Real World Testing

Overview

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The Office of the National Coordinator for Health Information Technology

Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.

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

What is Real World Testing?

Real World Testing is a process by which Health IT Developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL).

Real World Testing verifies that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange. These observations are described in a public and transparent way through Real World Testing plans and reported as Real World Testing results.

Successful Real World Testing means…

- Certified Health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary code sets;
- Certified Health IT is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and
- EHI is received by and used in the Certified Health IT

(from 85 FR 25766)

Who is Required to Conduct Real World Testing?

CONDITION OF CERTIFICATION

A health IT developer with Health IT Module(s) certified to one or more of the applicable certification criteria* **must** successfully test the real-world use of the technology for interoperability in the type of setting in which such technology is marketed.

*Any of the certification criteria outlined in §170.405(a); summarized on next slide

MAINTENANCE OF CERTIFICATION

ONC- ACB - Authorized Certification Body
CHPL - Certified Health IT Product List

A health IT developer of certified Health IT Module(s) **must**:

(1) Submit its real world testing plan to its ONC-ACB by a date that enables the ONC-ACB to publish the plan on the CHPL no later than December 15 of each calendar year.

(2) Submit its real world testing results to its ONC-ACB by a date that enables the ONC-ACB to publish the results on the CHPL no later than March 15 of each calendar year.

(3) Notify the responsible ONC-ACB of any non-conformity with Program requirements.

Real World Testing Non-conformities

Non-conformities may be discovered during Real World Testing.

If this occurs, ONC-ACBs have processes in place to help developers self-report non-conformities in a timely manner and work with the developers to have them corrected.

How it works:

- Familiarize yourself with your ONC-ACB's process for self-reported non-conformities.
- Communicate non-conformity findings to ONC-ACB within 30 days of discovery.
- Work with ONC-ACB to develop a plan to correct.

Health IT developers must report any non-conformity(ies) found during real world testing to the ONC-ACB within 30 days (§170.405(b)(2)(i))

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

Patient Engagement

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

Clinical Quality Measures

- ✓ §170.315(c)(1)—record and export
- ✓ §170.315(c)(2)—import and calculate
- ✓ §170.315(c)(3)—report

Electronic Exchange

- ✓ §170.315(h)(1) Direct Project
- ✓ §170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

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

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

Real World Testing Lifecycle

Real World Testing occurs on a yearly cycle, but planning, conducting, and reporting Real World Testing for each given year means that a developer's Real World Testing activities from different years can overlap.

Real World Testing Plan – Included Health IT Modules

Real World Testing plans are intended to describe measurement approaches for the year immediately following the plan's submission. The plan should address any Health IT Modules certified **by or before August 31** of the year in which the plan is submitted.

This process is required on an ongoing, yearly basis for all Health IT Modules certified to applicable certification criteria.

Real World Testing Plan – Included Health IT Modules

FAQ: Can I submit a testing plan for the following calendar year for a Health IT module and/or certification criteria certified after August 31?

- At a minimum, Health IT developers **must include** in their Real World Testing plan for the following calendar year **all health IT certified as of August 31.**
- Developers **may include** in their Real World Testing plan for the following calendar year any Health IT modules and/or certification criteria certified after August 31, but this is not required.
- Developers that chose to include updates made after the August 31 deadline in their testing plan for the following calendar year, must also include those modules and/or certification criteria as part of requirements in their next cycle of Real World Testing.

> ***Scenario:***
> If a Developer updates certification for a Health IT Module in October 2021 (after the August 31 deadline), they are not required to include that module in 2022 Real World Testing plans but will be required to include the Module for their 2023 Real World Testing plans. If they choose to include this Module in their 2022 Real World Testing plan, submitted by December 2021, they will also be required to resubmit that Module in their 2023 Real World Testing plan by December 2022.

Real World Testing – Plan Elements

Health IT Developers must address the following elements for each certification criterion applicable to the Health IT Module's scope of certification in their Real World Testing plan.

