

Real World Testing Plan Report ID, 20221117ia1

Product	PtAccess
Developer	Iatric Systems, Inc
Version	2.0
CHPL Product Number	15.05.05.2760.ISPT.01.00.1.180412
Real-World Testing URL	https://new.iatric.com/real-world-testing

Use Case (Patient Engagement): Certified Health IT Developer has developed Certified Health IT Module to promote patient engagement by providing patients access via the patient portal to their health information provided by the healthcare provider which may include additional relied-upon software. Criteria 170.315(e)(1) View, download, and transmit will be tested to confirm patient portal participants’ ability to view, download, and transmit their health data. By empowering patients with direct access to their health information via the patient portal, we can further promote patient engagement in their health care.

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. Criterion 170.315 (e)(1) View, download, and transmit to 3rd party will be tested.

Standard (and version)	Specified as required by ONC Health IT Certification Program, <u>2015 Edition-Cures Update</u>
Date of ONC-ACB notification (SVAP or USCDI)	8/10/2022
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	170.315 (e)(1): View, Download, and Transmit to a 3 rd Party

Expected Outcomes: Overall expected outcomes will demonstrate that the Health IT Module to include any relied upon the software is conformant to criterion [170.315 \(e\)\(1\): View, Download, and Transmit to 3rd Party](#) stipulated by the current 2015 Edition certification standards

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.	1/1/23-3/31/23 (Q1)
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/23-8/31/2023 (Q2-Q3)
End of Real-World Testing Period with Results	January 2024
Analysis and Report Creation	January 2024
Submit Real World Testing Report to ACB	January 15, 2024*
<i>*Timeline may be adjusted based on ACB’s RWT Results due date</i>	

Measure: Access to patient portal to view, download, and/or transmit health information received from a healthcare provider is used to best demonstrate conformance to certification criterion concerning 170.315(e)(1) outlined below.

Certification Criterion and Measurement	Requirement
170.315(e)(1) View, download and transmit	(i)(A)(5) Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization (i)(B)(2) Download ambulatory or inpatient summary using CCD Template (i)(B)(3) (inpatient setting) Download of transition of care/referral summaries (i)(C)(1) Transmit to the third party (i)(C)(2) (inpatient setting) Transmit transition of care/referral summaries
	Relied Upon Software iatricSystems DirectConnect Gateway (optional)

Justification: This criterion requires the ability of a certified Health IT module to provide patients (or patient-authorized representatives) access to their health data via the patient portal with the ability to view, download, and transmit their health data which may include the usage of optional relied upon software. Testing to validate conformance with criterion standards ensures the overall promotion of patient engagement.

Test methodology: PtAccess portal logs, system logs, transmission, and download logs will be reviewed to confirm patient and view data entered as inpatient and ambulatory, if available, as a patient (or patient-authorized representative) and confirm health data displays as expected. Proceeding to review selected data for download and transmission and confirm only selected data downloads as expected for transmission which may include relied-upon software if needed for transmission. System audit logs are to be reviewed to determine actions that are successful and confirm the mechanism used for sending and/or receiving a transmission of care using Edge protocols and downloading or transmitting EHI by patients using the portal. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation download and transmit operations.

The expected outcome is that the authorized user can complete view, download, and transmit requests/actions as expected and per 2015 Certified Edition requirements

- Error rates will be tracked and trended over time.

Authorized Representative

Name: Amy McKee

Email: amy.mckee@iatric.com

Phone: (978) 804-4100, x84047

Amy McKee

10/12/22, 10/30/22