



Understanding Draft USCDI Version 2 and Standards Version Advancement Process

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ONC Health IT Certification Program

The Office of the National Coordinator for Health Information Technology



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Agenda

- What is the United States Core Data for Interoperability (USCDI)?
- What is Draft USCDI v2?
- What is the Standards Version Advancement Process (SVAP)?
- Frequently Asked Questions



United States Core Data for Interoperability (USCDI)

ONC Health IT Certification Program
The Office of the National Coordinator for Health Information Technology



What is the United States Core Data for Interoperability (USCDI)?

- ONC-defined set of health data that must be expressed in Certified Health IT modules and made available for exchange using certain exchange standards, such as FHIR or C-CDA.
- USCDI data elements represent individual concepts: medication, allergy, procedure, or health concern.
- Some USCDI data elements must be expressed using specific health IT vocabulary standards, such as SNOMED CT or RxNorm.
- USCDI focuses on core data requirements for patient data access and certain other exchange and interoperability uses.
- USCDI is "content exchange standard agnostic" USCDI doesn't specify how and to what extent its elements are included in FHIR or C-CDA

Allergies and Intolerances ***NEW**



- Substance (Medication)
- Substance (Drug Class) ***NEW**
- Reaction ***NEW**

Assessment and Plan of Treatment



Care Team Members



Clinical Notes ***NEW**



- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals



Health Concerns



Immunizations



Laboratory



- Tests
- Values/Results

Medications



Patient Demographics



- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address ***NEW**
- Previous Address ***NEW**
- Phone Number ***NEW**
- Phone Number Type ***NEW**
- Email Address ***NEW**

Problems



Procedures



Provenance ***NEW**



- Author Time Stamp
- Author Organization

Smoking Status



Unique Device Identifier(s) for a Patient's Implantable Device(s)



Vital Signs



- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 years old) ***NEW**
- Weight-for-length Percentile (Birth - 36 months) ***NEW**
- Occipital-frontal Head Circumference Percentile (Birth - 36 months) ***NEW**



For more info:

HealthIT.gov/USCDI

How does USCDI relate to ONC's Health IT Certification Program?

USCDI is a required component for following 2015 Edition Cures Update Certification Criteria

Standardized API for patient and population services (§170.315(g)(10))

Transitions of care (§170.315(b)(1))

Clinical information reconciliation and incorporation (§170.315(b)(2))

View, download, and transmit to 3rd party (§170.315(e)(1))

Transmission to public health agencies –electronic case reporting (§170.315(f)(5))

Consolidated CDA creation performance (§170.315(g)(6))

