



ONC Health IT Certification Program Developer Roundtable

December 9, 2021

ONC Health IT Certification Program

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.
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Agenda

1. Opening Remarks
2. Real World Testing Plan Submission
3. CHPL Developer Access
4. § 170.315(g)(10): Standardized API for Patient and Population Services
5. § 170.315(b)(3): Electronic Prescribing
6. § 170.315(d)(12): Encrypt Authentication Credential

Opening Remarks



Rob Anthony, Director, Certification and Testing Division

Today's Speakers:

1. Shawn Spurlock, Public Health Analyst, Program Administration
2. Asara Clark, Senior Advisor, Program Administration
3. Papia Paul, Public Health Analyst, Program Administration
4. John Bender, Public Health Analyst, Tools and Testing
5. Keith Carlson, Health IT Specialist, Tools and Testing
6. Emily Zhou, Public Health Analyst, Tools and Testing
7. Scott Bohon, Public Health Analyst, Tools and Testing

Real World Testing Plan Submission

Asara Clark, Senior Advisor, Program Administration

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
- Electronic health information (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 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 Certified Health IT Developer **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 Certification Program requirements.

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 (APIs)

- ✓ § 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 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.





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.



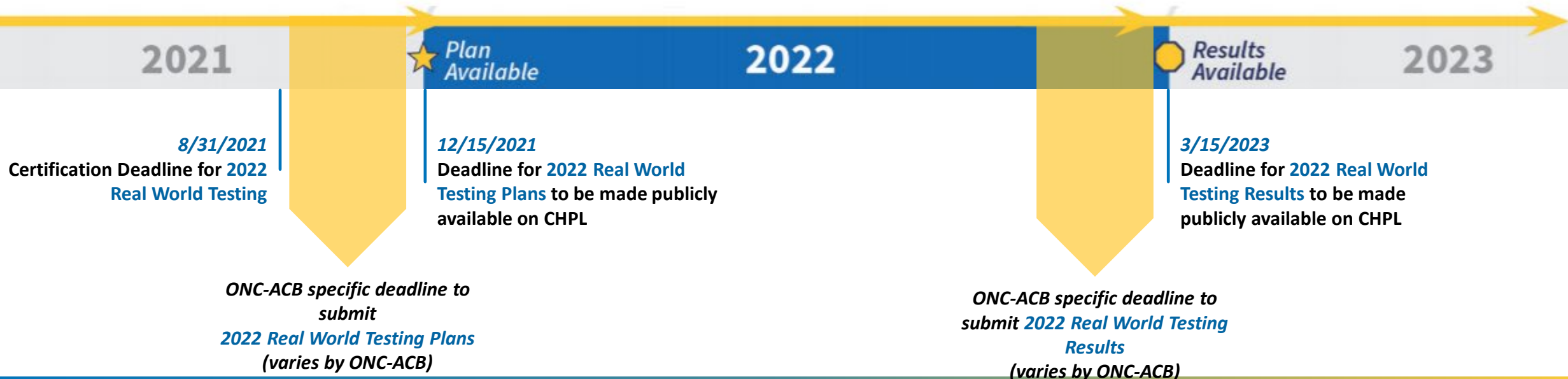
KEY: ★ Plan Available ✓ Results Available

Real World Testing Plan and Results Deadlines

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.




Real World Testing Resources – Plan Template

This **optional** template is available to assist developers with the creation of their Real World Testing plan but outlining all necessary elements required for submission.

Each section provides a field for submitting responses and/or explanations for how the Health IT Developer will address each required element in their Real World Testing approach.

Note: ONC-ACBs may have additional requirements for submission. Confirm all requirements with your respective ONC-ACB before submission.





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required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name:

Product Name(s):

Version Number(s):

Certified Health IT:

Product List (CHPL) ID(s):

Developer Real World Testing Page URL:

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.

All measures should 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.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

Real World Testing Resources – Resource Guide

This Resource Guide aims to assist developers in organizing the required elements related to the submission of a Real World Testing plan to support the Conditions and Maintenance of Certification for their applicable Health IT Modules.

Items outlined in this guide include:

- Clarifications on timeline requirements
- Details on the plan elements needed to meet requirements
- Guidance on special considerations for unique product(s), customer(s) and/or setting(s)
- Sample scenarios to illustrate the creation of a Real World Testing plan to support testing for:
 - Health IT Modules that must complete Real World Testing for a single certification criterion
 - Health IT Modules that must complete Real World Testing for multiple certification criteria

Real World Testing Resources

Visit <https://www.healthit.gov/topic/certification-ehrs/real-world-testing> for access all the materials discussed and more.

