



Office of the National Coordinator  
for Health Information Technology

# ONC Health IT Certification Program Developer Roundtable

March 22, 2023



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- This communication is produced and disseminated at U.S. taxpayer expense.



# Today's Speakers

1. Rob Anthony, Director
2. Jeff Smith, Deputy Director
3. Tony Myers, Branch Chief, Program Administration



# Agenda

1. Opening Remarks
2. 2015 Cures Update: A Year in Review
3. § 170.315(b)(10) Electronic Health Information (EHI) Export
4. Standards Version Advancement Process (SVAP)





# **2015 Cures Update: A Year in Review**

**Jeff Smith, Deputy Director**

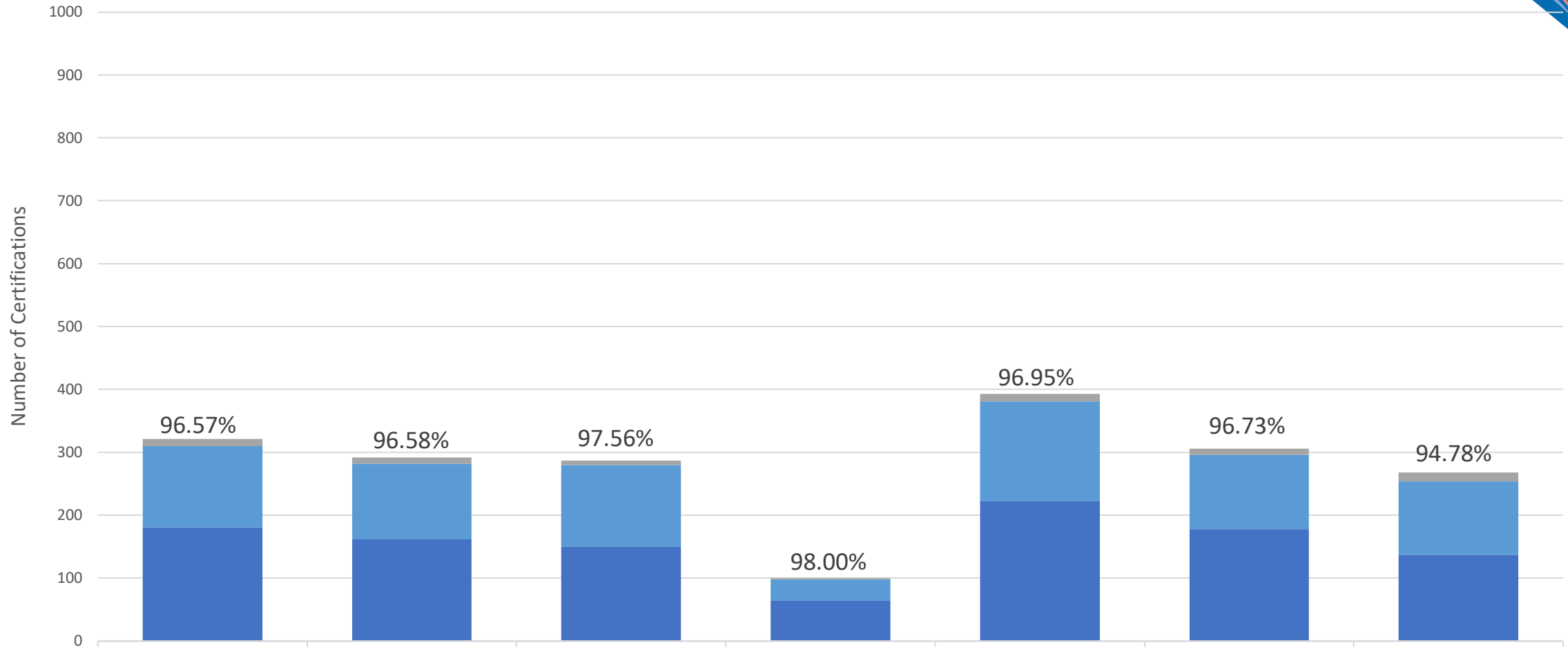


# Changes to the ONC Health IT Certification Program

The Cures Act Final Rule mandated many updates and enhancements to the Certification Program that will have lasting impacts for patients, clinicians, and Certified Health IT developers. These updates will:

