

2023 Real World Testing Plan Report ID,  
Clinical Document Exchange 20221117ia4

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>

**Standards and Updates**

Certified Health IT Module is marketed and actively in use by hospital healthcare settings where patients can access their health information. 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.

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.

Standard (and version)	Specified as required by ONC Health IT Certification Program, <u>2015 Edition-Cures Update</u>
Update Certification Criteria and Associated Product	170.315 (b)(1) Transitions of Care 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
Health IT CHPL ID	15.05.05.2760.ISCD.01.00.1.181101
Conformance Measure	Measure 1 Sharing

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
Relied Upon Software	IatricDirect Connect Gateway
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.

**Testing Method(s) and Key Findings****Measure 1**

§170.315(b)(1) Transitions of Care

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

**Summary**

Real World Testing of the Transition of Care has validated the content of the Continuity of Care, Referral Note, and Discharge Summary documents. Validation methods included the comparison of the document definition against the patient clinical content while considering the required standards.

The viewer and stylesheet provided with the product enabled a simplistic UI that allowed on-site review of the document with ease. No issues or oddities were encountered during the review.

Real World Testing also uncovered that our customers were not using Clinical Document Exchange for incorporation and reconciliation. Without real-world data, we were unable to perform our testing plan.

**Challenges Encountered**

Analysis of export data in (b)(1) revealed that all EHI documents were compiled and queued for delivery but not all EHI documents were actively received by the outbound clinical destination. This was not an error on the EHI Export side but a failure on the receiving side of the document.

Further, it was discovered that Clinical Document Exchange was not being actively used for their Reconciliation and Incorporation needs.

**Measure 2**

§170.315(b)(6) EHI Export – Single patient EHI export

**Summary**

Users of the Clinical Document Exchange could generate an OnDemand document for Export using the methods of DIRECT send, Print, or Zip (AES 128 Bit Encrypted Self Extracting Zip file). As with (b)(1), data content was validated against the EHR successfully.

During the review, the methods of Direct, Preview, Print, and Download/zip were tested without incident. Data and results were reviewed.

Additionally, a review of patient audit logs for 3 sites determined that this process was not often utilized. User error reports indicated no export failures or failures in the process.

**Challenges Encountered**

No challenges were encountered.

**Measure 1: Relied Upon Software**

**DirectConnect Gateway:** This product supports the use of Direct Secure Messaging (DSM) for the sending and receiving of patient-related documents and data. To implement DSM, the customer must contact Iatric Systems for the DirectConnect Gateway (DCG) product, which facilitates the communications between the applicable Iatric

and a Health Information Services Provider (HISP) - which is an organization that provisions, implements, and supports DSM infrastructure, addresses, and digital certificates. Please consult with Iatric Systems to obtain a detailed quote for DirectConnect Gateway (DCG), as well as DCG's specific server hardware and software requirements.

Standards and Updates

NA

Care Setting (list each care setting that was tested)

Hospital Care Setting

Metrics and Outcomes

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 an accurate CCDA match to the appropriate patient. Patient data from the transition of care/referral summary is reconciled with existing data in the EHR including, at minimum, the patient's problems, medications, and medication allergies.

<b>Methodology:</b> Identify an inpatient with all applicable data elements utilized in the three document types: Continuity of Care Document, Referral Note, and Discharge Summary.	
Identified an inpatient with all applicable data elements utilized in the three document types: Continuity of Care Document, Referral Note, and Discharge Summary.	✓
Ran the OnDemand routines utilized by the customer to create the three document types identified above.	✓
Validated the data sections for each document	✓
Validated the data elements for each section in the document	✓
Verified the accuracy of the data within each data element	✓
Displayed the information on-screen leveraging our style sheet	✓ See images 1, 2, and 3 below
Verified the displayed information was accurate, by comparing it to the data contained within the documents verified in steps 4-7.	✓

Image 1,  
Continuity of

Care

Press Highlights | Consolidated CDA Continuity of Care Document v2.1

Table of Contents	Personal Information																								
<ul style="list-style-type: none"> <li>Patient Care team information</li> <li>Advance Directives</li> <li>Relevant diagnostic tests and/or laboratory data</li> <li>Allergies and Adverse Reactions</li> <li>Problem List</li> <li>Vital Signs</li> <li>Functional Status</li> <li>Medications on Admission</li> <li>History of medication use</li> <li>Hospital Discharge medications</li> <li>History Of Encounters</li> <li>History of Procedures</li> <li>Hospital Discharge Instructions</li> <li>Social History</li> <li>Immunizations</li> <li>Family History</li> <li>Health Concerns</li> <li>Medical Equipment</li> <li>Hospital Discharge Diagnosis</li> <li>Reason for Referral</li> <li>Hospital Course</li> <li>Assessments</li> <li>Plan of Treatment</li> <li>Goals</li> <li>Instructions</li> <li>Mental Status</li> <li>Reason For Visit</li> <li>Discharge Summary Note</li> </ul>	<table border="1"> <tr> <td>Patient</td> <td>John Testerman</td> <td>Sex</td> <td>Male</td> </tr> <tr> <td>Date of birth</td> <td>March 22, 1980</td> <td>Ethnicity</td> <td>Not Reported or Unknown</td> </tr> <tr> <td>Race</td> <td>White</td> <td>Religion</td> <td>Protestant (not Catholic, non-specific)</td> </tr> <tr> <td>Marital Status</td> <td>Married</td> <td></td> <td></td> </tr> <tr> <td>Primary Language</td> <td>English</td> <td>Patient IDs</td> <td>XXXXXXXXXX XXXXXX</td> </tr> <tr> <td>Contact info</td> <td>XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX</td> <td></td> <td></td> </tr> </table>	Patient	John Testerman	Sex	Male	Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown	Race	White	Religion	Protestant (not Catholic, non-specific)	Marital Status	Married			Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX	Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX		
Patient	John Testerman	Sex	Male																						
Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown																						
Race	White	Religion	Protestant (not Catholic, non-specific)																						
Marital Status	Married																								
Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX																						
Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX																								