- **Fact Sheet – What it Means for Health IT Developers**
- **Plan Template**
- **Resource Guide**
- **Real World Testing Certification Companion Guide**
- **Previous Webinar Recording and Slides**

CHPL Developer Access

Papia Paul, Public Health Analyst, Program Administration

Certified Health IT Product List (CHPL)

- The CHPL is the authoritative, comprehensive listing of all health IT that has been successfully tested and certified by the ONC Health IT Certification Program.

<https://chpl.healthit.gov>

- Starting **January 2022**, ONC will begin registering active Certified Health IT Developers to the CHPL.
- Facilitates electronic submissions to meet the Attestations Condition and Maintenance of Certification requirements as specified in the ONC Cures Act Final Rule.
 - **Reminder:** The first 30-day attestation window is set to open **April 1, 2022**. More information will be forthcoming.
- **Next Steps:** Certified Health IT Developers should ensure their respective ONC-Authorized Certification Bodies (ONC-ACBs) have the most up-to-date information (i.e., name and email address) for at least one contact.
 - Note: Contact information will not be shared publicly, unless the developer requests the ONC-ACB to update its required public-facing contact on the CHPL, or for any purpose outside of the Certification Program.

§ 170.315(g)(10):

Standardized API for Patient and Population Services

Keith Carlson, IT Specialist, Tools and Testing



US Core “dataAbsentReason” elements

ONC Certification Requirements & US Core IG

“*Data response*” requirements in §170.315(g)(10)

- Certified Health IT modules must respond to requests for a single patient’s data according to the FHIR® and US Core and implementation specifications
- All data elements indicated as “mandatory” and “must support” by the standards and implementation specifications must be supported

US Core IG and Observation “dataAbsentReason” must support elements

- Some US Core Observation profiles contain must support “dataAbsentReason” elements
 - e.g., `Observation.dataAbsentReason` and `Observation.component.dataAbsentReason`
- Inferno was looking for at least one example of each of these elements in some Observation resource returned by the server under test

Inquiry we received regarding US Core “dataAbsentReason” elements

Inquiry: For certification to (g)(10), how is a system that never supports Observations without a value supposed to demonstrate support for “dataAbsentReason” elements? The inquirer suggested that for many systems if an observation is not recorded, the Observation resource will not exist.

Answer (and published CCG clarification):

- For ONC Health IT Certification, health IT developers that always provide HL7 FHIR "observation" values are not required to demonstrate Health IT Module support for “dataAbsentReason” elements
- These include "dataAbsentReason" and "component.dataAbsentReason" elements contained in the US Core implementation guide profiles that build on FHIR Vital Sign profiles
 - e.g., HL7 FHIR "observation," HL7 FHIR "observation-vitalsigns", and HL7 FHIR "observation-oxygensat"
- Health IT developers are still required to adhere to and demonstrate Health IT Module support for the “Missing Data” section of the US Core implementation guide

US Core “composite OR” search

Johnny Bender, Public Health Analyst, Tools and Testing

ONC Certification Requirements & US Core IG



“Data response” requirements in §170.315(g)(10)

- Certified Health IT modules must respond to requests for a single patient’s data according to USCDI, HL7 FHIR® and US Core IGs
- Includes mandatory capabilities in “US Core Server CapabilityStatement”

US Core IG and CareTeam.status search requirements

- US Core IG CareTeam profile
 - Contains SHALL requirement for "composite OR" search on CareTeam.status
 - For example: server SHALL be able to process client’s single search for CareTeam with status of either "active" or "inactive"
- Inferno was performing "composite OR" search & expected to see two CareTeam statuses
 - For example: server returns two CareTeam resources with statuses "active" and "inactive"

Inquiries we received regarding US Core “CareTeam.status” “composite OR” search

Inquiries:

- Systems only supports a single CareTeam resource that includes all care team members for a given patient
- Systems only supports "active" CareTeams
- Health IT developers indicated they were failing the Inferno "composite OR" CareTeam test

Response:

- "Composite OR search on status" is a “SHALL” requirement according to US Core IG; Health IT Modules must support this search functionality
- No accompanying requirement to support multiple CareTeam.status values
- Inferno tool updated to allow demonstration of “composite OR search on status” using a minimum of one CareTeam.status value



