Understanding Draft USCDI Version 2 and Standards Version Advancement Process

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March 18, 2021
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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)
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
### How does USCDI relate to ONC’s Health IT Certification Program?

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

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardized API for patient and population services (§170.315(g)(10))</td>
<td></td>
</tr>
<tr>
<td>Transitions of care (§170.315(b)(1))</td>
<td></td>
</tr>
<tr>
<td>Clinical information reconciliation and incorporation (§170.315(b)(2))</td>
<td></td>
</tr>
<tr>
<td>View, download, and transmit to 3rd party (§170.315(e)(1))</td>
<td></td>
</tr>
<tr>
<td>Transmission to public health agencies –electronic case reporting (§170.315(f)(5))</td>
<td>Update to USCDI by December 31, 2022 (replacing Common Clinical Data Set)</td>
</tr>
<tr>
<td>Consolidated CDA creation performance (§170.315(g)(6))</td>
<td></td>
</tr>
<tr>
<td>Application access –all data request (§170.315(g)(9))</td>
<td></td>
</tr>
</tbody>
</table>
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

**Certification**

- **6/30/2020**: General Effective Date, including Cure Update Certification Criteria
- **4/5/2021**: Health IT Developers Prohibited From Restricting Certain Communications
- **4/5/2021**: Specific Compliance Requirements Start for Several Conditions of Certification, Including Information Blocking, Assurances, APIs
- **12/15/2021**: Submit Initial Real World Testing Plans
- **12/31/2022**: New HL7 FHIR® API Capability and Other Cures Update Criteria Must Be Made Available
- **4/1/2022**: First Attestation to Conditions of Certification Required
- **3/15/2023**: Submit Initial Real World Testing Results
- **By 12/31/2023**: EHI Export Capability Must be Made Available

**Information Blocking**

- **4/5/2021 through 10/5/2022**: EHI definition is limited to the EHI identified by the data elements represented in the USCDI
- **On and after 10/6/2022**: EHI definition is no longer limited to the EHI identified by the data elements represented in the USCDI

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
## Submission Evaluation Criteria

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>COMMENT LEVEL</th>
<th>LEVEL 1</th>
<th>LEVEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maturity-Current Standards</td>
<td>May be represented by terminology standard or element of Standards Development Organization (SDO) balloted technical specification</td>
<td>Must be represented using terminology standard or element of SDO-balloted technical specification</td>
<td>Must be represented using terminology standard or element of SDO-balloted technical specification</td>
</tr>
<tr>
<td>Maturity-Current Use</td>
<td>Limited test environments, or pilots</td>
<td>Limited production environments, 1 or 2 different systems</td>
<td>At scale in production environments more than 2 different systems</td>
</tr>
<tr>
<td>Maturity-Current Exchange</td>
<td>Limited exchange with external organizations, on same or different EHR/HIT systems</td>
<td>Exchanged between 2 or 3 organizations with different EHR/HIT systems</td>
<td>Exchanged between 4 or more organizations with different EHR/HIT systems</td>
</tr>
<tr>
<td>Use Cases- # Stakeholders Impacted</td>
<td>Used by few stakeholders, or for narrowly defined conditions or events.</td>
<td>Pertinent to many, but not most patients, providers or events requiring its use</td>
<td>Pertains to majority of patients, providers or events requiring its use</td>
</tr>
</tbody>
</table>
Who submitted to ONDEC
## USCDI ONDEC Submissions

<table>
<thead>
<tr>
<th>Level Assignments</th>
<th>Data Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>109</td>
</tr>
<tr>
<td>Level 1</td>
<td>55</td>
</tr>
<tr>
<td>Comment Level</td>
<td>140</td>
</tr>
<tr>
<td>Total Data Elements Submitted</td>
<td>664*</td>
</tr>
</tbody>
</table>

*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
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