1. Advance interoperability through the use of FHIR-based APIs
2. Facilitate access to consistent data elements represented in the United States Core Data for Interoperability (USCDI)
3. Improve electronic prescribing efficiency and reliability
4. Provide transparency regarding the real world functionality of Certified Health IT
5. Enhance privacy and security

## Cures Update USCDI Criteria February 2023

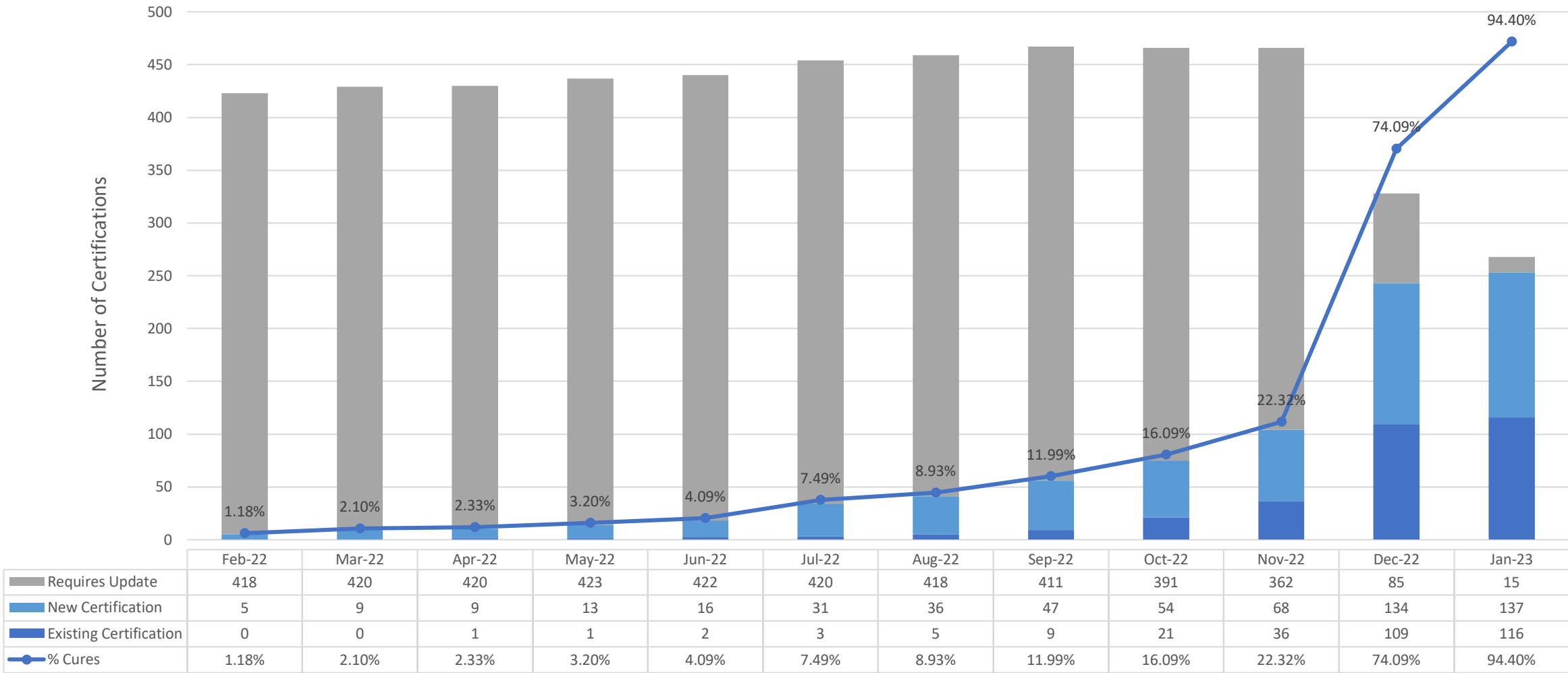


Requires Update	11	10	7	2	12	10	14
Existing Certification	129	120	130	34	159	118	117
New Certification	181	162	150	64	222	178	137
% Cures	96.57%	96.58%	97.56%	98.00%	96.95%	96.73%	94.78%
Total Certification	321	292	287	100	393	306	268



# § 170.315(g)(10) Standardized API for Patient and Population Services

## Feb 2023







# Conditions & Maintenance of Certification Compliance

- Attestations
