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

Summary of 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.

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Challenges Encountered

No challenges were encountered.

Measure 1 and 2: 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 Systems product and a Health Information Services Provider (HISP) - which is an organization that provisions, implements, and supports DSM infrastructure, addresses, digital certificates, etc. 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.

Methodology: 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	✓

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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 Document

Image 2, Referral Note

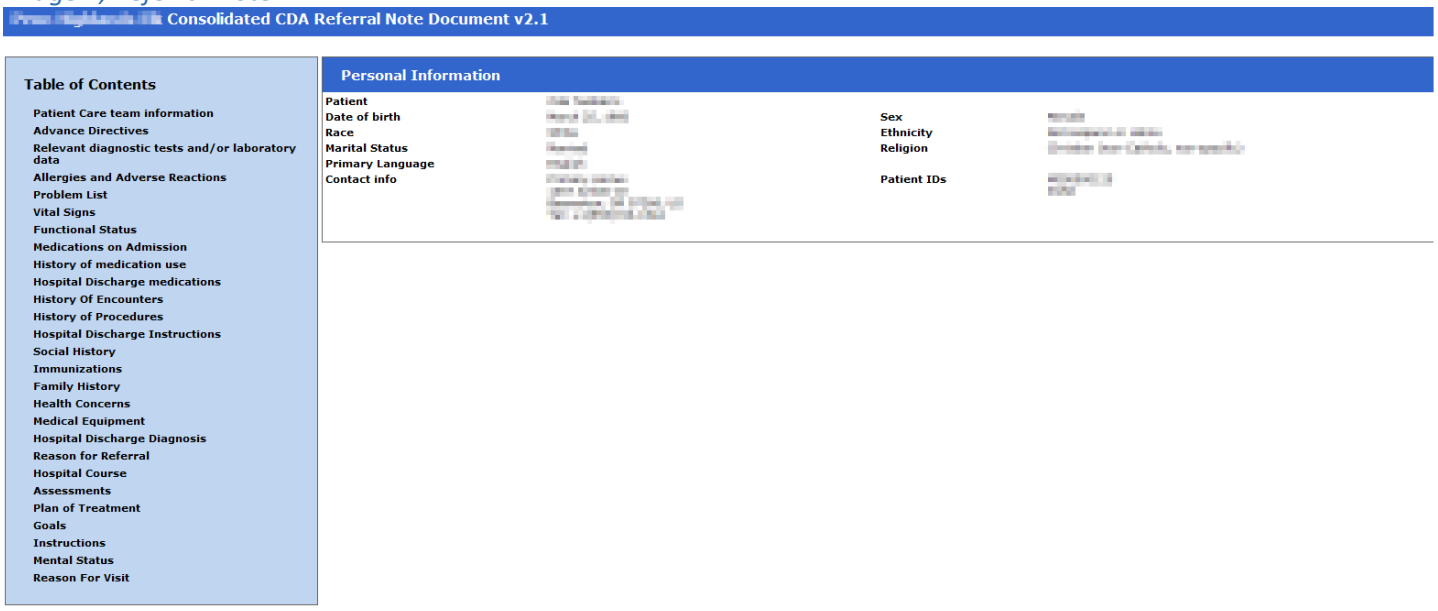

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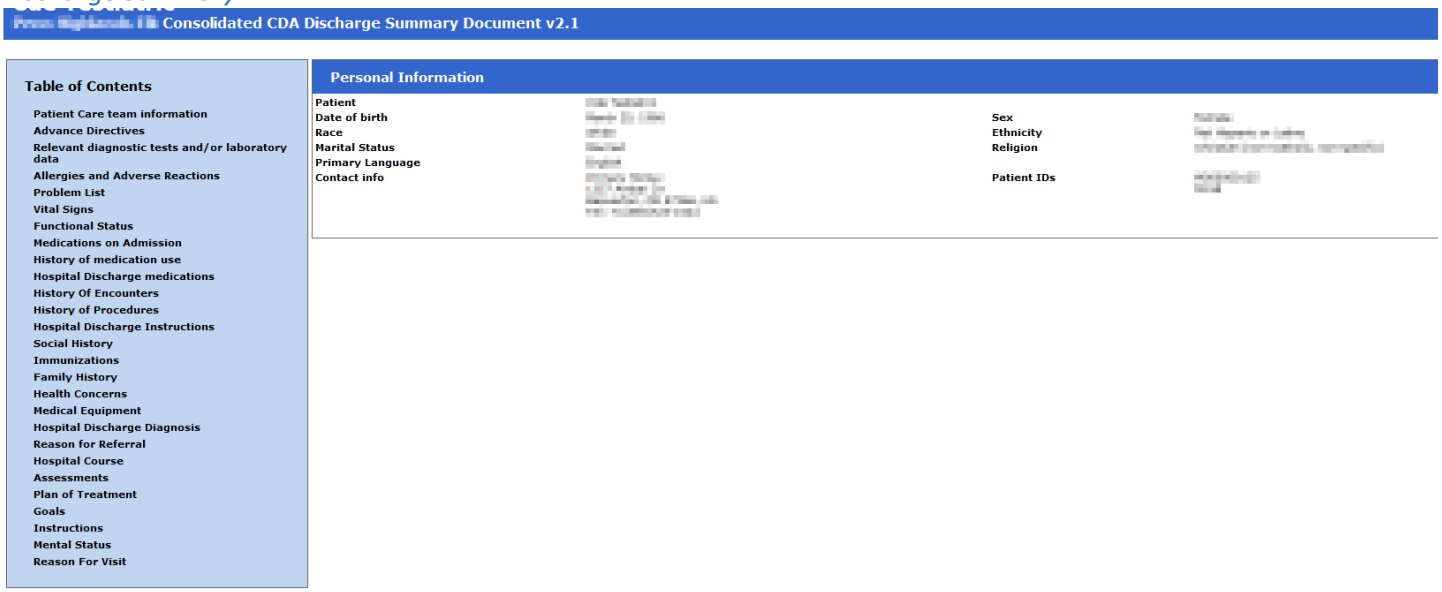
Image 3,

Discharge Summary



Additional Metrics

Site A: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2022 – March 31, 2022	3001 / 9030	33.23%
April 1, 2022 – June 30, 2022	3347 / 9998	33.47%
July 1, 2022 – September 30, 2022	3392 / 10080	33.65%
Site B: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2022 – March 31, 2022	1108 / 2999	36.94%
April 1, 2022 – June 30, 2022	1084 / 3092	35.05%
July 1, 2022 – September 30, 2022	1052 / 3242	32.44%
Site C: Transition of Care / Referral Loop	Total Transmitted	Percentage Transmitted
January 1, 2022 – March 31, 2022	35 / 250	14.00%
April 1, 2022 – June 30, 2022	78 / 360	21.66%
July 1, 2022 – September 30, 2022	101 / 453	22.29%

Methodology: Use an existing customer system to validate the successful matching of the Referral Note to the correct patient.	
Identified a recent Referral Note received from another vendor that was intended to be incorporated into the system.	**X**

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Used the routines utilized by the customer to parse the Referral Note.	X
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.	X
Used the routines utilized by the customer to display both the data contained within the file from another vendor as well as their system.	X
Verified the accuracy of displayed data by comparing it to the source file, as well as the data contained within the customer's system.	X
