DSS RxTracker v9 Test Plan

CHPL # 15.04.04.2925.RxTr.09.02.1.200330

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1. Introduction

1.1 Purpose

The purpose of this ONC test plan is to document the overall testing processes for RxTracker ONC Certification Edition 2015. This test plan describes the test strategy, testing activities and methods to determine RxTracker meets the "Real World Testing" ONC Cures technology for interoperability requirements.

1.2 Test Objective

This ONC Test plan supports:

- Meeting the regulatory test coverage of the 15 Edition ONC requirements per marketed environments.
- Execution of 100% of the test cases for each certified 15 edition ONC test component for RxTracker.
- Identification of the functional components and ONC requirements that should be targeted by tests.
- Provision of time estimates of the testing efforts.
- Description of test data and environments per DSS target marketing environments.
- Listing of deliverable elements that are certified within RxTracker and included in the CHPL listing.

1.3 Process and References

The processes and procedures that guide the implementation of this Test plan are:

- 2015 Edition Test Methods, Test Procedures and Conformance Method
- 2015 Edition Cures Real World Testing Regulations

The references that support the implementation of this test plan are:

- Health IT Standards References and Resource Documents are listed within each criteria test case.

2. Criteria to be Tested from 2015 Edition ONC Certification

2.1 Test Inclusion

RxTracker Test plan includes test scenarios for both Ambulatory and Inpatient settings. All data exchange and communications are secured and follow both HIPAA Privacy and compliance rules. ONC Technical standards have been carefully reviewed and implemented for testing.

Test cases have been created for the following criteria:

§170.315(b)(3) Electronic Prescribing

§170.315(b)(10) Electronic Health Information Export

2.2 Test Methodology

To demonstrate Interoperability and conformance compliance during the Real World Testing the user, following written scripts that are based on application workflow, conducts System Testing and Integration Testing.

- Data is sent and/or received properly between systems.
- Interfaces between applications move data correctly and completely. Test both sending and receiving when interfaces are bi-directional.
- Connectivity with external organizations is accurate and complete as authorized (e.g., continuity of care record to referrals, personal health records for patients, disease management to/from health plan).
- System access is appropriate per assigned privileges.
- Data are processed accurately.
- Data are correctly populated in the user interfaces, reports, and clinical documents.
- All system components that share data or depend on other components work together properly.
- The workflows reflect actual new processes and workflows.
- Usage is defined in and follows policies and procedures. Reinforce training as applicable.

3. General Information for All Measures

Product and CHPL ID	DSS RxTracker v9 - CHPL # 15.04.04.2925.RxTr.09.02.1.200330
Care Setting	Inpatient and Ambulatory
Test Environment	Customer PRD environment with the exception of b.10 which will use a TEST environment that mirrors the organization's production environment.
Real-world networks /tools	• Surescripts – For the data exchange between RxTracker and the Retail Pharmacy • Mirth – For the data exchange between RxTracker and the EHR • Exostar – If customer prescribes controlled substances in test cases (optional) Results will be captured through a variety of screenshots, reports and extracts.
Standards Update	Standards updated to USCDI (Y/N): Not Applicable