  - Certified Health IT developers are required to attest twice a year to compliance with the Conditions and Maintenance of Certification requirements.
  - In 2022, 100% of Certified Health IT developers successfully submitted their attestations for both of the 2022 Attestation periods.
- Real World Testing
  - The Cures Update introduced the Real World Testing Condition and Maintenance of Certification that requires developers certified to applicable certification criteria to successfully test the real world use of their health IT for interoperability in the type(s) of setting(s) in which the technology is marketed
  - By the beginning of January 2023, 100% of developers successfully submitted their 2023 Real World Testing plans.
  - As of today, over 98% of developers successfully tested their products during the 2022 Real World Testing year and made their results publicly available on the CHPL



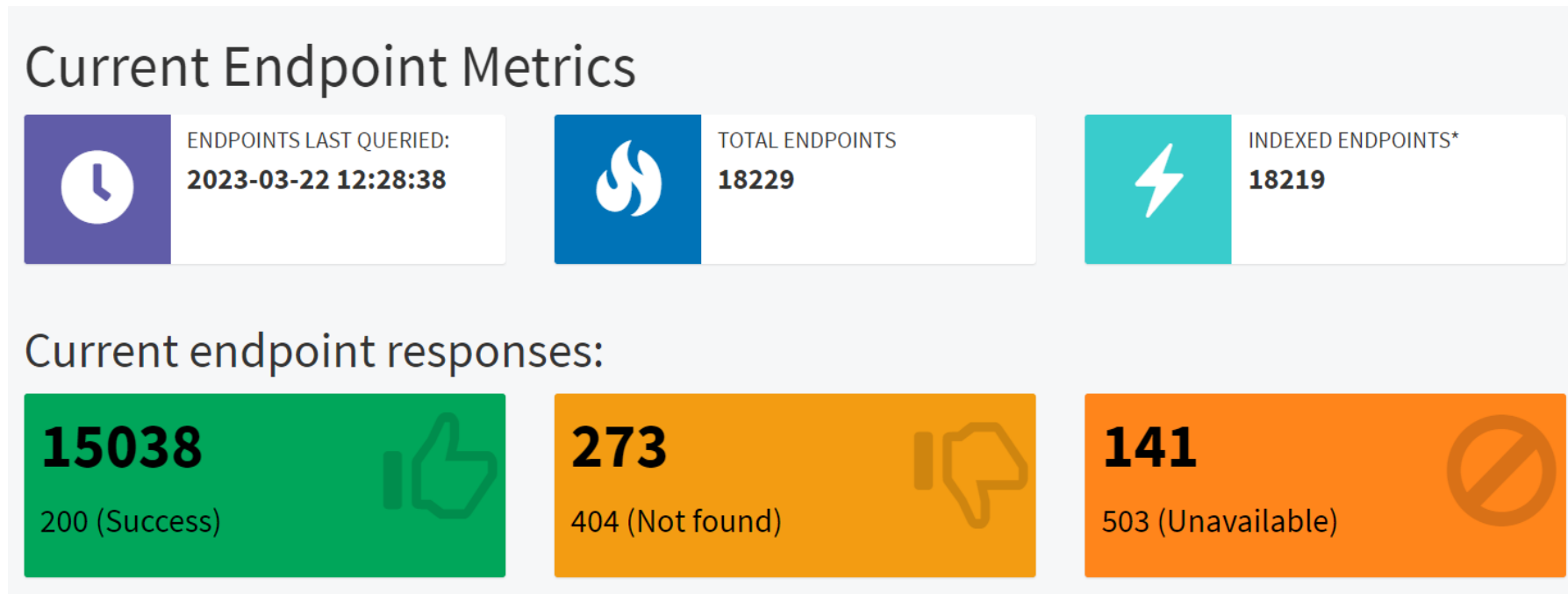
# Standards Version Advancement Process (SVAP)