Press Highlights | Consolidated CDA Referral Note Document v2.1

Table of Contents	Personal Information																								
<ul style="list-style-type: none"> <li>Patient Care team information</li> <li>Advance Directives</li> <li>Relevant diagnostic tests and/or laboratory data</li> <li>Allergies and Adverse Reactions</li> <li>Problem List</li> <li>Vital Signs</li> <li>Functional Status</li> <li>Medications on Admission</li> <li>History of medication use</li> <li>Hospital Discharge medications</li> <li>History Of Encounters</li> <li>History of Procedures</li> <li>Hospital Discharge Instructions</li> <li>Social History</li> <li>Immunizations</li> <li>Family History</li> <li>Health Concerns</li> <li>Medical Equipment</li> <li>Hospital Discharge Diagnosis</li> <li>Reason for Referral</li> <li>Hospital Course</li> <li>Assessments</li> <li>Plan of Treatment</li> <li>Goals</li> <li>Instructions</li> <li>Mental Status</li> <li>Reason For Visit</li> </ul>	<table border="1"> <tr> <td>Patient</td> <td>John Testerman</td> <td>Sex</td> <td>Male</td> </tr> <tr> <td>Date of birth</td> <td>March 22, 1980</td> <td>Ethnicity</td> <td>Not Reported or Unknown</td> </tr> <tr> <td>Race</td> <td>White</td> <td>Religion</td> <td>Protestant (not Catholic, non-specific)</td> </tr> <tr> <td>Marital Status</td> <td>Married</td> <td></td> <td></td> </tr> <tr> <td>Primary Language</td> <td>English</td> <td>Patient IDs</td> <td>XXXXXXXXXX XXXXXX</td> </tr> <tr> <td>Contact info</td> <td>XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX</td> <td></td> <td></td> </tr> </table>	Patient	John Testerman	Sex	Male	Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown	Race	White	Religion	Protestant (not Catholic, non-specific)	Marital Status	Married			Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX	Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX		
Patient	John Testerman	Sex	Male																						
Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown																						
Race	White	Religion	Protestant (not Catholic, non-specific)																						
Marital Status	Married																								
Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX																						
Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX																								

Image 2, Referral Note

Press Highlights | Consolidated CDA Discharge Summary Document v2.1

Table of Contents	Personal Information																								
<ul style="list-style-type: none"> <li>Patient Care team information</li> <li>Advance Directives</li> <li>Relevant diagnostic tests and/or laboratory data</li> <li>Allergies and Adverse Reactions</li> <li>Problem List</li> <li>Vital Signs</li> <li>Functional Status</li> <li>Medications on Admission</li> <li>History of medication use</li> <li>Hospital Discharge medications</li> <li>History Of Encounters</li> <li>History of Procedures</li> <li>Hospital Discharge Instructions</li> <li>Social History</li> <li>Immunizations</li> <li>Family History</li> <li>Health Concerns</li> <li>Medical Equipment</li> <li>Hospital Discharge Diagnosis</li> <li>Reason for Referral</li> <li>Hospital Course</li> <li>Assessments</li> <li>Plan of Treatment</li> <li>Goals</li> <li>Instructions</li> <li>Mental Status</li> <li>Reason For Visit</li> </ul>	<table border="1"> <tr> <td>Patient</td> <td>John Testerman</td> <td>Sex</td> <td>Male</td> </tr> <tr> <td>Date of birth</td> <td>March 22, 1980</td> <td>Ethnicity</td> <td>Not Reported or Unknown</td> </tr> <tr> <td>Race</td> <td>White</td> <td>Religion</td> <td>Protestant (not Catholic, non-specific)</td> </tr> <tr> <td>Marital Status</td> <td>Married</td> <td></td> <td></td> </tr> <tr> <td>Primary Language</td> <td>English</td> <td>Patient IDs</td> <td>XXXXXXXXXX XXXXXX</td> </tr> <tr> <td>Contact info</td> <td>XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX</td> <td></td> <td></td> </tr> </table>	Patient	John Testerman	Sex	Male	Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown	Race	White	Religion	Protestant (not Catholic, non-specific)	Marital Status	Married			Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX	Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX		
Patient	John Testerman	Sex	Male																						
Date of birth	March 22, 1980	Ethnicity	Not Reported or Unknown																						
Race	White	Religion	Protestant (not Catholic, non-specific)																						
Marital Status	Married																								
Primary Language	English	Patient IDs	XXXXXXXXXX XXXXXX																						
Contact info	XXXXXXXXXX XXXXXXXXXX XXXXXXXXXX																								

