Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

Real World Testing Plan – Clinical Quality Measures (CQMs)

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 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

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:	https://www.ihs.gov/promotinginteroperability/certificationoverview/

Use Case Scenarios

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. The user exports patient data using BQRE based on a date range. Based upon the patient records, a user exports, at any time and without any developer assistance, a data file formatted in accordance with the standard specified at §170.205(h)(2) HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3, Volume 1 for a single patient and for multiple patients for each eCQM.
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 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 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, 2021. As a result, the RWT effort for the calendar year 2022 will include these standards.

Standards Information	Description
Standard (and version)	CMS QRDA Category I HQR specified in §170.205(h)(3) - v1.0; Implementation Guide for 2021 CMS QRDA Category III EC & EP specified in §170.205(k)(3) – v1.1; Implementation Guide 2021
Updated certification criteria and associated product	§170.315(c)(3) - Clinical quality measures (CQMs) — report
Health IT Module CHPL ID	15.02.02.1673.A116.02.03.1.211001
Method used for standard update	SVAP
Date of ONC ACB notification	08/19/2021
Date of customer notification (SVAP only)	11/30/2021

Standards Information	Description
Conformance measure	CMS506v3 Safe Use of Opioids - Concurrent Prescribing CMS22v9 Preventive Care and Screening: Screening for High Blood Pressure CMS147v10 Preventive Care and Screening: Influenza Immunization
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(c)(1) Record and Export CQMs	This measure will catalogue the Recording and Exporting the data necessary to calculate each CQM.
Measure 2: §170.315(c)(2) Import and Calculate CQMs	This measure will catalogue the importation and calculation of CQMs for one or multiple patients.
Measure 3: §170.315(c)(3) Data File Creation	This measure will catalogue the creation of the data file used for transmission of CQMs.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Criteria Requirement
Measure 1: §170.315(c)(1) Record and Export CQMs	§170.315(c)(1) Clinical quality measures (CQMs) — record and export	(i) Record all data necessary to calculate CQMs (ii) Export Data file
Measure 2: §170.315(c)(2) Import and Calculate CQMs	§170.315(c)(2) Clinical quality measures (CQMs) — import and calculate	(i) Import a data file (ii) Calculation of CQMs
Measure 3: §170.315(c)(3) Data File Creation	§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	EHR logs (BUSA), 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	EHR logs (ECQM) and 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	EHR logs (ECQM) and 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)

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(c)(1) Record and Export CQMs	Ambulatory/Inpatient	The EHR system 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 Health IT Module (ECQM) supports the importation and calculation, for one or multiple patients, for CQMs.
Measure 3: §170.315(c)(3) Data File Creation	Ambulatory/Inpatient	The Health IT Module (ECQM) supports the creation of a data file for transmission of CQMs.

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(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

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.

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Date:	12/07/2021