The Approved SVAP Standards for 2022 included the advancement of 10 Standards

- There have been a total of 113 SVAP updates across 49 CHPL listings since SVAP began
- Several important updates have been made available through SVAP, including:
  - HL7® FHIR® US Core Implementation Guide STU 4.0.0, June 2021
  - HL7® FHIR® US Core Implementation Guide STU 5.0.1, June 2022
  - HL7® FHIR® SMART Application Launch Framework Implementation Guide Release 2.0.0, November 26, 2021
  - HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3-US Realm, May 2022
  - HL7® FHIR® Bulk Data Access (Flat FHIR®) (v2.0.0: STU 2), November 26, 2021
  - United States Core Data for Interoperability (USCDI), Version 2, July 2021
- List of certified health IT developers and Health IT Modules that have used SVAP is public available here: <https://chpl.healthit.gov/#/resources/download> (choose SVAP Summary from dropdown list)

# Lantern

- [Lantern](#) is an open source tool and dashboard that provides the public and, especially patients, application developers, and other API users insights into the adoption and availability of FHIR APIs across U.S. healthcare providers.



- Now that the compliance deadline has passed, ONC will turn to monitoring adoption and conformance in deployed systems through Lantern, while actively engaging with the health IT industry to ensure that the nation's 5,000 hospitals and 500,000+ clinicians with Cures Update technology can leverage FHIR-based APIs.

# 2022 Certification Program Resources

The ONC Health IT Certification Program's has published a number of resources to help the Health IT developer community navigate and understand the requirements of the 2015 Edition Cures Update including:


- [§ 170.315\(b\)\(10\) EHI Export Fact Sheet](#)
- [Cures Update Fact Sheet](#)
- [Real World Testing Resource Guide](#)
- [Direct Review Fact Sheet](#)
- [API Resource Guide](#)
- [SVAP Fact Sheet](#)

Please visit our [Program Resources](#) webpage for a more inclusive list of available resources.

# Congratulations!

- Cures Update deadline represents a genuine milestone for the ONC Certification Program and the entire health IT industry
  - Standards-based APIs and further adoption of FHIR sets course for
    - Increasing interoperability across clinical use cases and improved access for patients
    - Bidirectional exchange between clinical settings and public health
    - Less burdensome quality reporting and
    - More evidence generation and research (clinical, human services, etc.)
  - Use of SVAP and routinized standards development allows industry to move at pace with development
    - Removes ONC rulemaking as rate limiter for advanced functionality and standards adoption
    - Identifies areas where further standards development is needed



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## **§ 170.315(b)(10) Electronic Health Information (EHI) Export**

**Rob Anthony, Director**

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## § 170.315(b)(10) EHI Export

- The 2015 Cures Update includes the § 170.315(b)(10) EHI export criterion that replaces the 2015 Edition § 170.315(b)(6) Date export criterion
- Replacing § 170.315(b)(6) with § 170.315(b)(10) enables:
  - Providers to export all EHI stored in a Certified Health IT product for a single patient or for an entire patient population
  - Individual patient access to EHI
- Required to be certified and made available to end users by December 31, 2023