4. Measures used in Overall Approach

4.1 §170.315(b)(3) Electronic Prescribing

Measure	Successful transmission of electronic prescriptions created by Prescribers and/or mid-level providers in the RxTracker module to Surescripts in a format that can be utilized by the Retail Pharmacy for processing the prescriptions. Numerator # electronic prescriptions created by Prescribers and/or mid-level providers in the RxTracker module and transmitted to Surescripts in a format that can be utilized by the Retail Pharmacy for processing the prescriptions Denominator: # electronic prescriptions created by Prescribers and/or mid-level providers in the RxTracker module and transmitted to Surescripts Denominator Exception: • Error or rejection due to user permissions • Error or rejection due to communication issues Source of Data (Report): Real World Testing - Prescription Percentages Details on Errors are available on the specific reports, i.e., Real World Testing - Create new prescriptions (NEWRX) NOTES: • This applies to patients being discharged from the inpatient care setting as well as those in an ambulatory clinic setting; and to renewals and change requests, as well as new prescriptions. • No specific target percentage was included for the measure as the organization should expect that all transmissions will be successful; however, errors may occur due to user permissions which are configurable, communication issues, etc. In addition, the specific number of scenarios in the test may vary depending on the organization. • The time period of measurement is not applicable to this measure. Associated certification criteria: §170.315(b)(3) Electronic Prescribing.
Justification for Measure and Real World Testing Approach	RxTracker is appropriate for utilization in both inpatient and ambulatory care settings. Through the use of several scenarios that are organized in accordance with the clinical workflow for the ePrescribing functionality, all of the required components of the §170.315(b)(3) Electronic Prescribing criteria will be tested, i.e., • request a patient-specific medication history to include a current medication list (with full details on medication, indication and last fill date) from Surescripts that includes all retail pharmacies currently in use by the patient,

	• allow updating of the patient's medication history within RxTracker to include medications obtained through the Surescripts query, • create and transmit new prescriptions to Surescripts for processing at a specific Retail Pharmacy of the patient's choosing, • approve renewal requests received from the Retail Pharmacy to authorize refills from the Retail Pharmacy, • deny change requests received from the Retail Pharmacy, • reprocess a request for change for a prescription that has already been transmitted to Surescripts for processing at a Retail Pharmacy at the request of the pharmacist, • cancel a prescription already transmitted to Surescripts, and • view error messages received from Surescripts when there is a problem with the transmission of the transaction. As detailed in the Test Methods section, testing will also include prescribers, mid-levels and non-prescribers in both inpatient and ambulatory settings and will include the creation and transmission of new prescriptions for controlled substances in accordance 21CFR Part 1311.145. Reference: PART 1311 - Subpart C - Electronic Prescriptions (usdoj.gov)
Use Case	RxTracker is appropriate for utilization in a variety of care settings, i.e., Inpatient care with integration to a full EHR or Ambulatory with integration to an EHR. In the Inpatient Care setting, the integrated functionality is an integral part of the medication reconciliation at the time of both the inpatient admission (medication history to obtain a current medication list as the first step in writing admission medication orders) and the inpatient discharge (review/updating the medication list as part of the process for making any changes to the patient's prescriptions prior to discharge). In the ambulatory setting, providers can import/review/update medication history and ePrescribe including controlled substances. Depending on the specific configuration, RxTracker will utilize APIs/HL7 messaging to communicate with the EHR in addition to the communication with Surescripts to obtain/update the medication history and transmit the electronic prescriptions. Exostar is utilized for two-factor authentication.
Test Methods	RxTracker is designed for organizations that have ambulatory clinic settings in addition to those that have only inpatient settings, so scenarios will be included for patients to be admitted to the inpatient setting and then discharged for follow-up care in an affiliated ambulatory clinic. The size of the organization in terms of the number of beds or the number of unique prescribing locations does not impact functionality as it is designed to function on a web-based cloud solution. Prescriptive authority within RxTracker is based on user roles, i.e., prescribers and non-prescribers. Additional hybrid roles may be created for non-MD prescribers who may have prescriptive authority and serve as mid-level providers, including physician assistants and advance practice nurses. No specific number of users or locations need to be included as long as those tested have been appropriately configured. Types of data to be received from the integrated EHR via API/HL7 include patient demographics, ADT encounters, allergies, height/weight, diagnoses/problems and active inpatient medications. XMLs are generated for the prescription data and transmitted to Surescripts for further processing by the appropriate Retail Pharmacy. If controlled substances are included in the

