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 Certified Health IT 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 **Public Health** 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/

Contents

Use Case Scenario

USE CASE 1: (§170.315(f)(1) TRANSMISSION TO IMMUNIZATION REGISTRIES

Use Case	Use Case Overview
Use Case 1 (§170.315(f)(1) Transmission to immunization registries– Ambulatory and Inpatient)	The IHS has developed an electronic health record system to ensure the timely transmission of immunization records within an ambulatory and inpatient setting. This Certified Health IT Module is for use in situations where documentation needs to be coordinated between providers within and outside of a healthcare organization.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

- (f)(1) Create immunization information for electronic transmission

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

Measurement/Metric	Description
Measure 1: §170.315(f)(1) Transmission to immunization registries	The measure will demonstrate transmissions to immunization registries.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Measure 1: §170.315(f)(1) Transmission to immunization registries	§170.315(f)(1) Transmission to immunization registries	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 1: §170.315(f)(1) Transmission to immunization registries	The EHR system includes functionalities of creating immunization information for electronic transmission and enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 1: §170.315(f)(1) Transmission to immunization registries	For each test case, the Health IT Module generates the indicated HL7 v2.5.1 Z22 VXU immunization information message. For each test case, the Health IT Module consumes the associated acknowledgement message using the provided test data and according to the §170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5. The vaccines in the historical vaccine records are represented using §170.207(e)(3) HL7 Standard Code Set CVX—Vaccines Administered. The vaccines in the administered vaccine records are represented using §170.207(e)(4) National Drug Code (NDC) Directory–Vaccine NDC Linker.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 1: §170.315(f)(1) Transmission to immunization registries	Ambulatory /Inpatient	The EHR system supports the transmission of immunization records within an Ambulatory and inpatient system.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 1: §170.315(f)(1) Transmission to immunization registries	It is expected that providers will be able to create immunization information and enable a user to request, access and display the evaluated immunization history and forecast from an immunization registry for a patient. Error rates will be tracked and trended over time.

End of Use Case 1

USE CASE 2: (§170.315(f)(2) TRANSMISSION TO PUBLIC HEALTH AGENCIES

Use Case	Use Case Overview
Use Case 2 (§170.315(f)(2) Transmission to public health agencies– syndromic surveillance- Ambulatory and Inpatient)	The IHS has developed an electronic health record system to ensure the timely transmission of syndromic-based public health surveillance information. This Certified Health IT Module is for use in situations where documentation needs to be coordinated between providers within and outside of a healthcare organization.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

- (f)(2) Create syndrome-based public health surveillance information for electronic transmissions

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.

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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

Measurement/Metric	Description
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	The measure will demonstrate the ability to create and send syndrome-based public health surveillance. The public health agency will receive the syndromic based information electronically.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	§170.315(f)(2) Transmission to public health agencies—syndromic surveillance	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	The EHR system includes functionalities of creating syndrome-based public health surveillance information for electronic transmission.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	The EHR system includes functionalities of creating syndrome-based public health surveillance information for electronic transmission.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	Ambulatory /Inpatient	The EHR system supports the transmission to public health agencies–syndromic surveillance within an Ambulatory and inpatient system.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 2: §170.315(f)(2) Transmission to public health agencies–syndromic surveillance	It is expected that providers will be able to create syndrome-based public health surveillance information for electronic transmission to public health agencies. Error rates will be tracked and trended over time.

End of use case 2

USE CASE 3: (§170.315(f)(3) TRANSMISSION TO PUBLIC HEALTH AGENCIES–REPORTABLE LABORATORY TESTS AND VALUE/RESULTS

Use Case	Use Case Overview
Use Case 3 (§170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results-Ambulatory and Inpatient)	The IHS has developed an electronic health record system to ensure the creation of reportable laboratory tests and values/results. This Certified Health IT Module is for use in situations where documentation needs to be coordinated between providers within and outside of a healthcare organization.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

- (f)(3) Create reportable laboratory tests and values/results for electronic transmissions

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.*

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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

Measurement/Metric	Description
Measure 3: §170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	The measure will demonstrate the ability to create reportable laboratory tests and values/results for electronic transmissions to public health agencies.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
§170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	(i) Electronically create reportable laboratory tests and values/results messages which can be transmitted to public health agencies (ii) Represent data in the reportable laboratory test message	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 3: §170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	The EHR system includes functionalities of creating reportable laboratory tests and values/results for electronic transmission.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 3: §170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	The EHR system includes functionalities of creating reportable laboratory tests and values/results for electronic transmission.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 3: §170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	Ambulatory/Inpatient	The EHR system supports the transmission to public health agencies—reportable laboratory tests and value/results within an Ambulatory and inpatient system.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 3: §170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results	It is expected that providers will be able to electronically create reportable laboratory tests and values/results messages which can be transmitted to public health agencies. Error rates will be tracked and trended over time.

End of use Case 3

USE CASE 4: (§170.315(f)(5) TRANSMISSION TO PUBLIC HEALTH AGENCIES– ELECTRONIC CASE REPORTING

Use Case	Use Case Overview
Use Case 4 (§170.315(f)(5) Transmission to public health agencies—electronic case reporting- Ambulatory and Inpatient)	The IHS has developed an electronic health record system to ensure the consumption of trigger codes, in a table, to determine which encounters may be reportable. Matches patient visits or encounters to the trigger code based on parameters of the trigger code table. Creates a case report for electronic transmissions that include clinical data sets, encounter diagnoses, provider's names/office contact information/reasons for visits and an identifier representing the row and version of the trigger table that triggered the case report. This Certified Health IT Module is for use in situations where documentation needs to be coordinated between providers within and outside of a healthcare organization within an ambulatory and inpatient settings.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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

- (f)(5) Consume and maintain a table of trigger codes to determine which encounters may be reportable.
- (f)(5) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.
- (f)(5) Case report creation: Create a case report for electronic transmission and submission to EPI.

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.

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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

Measurement/Metric	Description
Measure 4: §170.315(f)(5) Transmission to public health agencies—electronic case reporting	The measure will demonstrate the creation of a case report based on trigger codes and electronic submission to a public health agency.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
§170.315(f)(5) Transmission to public health agencies—electronic case reporting	(i) Consume and maintain a table of trigger codes. (ii) Match information recorded in a patient visit or encounter to a trigger code in the trigger code table. (iii) When a trigger is matched the Health IT Module electronically creates an initial case report.	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 4: §170.315(f)(5) Transmission to public health agencies—electronic case reporting	The EHR system includes functionalities of consuming and maintaining a table of trigger codes to determine which encounters may be reportable. Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table. Create a case report for electronic transmission that includes, but not limited to, USCDI data elements, Encounter Diagnoses, the provider's name, office contact information, and reason for visit and an identifier representing the row and version of the trigger table that triggered the case report.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 4: §170.315(f)(5) Transmission to public health agencies—electronic case reporting	The EHR system includes functionalities of consuming and maintaining a table of trigger codes to determine which encounters may be reportable. Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table. Create a case report for electronic transmission that includes, but not limited to, USCDI data elements, Encounter Diagnoses, the provider's name, office contact information, and reason for visit and an identifier representing the row and version of the trigger table that triggered the case report.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 4: §170.315(f)(5) Transmission to public health agencies—electronic case reporting	Ambulatory /Inpatient	The EHR system supports the transmission to public health agencies—electronic case reporting within an Ambulatory and inpatient system.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 4: §170.315(f)(5) Transmission to public health agencies—electronic case reporting	It is expected that the EHR will be able to consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to a public health agency. Error rates will be tracked and trended over time.

End of Use Case 4

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 Real-World Testing 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 Real-World Testing Results.	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 Real-World Testing period/participants submit final collection of all data for analysis as real-world testing results to IHS.	Ambulatory/Inpatient	Quarter 4, 2024
Analysis and real-world testing results report creation.	Ambulatory/Inpatient	January 10, 2025
Real-world testing results submission to ACB.	Ambulatory/Inpatient	January 15, 2025

ATTESTATION

The Real World Testing plan 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 Real World Testing plan 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 Real World Testing requirements.

Authorized Representative Name:

Glenn Janzen

Authorized Representative Email:

Glenn.Janzen@ihs.gov

Authorized Representative Phone:

301.526.9656

Authorized Representative Signature:

Date: **Glenn V. Janzen -S**
Digitally signed by
Glenn V. Janzen -S
Date: 2023.11.29
13:29:59 -05'00'

[i] 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)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582