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 **Clinical Quality Measures (CQMs)** 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

CLINICAL QUALITY MEASURES

The following use cases will test and demonstrate conformance to the criterion within the Clinical Quality Measures (CQMs) category using the version of the adopted standard to which each Health IT Module was certified as described in the General Information section, which includes the CMS CQM SVAP Quality Reporting Document Architecture (QRDA) Category I for Hospitals (§ 170.205(h)(3)) v1.0 and QRDA Category III for Eligible Clinicians and Eligible Professionals (§ 170.205(k)(3)) v1.1 standards update as described in the Standards Updates section.

Use Case	Use Case Overview
Use Case 1 (§170.315(c)(1) CQM – Ambulatory/Inpatient)	User enters data through EHR and RPMS to document visit criteria based on the certified CQMs being tested.
Use Case 2 (§170.315(c)(3) CQM – Ambulatory/Inpatient)	Using the Health IT Module (ECQM), a user imports the QRDA CAT I reports. The Health IT Module calculates the aggregate report for ECQM and generates CAT III that can be exported.
Use Case 3 (§170.315(c)(3) CQM - Ambulatory/Inpatient)	The user can generate an aggregate and individual patient reports (QRDA Categories I/III) that are ready for submission.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The IHS have combined similar criterion that fall within the definition of this specific CQMs category, which include §170.315(c)(1) CQMs record and export, §170.315(c)(2) CQMs import and calculate and §170.315(c)(3) CQMs report.
CQMs are tools that help measure and track the quality of health care services for eligible professionals (EPs), eligible hospitals provide, as generated by a provider's electronic health record (EHR). Measuring and reporting CQMs helps to ensure that our health care system is delivering effective, safe, efficient, patient-centered, equitable, and timely care.

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

- (c)(1) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM.
- (c)(1) Export. A user must be able to export a data file at any time the user chooses.
- (c)(2) Import. Enable a user to import a data file for one or multiple patients.
- (c)(2) Calculate each and every clinical quality measure.
- (c)(3) Enable a user to electronically create a data report file for transmission of clinical quality measurement data.

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 include the following:

In addition, the (c)(3) criterion listed as part of this category was updated to the SVAP standards noted in the following table prior to August 31, 2023. As a result, the RWT effort for the calendar year 2024 will include these standards.

Standard (and version)	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 AND CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022
Updated certification criteria and associated product	§170.315(c)(3) - Clinical quality measures (CQMs) — report
Health IT Module CHPL ID	15.02.05.1673.RPMS.01.04.1.220302
Method used for standard update	SVAP
Date of ONC ACB notification	January 3, 2023
Date of customer notification (SVAP only)	December 30, 2022
Conformance measure	§170.315(c)(3) Data File Creation
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(c)(1) Record and Export CQMs	This measure will demonstrate the recording and exporting of data necessary to calculate CQMs.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	This measure will demonstrate the import and calculation of CQMs for one or multiple patients.
Measure 3: §170.315(c)(3) Data File Creation	This measure will demonstrate the creation of the data file used for transmission of CQMs.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (If applicable)
§170.315(c)(1) Clinical quality measures (CQMs) — record and export	(i) Record all data necessary to calculate CQMs (ii) Export Data file	
§170.315(c)(2) Clinical quality measures (CQMs) — import and calculate	(i) Import a data file (ii) Calculation of CQMs	
§170.315(c)(3) Clinical quality measures (CQMs) — report	(i) Creation of Data file	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 1: §170.315(c)(1) Record and Export CQMs	The user must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason." A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate: Ranging from one to multiple patients; and that includes all of the data captured for each and every CQM.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	Enable a user to import a data file for one or multiple patients and calculate each and every clinical quality measure for which it is presented for certification.
Measure 3: §170.315(c)(3) Data File Creation	Enable a user to electronically create a data file for transmission of CQM data.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 1: §170.315(c)(1) Record and Export CQMs	System logs (BQRE), and email logs will be reviewed to determine the frequency and the transport mechanism used by providers for recording and exporting CQMs. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	System logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.
Measure 3: §170.315(c)(3) Data File Creation	System logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.

Care Setting(s)

Measure/Metric	Care Setting	Justification
Measure 1: §170.315(c)(1) Record and Export CQMs	Ambulatory/Inpatient	The ECQM module supports the recording and exporting of CQMs for one or multiple patients.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	Ambulatory/Inpatient	The ECQM module supports the import and calculation, for one or multiple patients, for CQMs.
Measure 3: §170.315(c)(3) Data File Creation	Ambulatory/Inpatient	The ECQM module supports the creation of a data file for transmission of CQMs.

Expected Outcomes

Measurement/Metric	Expected Outcomes
Measure 1: §170.315(c)(1) Record and Export CQMs	It is expected that users will be able to Record and Export the data necessary to calculate the CQMs for one or multiple patients. Error rates will be tracked over time.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	It is expected that the user will be able to Import and Calculate each CQM. Error rates will be tracked over time.
Measure 3: §170.315(c)(3) Data File Creation	It is expected that the user will be able to create the data file for transmission of CQM data. Error rates will be tracked over time.

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 13:27:00 -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