Testing Method(s)/ Methodology(ies)

Care Setting(s)

Testing/Conformance Descriptions for Each Tested Criterion Requirement

Key Real World Testing Milestones

Expected Outcomes

Associated Measurement/Metric
(at least one)

Justification for Approach

FR §170.405(b)(1)(iii)

Designing a Real World Testing Plan

Determine Test Method(s)/ Methodology(ies) to Include

Health IT Developers have the flexibility to identify and test against measures they believe are most appropriate to provide transparency on how they will assess interoperability capabilities within the care settings and workflows where their Certified Health IT Modules are used.

Factors to consider when determining method(s)/methodology(ies):

- Size of the organizations that production systems support
- Type(s) of organizations and setting(s)
- Number of patient records and users
- System components and integrations
- Volume and types of data exchange

Testing Environments

The purpose of Real World Testing is to demonstrate that Health IT Modules continue to perform in conformance to their certification as they are deployed in production. Thus, real patient data and real production environments should be first considered when developing Real World Testing plans.

Although it is not specifically prohibited, developers are discouraged from using opensource test platforms or test platforms specific to their products as part of the Real World Testing process. Test tools and platforms deviate from the underlying goal of Real World Testing being conducted in and specific to the intended use cases and setting types in which the Certified Health IT is marketed.

Designing a Real World Testing Plan

Identify Partners in Each Care Setting Marketed

Health IT Developers must consider all setting types in which their product is marketed when determining their testing approach.

Not each setting marketed must be included in Real World Testing, but plans should address each type of clinical setting in which the Certified Health IT is marketed.

Developers must provide justification for their choice of care and/or practice settings and chosen approach.

When considering care settings for testing:

- Settings or health care provider types are not excluded from Real World Testing requirements based on (in)eligibility for any specific Federal health care program or initiative.
- A Real World Testing plan is not required for each individual product or each individual care setting location.
- Health IT Developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed.
- Health IT Developers should construct real world scenarios or use cases that test more than one care setting applicable to the Health IT Module.

Designing a Real World Testing Plan – Care Setting

FAQ: What care settings should be included in my Real World Testing plan?

- ONC does not specifically define or limit the care settings and leave it to the health IT developer to determine.
- As an example, health IT developers can consider categories, including but not limited to:
  - those used in the EHR Incentive Programs (https://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/Downloads/UserGuide_QNetHospitalObjectivesCQMs.pdf);
  - long-term and post-acute care;
  - pediatrics;
  - behavioral health; and/or
  - small, rural, and underserved settings

85 FR 25769

Designing a Real World Testing Plan

Establish a Schedule and Identify Key Milestones

Health IT Developers will include in their plans a timeline for conducting certain steps within their Real World Testing to establish milestones within the process.

- Milestones should include details on how and when the developer will implement measures and collect data within their chosen methods/methodologies over the course of the calendar year.
- Key milestones should be relevant and directly related to expected outcomes.

Designing a Real World Testing Plan

Describe Expected Outcomes

Health IT Developers should detail how the approaches chosen will produce outcomes that reflect successful Real World Testing.

Expected outcomes should:

- Provide transparency into what current and potential customers will know about the Certified Health IT Module(s) and its effectiveness in demonstrating interoperability when tested in the real world;
- Also reflect what should not be a result of a given action;
- Be measurable; and
- Indicate the level at which its Certified Health IT Module(s) are providing optimal user experience for its customers and other interested stakeholders.

Designing a Real World Testing Plan

Identify At Least One Measure

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification.

Developers with Health IT Modules certified to multiple criteria should expect that they may incorporate more than one measurement/metric.

Because the applicable criteria are specific to data exchange and interoperability, developers should avoid measurement/metrics that indicate pass/fail or yes/no results, especially where those measures would not demonstrate ongoing interoperability or functionality per se.

Designing a Real World Testing Plan

Provide Justification for Approach

Health IT Developers must describe how the measurements/metrics they select reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the Certified Health IT is marketed, and other factors relevant to the implementation of the Certified Health IT Module(s).

The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Submitting a Real World Testing Plan and Results

Real World Testing plans must be publicly available on the CHPL **by December 15th of each year.** Developers have one year to complete their testing of their submitted plan(s).