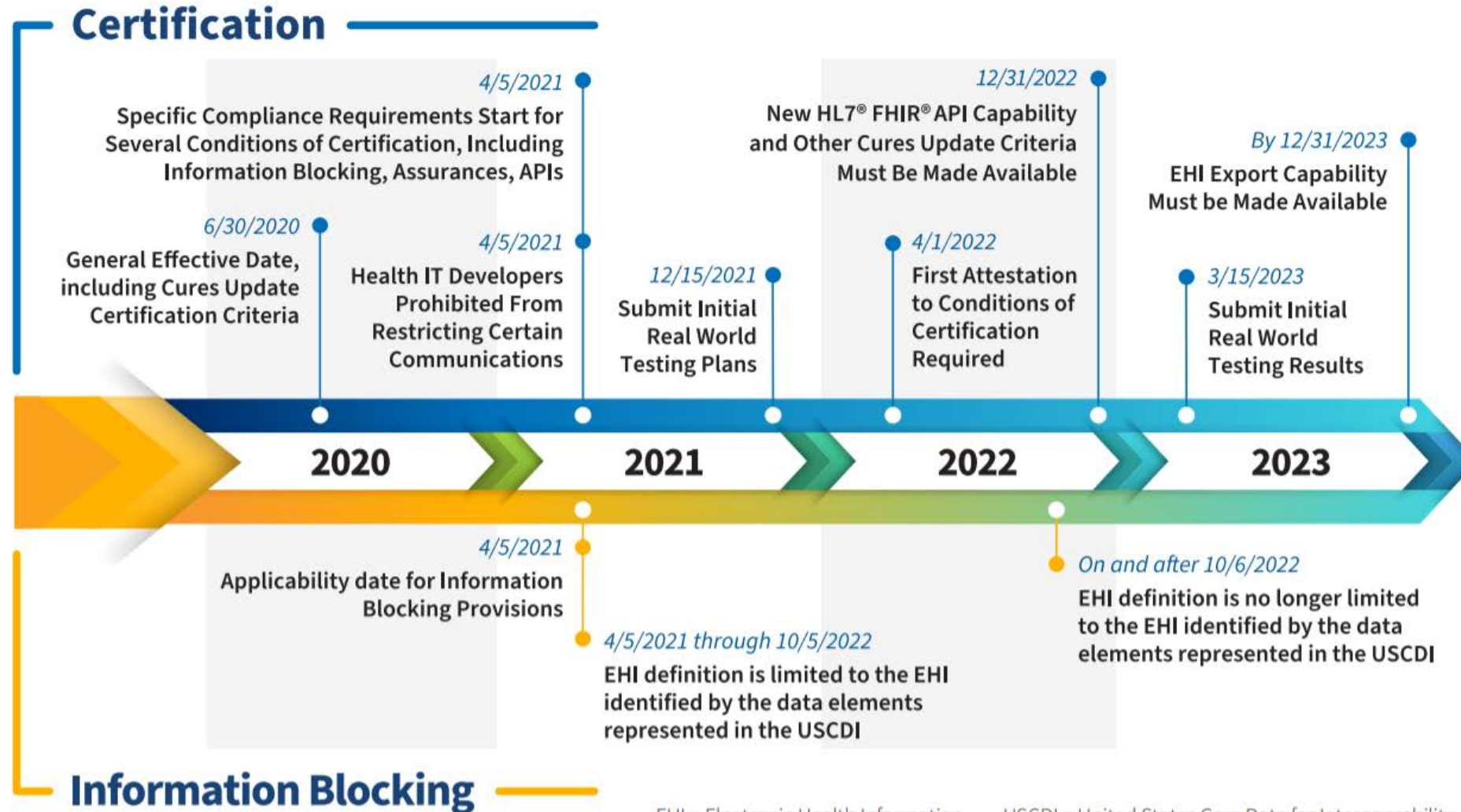
Application access –all data request (§170.315(g)(9))

Update to USCDI by
December 31, 2022
(replacing Common
Clinical Data Set)

USCDI, Certification, and Information Blocking



Information Blocking and the ONC Health IT Certification Program:
Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule



EHI = Electronic Health Information

USCDI = United States Core Data for Interoperability

USCDI Expansion Process

USCDI ONDEC (ONC New Data Element and Class) Submission System



USCDI ONDEC supports ONC's intent to develop new versions of the USCDI through a predictable, transparent, and collaborative process, allowing health IT stakeholders to submit new data elements and classes. Review the USCDI ONDEC Fact Sheet to learn more.

How It Works

Step 1. Submit new data elements and classes



Review Prep Sheet

See questions and prepare content for your submission - updated to include more information on ONC's evaluation of submissions

Start My Submission

Registered ISA users only - login or create account here



Step 2. ONC evaluates and assigns a level to each data element depending on the overall value, maturity and challenges to implementation

• Comment • Level 1 • Level 2



Step 3. ONC posts submitted data elements on the USCDI page by level

Submitters will have an opportunity to add or change information which could change its level determination.

Other stakeholders can review these submissions and contribute to their development through comments and collaboration with original submitters.



Step 4. Submissions achieving Level 2 by October of each year will be considered for inclusion in the draft of the next version of USCDI. ONC will present the draft to the Health IT Advisory Committee and the public for comment.



Step 5. ONC finalizes the next version of USCDI in July.

[HealthIT.gov/ONDEC](https://www.healthit.gov/ONDEC)

Submission Evaluation Criteria

CRITERIA	COMMENT LEVEL	LEVEL 1	LEVEL 2
Maturity-Current Standards	May be represented by terminology standard <u>or</u> element of Standards Development Organization (SDO) balloted technical specification	<u>Must</u> be represented using terminology standard <u>or</u> element of SDO-balloted technical specification	<u>Must</u> be represented using terminology standard <u>or</u> element of SDO-balloted technical specification
Maturity-Current Use	Limited test environments, or pilots	Limited production environments, 1 or 2 different systems	At scale in production environments more than 2 different systems
Maturity-Current Exchange	Limited exchange with external organizations, on same or different EHR/HIT systems	Exchanged between 2 or 3 organizations with different EHR/HIT systems	Exchanged between 4 or more organizations with different EHR/HIT systems
Use Cases-# 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

Who submitted to ONDEC



USCDI ONDEC Submissions

Level Assignments	Data Elements
Level 2	109
Level 1	55
Comment Level	140
Total Data Elements Submitted	664*

