Real World Testing Plan – Patient Care Coordination

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 Patient Care Coordination 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))
Version Number(s):	v4.1 and v5.0

General Information Name	Description
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 Patient Care Coordination 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 (Care Coordination: §170.315(b)(1) Transitions of Care – Ambulatory/Inpatient)	The IHS has developed an electronic health record system to ensure the timely availability of patient information 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. The shared documentation includes the creation of, the sending, and receiving of standardized transitions of care documents, which includes the common clinical data set (CCDS) and are shared between organizations using the Direct project SMTP protocol technology.
Use Case 2: (Care Coordination: §170.315(b)(2) Clinical Information Reconciliation and Incorporation – Ambulatory/Inpatient)	The IHS has developed an electronic health record system to ensure the timely reconciliation of patient information 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. The shared documentation includes transitions of care documents, which requires specific health information, such as medications, allergies, and problems to be reconciled in a timely manner to provide better patient care.
Use Case 3 (Care Coordination: §170.315(b)(3) Electronic Prescribing - Ambulatory)	The IHS has developed an electronic health record system to ensure prescriptions can be sent/received electronically to/from participating pharmacies. This Certified Health IT Module is for transmitting electronic prescriptions using the NCPDP NIST standard via the NCPDP v2017071 network. The transmissions of these electronic prescriptions include several message types between the IHS and participating pharmacies.

Use Case	Use Case Overview
Use Case 4 (Care Coordination: §170.315(b)(6) Data Export – Single Patient – Ambulatory/Inpatient)	The IHS has developed an electronic health record system to ensure the timely availability of patient information 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 or ported from one certified health IT system to another. The shared documentation includes the export of a single patient healthcare record in real-time.
Use Case 5 (Care Coordination: §170.315(b)(6) Data Export – Multiple Patient – Ambulatory/Inpatient)	The IHS has developed an electronic health record system to ensure the timely availability of patient information 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 or ported from one certified health IT system to another. The shared documentation includes the export of multiple patient healthcare records for a specific period date and time.
Use Case 6 (Patient Engagement – §170.315(e)(1) View, Download, Transmit Ambulatory/Inpatient)	The IHS has developed a web application called the Personal Health Record (PHR), where patients (and their authorized representative) can maintain and manage their health information in a private, secure, and confidential environment within an Ambulatory and/or Inpatient setting. The health IT must allow patients (and their authorized representatives) to view, download and transmit their health information within a patient (or authorized representative) specified timeframe.
Use Case 7 (Electronic Exchange – §170.315(h)(1) Direct Project Ambulatory/Inpatient)	The IHS has developed a secure email system called the RPMS Direct Secure Messaging System (RPMS Direct) in which users can electronically transmit (send and receive) health information to a third party. This application was developed using the Direct project, in which the IHS serves as its own HISP and is accredited by both EHNAC and DirectTrust proving the system adheres to the DirectTrust implementation standards.

Justification for Real World Testing Approach

The IHS have combined similar criterion that fall within a defined set of clinical categories: Care Coordination, Patient Engagement, and Electronic Exchange referred to as the Patient Care Coordination category, which include: §170.315(b)(1) Transitions of Care, §170.315(b)(2) Clinical Information Reconciliation and Incorporation, §170.315(b)(3) electronic prescribing, §170.315(b)(6) Data Export, §170.315(e)(1) View, Download and Transmit to 3rd party, §170.315(h)(1) Direct Project.

Patient Care Coordination are the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities and is often managed by the exchange of information among participants responsible for different aspects of

care. In addition, these activities allow doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information, electronically, improving the speed, quality, safety, and cost of patient care.

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

- (b)(1) Generate and Send a Transition of Care document for a patient to a referring provider via RPMS Direct Messaging.
- (b)(1) Receive a Transition of Care document for a patient from a referring provider via RPMS Direct Secure Messaging.
- (b)(2) Import and reconcile information from other facilities via Transition of Care document or from the patient or caregiver to ensure all relevant information is available for the care of the patient.
- (b)(3)How electronic prescribed medications are sent and received to treat specific diagnosis
  (b)(6) How users generate single and multiple patient Data Exports
- (e)(1) Patients and their authorized representatives can View, Download, and Transmit data for a specified timeframe via the PHR.
- (h)(1) Send and Receive health information to/from a 3rd party

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.

In addition, the (b)(3) Electronic Prescribing criteria was certified to the 2015 Edition Cures Update prior to August 31, 2021. As a result, the RWT effort for the calendar year 2022 will include these standards.

Note: The no other 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 only applicable to the (b)(3) criteria for the calendar year 2022 RWT effort.