# Who Is Required to Be Certified to § 170.315(b)(10)?

- The Assurances Maintenance of Certification requires Certified Health IT that electronically stores EHI to certify to the Cures Update § 170.315(b)(10) EHI Export criterion.
- What about:
  - Certified Health IT that is part of a larger product that stores EHI?
  - Certified Health IT that uses relied upon software (RUS) to export EHI?
  - Certified Health IT that leverages 3<sup>rd</sup> party EHI storage?
- What should developers submit to their ONC-ACB if they feel as if § 170.315(b)(10) does not apply to them?
- *Can a developer just direct customers to a 3<sup>rd</sup>-party solution and not have to certify to § 170.315(b)(10) themselves?*



# What Is EHI?

- Electronic Health Information (EHI) refers to “electronic protected health information” (ePHI) to the extent that it would be included in a designated record set as defined in 45 CFR 164.501
- EHI does not include:
  - Psychotherapy notes
  - Information compiled in a reasonable anticipation or, for use in, a civil, criminal, or administrative action/ proceeding.
- *“Does [X data need] to be included in the EHI Export?”*
  - Ask yourself these 2 questions:
    - Is it stored by the product of which the Certified Health IT Module is a part?
    - Would it qualify under the EHI definition above?



# EHI Export File Format Requirements

- All EHI export files are required to include an accessible and up-to-date hyperlink that allows any user to directly access the EHI export file format information without preconditions or additional steps.
  - Users of the export files will use the export format documentation to process EHI after it has been exported by a product.
- The EHI export file format should describe the structure and syntax of how the EHI is exported, but not the EHI itself.
- The export file(s) created must be electronic and in a computable format.
- *Can the export be a PDF?*



# Single Patient EHI Export Requirements

- Single patient EHI export functionality must:
  - Export EHI for a single patient at any time the user chooses without Developer assistance
    - Does not require “direct-to-patient” functionality , can be done on the provider/user side
  - Create an export in a timely fashion
  - Include all EHI for a single patient
  - Be in an electronic and computable format
  - Include a publicly accessible hyperlink of the export’s format
  - Be able to limit users who can perform an EHI export



# Patient Population EHI Export

- Patient population EHI Export functionality must:
  - Must include all EHI for a patient population
  - Must be electronic and in a computable format
  - Must include a publicly accessible hyperlink of the export's format
  - Could require action or support on the part of the health IT developer

## § 170.315(b)(10) Resources

For more information regarding the § 170.315(b)(10) EHI export criterion, please refer to the following resources:

1. [§ 170.315\(b\)\(10\) EHI Export Factsheet](#)
2. [§170.315\(b\)\(10\) Certification Companion Guide](#)

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# **Standards Version Advancement Process (SVAP)**

**Tony Myers, Branch Chief, Program Administration**

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# Standards Version Advancement Process (SVAP)

The SVAP allows health IT 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 and Certification






- Limited to standards adopted in the certification criteria to meet the Real World Testing Condition of Certification.
- Increased 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.