Used the routines utilized by the customer to incorporate the data into their system.	X
Generated a C-CDA document that includes the reconciled data utilizing the routines utilized but the customer.	X
Verified that the data contained in the C-CDA reflects the reconciled data accurately.	X

Image 5, Incorporation

Site A: Receive and Incorporate	Total Received	Percentage Received
January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%
Site B: Receive and Incorporate	Total Received	Percentage Received
January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%
Site C: Receive and Incorporate	Total Received	Percentage Received
January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%

Image 6, Medical Reconciliation Statistics

Site A: Medical Reconciliation	Total Received	Percentage Received
January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%
Site B: Medical Reconciliation	Total Received	Percentage Received

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January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%
Site C: Medical Reconciliation	Total Received	Percentage Received
January 1, 2022 – March 31, 2022	0 / 0	0%
April 1, 2022 – June 30, 2022	0 / 0	0%
July 1, 2022 – September 30, 2022	0 / 0	0%

Measure 1: Expected Outcome

It was expected that with electronic data exchange that healthcare providers were 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 customers were not utilizing this element of the product.

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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.	✓

	2015	2016	2017	2018	2019	2020	2021	2022
Site 1	0	0	0	0	0	0	0	0
Site 2	2	0	0	0	0	0	0	0
Site 3	0	1	2	8	0	0	0	0

Measure 2: Expected Outcome

It was expected that authorized users were 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

Authorized users were 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	March 2022 – September 2022
Medical Reconciliation testing and review	Hospital setting	March 2022 – September 2022
Incorporation testing and review	Hospital setting	March 2022 – September 2022
EHI Export testing and review	Hospital setting	March 2022 - September

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