End-user authorization of resource-level scopes

§170.315(g)(10) Resource Level Scopes

Background

- Health IT Modules must include ability for patients to authorize applications to receive their EHI based on FHIR resource-level scopes
- Patients need to have ability to authorize access to EHI at individual FHIR resource level
 - One specific FHIR resource (e.g., “Immunization”)
 - Up to all FHIR resources for USCDI + US Core
- Gives patients control over how much EHI they authorize applications to receive



§170.315(g)(10) Test Procedure for Authentication and Authorization for Patient and User Scopes

[Both (*EHR & Standalone Launch*)] The health IT developer demonstrates the ability of the Health IT Module to evaluate the authorization request and request end-user input, if applicable (required for patient-facing applications), including the ability for the end-user to authorize an application to receive EHI based on FHIR resource-level scopes for all of the FHIR resources associated with the profiles specified in the standard adopted in § 170.213 and implementation specification adopted in § 170.215(a)(2), including:

- “AllergyIntolerance”;
- “CarePlan”;
- “CareTeam”;
- “Condition”;
- “Device”;
- “DiagnosticReport”;
- “DocumentReference”;
- “Goal”;
- “Immunization”;
- “Medication” (if supported);
- “MedicationRequest”;
- “Observation”;
- “Patient”;
- “Procedure”; and
- “Provenance”.

§170.315(g)(10) Authentication/Authorization Example



Inferno Demo FHIR Server

Please select which scopes you would like to authorize:

- launch/patient
- openid
- fhirUser
- offline_access
- patient/Medication.read
- patient/AllergyIntolerance.read
- patient/CarePlan.read
- patient/CareTeam.read
- patient/Condition.read
- patient/Device.read
- patient/DiagnosticReport.read
- patient/DocumentReference.read
- patient/Encounter.read
- patient/Goal.read
- patient/Immunization.read
- patient/Location.read
- patient/MedicationRequest.read
- patient/Observation.read
- patient/Organization.read
- patient/Patient.read
- patient/Practitioner.read
- patient/Procedure.read
- patient/Provenance.read
- patient/PractitionerRole.read

Questions received regarding end-user authorization requirements

Inquiries:

- Is grouping of resource-level scopes allowed?
 - Some FHIR resources are highly dependent and warrant grouping
 - As the USCDI grows over time the list of individual FHIR resources will grow and become unsustainable from a UI perspective
- Is grouping all resources together and presenting a blanket accept or deny choice to the end-user allowed?
- Is allowing a patient to authorize more finely grained scopes permissible?

Clarifications regarding end-user authorization requirements



CCG Clarifications:

- Health IT Modules must include ability for patients to authorize an application to receive their electronic health information (EHI) based on FHIR resource-level scopes
 - From one FHIR resource (e.g., “Immunization”) up to all FHIR resources for US Core IG & USCDI
- Not prohibited from presenting authorization scopes in more user-friendly format
 - For example:
 - Grouping resources under categories
 - Renaming the scopes for easier comprehension by the end-user
 - Using more granular scopes
 - Ability for patients to authorize applications based on resource-level scopes must be available, if requested, by the patient

§ 170.315(b)(3): Electronic Prescribing

Emily Zhou, Public Health Analyst, Tools and Testing

§170.315(b)(3) Inquiries

- Some vendors have reported issues with failing the Renewal Scenarios 1,2, and 5 tests on the NCPDP eRx test tool. The identified issue is that the system under test (SUT) is pulling medication names from FDB or MULTUM drug databases, which in many cases hosts different medication names from the names expected by NCPDP test tool. Because of this discrepancy, the expected medication name is at times different, and causes the renew response to be "Replace" instead of "Approved" resulting in a failed testing for the renewal scenario.
- ONC's response:
 - If the system can show the application meets the (b)(3) criterion requirements (through Replace vs. Approved response type) for renewal transactions, then the SUT should pass certification testing via a notable exception.
 - Please note that the (b)(3) criterion also requires the use of RxNorm codes where corresponding codes exist. RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, and it can mediate messages between systems not using the same software and vocabulary. RxNorm files are available through the [NLM download server](#).