***Includes Merged/Duplicated data elements**

Draft USCDI version 2

Update Process

How did ONC select which Level 2 data elements made Draft USCDI v2

- Significant gaps in USCDI v1 concepts
- Supported by existing ONC Certification
- Modest technical standards development
- Modest aggregate lift for vendor development and implementation, esp. during pandemic

Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment

- Assessment and Plan of Treatment

Care Team Members

- Care Team Members
- Provider Name
- Provider Identifier

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Diagnostic Imaging

- Diagnostic Imaging Order
- Diagnostic Imaging Report
- Diagnostic Imaging Narrative

Encounter Information

- Encounter Type
- Encounter Diagnosis
- Encounter Time

Goals

- Patient Goals

Health Concerns

- Health Concerns

Immunizations

- Immunizations

Laboratory

- Tests
- Values/Results
- Laboratory Report Narrative
- Pathology Report Narrative

Medications

- Medications

Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems

- Problems
- Date of Diagnosis
- Date of Resolution

Procedures

- Procedures

Provenance

- Author Time Stamp
- Author Organization

Smoking Status

- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

- Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs

- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 Years)
- Weight-for-length Percentile (Birth-36 Months)
- Occipital-frontal Head Circumference Percentile (Birth-36 Months)

Key: ★ New Data Class or Element
 ➡ Data Element reclassified

Draft USCDI v2

Updated Applicable Vocabulary Standards Versions

• USCDI v1

- RxNorm - January 6, 2020
- SNOMED CT – September 2019
- LOINC 2.67
- ICD-10-PCS 2020
- CVX - January 31, 2020
- Vaccine NDC Linker - January 31, 2020
- CPT 2020



Updated

• Draft USCDI v2

- RxNorm - January 4, 2021
- SNOMED CT - September 2020
- LOINC 2.69
- ICD-10-PCS 2021
- CVX - November 16, 2020
- Vaccine NDC Linker - November 13, 2020
- CPT 2021

USCDI Version Update Process





Standards Version Advancement Process (SVAP)

ONC Health IT Certification Program

The Office of the National Coordinator for Health Information Technology



Standards Version Advancement Process

The Standards Version Advancement Process (SVAP) allows developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use approved newer versions of standards than are adopted in regulation so long as certain conditions are met.

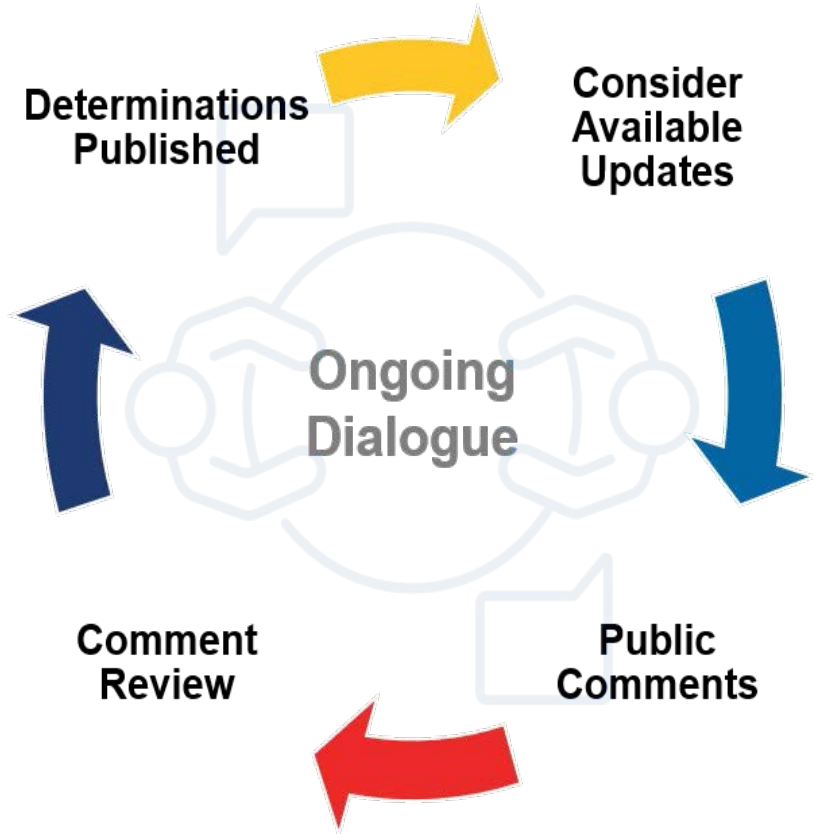
Why Is This Important?