Real World Testing results must then be publicly available on the CHPL **by March 15th of each year** following their year of testing.

NOTE: For both testing plans and results ONC-ACBs will determine a date by which the plans and results report must be submitted in order to allow time to review for completeness before making publicly available.

Updates to Certification Criteria

The ONC Cures Act Final Rule requires Health IT Developers to update their Certified Health IT Modules to new standards for specific certification criteria. Real World Testing plans must include all Certified Health IT updated to newer versions of standards **prior to August 31 of the year** in which the updates were made.

How to ensure Certified Health IT is updated:

- ✓ Review the 2015 Edition Cures Update for relevant criteria updates and associated timelines for your Health IT modules.
- ✓ Work with your ONC-ACB to ensure all updates to selected criteria cover the scope of certification.
- ✓ Notify customers of updates to respective products.
- ✓ Once updates are complete, ONC-ACB will update product status on the CHPL.
- ✓ Developers should account for updates in their Real World Testing Plan. Updated criteria should be integrated into measures.

Updates to Certification Criteria

Required updates with associated timelines exist for the following sections related to the 2015 Edition Criteria.

Standards Version Advancement Process (SVAP)

This **voluntary process** allows Health IT Developers to update their Certified Health IT Modules to use more advanced versions of standards and implementation specifications than the version(s) incorporated by reference in the regulation for the certification criteria. SVAP is only available for ONC-approved newer versions of adopted standards.

USCDI Updates

Updated Criterion(a): Updates required to support USCDI v1 for Health IT modules certified to § 170.315(b)(1), (b)(2), (e)(1), (f)(5), (g)(6) and/or (g)(9).

Compliance Deadline: December 31, 2022.

C-CDA Companion Guide Updates

Updated Criterion(a): Updates required to support Consolidated Clinical Document Architecture (C–CDA) Companion Guide for Health IT Modules certified to § 170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9).

Compliance Deadline: December 31, 2022.

Electronic prescribing

Updated Criterion(a): Updates required to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2017071 for Health IT Modules certified to the §170.315(b)(3).

Compliance Deadline: December 31, 2022.

Security tags

Updated Criterion(a): Updated to revised versions are required for Health IT Modules certified to § 170.315(b)(7) and/or (b)(8)

Compliance Deadline: December 31, 2022.

ASTM updates

Updated Criterion(a): Updates required to support ASTM E2147—18 for Health IT Modules certified to §170.315(d)(2), (d)(3), and/or (d)(10).

Compliance Deadline: December 31, 2022.

Clinical Quality Measures – Report

Updated Criterion: Updates required to support CMS QRDA Implementation Guide for Health IT Modules certified to § 170.315(c)(3).

Compliance Deadline: December 31, 2022.