	prescriptive authority for any users at the organization, that scenario should be included in the testing as the functionality involves additional data exchange via API with Exostar for the two- factor authentication. A series of reports within the RxTracker Administrative Module allow the authorized representatives who had the required permissions to generate specific reports that do not include PHI and allow monitoring of ongoing performance in the production environment on a regular basis. These reports included: • Real World Testing - Prescription Percentages ➢ Rx History Query Success ➢ Rx History Query Error ➢ New Rx Success ➢ New Rx Errors ➢ Change Rx Success ➢ Change Rx Errors ➢ Renewal Rx Success ➢ Renewal Rx Errors ➢ Cancel Rx Success ➢ Cancel Rx Errors • Real World Testing - Create new prescriptions (NEWRX) • Real World Testing - Change prescriptions (RXCHG, CHRES) • Real World Testing - Cancel prescriptions (CANRX, CANRES) • Real World Testing - Request and receive medication history information (RXHREQ, RXHRES) Testing can be done using data from a production (PRD) environment as the reports do not include PHI.
Test Data using PRD environment	Data will be entered into Juno EHR as part of ongoing clinical workflow. The volume of electronic prescriptions is sufficient for a given period, generally using a full month sample size, that no additional data entry is needed.
Approach and Expected Outcome	Testing is organized according to the clinical workflow. If the testing is being done in a PRD environment, reviewing the data for the specified period using the specified reports will provide sufficient details to be sure that the various criteria have been addressed. These reports are in addition to the aggregate report of Prescription Percentages referenced above in the Measure details. NOTES: • The alignment with the ONC 2015 Edition Cures Test Procedure is included for each required criteria. Reference: Electronic prescribing | HealthIT.gov • In the case of (A)(7), the assistance of the vendor is required to view the transaction status in the Admin console. § 170.315(b)(3) *Electronic prescribing.* (ii) For technology certified subsequent to June 30, 2020:

	(A) Enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows: (1) Create new prescriptions (NewRx). (2) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse). (3) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse). (4) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). (6) Request and receive medication history (RxHistoryRequest, RxHistoryResponse). (7) Relay acceptance of a transaction back to the sender (Status). (8) Respond that there was a problem with the transaction (Error). (9) Respond that a transaction requesting a return receipt has been received (Verify). (C) For the following prescription-related transactions, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements: <Diagnosis><Primary> or <Secondary>: (1) Required transactions i. Create new prescriptions (NewRx). ii. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse). iii. Request to cancel prescriptions (CancelRx). iv. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). vi. Receive medication history (RxHistoryResponse). (E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc). (F) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

4.2 §170.315(b)(10) Electronic Health Information Export

Use Case	Specific RxTracker users with required permissions can generate an export of a folder with a series of files with patient specific data that can then be saved to a designated folder accessible to specified users. As part of the folder contents, there is a publicly accessible hyperlink.
Certification Criteria	§ 170.315 (b)(10) *Electronic Health Information export*- 1. *Single patient electronic health information export.* 1. Enable a user to timely create an export file(s) with all of a single patient's electronic health information that can be stored at the

	time of certification by the product, of which the Health IT Module is a part. 2. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. 3. Limit the ability of users who can create such export file(s) in at least one of these two ways: 1. To a specific set of identified users 2. As system administrator function. 4. The export file(s) created must be electronic and in a computable format. 5. The publicly accessible hyperlink of the export's format must be included with the exported file(s). 2. *Patient population electronic health information export*. Create an export of all the electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part. 1. The export created must be electronic and in a computable format. 2. The publicly accessible hyperlink of the export's format must be included with the exported file(s). 3. *Documentation*. The export format(s) used to support paragraphs (b)(10)(i) and (ii) of this section must be kept up-to-date.
Justification	Once testing for the §170.315(b)(10) has been completed, the exported folder with the data files will be available in the specified location. The format of the file will be in a computable format.
Test Methodology	Must do required configuration in advance-both users and file location. Permissions for the EHR (b)(10) Export functionality are assigned to a specific role in Administrative panel. The specific role with the required permission is then assigned to the users as deemed appropriate. One or more "Single Patient Export Directory Locations" can be configured for use. Once configured, choices will be viewable once the patient has been selected. The content of the patient specific data in the exported folder will vary as the data/files will depend on the specific data on the specific patient.
Test Data	Data will be entered into RxTracker as part of ongoing clinical workflow. At a minimum, this data will include the following (if entered on a given patient): ➢ Common Clinical Data Set items ❖ Patient Name ❖ Sex ❖ Date of Birth ❖ Race and Ethnicity ❖ Medication Allergies ❖ Medications including (frequencies, dose & route) ❖ Problems ❖ Vital Signs (height & weight) ➢ Cognitive status ➢ Discharge instructions
Expected Outcomes	The export file(s) created is electronic and in a computable format. See Appendix A for the details for Test Data Entry.

