Office of the National Coordinator for Health Information Technology

ONC Health IT Certification Program Developer Roundtable

July 12, 2023

Please Note:

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Today's Speakers

1. Robert Anthony, Director, Certification and Testing
2. Shawn Spurlock, Public Health Analyst, Certification and Testing
3. Andrew Hayden, Public Health Analyst, Standards

Agenda

1. Opening Remarks
2. § 170.315(b)(10) Electronic Health Information (EHI) Export
3. Standards Version Advancement Process (SVAP)

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

Robert Anthony, Director, Certification and Testing

§ 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 3rd 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 3rd-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?
- Can information outside of the EHI definition be included in the EHI Export?
  - The ONC Health IT Certification Program does not place requirements on the EHI that can be exported under the § 170.315(b)(10) functionality beyond what is defined in regulation as EHI.

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

HISP Functionality

- A Health Information Service Provider (HISP) with functionality that is certified under the ONC Health IT Certification Program must provide its customers with functionality certified to § 170.315(b)(10) if it stores messages that contain EHI.
  - This requirement is based on the scope of EHI that is stored by the product at the time of certification.
  - “We can’t see inside messages . . .”
  - EHI means “electronic protected health information” (ePHI) as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity. AND
  - The EHI definition represents the same ePHI that a patient would have the right to request a copy of pursuant to the HIPAA Privacy Rule.

§ 170.315(b)(10) & Information Blocking

- Do hospitals or providers need to have § 170.315(b)(10) functionality in place to comply with Information Blocking requirements?
  - § 170.315(b)(10) is not explicitly designed to fulfill Information Blocking requirements.
  - § 170.315(b)(10) is a developer requirement, not a provider requirement.
  - ONC regulations only place requirements on developers to make the functionality available to its end users. There are no ONC regulatory requirements on end users or providers related to the use of the functionality.

§ 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

Standards Version Advancement Process (SVAP)

Shawn Spurlock, Public Health Analyst, Certification and Testing

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

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

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
  - Closed: May 22, 2023
- 2023 SVAP Announcement
  - July 12, 2023
- 2023 SVAP Effective (60-Day Delay)
  - September 11, 2023
- 2024 SVAP Public Comment Period
  - Opens: February 2024
  - Closes May 2024 (90 days)

SVAP Annual Process
https://www.healthit.gov/SVAP

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

SVAP Resources

- **2023 SVAP Fact Sheet:** https://www.healthit.gov/sites/default/files/2023-07/2023_SVAP_Fact_Sheet.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

Approved SVAP Standards for 2023

Andrew C. Hayden, Public Health Analyst, Standards

2023 SVAP Standards Overview

- 6 Commenters: National Association of Community Health Centers (NACHC), MEDITECH, Oracle Health, College of American Pathologists (CAP), CDC National Syndromic Surveillance Program (NSSP), EHR Association
  - USCDI: In favor of moving to USCDI v3 from v2 provided in tandem with latest versions of US Core and C-CDA Companion Guide
  - QRDA I, III: In favor of advancing HL7 and CMS annual updates
- US Core IG STU 6.1.0 and C-CDA Companion Guide Release 4.1 will move industry towards consistent implementation of USCDI v3
- To support implementation of the SVAP 2023 Approved Standards, ONC will update all associated test data and tools

Approved Standards for 2023

United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata
HL7® FHIR® US Core Implementation Guide STU 6.1.0, June 30, 2023
HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, June 2023
HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), December 2022
CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023 (March 2023)
CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023 (December 2022)

United States Core Data for Interoperability (USCDI)

Current Standard/ Implementation Specification listing in IBR (170.299)	2023 Approved Standard	2022 Approved Standard	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata	United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata	United States Core Data for Interoperability (USCDI), Version 2, July 2021	§ 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

HL7® FHIR® US Core Implementation Guide

Current Standard/ Implementation Specification listing in IBR (170.299)	2023 Approved Standard	2022 Approved Standard	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
HL7® FHIR® US Core Implementation Guide STU 3.1.1, August 8, 2020	HL7® FHIR® US Core Implementation Guide STU 6.1.0, June 30, 2023	HL7® FHIR® US Core Implementation Guide STU 4.0.0, June 2021 HL7® FHIR® US Core Implementation Guide STU 5.0.0, May 2022	§ 170.215(a)(2)	§ 170.315(g)(10) - Standardized API for patient and population services

HL7® C-CDA Templates for Clinical Notes R2.1 Companion Guide

Current Standard/ Implementation Specification listing in IBR (170.299)	2023 Approved Standard	2022 Approved Standard	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2-US Realm, October 2019	HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1-US Realm, June 2023	HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3-US Realm, May 2022	§ 170.205(a)(5)	§ 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

HL7® Quality Reporting Document Architecture – Category I (QRDA I)

Current Standard/ Implementation Specification listing in IBR (170.299)	2023 Approved Standard	2022 Approved Standard	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
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	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, STU Release 5.3 with Errata (US Realm), December 2022	N/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 QRDA I 2023 and CMS QRDA III 2022

Current Standard/ Implementation Specification listing in IBR (170.299)	2023 Approved Standard(s)	2022 Approved Standard	Regulatory Text Citation for Standard/ Implementation Specification Adopted	Certification Criteria(on) References Standard/ Implementation Specification
CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023 (March 2023)	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 (July 2021)	§ 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	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023 (December 2022)	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (December 2021)	§ 170.205(k)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report

Thank you!

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