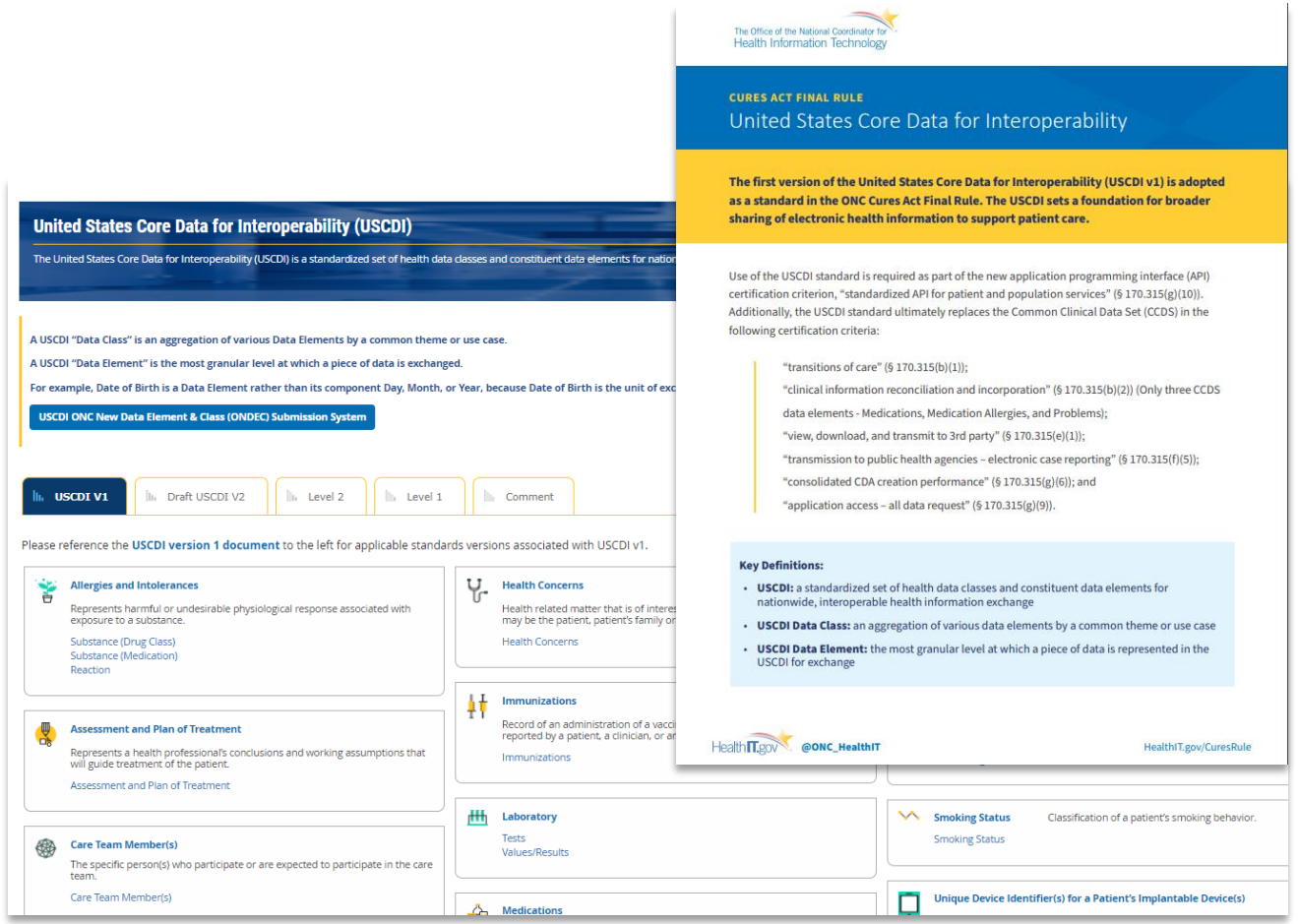
Updates to Certification Criteria – USCDI

USCDI (United States Core Data for Interoperability) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

Developers are required to update their Certified Health IT to support the USCDI v1 for specific formerly Common Clinical Data Set (CCDS)-dependent 2015 Edition certification criteria (listed below).

As outlined in the Real World Testing Condition and Maintenance of Certification, any Health IT Modules certified to any of these criterion must be updated to be compliant with the revised versions and provide its customers with the updated Certified Health IT by December 31, 2022.

- § 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)(6) Consolidated CDA creation performance; and/or
- § 170.315(g)(9) Application access—all data request



USCDI Website:
https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
Fact Sheet:
https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf

Updates to Certification Criteria – SVAP

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 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.