## SVAP Certification

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



## Applicable Real World Testing Certification Criteria

 <b>Care Coordination</b>		
<a href="#">§ 170.315(b)(1) Transitions of care</a>	<a href="#">§ 170.315(b)(6) Data export</a>	<a href="#">§ 170.315(b)(9) Care plan</a>
<a href="#">§ 170.315(b)(2) Clinical information reconciliation and incorporation</a>	<a href="#">§ 170.315(b)(7) Security tags - summary of care - send</a>	<a href="#">§ 170.315(b)(10) Electronic Health Information export</a>
<a href="#">§ 170.315(b)(3) Electronic prescribing</a>	<a href="#">§ 170.315(b)(8) Security tags - summary of care - receive</a>	
<b>★★★ Clinical Quality Measures</b>	 <b>Patient Engagement</b>	 <b>Electronic Exchange</b>
<a href="#">§ 170.315(c)(1)—record and export</a>	<a href="#">§ 170.315(e)(1) View, download, and transmit to 3rd party</a>	<a href="#">§ 170.315(h)(1) Direct Project</a>
<a href="#">§ 170.315(c)(2)—import and calculate</a>		<a href="#">§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM</a>
<a href="#">§ 170.315(c)(3)—report</a>		
 <b>Public Health</b>	 <b>Application Programming Interfaces</b>	
<a href="#">§ 170.315(f)(1) Transmission to immunization registries</a>	<a href="#">§ 170.315(g)(7) Application access—patient selection</a>	
<a href="#">§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance</a>	<a href="#">§ 170.315(g)(8) Application access—data category request</a>	
<a href="#">§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results</a>	<a href="#">§ 170.315(g)(9) Application access— all data request</a>	
<a href="#">§ 170.315(f)(4) Transmission to cancer registries</a>	<a href="#">§ 170.315(g)(10) Standardized API for patient and population services</a>	
<a href="#">§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting</a>		
<a href="#">§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting</a>		
<a href="#">§ 170.315(f)(7) Transmission to public health agencies — health care surveys</a>		

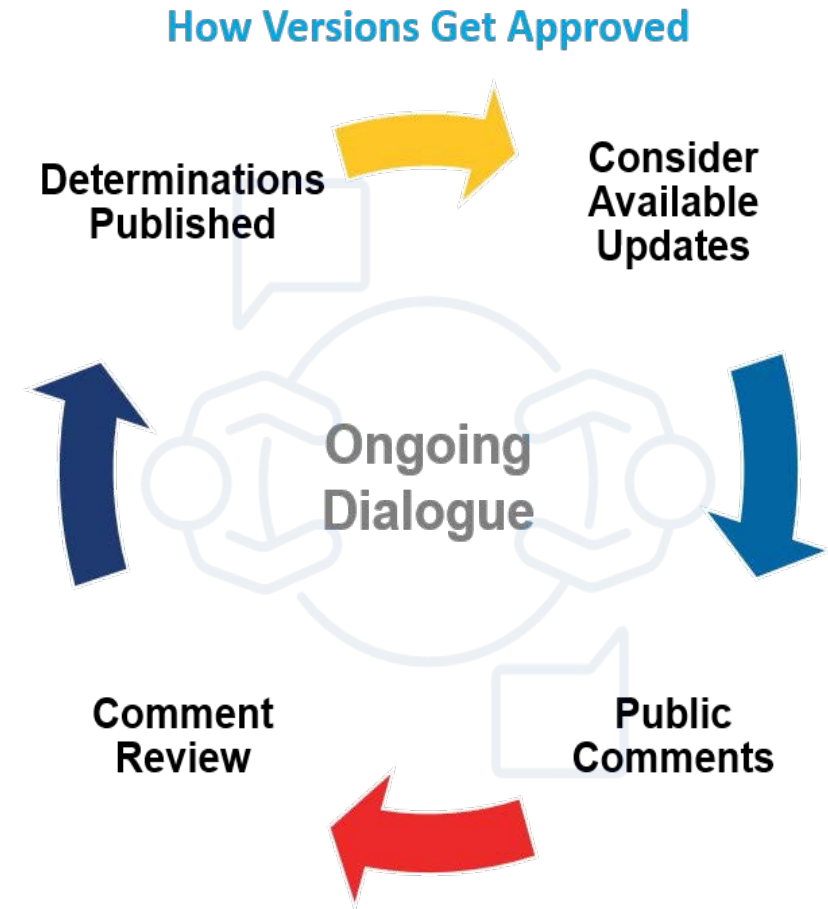


## How to use SVAP

- 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.