Standards Information	Description
Standard (and version)	§ 170.205(b)(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071 § 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update
Updated certification criteria and associated product	(b)(3) Electronic Prescribing
Health IT Module CHPL ID	15.02.02.1673.A116.02.03.1.211001

Standards Information	Description
Method used for standard update	ONC Certification with Underwriters Laboratories. ONC Test Method; Version: 2.3 NCPDP E-prescribing; Version: 1.2.39 ONC Test Method; Version: 2.3.24
Date of ONC ACB notification	08/19/2021
Date of customer notification (SVAP only)	09/15/2021
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(b)(1) Information Sharing	This measure will catalogue the transport mechanisms used to share transitions of care documents, as well as track usage of the various transport mechanisms.
Measure 2: §170.315(b)(2) Information Reconciliation	This measure will catalogue the mechanisms used to reconcile transitions of care documents.
Measure 3: §170.315(b)(3) e-Prescribe Medication	This measure will catalogue the transport mechanisms used to electronically prescribe medications using the NCPDP Network.
Measure 4: §170.315(b)(6) Single Patient Export	This measure will assess functionality used to export data for a single patient.
Measure 5: §170.315(b)(6) Multiple Patient Export	This measure will assess functionality used to export data for multiple patients.
Measure 6: §170.315(e)(1) View, Download, Transmit	The measure will catalogue the viewing, downloading, and transmitting of health information via an encrypted secure (Direct) or unsecure (SMTP) method for a timeframe specified by a patient or their authorized representative using their PHR.
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	The measure will catalogue the electronic transmission of health information to a 3rd party using the RPMS Direct system.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Criteria Requirement
Measure 1: §170.315(b)(1) Information Sharing	§170.315(b)(1) Transitions of Care (ToC)	(i)(A) Send transition of care/referral summaries (i)(B) Receive transition of care/referral summaries (ii)(B) Display human readable version of the ToC
Measure 2: §170.315(b)(2) Information Reconciliation	§170.315(b)(2) Clinical information reconciliation and incorporation	(ii) Manually match CCDA with patient (iii)(A) Display Medications, Allergies and Intolerances, Problems (iii)(B) – (D) Incorporate Medications, Allergies, Problems
Measure 3: §170.315(b)(3) e-Prescribe Medication	§170.315(b)(3) Electronic prescribing	(ii)(A) Send/Receive prescription transactions electronically (ii)(C) Send/Receive reason for the ePrescription (ii)(E) ePrescibed oral liquid meds in mL (ii)(F) Leading and Training Zeros
Measure 4: §170.315(b)(6) Single Patient Export	§170.315(b)(6) Data Export	(ii) Create an export summary for a single patient (iii)(A) User can set date range for export (iii)(B) Export in real-time (iv) Save export

Measurement/Metric	Associated Certification Criteria	Criteria Requirement
Measure 5: §170.315(b)(6) Multiple Patients Export	§170.315(b)(6) Data Export	(ii) Create an export summary for a multiple patients (iii)(A) User can set date range for export (iii)(B) Export on specific date/time (iv) Save export
Measure 6: §170.315(e)(1) View, Download, Transmit	§170.315(e)(1) View, download and transmit	(i)(A) View an ambulatory summary or inpatient summary (i)(B) Download an ambulatory summary or inpatient summary (i)(C) Transmit a message using secure or unsecure method (i)(D) Timeframe Selection
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	§170.315(h)(1) Direct Project	(i) The Health IT can electronically transmit (send and receive) health information to a 3rd party

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
Measure 1: §170.315(b)(1) Information Sharing	The EHR system includes three (3) functionalities of interest: (A) Send transition of care/referral summaries, (B) Receive transition of care referral summaries, and (C) Display in human-readable format. Transitions of care documents are shared using the Direct project protocols (e.g., SMTP, Direct) via encrypted transmissions. This metric will provide information on the types of transmissions deployed (e.g., what types of protocols and encrypted transmission) and the frequency of usages. In addition users will be able to view the ToC in a human readable format.
Measure 2: §170.315(b)(2) Information Reconciliation	The EHR system CIR Tool is intended to allow providers and other clinical staff to reconcile information from other facilities or from the patient or caregiver to ensure all relevant information is available for the care of the patient. Information may be obtained from sources such as documents sent to your facility in the Consolidated Clinical Document Architecture (CCDA) format, or from a patient or caregiver interview, a medication list the patient or caregiver has, actual medication bottles, or any other source that can provide information regarding problems, adverse reactions, or medications.

Measurement/Metric	Justification
Measure 3: §170.315(b)(3) e-Prescribe Medication	The EHR system allows providers to send and receive prescription messages electronically via the NCPDP Secure Network to participating pharmacies with the NCPDP network. In addition, electronically prescribed medications include reason for prescription, contain a leading zero when applicable, no trailing zeros, and any oral liquid medications are prescribed in "mL" dosage.
Measure 4: §170.315(b)(6) Single Patient Export	The export of patient data is another way to share information with an external organization. The export is typically used when there is a need for a full patient record. This metric will provide information on the type of data exported for a single patient and the frequency of usage.
Measure 5: §170.315(b)(6) Multiple Patients Export	The export of multiple patient data is another way to share information with an external organization. Multiple patient exports are typically used when there is a need for a patient records contained within a system and is ported to another certified health IT system. This metric will provide information on the type of data exported for a single patient and the frequency of usage.
Measure 6: §170.315(e)(1) View, Download, Transmit	The PHR system includes three (3) functionalities of Interest: (A) The Viewing of personal health information within a specified timeframe (D), (B) Downloading their personal Health information and (C) The ability to transmit personal health information to others. Real world testing will include the functions necessary to satisfy these functionalities, thus demonstrating real world interoperability and applicability.
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	The Health IT can electronically transmit (send and Receive) health information to a 3rd party using the RPMS Direct Secure Messaging system.

