Real World Testing Plan Report ID,
Clinical Document Exchange: 20211203iat-2

Product	Clinical Document Exchange
Developer	Iatric Systems, Inc
Version	1.5
CHPL Product Number	15.05.05.2760.ISCD.01.00.1.181101
Real-World Testing URL	https://new.iatric.com/real-world-testing

Use Case (Care Coordination): Certified Health IT Developer has developed Certified Health IT Module to promote the deliberate sharing (exchange) of patient health information among participants involved in patient's healthcare to further promote interoperability and effective patient care. Criteria 170.315 (b)(1) Transitions of Care, 170.315 (b)(2) Clinical Information Reconciliation and Incorporation, and 170.315 (b)(6) Data Export will be tested to confirm the healthcare provider's ability to send and receive transition of care messages, incorporate and reconcile clinical information, and medication list, allergies, with designated healthcare recipient and create an export summary.

Certified Health IT Module is marketed and actively in use by hospital healthcare settings. For this reason, the Real-World Testing plan will apply to a hospital setting. Criteria 170.315 (b)(1) Transitions of Care, 170.315 (b)(2) Clinical Information Reconciliation and Incorporation, and 170.315 (b)(6) Data Export will be tested.

Criteria involved in testing include 170.315 (b)(1) Transitions of Care, 170.315 (b)(2) Clinical Information Reconciliation and Incorporation, and 170.315 (b)(6) Data Export.

Standard (and version)	Specified as required by ONC Health IT Certification Program, 2015 Edition
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

Overall expected outcomes will validate applications conformant to software's applicable criteria to exchange and transmit patient health data, patient matching to ensure accurate clinical information reconciliation, and create export summary as stipulated by the current 2015 Edition certification.

Key Milestone	Date/Timeframe
Initial Real-World Testing with current development healthcare facility partner where we have access to their system for testing and potential development using real patient data for real-world setting type testing.	1/1/22-3/31/22 (Q1)
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/22-8/31/2022 (Q2-Q3)
End of Real-World Testing Period with Results	January 2023

Analysis and Report Creation	January 2023
Submit Real World Testing Report to ACB	January 15, 2023*
**Timeline may be adjusted based on ACB's RWT Results due date*	

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing (exchange) of EHI and the user's ability to create export summary as needed.

Measure 1: Sharing - Send and receive Transition of Care (TOC) messages with other providers to close the referral loop. The patient's ePHI will be exchanged using a C-CDA 2.1 care summary/referral summary ensuring accurate CCDA match to the appropriate patient. Patient data from the transition of care/referral summary reconciled with existing data in the EHR including, at minimum, the patient's problems, medications, and medication allergies.

Certification Criterion and Measurement	Requirement
170.315(b)(1) Transitions of care	(i)(A) Send transition of care/referral summaries (i)(B) Receive transition of care/referral summaries
170.315(b)2 – Clinical information reconciliation and incorporation	(ii) - Properly match a received ToC to the correct patient. (iii)(B) - (D) - review, validate, and incorporate a patient's medication list, allergies and intolerances list, and problem list.

Justification: In the hospital setting, we chose to concentrate on the aspects of this criteria that would best demonstrate streamlined provider-to-provider patient referrals and transitions of care with the ultimate goal being higher quality patient care. Electronically exchanging patient data with the ability to reconcile clinical data rather than relying on a manual data entry promotes interoperability between healthcare providers meeting and furthers the goal of enhanced and effective patient care.

Testing Methodology:

170.315 (b)(1) Transitions of Care.

1. We will be using an existing customer system to validate the successful creation and display of the document types required for 170.315 (b)(1) Transitions of Care.
2. We will work with the customer to identify an inpatient that has all the applicable data elements utilized in the three document types our software is utilized to create. These are Continuity of Care Document, Referral Note, and Discharge Summary.
3. We will run the routines utilized by the customer to create the three document types identified above.
4. We will validate the data sections for each document are contained in the corresponding documents created.
5. We will validate the appropriate data elements for each section are contained in the corresponding data sections as expected.
6. We will verify the accuracy of the data within each data element.

7. We will display the information on-screen leveraging our style sheet.
8. We will verify the displayed information is accurate, by comparing it to the data contained within the documents verified in steps 4-7.

§170.315(b)(2) Clinical Information Reconciliation and Incorporation

1. We will be using an existing customer system to validate the successful matching of Referral Note to the correct patient for §170.315(b)(2) Clinical Information Reconciliation and Incorporation.
2. We will work with the customer to identify a recent Referral Note recently received from another vendor, that is intended to be incorporated into their system.
3. We will use the routines utilized by the customer to parse the Referral Note.
4. We will use the routines utilized by the customer to ensure the Referral Note received identified the appropriate patient and successfully matched the patient in the Referral Note to the patient in their system.
5. We will use the routines utilized by the customer to display both the data contained within the file from another vendor as well as their system.
6. We will verify the accuracy of displayed data by comparing it to the source file, as well as the data contained within the customer's system.
7. We will use the routines utilized by the customer to incorporate the data into their system.
8. We will generate a C-CDA document that includes the reconciled data utilizing the routines utilized but the customer.
9. We will verify that the data contained in the C-CDA reflects the reconciled data accurately.

Expected Outcome**:** It is expected that with electronic data exchange that healthcare providers will be able to share EHI and accurately reconcile patient clinical data. Testing results to confirm conformance to 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

Measure 2: Export – this measure will assess functionality to export EHI for a single patient for the 170.315(b)(6) criterion.

Certification Criterion and Measurement	Requirement
170.315(b)(6) – Data Export	(i)(A) – set configuration options for data elements when creating export summaries (ii) – create export summaries using the Continuity of Care Document template (iii)(A) – set/enter date and period (iv) – set the storage location

Justification**:** In the hospital setting, we chose to concentrate on the aspects of this criterion that would facilitate interoperability by providing authorized users with the ability to export data from the system for one patient or multiple patients in real-time without the assistance of a developer formatted using the CCD document template in accordance 2015 Edition Health IT standards.

Testing Methodology: §170. 315(b)(6) EHI export – Single patientEHI export

- We will be using an existing customer system to validate the successful export of patient care data in real-time by the authorized user.
- We will work with the customer and identify the successful export of a single patient record as intended.
- We will use the routines utilized by the customer and logs to confirm the successful export of the intended patient record.
- The resulting export is inspected to ensure it is the file requested.
- We will verify the accuracy of displayed data by comparing it to the source file, as well as the data contained within the customer's system.

Expected Outcome**:** It is expected that t is expected that authorized users will be able to share EHI using the export function. Testing results to confirm conformance to 2015 Certified Edition requirements. Error rates are tracked and analyzed over time

Authorized Representative
Name: Amy McKee
Email: amy.mckee@iatric.com
Phone: (978) 804-4100, x84047
Date: 11/27/21 updated