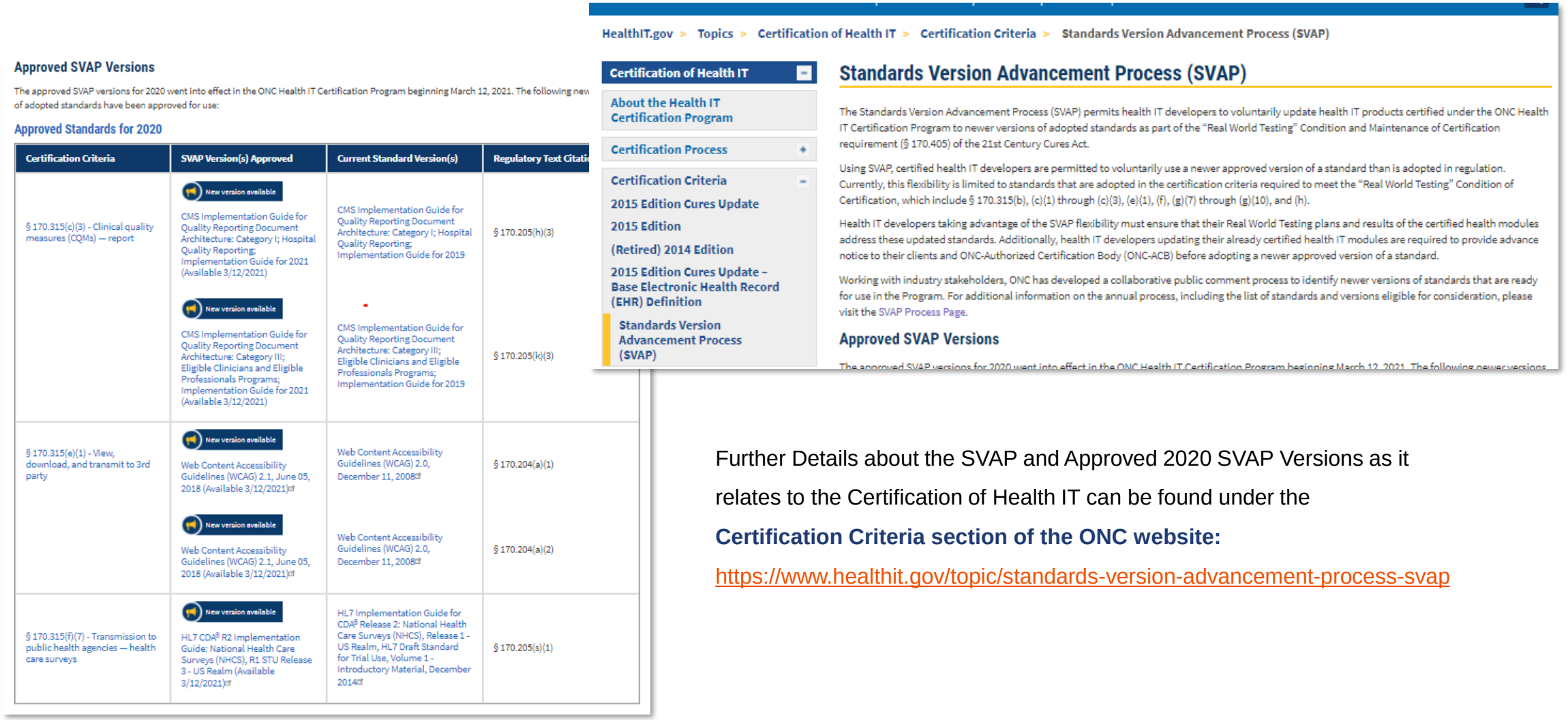
Standards Version Advancement Process

How will updates be made to consider newer versions?

- ONC has established a collaborative process to identify a more advanced version of standards or implementation specifications for approval by the National Coordinator.
- Industry input will be considered via public comments on an annual basis.
- Approved versions will be posted in January of each year and Health IT developers can begin incorporating new versions into their certified health IT products 60 days after new versions are posted.

https://www.healthit.gov/SVAP

Standards Version Advancement Process



Approved SVAP Versions

The approved SVAP versions for 2020 went into effect in the ONC Health IT Certification Program beginning March 12, 2021. The following new of adopted standards have been approved for use:

Approved Standards for 2020

Certification Criteria	SVAP Version(s) Approved	Current Standard Version(s)	Regulatory Text Citati
§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2019	§ 170.205(h)(3)
	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2019	§ 170.205(k)(3)
§ 170.315(e)(1) - View, download, and transmit to 3rd party	New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021)	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	§ 170.204(a)(1)
	New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021)	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	§ 170.204(a)(2)
§ 170.315(f)(7) - Transmission to public health agencies — health care surveys	New version available HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3 - US Realm (Available 3/12/2021)	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)

HealthIT.gov > Topics > Certification of Health IT > Certification Criteria > Standards Version Advancement Process (SVAP)

Certification of Health IT

- About the Health IT Certification Program
- Certification Process
- Certification Criteria
- 2015 Edition Cures Update
- 2015 Edition
- (Retired) 2014 Edition
- 2015 Edition Cures Update – Base Electronic Health Record (EHR) Definition
- Standards Version Advancement Process (SVAP)

Standards Version Advancement Process (SVAP)

The Standards Version Advancement Process (SVAP) permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act.