# The SVAP Cycle

- To keep pace with the industry's standards development efforts, the process to identify, approve, and make available newer versions of standards takes place on an annual cycle
- The cycle commences each with the opening of the Public Comment Period and concludes when the Approved SVAP Standards become effective.



# 2023 SVAP Timeline

- 2023 SVAP Public Comment Period
  - Opened: February 21, 2023
  - Closes: May 22, 2023
- 2023 SVAP Announcement
  - June 2023
- 2023 SVAP Effective (60-Day Delay)
  - August 2023

## SVAP Annual Process

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

# Public Comment Period

- 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.
- Comments received during this period play a crucial role in selecting final SVAP standards that closely reflect current industry needs and trends.



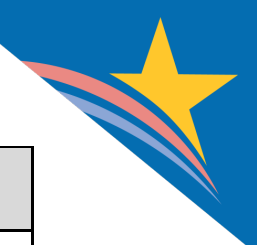


## Previously Approved SVAP Standards

- 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.
  - 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.

### SVAP Certification Complete List:

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



Current Standard/ Implementation Specification listing in IBR (170.299)	2020/2022 Approved Standard	New Version Under Consideration	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	<a href="#">Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018</a> <b>2020 Approved Standard</b>	<a href="#">Web Content Accessibility Guidelines (WCAG) 2.2, January 25, 2023</a>	§ 170.204(a)(1)	§ 170.315(e)(1) - View, download, and transmit to 3rd party
Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	<a href="#">Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018</a> <b>2020 Approved Standard</b>	<a href="#">Web Content Accessibility Guidelines (WCAG) 2.2, January 25, 2023</a>	§ 170.204(a)(2)	§ 170.315(e)(1) - View, download, and transmit to 3rd party
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	N/A	<a href="#">HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), Volume 1 Introductory Material, December 2022</a>	§ 170.205(h)(2)	§ 170.315(c)(1) - Clinical quality measures (CQMs) — record and export § 170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate
HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2 - Templates and Supporting Material, June 2015	N/A	<a href="#">HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), Volume 2 Templates and Supporting Material, December 2022</a>	§ 170.205(h)(2)	§ 170.315(c)(1) - Clinical quality measures (CQMs) — record and export § 170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate
CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	<a href="#">CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 (July 2021)</a>	<a href="#">CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023</a>	§ 170.205(h)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report
CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020	<a href="#">CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (December 2021)</a>	<a href="#">CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023</a>	§ 170.205(k)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report
United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata	<a href="#">United States Core Data for Interoperability (USCDI), Version 2, July 2021</a>	<a href="#">United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata</a>	§ 170.213	§ 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

# 2023 Proposed Standards

The SVAP public comment period for the 2023 SVAP cycle will be open until May 22, 11:59 P.M. ET.

To view and provide comment on the current list of Proposed 2023 SVAP Standards, please visit the Standards SVAP webpage:

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



# SVAP Resources

- **2022 SVAP Fact Sheet:** [https://www.healthit.gov/sites/default/files/page/2022-06/2022 Approved SVAP Fact Sheet.pdf](https://www.healthit.gov/sites/default/files/page/2022-06/2022%20Approved%20SVAP%20Fact%20Sheet.pdf)
- **SVAP Certification Page:** <https://www.healthit.gov/topic/standards-version-advancement-process-svap>
  - Obtain the list of approved SVAP versions and operational information for certification
- **SVAP Process Page:** <https://www.healthit.gov/svap>
  - View information on the annual process, including the list of eligible standards and their versions for consideration
- **ONC Standards Bulletin:** <https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin>
  - View and sign up for healthcare stakeholder alerts that include updates about ONC health IT standards initiatives such as the SVAP
- **Certification Program Resources:** <https://www.healthit.gov/topic/certification-ehrs/certification-resources>
  - Access reference documents and other resources related to ONC's Health IT Certification Program



# Thank you!

Please submit questions, concerns, or feedback to  
<https://inquiry.healthit.gov/>