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

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. Measures used in Overall Approach

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 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.
Product and CHPL ID	DSS RxTracker v9 CHPL # 15.04.04.2925.RxTr.09.02.1.200330
Care Setting	Inpatient and Ambulatory
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. Testing can be done using data from a production (PRD) environment as the reports do not include PHI. If a PRD environment is not available, testing should be conducted in a TEST environment that mirrors the organization's production environment.
Test Environment	Customer PRD environment or 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) In the event that testing is done using a TEST environment and test data, access to the Surescripts Admin Console requires assistance from the vendor for the following: • entry of test data (included in test script) to serve in Renewals and Change Request messages • to view the status of the messages Results will be captured through a variety of screenshots, reports and extracts.
Standards Update	Standards updated to USCDI (Y/N): Not Applicable
Test Data using PRD environment	Prior to testing, the organization is responsible for pre-building test providers and patients defined in each scenario. The tester must be assigned to the appropriate role, with prescriptive authority, and the environment must be configured appropriately to execute all scenarios. No specific number of use cases will be tested to increase the volume of tests; however, date ranges of approximately 1 week would likely be sufficient to provide a representative sample for each scenario.

	Patients will be entered in the organization's EHR and sent to RxTracker via API/HL7 messages. Types of data to be received from the integrated EHR includes patient demographics, ADT encounters, allergies, height/weight and diagnoses. Specific data is included in each of the test scripts. Data will be available in Surescripts for the various test scripts in advance to utilize for the Medical History queries, the renewal requests and the change requests. Communication to/from Surescripts will via XML messages. Care Settings: Prescriptions from both inpatient settings (discharge medications) and ambulatory settings should be included if possible. Patients: Adults and pediatric populations • both male and female; however, gender is not utilized for demonstrating any impact on functionality • patients with known Allergies to medications and some with No Known Allergies; however, no specific steps are included to address allergy checking functionality since that is not part of the 170.315(b)(3) criteria • various diagnoses; however, order checking is not part of the 170.315(b)(3) criteria so it is not addressed by the testing scenarios NOTE: In the event that data is not available in the PRD environment to address Scenario #4, that can be done separately in a TEST environment. Prescriber Users: Physician and Mid-level • The prescriptive authority for both the physician and the mid-level (PA) often the same; however, if that is not the case for the state in which the organization is located, efforts should be made to include both types of prescribers in the test data. Medications: • Data should include Medication history from Surescripts from multiple pharmacies. • Data should include some prescriptions for Controlled Substances. • Data needs to include some prescriptions for medications with dosages less than 1.0 to address Scenario #3.
Test Data using TEST environment	Prior to testing, the organization is responsible for pre-building test providers and patients defined in each scenario. The tester must be assigned to the appropriate role, with prescriptive authority, and the environment must be configured appropriately to execute all scenarios. No specific number of uses cases will be tested to increase the volume of tests. Instead, the plan includes a minimum number of test scenarios based on the scope of the functionality being tested. While each of the scenarios includes specific details for patient data, the names of the patients, providers, etc. can be altered as the organization deems appropriate; however, for the scenarios that require assistance from the vendor, those details will

	need to be clearly communicated as being different than what was included in the scenario test script. Patients will be entered in the organization's EHR and sent to RxTracker via API/HL7 messages. Types of data to be received from the integrated EHR includes patient demographics, ADT encounters, allergies, height/weight and diagnoses. Specific data is included in each of the test scripts. Data will be entered in Surescripts by the vendor as required for the various test scripts in advance to utilize for the Medical History queries, the renewal requests and the change requests. Communication to/from Surescripts will via XML messages. Care Settings: • Inpatient-Scenarios LP: #1, #2 and #3 • Ambulatory-Scenarios LP: #4, #5 and #6 Patients: • Adults-John Yosemite, Susanne Adirondack and Mary Smith • Pediatric: Elizabeth Itasca (Scenario # 4) -used for entry of a prescription that utilizes weight-based dosing • Both male and female patients are included for display purposes; however, gender is not utilized during testing for demonstrating any impact on functionality • Both patients with known Allergies to medications and some with No Known Allergies are included for display purposes; however, no specific steps are included to address allergy checking functionality since that is not part of the 170.315(b)(3) criteria. • Diagnoses are included for some scenarios for documenting indications; however, order checking is not part of the 170.315(b)(3) criteria so it is not addressed by the testing scenarios. Prescriber Users: Physician and Mid-level • The prescriptive authority for both the physician and the mid-level (PA) is the same in the test scenarios included; however, if that is not the case for the state in which the organization is located, the test data for Scenario # 4 should be changed to make the prescriber a physician. Medications: • Medication history from Surescripts includes data from multiple pharmacies • A variety of medications have been included in the test scenarios in order to test specific functionality. ➢ Oral liquid medications and weight-based dosing are included in Scenario # 4. ➢ Medications with dosages less than 1.0 are included in Scenario # 3