Using SVAP, certified health IT developers are permitted to voluntarily use a newer approved version of a standard than is adopted in regulation. Currently, this flexibility is limited to standards that are adopted in the certification criteria required to meet the "Real World Testing" Condition of Certification, which include § 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(10), and (h).

Health IT developers taking advantage of the SVAP flexibility must ensure that their Real World Testing plans and results of the certified health modules address these updated standards. Additionally, health IT developers updating their already certified health IT modules are required to provide advance notice to their clients and ONC-Authorized Certification Body (ONC-ACB) before adopting a newer approved version of a standard.

Working with industry stakeholders, ONC has developed a collaborative public comment process to identify newer versions of standards that are ready for use in the Program. For additional information on the annual process, including the list of standards and versions eligible for consideration, please visit the SVAP Process Page.

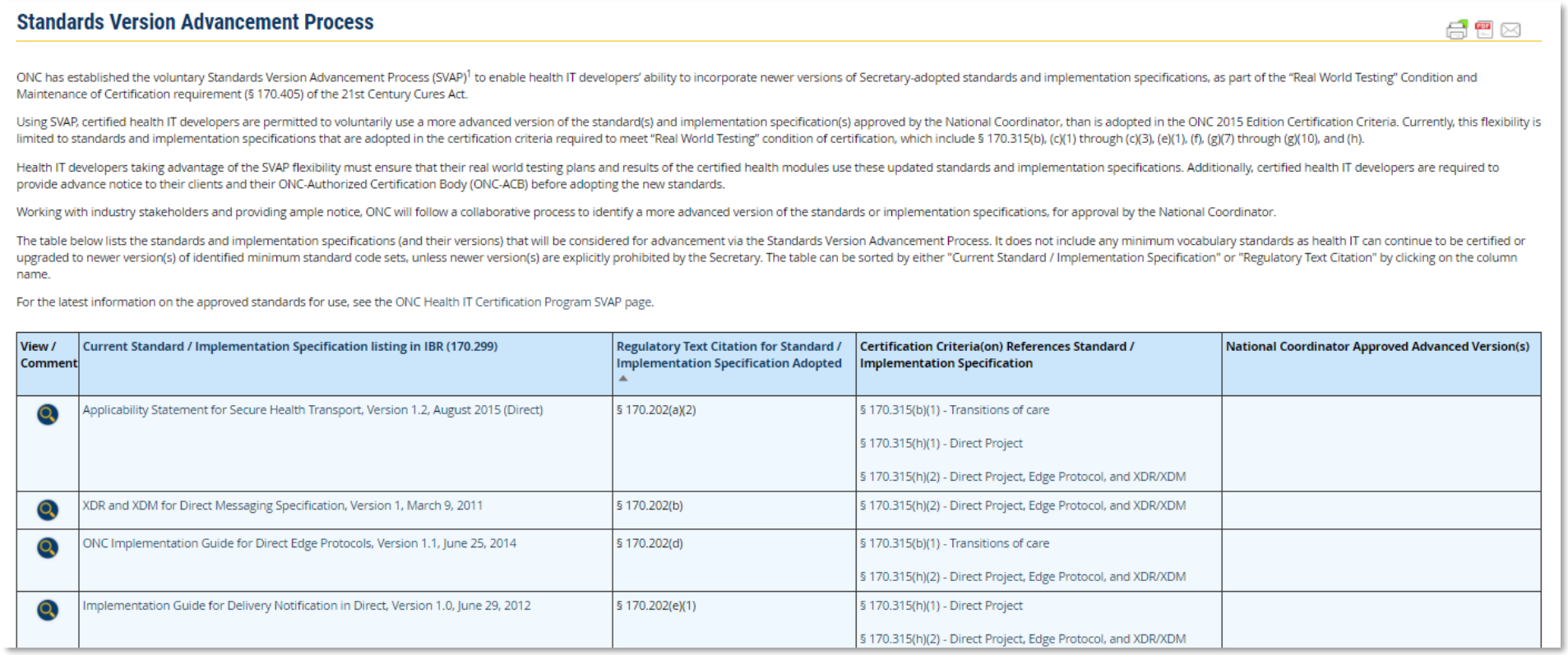
Approved SVAP Versions

The approved SVAP versions for 2020 went into effect in the ONC Health IT Certification Program beginning March 12, 2021. The following newer versions

Further Details about the SVAP and Approved 2020 SVAP Versions as it relates to the Certification of Health IT can be found under the **Certification Criteria section of the ONC website:**

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

Standards Version Advancement Process



Standards Version Advancement Process

ONC has established the voluntary Standards Version Advancement Process (SVAP)[1] to enable health IT developers' ability to incorporate newer versions of Secretary-adopted standards and implementation specifications, as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act.

Using SVAP, certified health IT developers are permitted to voluntarily use a more advanced version of the standard(s) and implementation specification(s) approved by the National Coordinator, than is adopted in the ONC 2015 Edition Certification Criteria. Currently, this flexibility is limited to standards and implementation specifications that are adopted in the certification criteria required to meet "Real World Testing" condition of certification, which include § 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(10), and (h).

Health IT developers taking advantage of the SVAP flexibility must ensure that their real world testing plans and results of the certified health modules use these updated standards and implementation specifications. Additionally, certified health IT developers are required to provide advance notice to their clients and their ONC-Authorized Certification Body (ONC-ACB) before adopting the new standards.

