

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20241206ia1

Developer Name: Iatric Systems, Inc

Product Name(s): PtAccess

Version Number(s): 2.0

Certified Health IT Product List (CHPL) ID(s): 15.05.05.2760.ISPT.01.00.1.180412

Developer Real World Testing Plan Page URL: <https://new.iatric.com/real-world-testing>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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 and 170.315(b) (10) Electronic Health Information Export 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 for criteria 170.315(e)(1) View, download, and transmit and 170.315(b) (10) Electronic Health Information Export tested.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

The PtAccess product does not include voluntary SVAP standards updates.

MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

Description of Measurement/Metric

Measurement/Metric	Description
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
170.315 (b)(10) <i>Electronic Health Information export</i>	<ol style="list-style-type: none"> 1. <i>Single patient electronic health information export.</i> <ol style="list-style-type: none"> 1. Enable a user to timely create an export file(s) with all of a single patient’s electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part. 2. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. 3. Limit the ability of users who can create such export file(s) in at least one of these two ways: <ol style="list-style-type: none"> 1. To a specific set of identified users 2. As system administrator function. 4. The export file(s) created must be electronic and in a computable format. 5. The publicly accessible hyperlink of the export’s format must be included with the exported file(s). 2. <i>Patient population electronic health information export.</i> Create an export of all the electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part. <ol style="list-style-type: none"> 1. The export created must be electronic and in a computable format. 2. The publicly accessible hyperlink of the export’s format must be included with the exported file(s). 3. <i>Documentation.</i> The export format(s) used to support paragraphs (b)(10)(i) and (ii) of this section must be kept up to date.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
170.315(e)(1) View, download and transmit	170.315(e)(1) View, download and transmit	Facilitates communication with customer's HISP. Iatric Systems DirectConnect Gateway, relied upon software, as needed, depending upon the customers request and setup.
170.315 (b)(10) Electronic Health Information export	170.315 (b)(10) Electronic Health Information export	NA

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
170.315(e)(1) View, download and transmit	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.
170.315(b) (10) Electronic Health Information Export	This measure will assess the ability to export the limited data stored by the software to end users.

Care Setting(s)

Care Setting	Justification
Hospital Setting	Certified Health IT Module is supported for use by hospital healthcare settings. For this reason, the Real-World Testing plan will apply to a hospital setting. Criterion 170.315(b)(10) Electronic Health Information Export. This is not a patient care product.

Expected Outcomes

- 1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets,
- 2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
- 3) EHI is received by and used in the certified health IT.

Measurement/Metric	Expected Outcomes
170.315(e)(1) View, download and transmit	Overall, all expected outcome is that the is that the authorized user can complete view, download, and transmit requests/actions as expected and per the criterion regulations. Error rates tracked and trended over time.

170.315(b) (10) Electronic Health Information Export	<p>Overall expected outcomes will validate conformance to criteria 170.315 (b)(10) – Electronic Health Information export of health data stored in software by end users.</p> <p>System logs will be reviewed for indication of export completion as expected. It is expected that authorized users will be able to share EHI using the export function. Error rates will be tracked and analyzed over time. If errors occur, investigate and document for resolution planning, if needed.</p>
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SCHEDULE OF KEY MILESTONES.

Key Milestone	Date/Timeframe	Care Setting
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.	1/15/25-3/31/25 (Q1)	Hospital Setting
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/25-8/31/25 (Q2-Q3)	Hospital Setting
End of Real-World Testing Period with Results	January 2026	Hospital Setting
Analysis and Report Creation	January 2026	Hospital Setting
Submit Real World Testing Report to ACB	February 1, 2026*	Hospital Setting
*Timeline may be adjusted based on ACB's RWT Results due date		

ATTESTATION The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

This Real World Testing 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: Amy McKee

Authorized Representative Email: amy.mckee@iatric.com

Authorized Representative Phone: (978) 804-4100, x84047

Authorized Representative Signature: *Amy McKee*

Date: 12/6/2024

ⁱ Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

ⁱⁱ <https://www.federalregister.gov/d/2020-07419/p-3582>