	➢ Prescription for Controlled Substance for use in testing 2 Factor authentication is included in Scenario # 5
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 reports listed in each scenario 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. If the testing in being done in a TEST environment, the criteria being tested grouped according to the specific scenario. The specific criteria is referenced for each scenario. The steps for the testing and the Expected Outcome for each step are detailed in the embedded documents for each scenario included below. In general, the Interoperability and electronic health information exchanged is accomplished successfully without errors or message failures during the exchange. 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.
Scenario #1	**Reference Criteria**: • Paragraph § 170.315(b)(3)(ii)(A)(6) Request and receive medication history (RxHistoryRequest, RxHistoryResponse). • Paragraph § 170.315 (b)(3)(ii)(C)(1)(vi) Receive medication history (RxHistoryResponse). **Approach:** Request a patient-specific medication history to include a current medication list (with full details on the medication, source, prescriber, indication and last fill date) from Surescripts that includes all retail pharmacies currently in use by the patient. • Send a request for a medication history, *RxHistoryRequest***,** a message is generated. • Receive a response to a request for a medication history, *RxHistoryResponse* message is processed and data is displayed. **Expected Outcome:** Interoperability and information exchanged is accomplished successfully without errors or message failures during the exchange. Patient's retail pharmacy history displays in the application. **Report:** Real World Testing - Request and receive medication history information (RXHREQ, RXHRES) See attached test script for step by step details if testing is to be done in TST environment
Scenario #2	**Reference Criteria:** Not Applicable **Approach:** Allow updating of the patient's medication history within RxTracker to include medications obtained through the Surescripts query, See attached test script for step by step details if testing is to be done in TST environment

Scenario #3	**Reference Criteria:** • Paragraph § 170.315 (b)(3)(ii)(A)(1) Create new prescriptions (NewRx). • Paragraph § 170.315 (b)(3)(ii)(A)(2) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse). • Paragraph § 170.315 (b)(3)(ii)(C)(1)(i) Create new prescriptions (NewRx). • Paragraph § 170.315 (b)(3)(ii)(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. **Approach:** • Create and transmit new prescriptions to Surescripts for processing at a specific Retail Pharmacy of the patient's choosing. The prescription will include a dose that is less than 1.0 so it requires a leading 0 before the decimal point. • 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. **Expected Outcome:** Formatting of the dose requires leading zeroes before the decimal point for amounts less than one and does not allow trailing zeroes after a decimal point when a user prescribes medications. Interoperability and information exchanged is accomplished successfully without errors or message failures during the exchange. **Report:** Real World Testing - Create new prescriptions (NEWRX) **Report:** Real World Testing - Change prescriptions (RXCHG, CHRES) See attached test script for step by step details if testing is to be done in TST environment
Scenario #4	**Reference Criteria:** • Paragraph § 170.315 (b)(3)(ii)(A)(4) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). • Paragraph § 170.315 (b)(3)(ii)(C)(1)(iv) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). • Paragraph § 170.315 (b)(3)(ii)(E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc). **Approach:** • Approve renewal requests received from the Retail Pharmacy to authorize refills received from the Retail Pharmacy. The prescription will include an oral liquid medication for a pediatric patient that requires weigh based dosing. NOTE: This testing requires vendor involvement in order to have access to the Surescripts Admin Console for entry of test data. **Expected Outcome:** Limiting a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc). Interoperability and information exchanged is accomplished successfully without errors or message failures during the exchange.

	Report: Real World Testing - Receive fill status notifications (RXFILL) **Report:** Real World Testing - Refill prescriptions (REFREQ, REFRES) See attached test script for step by step details if testing is to be done in TST environment
Scenario #5	**Reference Criteria:** • Paragraph § 170.315 (b)(3)(ii)(A)(3) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse). • Paragraph § 170.315 (b)(3)(ii)(C)(1)(iii) Request to cancel prescriptions (CancelRx). • Paragraph § 170.315 (b)(3)(ii)(A)(9) Respond that a transaction requesting a return receipt has been received (Verify). **Approach:** Immediately cancel a prescription already transmitted to Surescripts. **Expected Outcome:** Interoperability and information exchanged is accomplished successfully without errors or message failures during the exchange. **Report:** Real World Testing - Cancel prescriptions (CANRX, CANRES) See attached test script for step by step details if testing is to be done in TST environment
Scenario #6	**Reference Criteria**: • Paragraph § 170.315 (b)(3)(ii)(A)(7) Relay acceptance of a transaction back to the sender (Status). • Paragraph § 170.315 (b)(3)(ii)(A)(8) Respond that there was a problem with the transaction (Error). **Approach:** View error messages received from Surescripts when there is a problem with the transmission of the transaction. NOTE: Scenario #6 is ONLY required if testing is to be done in TST environment and requires vendor involvement in order to have access to the Surescripts Admin Console for entry of test data and to view the status of the messages. **Expected Outcome:** Interoperability and information exchanged is usually accomplished successfully without errors or message failures during the exchange; however, in those instances in which there is an error, the error code and descriptions are sent in the message acknowledgement in response to the failure so that the user is aware and can take appropriate action.

	See attached test script for step by step details if testing is to be done in TST environment

4. Schedule of Key Milestones

Key Milestone	Date/Timeframe
Release of documentation for the Real World Testing to be provided to authorized representatives and providers running the Child Wellness App. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	December 1, 2022
Begin collection of information as laid out by the plan.	January 1, 2023
Meet with previously identified providers and authorized representatives to ensure that Real World Testing protocols are effective.	March 1, 2023
Follow-up with providers and authorized representatives to understand any issues arising with the data collection.	Quarterly, 2023
Data collection and review.	Quarterly, 2023
End of Real World Testing period/final collection of all data for analysis.	January 2023
Analysis and report creation.	January 15, 2023
Submit Real World Testing report to ACB (per their instructions).	February 1, 2024

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, Manager Professional Services	Authorized Representative Phone:	561-402-9621
Authorized Representative Signature:	Hilary Kloska	Date Signed:	10/27/2022