• **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

*Updated*
USCDI Version Update Process

**2020**
- **USCDI v1 Final**

**2021**
- **USCDI v2 Draft**
- **USCDI v2 Final**
  - Considered for 2021 SVAP

**2022**
- **USCDI v3 Draft**
- **USCDI v3 Final**
  - Considered for 2022 SVAP
Standards Version Advancement Process (SVAP)
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

Determinations Published

Consider Available Updates

Ongoing Dialogue

Comment Review

Public Comments

https://www.healthit.gov/SVAP
### Applicable Real World Testing Certification Criteria

<table>
<thead>
<tr>
<th>Care Coordination</th>
<th>Clinical Quality Measures</th>
<th>Patient Engagement</th>
<th>Electronic Exchange</th>
<th>Public Health</th>
<th>Application Programming Interfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ 170.315(b)(1) Transitions of care</td>
<td>§ 170.315(c)(1)—record and export</td>
<td>§ 170.315(e)(1) View, download, and transmit to 3rd party</td>
<td>§ 170.315(h)(1) Direct Project</td>
<td>§ 170.315(f)(1) Transmission to immunization registries</td>
<td>§ 170.315(g)(7) Application access—patient selection</td>
</tr>
<tr>
<td>§ 170.315(b)(2) Clinical information reconciliation and incorporation</td>
<td>§ 170.315(c)(2)—import and calculate</td>
<td>§ 170.315(e)(2) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(f)(2) Transmission to public health agencies—syndromic surveillance</td>
<td>§ 170.315(g)(8) Application access—data category request</td>
</tr>
<tr>
<td>§ 170.315(b)(3) Electronic prescribing</td>
<td>§ 170.315(c)(3)—report</td>
<td>§ 170.315(e)(3) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(h)(3) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results</td>
<td>§ 170.315(g)(9) Application access—all data request</td>
</tr>
<tr>
<td>§ 170.315(b)(6) Data export</td>
<td>§ 170.315(c)(4) Transmission to cancer registries</td>
<td>§ 170.315(e)(4) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(h)(4) Direct Project, Edge Protocol, and XDR/XDM</td>
<td>§ 170.315(f)(4) Transmission to public health agencies— electronic case reporting</td>
<td>§ 170.315(g)(10) Standardized API for patient and population services</td>
</tr>
</tbody>
</table>
### Approved Standards for 2020

<table>
<thead>
<tr>
<th>Certification Criteria</th>
<th>SVAP Version(s) Approved</th>
<th>Current Standard Version(s)</th>
<th>Regulatory Text Citation</th>
</tr>
</thead>
</table>
| § 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 |

**January**
Approved Standards Announced

**March**
Available for Certification

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

2020
- USCDI v1 Final
- 2020 Comment Period
- Open Period for Standards & IGs
- ONC Review/Approval

2021
- USCDI v2 Draft
- 2021 Comment Period
- Open Period for Standards & IGs
- ONC Review/Approval
- Delayed Effective for SVAP 2020

2022
- USCDI v3 Final
- 2022 Comment Period
- Open Period for Standards & IGs
- ONC Review/Approval
- Delayed Effective for SVAP 2021

- ONC Approved Standards for 2020
- Available for Certification (60 days after release of SVAP 2020)
- ONC Approved Standards for 2021
- Available for Certification (60 days after release of SVAP 2021)
- ONC Approved Standards for 2022

ONC Review/Approval

Public Comment v2
ONC Review/Approval
Public Comment v3
ONC Review/Approval

October 2020
January 2021
April 2021
July 2021
October 2021
January 2022
April 2022
July 2022
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.
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.
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](https://www.healthit.gov/uscdi)
  - Submit to the ONC New Data Element and Class (ONDEC) Submission System: [https://www.healthit.gov/ondec](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](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](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](https://www.healthit.gov/topic/certification-ehrs/certification-resources)
Sign up for and also view previous alerts for healthcare stakeholders that include updates about ONC health IT standards initiatives

https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin