

# Real World Testing Plan – Public health

## Background & Instructions

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

General Information Name	Description
Plan Report ID Number: [For ONC-Authorized Certification Body use only]:	20211111IND
Developer Name:	The Indian Health Service
Product Name(s):	Resource and Patient Management System Electronic Health Record (RPMS Suite (BCER))

General Information Name	Description
Version Number(s):	v4.1 and v5.0
Certified Health IT:	2015 Certified Health IT
Product List (CHPL) ID(s):	15.02.02.1673.A116.02.03.1.211001
Developer Real World Testing Page URL:	<a href="https://www.ihs.gov/promotinginteroperability/certificationoverview/">https://www.ihs.gov/promotinginteroperability/certificationoverview/</a>

## Use Case Scenarios

The following use cases will test and demonstrate conformance to the criterion within the Public Health 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
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.
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.
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.
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 IHS have combined similar criterion that fall within the definition of this specific Public Health, which include: §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, and §170.315(f)(5) Transmission to public health agencies — electronic case reporting.

Public Health ensures that the right technologies are used to improve timely delivery of quality data and assist data-driven decision making. It builds bridges across public health work area by translating between these communities, creating opportunities for interoperable information pathways.

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
- (f)(2) Create syndrome-based public health surveillance information for electronic transmissions
- (f)(3) Create reportable laboratory tests and values/results for electronic transmissions
- (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 Versions 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 publicly 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, 2021; therefore, this section is not applicable for the calendar year 2022 RWT effort.

Standards Information	Description
<b>Standard (and version)</b>	As noted in the CHPL listing for each of the criteria listed in this RWTP.
<b>Updated certification criteria and associated product</b>	None
<b>Health IT Module CHPL ID</b>	15.02.02.1673.A116.02.03.1.211001

Standards Information	Description
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

This section of the RWTP describes the measure(s) participants will use to address each certified criterion as part of this RWT effort.

### Description of Measurement/Metric

Measurement/Metric	Description
Measure 1: §170.315(f)(1) Transmission to immunization registries	The measure will catalogue the mechanisms used to transmit immunization registries.
Measure 2: §170.315(f)(2) Transmission to public health agencies – syndromic surveillance	The measure will catalogue the mechanisms used to create syndrome-based public health surveillance information for electronic transmission. The syndromic surveillance generated for CHIT is on demand for a selected patient and visit.
Measure 3: §170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	The measure will catalogue the mechanisms used to create reportable laboratory tests and values/results for electronic transmissions. The reportable laboratory tests with values/results messages generated for CHIT is on demand for a selected patient and accession.
Measure 4: §170.315(f)(5) Transmission to public health agencies — electronic case reporting	The measure will catalogue the mechanisms used to consume and maintain a table of trigger codes to determine which encounters may be reportable. This approach verifies reportable conditions entered into the EHR trigger the creation of a case report based on the trigger codes.

## Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Criteria Requirement
Measure 1: §170.315(f)(1) Transmission to immunization registries	§170.315(f)(1) Transmission to immunization registries	(i) create immunization information  (ii) enables a user to request, access and display the evaluated immunization history
Measure 2: §170.315(f)(2) Transmission to public health agencies – syndromic surveillance	§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	(i) Create syndrome-based public health surveillance information for electronic transmission to public health agencies.
Measure 3: §170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	§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
Measure 4: §170.315(f)(5) Transmission to public health agencies — electronic case reporting	§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 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.
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.



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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.
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, the Common Clinical Data Set, 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 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.
Measure 2: §170.315(f)(2) Transmission to public health agencies – syndromic surveillance	The Health IT Module creates syndromic surveillance content by running the RPMS option by patient and visit. The file will be generated and can be confirmed using both the audit (BUSA) log and location where the file is created for the Division of Epidemiology.  Audit (BUSA) logs will confirm that option was run, as well as the host files being available after the option is run. Note: No response is required from the Division of Epidemiology.
Measure 3: §170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	The Health IT Module creates Reportable Lab content by running the RPMS option by patient and lab accession number. The file will be generated and can be confirmed using both the audit (BUSA) log and location where the file is created for the Division of Epidemiology.  Audit (BUSA) logs will confirm that option was run, as well as the host files being available after the option is run. Note: No response is received from the Division of Epidemiology.



Measurement/Metric	Test Methodology
Measure 4: §170.315(f)(5) Transmission to public health agencies — electronic case reporting	The Health IT Module consumes a table of trigger codes to determine which encounters may be reportable. The Health IT module matches one or more patient visits or encounters to the parameters of the trigger code table. Note: If a patient record is updated with one of these triggers, the system will identify the patient and generate a case report.

## Care Setting(s)

The IHS markets its CHIT in two major care settings (ambulatory and inpatient), which are defined as:

**Ambulatory Care Setting:** Ambulatory care settings include encounters with a health care provider (including covered contractors) in an organized clinic within an IHS facility where the patient or a personal representative (designated only to pick up prescriptions) is present (physically or telehealth) and services are not part of an inpatient stay, and require encounter record. A licensed, credentialed health care provider, or other provider qualified by the medical staff or facility administrator, must write a note in the health record.

**Inpatient Care Setting:** A patient admitted for inpatient services based on the standing, verbal, or written order by a physician or a licensed independent practitioner. Admission involves the occupancy of an adult or pediatric hospital bed or newborn infant bassinet and the maintenance of a hospital chart during observation, care, diagnosis, or treatment. If, after discharge, an inpatient returns to the hospital for admission, it is a separate admission. Adults without complaint or sickness who are at the hospital for the benefit of a hospitalized patient or for the convenience of the hospital are not inpatients.

Each measurement/metric within this RWTP will be executed/tested in the care setting(s) identified in the following table:

Measurement/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 and Ambulatory and inpatient system.
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 and Ambulatory and inpatient system.
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 and Ambulatory and inpatient system.
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

This section describes the expected outcomes from each measure listed in this RWTP. Participants will complete the Measurement//Metric Results column in detail, which will be included in as part of the RWT Results report.

Measurement/Metric	Expected Outcomes	Measurement/Metric Result
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.	
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 when the files cannot be created on-demand using the RPMS option.	
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 when the files cannot be created on-demand using the RPMS option.	
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. Match information recorded in a patient visit or encounter to a trigger code in the trigger code table. When a trigger is matched in accordance with provision (f)(5)(ii), the Health IT Module electronically creates an initial case report.	

## Schedule of Key Milestones

This section includes a schedule of key milestones for this RWT effort.



**Note:** Since the IHS markets to two specific care settings, the care setting column may include one or both care settings. As a result, the milestones and dates will be the same regardless of the care setting.

Key Milestone	Care Setting	Date/Timeframe
Initial outreach for site participation	Ambulatory/Inpatient	October 15, 2021
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	December 15, 2021
Begin collection of information as laid out by the plan for the period.	Ambulatory/Inpatient	January 5, 2022
Planned System updates to allow for collection of data any updates.	Ambulatory/Inpatient	Quarterly, 2022, as needed
Follow-up with authorized representatives/participants and providers on a regular basis to understand any issues arising with the data collection.	Ambulatory/Inpatient	Quarterly, 2022
End of Real-World Testing period/participants submit final collection of all data for analysis as real-world testing results to IHS.	Ambulatory/Inpatient	December 15, 2022
Analysis and real-world testing results report creation.	Ambulatory/Inpatient	January 12, 2023
Real-world testing results submission to ACB	Ambulatory/Inpatient	January 15, 2023

## Attestation

This RWTP is complete and satisfies the ONC CMOc requirement for RWT. The IHS approves this plan is completed and approved for execution for its RWT participants.

Authorized Representative	Representative Details
<b>Authorized Representative Name:</b>	Jeanette Kompkoff
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# Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

<b>Authorized Representative</b>	<b>Representative Details</b>
<b>Authorized Representative Signature:</b>	On behalf of Jeanette Kompkoff
<b>Date:</b>	12/07/2021