

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) 2023 SVAP Fact Sheet

This fact sheet describes the voluntary Standards Version Advancement Process (SVAP) available to health IT developers participating in the ONC Health IT Certification Program (Certification Program). This resource assists Certified Health IT developers in understanding SVAP and their responsibilities if they choose to leverage this flexibility.

What is SVAP?

The ONC Cures Act Final Rule (Final Rule) established the voluntary Standards Version Advancement Process (SVAP) flexibility as part of the Real World Testing Condition and Maintenance of Certification (45 CFR 170.405) required by the 21st Century Cures Act. SVAP allows Certified Health IT developers participating in the Certification Program to voluntarily update their Health IT Modules and to provide these approved newer versions of standards to customers prior to their adoption in regulation so long as certain conditions are met.

SVAP allows for advanced versions of standards to be approved for use under the Certification Program in a more timely and flexible manner than is possible for new versions of standards that are adopted through ONC rulemaking. It also gives Certified Health IT developers the ability to conduct ongoing maintenance on their certified health IT to incorporate these new and more advanced standard versions, which is essential to supporting interoperability in the real world.



After reviewing this fact sheet, readers will understand:

- What is SVAP
- What are the Approved Standards for 2023
- How to use SVAP
- Where to find additional SVAP information

The process to identify, approve, and make available newer versions of standards takes place on an annual cycle to keep pace with the industry's standards development efforts. Working with stakeholders and providing ample notice, ONC's collaborative public comment process seeks feedback each year on newer versions of eligible standards that are also ready for adoption in the Certification Program through the SVAP. For more information on the SVAP public comment process, please visit https://www.healthit.gov/isa/standards-version-advancement-process.



Approved SVAP versions are announced in June each year and become effective for Certification Program use after a 60-day period in August of that year.



Approved Standards for 2023

The SVAP flexibility is limited to the standards adopted in the certification criteria that meet the Real World Testing Condition and Maintenance of Certification requirement. As part of ONC's review and assessment of the 2022 SVAP Cycle public comments, the newer versions of adopted standards listed in the table below have been approved for use in the Certification Program.

2023 Approved SVAP Standard	Regulatory Standard Version	Certification Criteria(on)	Regulatory Text Citation
United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata	United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata	§ 170.315(b)(1) - Transitions of care § 170.315(b)(2) - Clinical information reconciliation and incorporation § 170.315(e)(1) - View, download, and transmit to 3rd party § 170.315(f)(5) - Transmission to public health agencies - electronic case reporting; § 170.315(g)(9) - Application access - all data request § 170.315(g)(10) - Standardized API for patient and population services	§ 170.213
HL7® FHIR® US Core Implementation Guide STU 6.1.0, June 30, 2023	HL7® FHIR® US Core Implementation Guide STU 3.1.1, August 8, 2020	§ 170.315(g)(10) - Standardized API for patient and population services	§ 170.215(a)(2)
HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1.0-US Realm, June 30 2023	HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2-US Realm, October 2019	§ 170.315(b)(1) - Transitions of care § 170.315(b)(2) - Clinical information reconciliation and incorporation § 170.315(b)(9) - Care plan § 170.315(e)(1) - View, download, and transmit to 3rd party § 170.315(g)(9) - Application access - all data request	§ 170.205(a)(5)





2023 Approved SVAP Standard	Regulatory Standard Version	Certification Criteria(on)	Regulatory Text Citation
HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, STU Release 5.3 with errata (US Realm), Volume 1 - Introductory Material, December 2022	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 - Introductory Material, June 2015	§ 170.315(c)(1) - Clinical quality measures (CQMs) — record and export § 170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate	§ 170.205(h)(2)
CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting: Implementation Guide for 2023	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	§ 170.205(h)(3)
CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	§ 170.205(k)(3)

Certified Health IT developers can begin voluntarily incorporating these standard versions on September 11, 2023.

These are the standards that have been approved for the 2023 SVAP cycle. For a complete list of all SVAP approved standards that can be used in the Certification Program, see the ONC Health IT Certification Program SVAP page.

Please note that ONC is extending the availability of USCDI v2 while the ONC conformance testing tools are updated. This includes the Edge Testing Tool's (ETT) C-CDA validators and the Inferno Frameworks g.10 Standardized API test kit. In order to SVAP to a newer version of USCDI, a developer has to conform to either the HL7 FHIR US Core Implementation Guide (IG) or the HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide.

Health IT developers will be able to continue using the current USCDI v2 test tools and may certify products to USCDI v2 until the USCDI v3 test tools are made available in December 2023. Once the USCDI v3 test tools are available, developers will no longer be able to advance to USCDI v2.





How to Use SVAP

For the approved SVAP versions, Certified Health IT developers choosing to leverage the SVAP flexibility can do so on initial certification of their Health IT Module or to maintain certification for their Module. To take advantage of the flexibility to update to newer approved versions, a Certified Health IT developer will need to:

- For existing certifications only, provide advance notice to all affected customers and their 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; and
 - whether they 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 to confirm they meet the updated requirements.
- Maintain the updated Certified Health IT Module(s) in full conformance with all applicable Certification
 Program requirements, which includes ensuring their Real World Testing plans and results address the
 updated standards.

Unless ONC specifically excludes the use of additional data elements or electronic standards in rulemaking, there is nothing that prevents a health IT developer from supporting additional data elements, functionalities, or electronic standards in its health IT modules. This could include the partial support of any of the SVAP versions of standards or individual data classes or elements from an SVAP version of USCDI. However, health IT developers may not indicate that those modules are certified to such standards or data elements unless the health IT module provides full support for the entire SVAP version of the standard and the developers has taken all of the steps listed above. Only when all of the above steps have been completed will a health IT module be considered certified to an SVAP version of a standard and then subsequently updated on the Certified Health IT Product List (CHPL).

Previously Approved SVAP Standards

A version of an adopted standard approved for use during any SVAP cycle remains available for certification until a newer SVAP version of that standard is approved.

If a newer SVAP version is approved, the previously approved SVAP version will be replaced and no longer available for use in the Certification Program. However, please note the following:

- Certified Health IT developers do not need to keep advancing to newer SVAP versions once they choose to use SVAP.
- No new certifications can be made to the replaced SVAP version once the newer version goes into effect in the Certification Program.
- Any certifications to the replaced SVAP version will still be valid.

For more information on how to use SVAP in the Certification Program, please contact your ONC-ACB.







SVAP Resources

- <u>SVAP</u>: See the most recent list of Approved Standards for SVAP and operational information for certification.
- <u>SVAP Annual Process</u>: View information on the annual process, including the list of standards versions being considered for the next Approved Standards List.
- ONC Standards Bulletin: View and sign up for healthcare stakeholder alerts that include updates about ONC health IT standards initiatives such as the SVAP.
- <u>Certification Program Resources</u>: Access reference documents and other resources related to ONC's Health IT Certification Program.

Note: While every effort has been made to ensure the accuracy of restatements of <u>45 CFR Part 170</u>, this resource is not a legal document. The official requirements are contained in the relevant laws and regulations.