Measure	Successful generation and export of a folder with a series of files that contain all of the data from RxTracker for a given patient. • **Measure b10** % reviewed files that were created where valid content was confirmed by a visual inspection *Numerator= # files reviewed with expected data based on comparison with content in RxTracker* *Denominator = # files reviewed in extract folder* *Files reviewed should include (at a minimum): Problems, Meds, Allergies, Diagnoses*

5. Schedule of Key Milestones

Key Milestone	**Date/Timeframe**
Release of documentation for the Real World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	December 1, 2024
Begin collection of information as laid out by the plan.	January 1, 2025
Meet with previously identified providers and authorized representatives to ensure that Real World Testing protocols are effective.	March 1, 2025
Follow-up with providers and authorized representatives to understand any issues arising with the data collection.	Quarterly, 2025
Data collection and review.	Quarterly, 2025
End of Real World Testing period/final collection of all data for analysis.	January 2026
Analysis and report creation.	January 15, 2026
Submit Real World Testing report to ACB (per their instructions).	February 1, 2026

5. Attestation

This Real World Test 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 and Title:	Hilary Kloska Director, Clinical Content	Authorized Representative Phone:	561-402-9621
Authorized Representative Signature:	Hilary Kloska	Date Signed:	10/18/2024

6. Appendices

6.1 Appendix A §170.315(b)(10) Electronic Health Information Report

6.1.1 Criteria

- §170.315(b)(10) – Electronic Health Information Export

6.1.2 Test Data Entry

Actual patient data should be utilized for the testing. No specific data is required; however, clinical documentation should include, at a minimum, allergies, medications, problems, vital signs, smoking status and diagnoses.

6.1.3 Test Script Prerequisites

- Configuration of permissions based on role
- Configuration of users with specific role
- Configuration of the Single Patient Export Directory Location such that it is accessible by the user who will be exporting the data.

6.1.4 Measure Data

Successful generation and export of a folder with a series of files that contain all the data from RxTracker for a given patient.

- **Measure b10** % reviewed files that were created where valid content was confirmed by a visual inspection

Numerator= # files reviewed with expected data based on comparison with content in RxTracker
Denominator = # files reviewed in extract folder
Files reviewed should include (at a minimum): Problems, Meds, Allergies, Diagnoses

Testing is focused on the files created on the designated directory location.

Step	Steps to Access/View files	Expected Outcome
Step 1	Navigate to the designated directory location.	Location will include a folder with patient data files.
Step 2	Change the formatting of the display to include the listing of all of the files in the folder to make it easier to find/access the desired data file.	Alphabetical display of all of the files available for the specific patient based on the data in RxTracker at the time the export was created.
Step 3	Determine which data will be reviewed. At a minimum, review the following: Problems, Meds, Allergies, Diagnoses	Majority of patients should have data for these, though Allergies may just be No known allergies
Step 4	Open the specific file noted above in Notepad++ to view the data **Compare the data shown in the file to that in RxTracker for the specific patient encounter.** Examples: Problems: Use files • persons_problems.csv Medications: Use files • outpatient_medications.csv Allergies: Use files • persons_allergies.csv Diagnoses: Use files • diagnoses.csv	Data should match