

REAL WORLD TESTING PLAN

BACKGROUND

Under the ONC Health IT Certification Program (Program), **the Indian Health Service (IHS)** is required to conduct Real World Testing (RWT) of their Certified Health IT (CHIT); otherwise referred to as the IHS Electronic Health Record (EHR). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify responsibilities for conducting Real World Testing.

As a participant in the ONC Health IT Certification Program, the IHS must conduct RWT annually as a Condition and Maintenance of Certification (CMoC) requirement. This annual requirement is outlined in the ONC 21st Century Cures Act Final Rule, which demonstrates interoperability and functionality of the IHS CHIT in real world settings and scenarios. RWT verifies the IHS CHIT continues to perform as intended by conducting and measuring observations of interoperability and data exchange for the criteria specified in this Real World Testing Plan (RWTP). These observations will be reported by each participant to the IHS, which will be consolidated and submitted as Real World Testing Results (RWTR).

INSTRUCTIONS

The information in this RWTP is organized by specific criteria included in the **Application Programming Interfaces (APIs)** category. This plan contains sections, which explains/clarifies how the RWT approach addresses each criteria within this category. RWT participants will execute/complete the use case(s) in this RWTP using their normal workflows and processes in the appropriate care setting defined in the care setting(s) section, report any issues/non-conformities found during RWT within 30 days of finding, and provide the IHS with RWTR on the measurements/metrics listed in this RWTP by the date identified in Schedule of Key Milestones section.

GENERAL INFORMATION

Plan Report ID Number:	20231103ind
Developer Name:	The Indian Health Service
Product Name:	Resource and Patient Management System Electronic Health Record
Version Number:	BCERv6.2
Certified Health IT Product List (CHPL) ID:	15.02.05.1673.RPMS.01.04.1.220302
Developer Real World Testing Plan Page URL:	https://www.ihs.gov/promotinginteroperability/certificationoverview/real-world-testing/

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Use Case Scenario

APPLICATION ACCESS

The following use cases will test and demonstrate conformance to the criterion within the APIs category using the version of the adopted standard to which each Health IT Module was certified as described in the General Information section.

Use Case	Use Case Overview
Application Access: §170.315(g)(7) (Patient selection) §170.315(g)(9) (all data request) § 170.315(g 10) (Standardized API for patient and population services)	The IHS has developed an API that receives a request from another software component/service with enough information about a patient to identify the patient and returns a unique token. The Health IT Module's API will use that token to respond to categories data subsets or full set of data requests for each data category during a specified timeframe within an Ambulatory and Inpatient setting.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The IHS has combined similar criterion that fall within the definition of this specific APIs category, which include:

- §170.315(g)(7), Application access—patient selection
- §170.315(g)(9) Application access—all data request
- § 170.315(g 10) Application access—Standardized API for patient and population services

APIs simplify software development and innovation by enabling applications to exchange data and functionality easily and securely.

The justification for this APIs category RWT approach is to execute the functions users perform to demonstrate interoperability for the following activities:

- (g)(7) Receive a request with sufficient information to uniquely identify a patient and return a token that can be used by an application to subsequently execute requests for that patient's data.
- (g)(9) Respond to full set of data requests for each data category using the unique token specified in the United States Core Data for Interoperability (USCDI) in a summary record within a specified timeframe.
- (g)(10) Authentication and authorization during the process of granting access to patient data, user scopes and system scopes.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

The RWT for this category will include the standards used as part of the 2015 CHIT certification, which is publicized on the ONC Certified Health IT Product List (CHPL) website.

Note: The criterion listed as part of this category have not been updated to any new standards, SVAP, or USCDI prior to August 31, 2023; therefore, this section is not applicable for the calendar year 2024 RWT effort.

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	15.02.05.1673.RPMS.01.04.1.220302
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A
USCDI updated certification criteria (and USCDI version)	N/A

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to RWT.

Measurement/Metric	Description
Measure 1: §170.315(g)(7)— Application Access (Patient selection)	This measure will catalogue the transport mechanisms used to request information to uniquely identify patients and return a unique token.
Measure 2: §170.315(g)(9)— Application Access (all data request)	This measure will catalogue the response to requests for all patient data for each data category within a specified timeframe.
Measure 3: § 170.315(g 10) (Standardized API for patient and population services)	This measure will catalogue the request for token and revocation and authentication and authorization for granting application access. The EHR is capable of receiving and responding to the API request with Okta token.

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your RWTP for any metrics that would involve use of that software in testing.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
§170.315(g)(7) Application access—patient selection	(i) Receive a request with sufficient information to uniquely identify a patient and return a unique token, which can be used by an application to subsequently execute requests for that patient's data.	N/A
§170.315(g)(9) Application access—all data request	(i)(A) Respond to requests for patient data (i)(B) Respond to requests for all patient data requests associated with a specific date	N/A
§ 170.315(g 10) (Standardized API for patient and population services)	(i) Data response. (ii) <i>Supported search operations.</i> (iii) <i>Application registration.</i> Enable an application to register with the Health IT Module's "authorization server." (iv) <i>Secure connection.</i> (v) <i>Authentication and authorization.</i> (vi) <i>Patient authorization revocation.</i> (vii) <i>Token introspection.</i> (viii) Documentation.	• InterSystems Healthshare HSAP-2021.2 AND • Okta web Console Version 2022.07.0 C AND • Okta AD Agent Version 3.11.0.0

Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct RWT.