- Provides flexibility to approve newer versions of adopted standards without rulemaking.
- Institutes a predictable and timely approach within the Certification Program to keep pace with the industry's standards development efforts.
- Supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

ONC established the voluntary SVAP flexibility as part of the “Real World Testing” Condition and Maintenance of Certification requirement of the 21st Century Cures Act.

SVAP Approval Cycle

How Versions Get Approved



<https://www.healthit.gov/SVAP>

View / Comment (170.259)	Current Standard / Implementation Specification listing in IBR	Regulatory Text Citation for Standard / Implementation Specification Adopted *	Certification Criteria(ion) References Standard / Implementation Specification	National Coordinator Approved Advanced Version(s)
2	Applicability Statement for Secure Health Transport, Version 1.2, August 2015 (Direct)	§ 170.202(a)(2)	§ 170.315(b)(1) - Transitions of care § 170.315(h)(1) - Direct Project § 170.315(h)(2) - Direct Project, Edge Protocol, and XDR/XDM	
2	XDR and XDM for Direct Messaging Specification, Version 1, March 9, 2011	§ 170.202(b)	§ 170.315(h)(2) - Direct Project, Edge Protocol, and XDR/XDM	
2	ONC Implementation Guide for Direct Edge Protocols, Version 1.1, 2014-08-2020-04	§ 170.202(d)	§ 170.315(b)(1) - Transitions of care	

HealthITBuzz
The Latest on Health Information Technology from ONC

Health IT Buzz > Interoperability > Advancing Standards: Standards Version Advancement Process (SVAP) and Interoperability

Interoperability

Advancing Standards: Standards Version Advancement Process (SVAP) and Interoperability Standards Advisory (ISA)

Chris Muir and Brett Andriesen | SEPTEMBER 8, 2020

HealthIT.gov



NEW: ISA & SVAP Comment Periods Open Through November 9

On the heels of the [USCDI ONDEC Submission System](#) launched in July, ONC is providing more opportunities to submit feedback and input into standards and interoperability efforts. Today, we are launching the inaugural Standards Version Advancement Process (SVAP) comment period, alongside the annual Interoperability Standards Advisory (ISA) review and comment period. Submit feedback by **November 9 at 11:59 PM ET**. Learn more in our latest [Health IT Buzz Blog post](#).

Applicable Real World Testing Certification Criteria

Care Coordination

[§ 170.315\(b\)\(1\) Transitions of care](#)

[§ 170.315\(b\)\(2\) Clinical information reconciliation and incorporation](#)

[§ 170.315\(b\)\(3\) Electronic prescribing](#)

[§ 170.315\(b\)\(6\) Data export](#)

[§ 170.315\(b\)\(7\) Security tags - summary of care - send](#)

[§ 170.315\(b\)\(8\) Security tags - summary of care - receive](#)

[§ 170.315\(b\)\(9\) Care plan](#)

[§ 170.315\(b\)\(10\) Electronic Health Information export](#)

★★★ Clinical Quality Measures

[§ 170.315\(c\)\(1\)—record and export](#)

[§ 170.315\(c\)\(2\)—import and calculate](#)

[§ 170.315\(c\)\(3\)—report](#)

Patient Engagement

[§ 170.315\(e\)\(1\) View, download, and transmit to 3rd party](#)

Electronic Exchange

[§ 170.315\(h\)\(1\) Direct Project](#)

[§ 170.315\(h\)\(2\) Direct Project, Edge Protocol, and XDR/XDM](#)

Public Health

[§ 170.315\(f\)\(1\) Transmission to immunization registries](#)

[§ 170.315\(f\)\(2\) Transmission to public health agencies — syndromic surveillance](#)

[§ 170.315\(f\)\(3\) Transmission to public health agencies — reportable laboratory tests and value/results](#)

[§ 170.315\(f\)\(4\) Transmission to cancer registries](#)

[§ 170.315\(f\)\(5\) Transmission to public health agencies — electronic case reporting](#)

[§ 170.315\(f\)\(6\) Transmission to public health agencies — antimicrobial use and resistance reporting](#)

[§ 170.315\(f\)\(7\) Transmission to public health agencies — health care surveys](#)

Application Programming Interfaces

[§ 170.315\(g\)\(7\) Application access— patient selection](#)

[§ 170.315\(g\)\(8\) Application access— data category request](#)

[§ 170.315\(g\)\(9\) Application access— all data request](#)