§170.315(b)(3) NCPDP Test Tool Update

- NCPDP 2017071 eRx test tool has been updated to include a new medication history test scenario to support intermediary implementations on December 3rd.
 - Added an Intermediary connection and updated Test Stories and Test Steps to PBM Medication History scenarios 1, 2, and 3.
- The (b)(3) e-Prescribing criterion test procedure has been updated to include a new medication history test scenario to support intermediary implementations on December 8th.

eRx Test Tool Update

- ▼ Medication History Tests (Complete either PBM or Pharmacy Scenario)
 - ▼ Pharmacy Benefit Manager(PBM)Scenarios
 - ▼ Medication History Scenario 1 - PBM/Pharmacy returns medication history in a single response
 - ▶ XML
 - ▼ **XML (Intermediate Connection via an Intermediary)**
 - ➔ 1.Prescriber creates a RxHistoryRequest and sends to the PBM.
 - ← 2.PBM acknowledges receipt of the RxHistoryRequest message.
 - ← 3.PBM creates a RxHistoryResponse and send to the prescriber.
 - ➔ 4.Prescriber acknowledges receipt of the RxHistoryResponse message.
 - ▶ Medication History Scenario 2 (Optional)
 - ▶ Medication History Scenario 3 - PBM/Pharmacy is not able to provide medication history information (no information available)
 - ▶ Pharmacy Scenarios

(b)(3) TP Update

Paragraph (b)(3)(ii)(A)(6)

System Under Test	Test Lab Verification
<p>1. The health IT developer requests and receives a patient's medication history (RxHistoryRequest, RxHistoryResponse) in accordance with (b)(3)(ii)(A)(6).</p>	<p>1. The tester verifies that the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:</p> <ul style="list-style-type: none"> a. Send a request for a medication history (RxHistoryRequest); and b. Receive a response to a request for a medication history (RxHistoryResponse); or c. Receive a Status message (Status) in response to a request for a medication history (RxHistoryRequest) and receive a response to a request for a medication history (RxHistoryResponse).

§170.315(b)(3) NCPDP Test Tool Survey

NCPDP eRx validation tool survey to ask stakeholders for potential improvements and enhancements **opens on November 1st and closes on January 5th.**

The survey is located at <https://www.surveymonkey.com/r/2HZ9269>

- * 1. In the Context-Free area of the website, are there any improvements or enhancements needed?
- * 2. In the Context-Based area of the website, are there any improvements or enhancements needed?
- * 3. In the Documentation – General Documents area of the website, are there any improvements or enhancements needed?
- * 4. In the Documentation – NCPDP ePrescribing 2017071's Documents area of the website, are there any improvements or enhancements needed?
- 5. Outside of the areas already mentioned above, are there any other items you have comments on related to the testing tool?
- * 6. Name:
- * 7. Company Name:
- * 8. Email Address:



§ 170.315(d)(12): Encrypt Authentication Credential

Scott Bohon, Public Health Analyst, Tools and Testing

Question about § 170.315 (d)(12)

Question

“For d12 we wanted to confirm that the authentication credentials must be encrypted using a FIPS 140-2 approved algorithm and that a vendor that just hashes the authentication credentials using a FIPS 140-2 algorithm does not meet the requirement?”

Criterion Regulation Text

§170.315 (d)(12) *Encrypt authentication credentials*. Health IT developers must make one of the following attestations and may provide the specified accompanying information, where applicable:

- Yes – the Health IT Module encrypts stored authentication credentials in accordance with standards adopted in § 170.210(a)(2).
- No – the Health IT Module does not encrypt stored authentication credentials. When attesting “no,” the health IT developer may explain why the Health IT Module does not support encrypting stored authentication credentials.

Question about § 170.315 (d)(12)

Preamble Citation (85 FR 25700)

“Encrypting authentication credentials could include password encryption or cryptographic hashing, which is storing encrypted or cryptographically hashed passwords, respectively.”

Answer

- The ONC Cures Act Final Rule preamble clarifies that “encryption” in the context of the § 170.315 (d)(12) criterion refers to both cryptographic encryption and cryptographic hashing as performed by the algorithms contained within the standard adopted at §170.210(a)(2), Annex A of FIPS 140-2.
- Therefore, storing authentication credentials hashed by a hashing algorithm from Annex A of FIPS 140-2 is acceptable in fulfilling a “yes” attestation for this criterion.




Discussion

*Please use the Raise Hand function










Please share your health IT-related feedback or concerns that you wish to bring to ONC's attention

Welcome to the Health IT Feedback and Inquiry Portal

Complaints

 Report Information Blocking	 Health IT Safety	 Certified Health IT
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Questions

 Information Blocking	 ONC Health IT Certification	 Trusted Exchange Framework and Common Agreement (TEFCA)
 Health IT Standards	 Privacy and Security	 Security Risk Assessment (SRA) Tool
 Medical Records Access	 ONC Events and Media	 Other

<https://inquiry.healthit.gov>