Measurement/Metric	Justification
Measure 1: §170.315(g)(7)— Application Access (Patient selection)	Be able to receive a request with sufficient information to uniquely identify a patient and return a token that can be used by an application to subsequently execute requests for that patient's data.
Measure 2: §170.315(g)(9)— Application Access (all data request)	Be able to respond to full set of data requests for each data category using the unique token specified in the USCDI in a summary record within a specified timeframe.
Measure 3: § 170.315(g 10) (Standardized API for patient and population services)	Be able to authenticate and authorize during the process of granting access to patient data, user scopes and system scopes. The EHR is capable of receiving and responding to the API request with Okta token.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 1: §170.315(g)(7)— Application Access (Patient selection)	PHR logs will be reviewed for API usage to determine the frequency used by patients for accessing their data through the API. Log files obtained during RWT will be de-identified and used for analysis in several areas to validate the proper operation of the API for the calculation of the metric on the specific types of access requested. This test methodology will primarily test the conformance of the implementation.
Measure 2: §170.315(g)(9)— Application Access (all data request)	PHR logs will be reviewed for API usage to determine the frequency used by patients for accessing their data through the API. Log files obtained during RWT will be de-identified and used for analysis in several areas to validate the proper operation of the API for the calculation of the metric on the specific types of access requested. This test methodology will primarily test the conformance of the implementation.
Measure 3: § 170.315(g 10) (Standardized API for patient and population services)	System logs and requests will be reviewed to determine the frequency for patient and user scope requests. Log files obtained during RWT will be de-identified and used for analysis in several areas to validate the proper authentication and access were granted. This test methodology will primarily test the conformance of the implementation.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 1: §170.315(g)(7)—Application Access (Patient selection)	Ambulatory/Inpatient	Be able to receive a request with sufficient information to uniquely identify a patient and return a token that can be used by an application to subsequently execute requests for that patient's data for an ambulatory and inpatient setting.
Measure 2: §170.315(g)(9)—Application Access (all data request)	Ambulatory/Inpatient	Be able to respond to the full data request specified in the USCDI at one time in a summary record within an ambulatory and inpatient setting for a specified timeframe.
Measure 3: §170.315(g 10) (Standardized API for patient and population services)	Ambulatory/Inpatient	Be able to authenticate and authorize appropriate access and revoke an authorized applications access per patient direction.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 1: §170.315(g)(7)—Application Access (Patient selection)	The Health IT Module's API receives a request from the health IT developer's identified application for a specific patient ID or other token. The Health IT Module's API returns a specific token, which can be used by the identified application to subsequently execute requests for that patient's data. Error rates will be captured over time using the PHR application logs.
Measure 2: §170.315(g)(9)—Application Access (all data request)	Using the token returned by the API as part of the §170.315(g)(7) response, the Health IT Module's API responds to requests for "all patient data" and returns the full set of data requests for each data category specified in the USCDI in a summary record within a specified timeframe. Error rates will be captured over time using the PHR application logs.
Measure 3: §170.315(g 10) (Standardized API for patient and population services)	The Health IT module will demonstrate appropriate authentication and authorization upon granting access. As expected, the EHR is capable of receiving and responding to the API request with Okta token. Error rates will be captured over time using the application logs.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Outreach and communication to obtain site participation and commitment	Ambulatory/Inpatient	Quarter 1, 2024
Release of documentation for the RWT to be provided to authorized representatives/participants and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	Ambulatory/Inpatient	Quarter 2, 2024
Begin data collection of RWTR	Ambulatory/Inpatient	Quarterly, 2024
Follow-up with authorized representatives/participants and providers on a regular basis to understand any issues arising with the data collection.	Ambulatory/Inpatient	Quarterly, 2024
End of RWT period/participants submit final collection of all data for analysis as real-world testing results to IHS.	Ambulatory/Inpatient	Quarter 4, 2024
Analysis and RWTR report creation.	Ambulatory/Inpatient	January 10, 2025
RWTR submission to ACB	Ambulatory/Inpatient	January 15, 2025

ATTESTATION

The RWTP must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.ⁱⁱ

This RWTP is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's RWT requirements.

Authorized Representative Name:

Glenn Janzen

Authorized Representative Email:

Glenn.Janzen@ihs.gov

Authorized Representative Phone:

301.526.9656

Authorized Representative Signature:

Glenn V.
Janzen -S

Digitally signed by
Glenn V. Janzen -S
Date: 2023.11.29
13:25:00 -05'00'

Date: _____

Certified Health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; Certified Health IT is exchanging 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. (85 FR 25766)

ⁱ <https://www.federalregister.gov/d/2020-07419/p-3582>