[§ 170.315\(g\)\(10\) Standardized API for patient and population services](#)

Approved Standards for 2020

Certification Criteria	SVAP Version(s) Approved	Current Standard Version(s)	Regulatory Text Citation
§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2021	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	§ 170.205(h)(3)
	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2021	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020	§ 170.205(k)(3)
§ 170.315(e)(1) - View, download, and transmit to 3rd party	Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	§ 170.204(a)(1) – Level A Conformance § 170.204(a)(2) – Level AA Conformance
§ 170.315(f)(7) - Transmission to public health agencies — health care surveys	HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3 - US Realm	HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 - US Realm, HL7 Draft Standard for Trial Use, Volume 1 - Introductory Material, December 2014	§ 170.205(s)(1)

January
Approved Standards
Announced





60-day delay



March
Available for
Certification

<https://www.healthit.gov/topic/standards-version-advancement-process-svap>

SVAP and Certification

-  Limited to standards adopted in the certification criteria to meet the “Real World Testing” Condition of Certification.
-  Choose flexibility when seeking initial certification or to maintain certification of a Health IT Module.
-  Ensure standards version updates are effectively implemented.
-  Address standards version updates in annual Real World Testing plans and results.

How Does It Work?

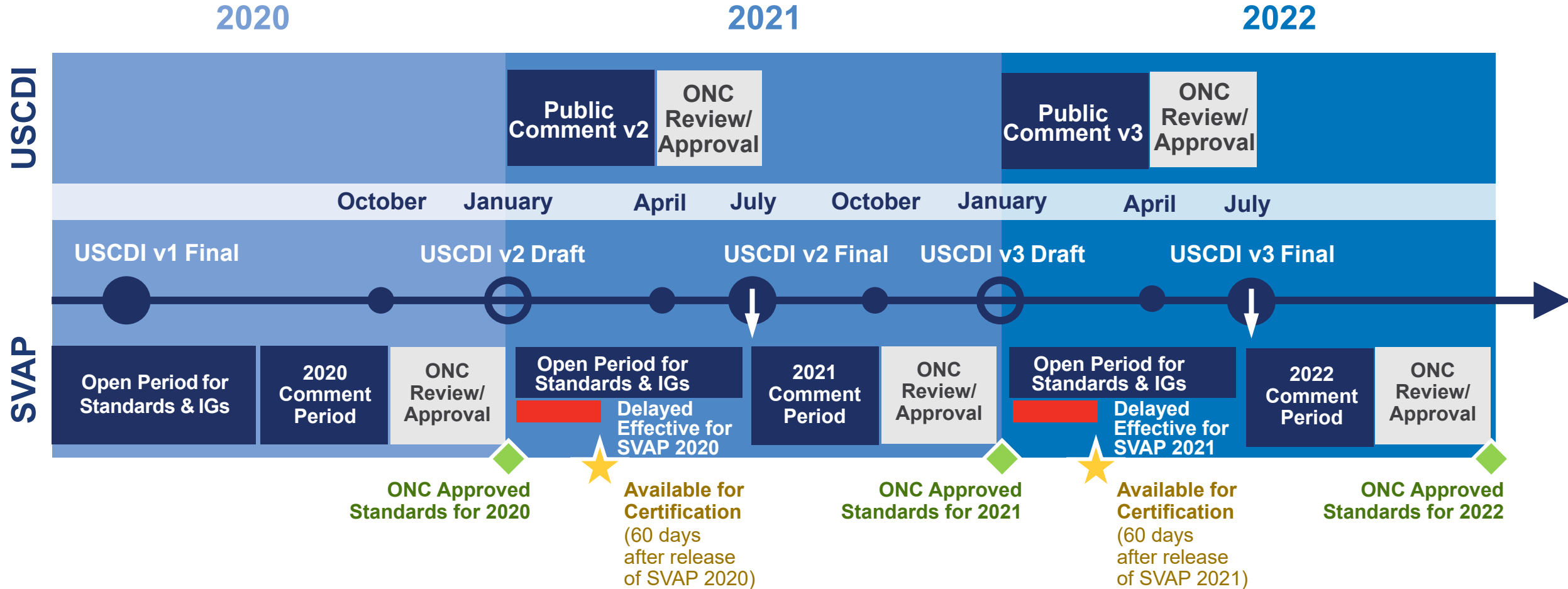
To take advantage of the flexibility to update to newer approved versions, a developer will need to:

- Provide advance notice to all affected customers and its ONC-Authorized Certification Body (ONC-ACB)
 - ✓ expressing intent to update to the more advanced version of the standard;
 - ✓ expectations for how the update will affect interoperability of each affected Health IT Module;
 - ✓ whether intend to continue to support the certificate(s) for the existing certified Health IT Module(s) version
- Successfully demonstrate conformance with approved more recent versions of the standard(s) included in each updated certification criterion.
- Maintain the updated certified Health IT Module(s) in full conformance with all applicable Program requirements.



