

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: PH—20241206ia3

Developer: Iatric Systems, Inc.

Public Health Syndromic Surveillance Version 1.6 CHPL Product # 15.05.05.2760.ISSR.01.00.0.180820 https://new.iatric.com/real-world-testing	Public Health Reportable Labs Version 1.6 CHPL Product # 15.05.05.2760.ISRL.01.00.0.180918 https://new.iatric.com/real-world-testing	Public Health Immunizations Version 1.6 CHPL Product # 15.05.05.2760.ISIR.01.00.0.181129 https://new.iatric.com/real-world-testing
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JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Public health Reporting solutions software (health IT module) provides healthcare providers a method to send immunization, reportable lab and microbiology results, and syndromic surveillance type data to public health agencies promptly to meet state and other regulatory requirements. Public health Reporting interfaces may improve patient-centric preventative care, bring attention to the readiness of state public health agencies, and concentrate the development of standardized data elements and data exchange to support public health efforts. In addition, healthcare providers can stop manual processes that cost time and that may potentially not follow recommended practices related to ePHI. A care setting involves a healthcare facility with a variety of patient locations based on the healthcare provider's workflow.

Certified Health IT Module is marketed and actively in use by hospital healthcare settings. or for this reason, the Real-World Testing plan will apply to a hospital setting. Criteria 170.315(f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results, 170.315(f)(2) Transmission to Public Health Agencies - Syndromic Surveillance, and 170.315(f)(1) Transmission to Immunization Registries will be tested.

Criteria involved in the test is as follows, 170.315(f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results, 170.315(f)(2) Transmission to Public Health Agencies - Syndromic Surveillance, and 170.315(f)(1) Transmission to Immunization Registries.

STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) STANDARDS UPDATES

Public Health Syndromic Surveillance, Public Health Reportable Labs, and Public Health Immunization products do not include voluntary SVAP standards updates.

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

Description of Measurement/Metric

Measurement/Metric	Description
170.315(f)(1) - Transmission to Immunization Registry	Create immunization information for electronic transmission following the standard and applicable implementation specifications specified in §170.205(e)(4), the version of the standard specified in §170.207(e)(3) for historical vaccines, and the version of the standard specified in §170.207(e)(4)

	for administered vaccines.
170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	Create syndrome-based public health surveillance information for electronic transmission by the standard (and applicable implementation specifications) specified in § 170.205(d)(4)
170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	Create reportable laboratory tests and values/results for electronic transmission in accordance with: <ol style="list-style-type: none"> 1. The standard (and applicable implementation specifications) specified in § 170.205(g). 2. At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	NA
170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	
170.315(f)(1) - Transmission to Immunization Registry	170.315(f)(1) - Transmission to Immunization Registry	

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
170.315(f)(1) - Transmission to Immunization Registry	In the hospital setting, we chose to focus on aspects of this criterion that would provide the most patient care value in an actual setting. Public health registries can be helpful to patient care, epidemiologists, and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.
170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	In the hospital setting, we chose to focus on aspects of this criterion that would provide the most patient care value in an actual setting. Public health agencies can be helpful to patient care, epidemiologists, and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.
170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	In the hospital setting, we chose to focus on aspects of this criterion that would provide the most patient care value in an actual setting. Public health agencies can be helpful to patient care, epidemiologists, and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.

Care Setting(s)

Care Setting	Justification
Hospital Care Setting: 170.315(f)(1) - Transmission to Immunization Registry Hospital Setting 170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance 170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	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(f)(1), 1703.315(f)92), and 170.315(f)(3).

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(f)(1) - Transmission to Immunization Registry Hospital Setting	Overall, all expected that the data transmitted will be identical with that of the data received and the data will be successfully processed by the receiving entity. This will be confirmed by the validation websites. Testing results to confirm conformance to measure requirements and regulations. Error rates are tracked and analyzed over time.
170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	Overall, it is expected that the data transmitted will be identical with that of the data received and the data will be successfully processed by the receiving entity. This will be confirmed by the validation websites. Testing results to confirm conformance to measure requirements and regulations. Error rates are tracked and analyzed over time.
170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	Overall, it is expected that the data transmitted will be identical with that of the data received and the data will be successfully processed by the receiving entity. This will be confirmed by the validation websites. Testing results to confirm conformance to measure requirements and regulations. Error rates are tracked and analyzed over time.

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
<i>*Timeline may be adjusted based on ACB's RWT Results due date</i>		

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>