Testing Method(s)/Methodology(ies)

Measurement/Metric	Test Methodology
Measure 1: §170.315(b)(1) Information Sharing	EHR logs, system logs, and Direct mail logs will be reviewed to determine the frequency and the transport mechanism used by providers for sending/receiving transitions of care using the Direct protocols. 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(b)(2) Information Reconciliation	EHR logs 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.

Measurement/Metric	Test Methodology
Measure 3: §170.315(b)(3) e-Prescribe Medication	EHR logs, system logs, and prescription message logs will be reviewed to determine the frequency and the transport mechanism used by providers for sending/receiving electronically prescribed using the NCPDP network. 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 failed electronic prescription transmissions as a % of total electronic prescription transmissions. • Measure electronic prescriptions with a diagnosis as a % of total electronic prescriptions. • Measure electronic prescriptions with decimal dosages containing no leading zero when applicable or with a trailing zero as a % of total electronic prescriptions with decimal dosages. • Measure electronic prescriptions for oral liquid medications without a "mL" dosage as a % of total electronic prescriptions for oral liquid medications.
Measure 4: §170.315(b)(6) Single Patient Export	EHR logs 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 5: §170.315(b)(6) Multiple Patients Export	EHR logs 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 6: §170.315(e)(1) View, Download, Transmit	PHR logs will be reviewed for each period to determine the frequency of patient (or authorized representative) PHR activity/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 view, download, and transmit. This test methodology will primarily test the conformance of the implementation.
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	Verification of the identified health information is successfully transmitted to a 3rd party using the RPMS Direct system, in accordance with specified standards. The tester verifies that health information can be sent/received successfully and all sent messages to a Direct Trust partner returns an Message Disposition Notification (MDN). RPMS Direct Secure Messaging system logs will be used to determine the frequency of transmitted messages. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of view, download, and transmit. 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(b)(1) Information Sharing	Ambulatory /Inpatient	The EHR system supports the deployment and tracking of documentation within and outside of the ambulatory and inpatient setting.
Measure 2: §170.315(b)(2) Information Reconciliation	Ambulatory /Inpatient	The EHR system supports the deployment and tracking of documentation within and outside of the ambulatory and inpatient setting.
Measure 3: §170.315(b)(3) e-Prescribe Medication	Ambulatory	The EHR system supports the deployment and tracking of documentation within and outside of the ambulatory setting.
Measure 4: §170.315(b)(6) Single Patient Export	Ambulatory /Inpatient	The EHR system supports the deployment and tracking of documentation within and outside of the ambulatory and inpatient setting.
Measure 5: §170.315(b)(6) Multiple Patients Export	Ambulatory /Inpatient	The EHR system supports the deployment and tracking of documentation within and outside of the ambulatory setting.
Measure 6: §170.315(e)(1) View, Download, Transmit	Ambulatory/Inpatient	The certified health IT system supports the deployment and tracking of PHR activity within and outside of the ambulatory and inpatient setting.

Measurement/Metric	Care Setting	Justification
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	Ambulatory/Inpatient	The certified health IT system supports the deployment and tracking of documentation within and outside of the ambulatory and inpatient setting.

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 Results
Measure 1: §170.315(b)(1) Information Sharing	It is expected that providers will be able to share transitions of care using the transmission mechanisms provided and view transitions of care documents in a human readable format. Error rates will be tracked and trended over time.	
Measure 2: §170.315(b)(2) Information Reconciliation	It is expected that users will be able to match received CCDA data to the patient, display, and incorporate medications, allergies, and problems into the patient's record using the EHR CIR tool. Error rates will be tracked and trended over time.	
Measure 3: §170.315(b)(3) e-Prescribe Medication	It is expected that providers will be able to send/receive electronic prescriptions and messages as described to/from participating NCPDP pharmacies using the NCPDP Network. Error rates will be tracked and trended over time.	
Measure 4: §170.315(b)(6) Single Patient Export	It is expected that authorized users will be able to export and share data for a single patient using the export function. Error rates will be tracked and trended over time.	
Measure 5: §170.315(b)(6) Multiple Patients Export	It is expected that authorized users will be able to export multiple patient data using the export function. Error rates will be tracked and trended over time.	

Measurement/Metric	Expected Outcomes	Measurement/Metric Results
Measure 6: §170.315(e)(1) View, Download, Transmit	It is expected that Patients (or their authorized representative) will be able to View, Download and Transmit CCDA (English/human readable), Laboratory test reports and Diagnostic images. Error rates will be tracked over time.	
Measure 7: §170.315(h)(1) Electronic Exchange (Direct Project)	It is expected that health information can be sent and received successfully by the Health IT Module using the RPMS Direct system. 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.

Authorized Representative	Representative Details
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Date:	12/07/2021