

Real World Testing Plan Report ID,  
Public Health Reporting: 20211203iat-4

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>

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. 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.

Standard (and version)	Specified as required by ONC Health IT Certification Program, <u>2015 Edition</u>
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

Overall expected outcomes will validate applications conformance to applicable criteria to exchange and transmit patient health data to the intended recipient as stipulated by the current 2015 Edition certification.

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.	1/1/22-3/31/22 (Q1)
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/22-8/31/2022 (Q2-Q3)
End of Real-World Testing Period with Results	January 2023
Analysis and Report Creation	January 2023
Submit Real World Testing Report to ACB	January 15, 2023*
<i>*Timeline may be adjusted based on ACB's RWT Results due date</i>	

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the successful transmission of public health data related to criteria 170.315(f)3), 170.315(f)2), and 170.315(f)1).

Measure 1: Transmission of Immunization Data – Create and send immunization records to an immunization registry.

Certification Criterion and Measurement	Requirement
170.315(f)1) - Transmission to Immunization Registry	(i)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.

Justification: 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 very helpful to patient care, epidemiologists, and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.

Testing Methodology: 170.315(f)1) Transmission to Immunization Registries

1. We will be using an existing customers system to validate the successful creation of a message of identified immunization records for criterion 170.315(f)1).
2. We will work with the customer to identify patients with applicable historical and administered vaccines.
3. We will use the routines utilized by our customers to validate the messages were created.
4. We will validate the content of the messages matches the data for the identified patient in their system and verify the accuracy of the data.

Expected Outcome: 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 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

Measure 2: Transmission of Syndromic Surveillance – Create and send syndromic surveillance records to a public health registry.

Certification Criterion and Measurement	Requirement
170.315 (f)2) Transmission to Public Health Agencies - Syndromic Surveillance	Create reportable laboratory tests and values/results for electronic transmission following the standard (and applicable implementation specifications) specified in 170.205(g) and the versions of the standards specified in 170.207(a)(3) and (c)(2).

Justification: 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 very helpful to patient care, epidemiologists,

and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.

Testing Methodology: 170.315 (f)(2) Transmission to Public Health Agencies - Syndromic Surveillance

1. We will be using an existing customers system to validate the successful creation of a message of identified syndromic surveillance of a patient for criterion 170.315(f)(2).
2. We will work with the customer to identify patients with syndromic surveillance data.
3. We will use the routines utilized by our customers to validate the messages were created.
4. We will validate the content of the messages matches the data for the identified patient in their system.

Expected Outcome: 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 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

Measure 3: Transmission of Lab Test Data - Create and send reportable electronic lab tests and values/results to a public health agency.

Certification Criterion and Measurement	Requirement
170.315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	Create syndrome-based public health surveillance information for electronic transmission by the standard (and applicable implementation specifications) specified in § 170.205(d)(4)

Justification: 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 very helpful to patient care, epidemiologists, and government for identifying disease outbreaks, epidemics, pandemics, and potential monitoring of social disparities.

Testing Methodology: 170. 315 (f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results

1. We will be using an existing customers system to validate the successful creation of a message of identified laboratory tests and values/results for 170.315(f)(3).
2. We will work with the customer to identify patients with applicable laboratory results.
3. We will use the routines utilized by our customers to validate the messages were created.
4. We will validate the content of the messages matches the data for the identified patient in their system.

Expected Outcome: 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 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

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