USCDI & SVAP

USCDI and SVAP Timeline



USCDI/SVAP FAQs – Mapping Clinical Notes

Is my organization required to map all of our other note types (e.g., Nursing Notes, Operative Notes, Care Plan Notes, ED Progress Notes) to the eight Clinical Note data elements USCDI v1 requires and make them available for exchange?

No.

ONC provides general definitions and scope for the eight Clinical Notes note types, but does not specify the content within each note type, nor does it specify which other note types should be mapped to the eight Clinical Note data element types in USCDI v1.

Providers and/or developers may choose to map Nursing Notes and/or other note types to the Progress Note data element in Clinical Notes to support access and interoperability of a wider range of note types than specified in USCDI.

Important reminder: Regardless of the decision to map notes to USCDI Clinical Notes data elements, on or after October 6, 2022, an actor must respond to a request for access, exchange, or use of EHI with EHI that meets the broader EHI definition found in 45 CFR 171.102. The limitation of EHI to only content in USCDI no longer applies.

USCDI/SVAP FAQs – Updating to USCDI v2

Will I be required to update my Certified Health IT Module to USCDI v2?

No.

USCDI v2 will be a candidate for the Standards Version Advancement Process (SVAP) Approved Standards for 2021, which will be announced in January 2022. If USCDI v2 is included in the Approved Standards for 2021 –

- Health IT Developers with an already certified Health IT Module will be permitted to update to a newer approved version of the USCDI within the scope of the certification criteria without having to retest or recertify.
- Health IT Developers seeking to obtain an initial certification for a Health IT Module will be permitted to certify directly to a newer version of USCDI approved under SVAP.

USCDI/SVAP FAQs – USCDI v2 – All or None?

If I voluntarily update my Certified Health IT Module to USCDI v2, do I need to include all the new data classes and data elements?

Yes.

Under the ONC Health IT Certification Program, a Health IT Developer must update to all the new data classes and/or data elements to meet the USCDI v2 requirements. For example, you would not be able to include the data class Encounter Information and not update to the data class Diagnostic Imaging.

USCDI/SVAP FAQs – USCDI v2 Update Timeline

When can I update my Certified Health IT Module to USCDI v2 in the ONC Health IT Certification Program?

SVAP Approved Standards will be announced each January. This will be followed by a 60-day delayed effective period, after which newer approved versions of adopted standards will be available for certification.

If USCDI v2 is included as an SVAP Approved Standard for 2021, Health IT Developers may voluntarily begin updating their Certified Health IT Modules in the Program no earlier than 60 days after the announcement in January 2022.

USCDI/SVAP FAQs – SVAP – Any or All?

Do I have to update my Certified Health IT Module to all of the approved SVAP versions?

No.

A Health IT Developer is able to choose which of the newer standard versions approved for use through SVAP to include in its updated Certified Health IT Module and is able to do so on an itemized, standard-by-standard basis at its discretion.

If you choose to leverage the SVAP flexibility, you may voluntarily update your Certified Health IT Module to any or all newer standard versions approved for use, depending on the certification criteria that reference the standard.

If several different approved SVAP versions that impact different certification criteria within the scope of a Certified Health IT Module are available, you are able to just update one certification criterion to one or more of the applicable new standards. You would not have to update your Certified Health IT Module to all of the approved SVAP versions all at once in order to take advantage of the SVAP flexibility.

USCDI and SVAP Resources

- **USCDI**

- Access and comment on the USCDI, including the Draft USCDI v2: <https://www.healthit.gov/uscdi>
- Submit to the ONC New Data Element and Class (ONDEC) Submission System: <https://www.healthit.gov/ondec>

- **SVAP**

- View information on the annual process, including the list of eligible standards and their versions for consideration: <https://www.healthit.gov/svap>
- Obtain the list of approved SVAP versions and operational information for certification: <https://www.healthit.gov/topic/standards-version-advancement-process-svap>

- **Certification Resources**

- Access reference documents and other resources related to ONC's Health IT Certification Program: <https://www.healthit.gov/topic/certification-ehrs/certification-resources>

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.

HealthIT.gov



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