received from stakeholders on 22 standards and implementation specifications. Following a detailed review and assessment, ONC finalized a list of standards and implementation specifications that can be advanced to under the ONC Health IT Certification Program. Please see the SVAP Approved Standards for 2020 on the [ONC Certification Program SVAP webpage](#).

USCDI Expansion

In consideration of the HITAC's [recommendations](#) for the USCDI expansion process as well as public feedback and public comment on ONC regulations, the [ONC New Data Element and Class \(ONDEC\)](#) submission system was established. This provides a transparent system for stakeholders to submit data elements and data classes for consideration as part of USCDI. It includes established evaluation criteria to classify each submitted data element into one of three levels (comment, level 1, or level 2) depending on the overall value, maturity, and any known challenges to implementation.

CRITERIA	“COMMENT” LEVEL	LEVEL 1	LEVEL 2
Maturity-Current Standards	May be represented by terminology standard or be an element of balloted technical specification such as an implementation guide	Must be represented using terminology standard or element of Standards Development Organization (SDO) balloted technical specification	Must be represented using terminology standard or element of SDO balloted technical specification
Maturity-Current Use	Used only in limited test environments, or only in pilots	Used in limited production environments, 1 or 2 different systems	Used at scale in production environments using more than 2 different systems
Maturity-Current Exchange	May have limited exchange with external organizations, on same or different EHR/HIT systems, using specified standard(s)	Exchanged between 2 or 3 organizations with different EHR/HIT systems, using specified standards.	Exchanged between 4 or more organizations with different EHR/HIT systems, using specified standards.
Use Case-Number of Stakeholders Impacted	Used by few stakeholders, or for narrowly defined conditions or events.	Pertinent to many, but not most patients, providers or events requiring its use	Pertains to majority of patients, providers or events requiring its use

As the USCDI expansion process matures, it is anticipated that the evaluation of the annual submissions will continue to be refined and may change based on trends within the submissions received, high priority target areas, and other potential factors. The ONC Interoperability Standards Advisory (ISA), the ONC Standards Bulletin, the SVAP, and continued work with the HITAC (including continued review of the Interoperability Standards Priorities Target Areas established under the Cures Act) will help inform the USCDI expansion process. Additionally, continued engagement between ONC and the health care community at large will help refine the USCDI process over time and identify and resolve gaps in standards supporting high priority target areas for health IT and health care.



Draft USCDI Version 2 Considerations

ONC received 664 data elements in 44 data classes (14 existing and 30 newly proposed data classes) from 64 submitters through the ONDEC submission system for consideration for the Draft USCDI Version 2 (USCDI v2). One hundred and nine (109) data elements met the criteria for “level 2,” but including all of these data elements at once for Draft USCDI v2 would likely overwhelm providers and health IT developers. As a result, specific level 2 data elements were prioritized for Draft USCDI v2 and reflect data classes and elements that are most relevant and broadly applicable, have clearly defined use cases, and offer a clear value proposition.

A key factor as part of the prioritization this year is the ongoing COVID-19 public health emergency. Clinicians, hospitals, health systems and health IT developers have conveyed that the COVID-19 public health emergency monopolizes their time and attention and has strained resources, limiting their ability to prepare for or implement updates to systems to meet changing program requirements. Health IT developers have been allocating resources to address the urgent and constantly changing technological needs of health care providers, public health entities, and health care systems dealing with the COVID-19 public health emergency.

While developers of certified health IT will not be compelled to upgrade their certified health IT when the final USCDI v2 is published, the intent behind the annual, incremental expansion of the USCDI and the annual SVAP cycle is to support updates to baseline standards and transparently identify where future regulatory direction could go. As a result, careful consideration will be made in terms of the overall impact on and ability of health IT developers and their customers to design, upgrade, and implement new versions of USCDI and standards specified in SVAP.

Therefore, the Draft USCDI v2 focused on a modest expansion that aims to balance minimal development burden with maximum impact. Specifically, the Draft USCDI v2 reflects where a level 2 data element could fill a significant gap within an existing USCDI v1 data class and was already supported by current versions of the Consolidated Clinical Document Architecture (C-CDA) and HL7® FHIR US Core Implementation Guide.

The [Draft USCDI v2](#) was published on January 12, 2021 and public comment is sought on the Draft USCDI v2 as well as other Level 2 assessments.

Public Comment Process

Over the next 3 months, the public is encouraged to evaluate the [Draft USCDI v2](#) and submit comments to ONC on the data classes and elements that should be included in the final USCDI v2.

Comments will be accepted until April 15, 2021 on the main [Draft USCDI v2 page](#) or on individual data class or data element pages. ONC will consider these comments and recommendations and begin preparing the final USCDI v2 for publication in July 2021.



Opportunities to Get Involved

The USCDI and SVAP, including the ONDEC process, offer value to stakeholders by providing insights into potential standards initiatives including opportunities for data harmonization, value set development and stewardship, and stakeholder-led workgroups on specific data classes. There are several examples of existing initiatives that health IT and health care organizations may consider building on efforts for USCDI data element submission.

Specialty societies can play a critical role in identifying specialty setting clinical priorities, quality metrics, and relevant data elements and/or value sets. Data element catalogs or libraries provide a centralized resource of data elements including those that may be captured to support specific clinical concepts (e.g., care assessment questions and responses) as well as associated health IT standards. The [CMS Data Element Library](#), known as the DEL, provides a timely example of a federal investment for establishing a data element library in support of appropriate treatment and settings for post acute-care. Stakeholder-led efforts to identify clinical priorities and opportunities for greater harmonization and alignment with elements involved in care assessment, treatment, and referral are valuable not only for informing future USCDI updates but also for contributing to any new or existing data element catalog or library. A data element library may exist external to the federal government and support a wide range of treatment, coordination, and data exchange use cases including specialty specific registry reporting for public health and quality improvement purposes.

USCDI submissions may in turn help to identify where gaps exist in vocabulary and implementation standards to capture a specific data element within a data class. They may also help further refine the clinical concepts most ready for pilot opportunities in order to work toward future versions of USCDI (including from federal and non-federal stakeholders, for example, health foundations). With this information, more precise investments in pilots or other related activities to advance data element maturity can be made.

For more information on the materials discussed in this Bulletin, please see the [ONC Website](#) or links to the following resources:

- [Draft USCDI v2](#)
- [USCDI Home Page](#)
- [SVAP: Approved Standards for 2020](#)

To be notified when future Standards Bulletins are released in the future, please subscribe to the [Standards Eblast](#).