Working with industry stakeholders and providing ample notice, ONC will follow a collaborative process to identify a more advanced version of the standards or implementation specifications, for approval by the National Coordinator.

The table below lists the standards and implementation specifications (and their versions) that will be considered for advancement via the Standards Version Advancement Process. It does not include any minimum vocabulary standards as health IT can continue to be certified or upgraded to newer version(s) of identified minimum standard code sets, unless newer version(s) are explicitly prohibited by the Secretary. The table can be sorted by either "Current Standard / Implementation Specification" or "Regulatory Text Citation" by clicking on the column name.

For the latest information on the approved standards for use, see the ONC Health IT Certification Program SVAP page.

View / Comment	Current Standard / Implementation Specification listing in IBR (170.299)	Regulatory Text Citation for Standard / Implementation Specification Adopted	Certification Criteria(on) References Standard / Implementation Specification	National Coordinator Approved Advanced Version(s)
	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	
	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	
	ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014	§ 170.202(d)	§ 170.315(b)(1) - Transitions of care § 170.315(h)(2) - Direct Project, Edge Protocol, and XDR/XDM	
	Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012	§ 170.202(e)(1)	§ 170.315(h)(1) - Direct Project § 170.315(h)(2) - Direct Project, Edge Protocol, and XDR/XDM	

Further details around SVAP's collaborative advancement process and standards/implementation guides being considered for future advancement via this process can be found on the **ONC's ISA page under the 21st Century Cures tab:**

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

Real World Testing Resources

- **Fact Sheet**
  - https://www.healthit.gov/sites/default/files/page/2021-02/Real-World-Testing-Fact-Sheet.pdf
- **Real World Testing Plan Template *Coming Soon!***
  - Note: ONC-ACBs may have additional requirements for submission.
- **Resource Guide *Coming Soon!***
  - How-to guide to assist in the development of measures and completion of testing plan template(s)
  - Based on input collected by developer community
  - No new requirements will be outlined within this resource
  - Developers do not need to wait for this resource to begin planning their Real World Testing; this resource is purely informational

The Office of the National Coordinator for Health Information Technology

Contact ONC

Add additional call to action or relevant speaker information and contact details.

Phone: 202-690-7151

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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