Image 3, Discharge Summary

Additional Metrics

Site A: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2023 – March 31, 2023	492 / 1872	26.28%
April 1, 2023 – June 30, 2023	482 / 1890	25.50%
July 1, 2023 – September 30, 2023	408 / 1869	21.82%
October 1, 2023 – December 31, 2023	438 / 1778	24.63%

Site B: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2023 – March 31, 2023	1214 / 11022	11.01%
April 1, 2023 – June 30, 2023	1284 / 12276	10.45%
July 1, 2023 – September 30, 2023	1030 / 12583	8.18%
October 1, 2023 – December 31, 2023	708 / 11879	5.96%
Site C: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2023 – March 31, 2023	101 / 321	31.46%
April 1, 2023 – June 30, 2023	92 / 260	35.38%
July 1, 2023 – September 30, 2023	28 / 171	16.37%
October 1, 2023 – December 31, 2023	9 / 116	7.75%

<p><b>Methodology:</b> Use an existing customer system to validate the successful matching of the Referral Note to the correct patient.</p>	
Identified a recent Referral Note received from another vendor that was intended to be incorporated into the system.	<b>X</b>
Used the routines utilized by the customer to parse the Referral Note.	<b>X</b>
Used 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.	<b>X</b>
Used the routines utilized by the customer to display both the data contained within the file from another vendor as well as their system.	<b>X</b>
Verified the accuracy of displayed data by comparing it to the source file, as well as the data contained within the customer's system.	<b>X</b>
Used the routines utilized by the customer to incorporate the data into their system.	<b>X</b>
Generated a C-CDA document that includes the reconciled data utilizing the routines utilized but the customer.	<b>X</b>
Verified that the data contained in the C-CDA reflects the reconciled data accurately.	<b>X</b>

Image 5,

*Incorporation*

Site A: Receive and Incorporate	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 - December 31, 2023	0 / 0	0%
Site B: Receive and Incorporate	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 – December 31, 2023	0 / 0	0%
Site C: Receive and Incorporate	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 – December 31, 2023	0 / 0	0%

*Image 6, Medical Reconciliation Statistics*

Site A: Medical Reconciliation	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 – December 31, 2023	0 / 0	0%
Site B: Medical Reconciliation	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 – December 31, 2023	0 / 0	0%
Site C: Medical Reconciliation	Total Received	Percentage Received
January 1, 2023 – March 31, 2023	0 / 0	0%
April 1, 2023 – June 30, 2023	0 / 0	0%
July 1, 2023 – September 30, 2023	0 / 0	0%
October 1, 2023 – December 31, 2023	0 / 0	0%

**Measure 1: Expected Outcome**

It was expected that with electronic data exchange that healthcare providers would be able to share EHI and accurately reconcile patient clinical data. Testing results confirmed conformance to 2015 Certified Edition requirements. Error rates were tracked and analyzed over time.

**Measure 1: Actual Outcome**

A review of our data-sharing capabilities confirmed that our data was successfully generated and exported upon patient discharge. The data were validated against the document definition, confirming proper patient content.

A review of

“Incorporation” and “Medical Reconciliation” showed that the three sample customers were not utilizing this element of the product.

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

Methodology: Use an existing customer system to validate the successful export of patient care data in real time by the authorized user.	
Use logs to confirm the successful export of the intended patient record.	✓
Inspect the resulting export to ensure it was the file requested.	✓
Verify the accuracy of displayed data by comparing it to the source file and data contained within the customer's system.	✓

**Measure 2: Expected Outcome**

	2023
Site A	2
Site B	62
Site C	0

It was expected that authorized users would be able to share EHI using the export function. Testing results confirmed conformance to 2015 Certified Edition requirements. Error rates were tracked and analyzed over time.

**Measure 2: Actual Outcome**

2023 analysis confirms that users continue to be able to export EHI when requested, but statistical review reveals that it was not a common occurrence.

**KEY MILESTONES**

Key Milestone	Care Setting	Date/Timeframe
The transition of Care testing and review	Hospital setting	January 2023 – December 2023
Medical Reconciliation testing and review	Hospital setting	January 2023 – December 2023
Incorporation testing and review	Hospital setting	January 2023 – December 2023
EHI Export testing and review	Hospital setting	January 2023 – December 2023

**Authorized Representative**

Name: Amy McKee  
 Email: [amy.mckee@iatric.com](mailto:amy.mckee@iatric.com)  
 Phone: (978) 804-4100, x84047  
 February 5, 2024