

REAL WORLD TESTING RESULTS REPORT 2023

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (Certification Program), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans and results reports.

<u>A Real World Testing plan template</u> was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the results report will include a list of these changes, the reasons for them, and how intended outcomes were more efficiently met as a result.

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Certification Program requirements referenced in this resource.

- Real World Testing-What It Means for Health IT Developers Fact Sheet
- •Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

•21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, <u>85 FR 25642</u> (May 1, 2020) (**ONC Cures Act Final Rule**) o Section VII.B.5 — "Real World Testing"



TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Patagonia Health Product Name(s): Patagonia Health EHR

Version Number(s): 6

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2139.Pata.06.01.1.221227

Developer Name: EMR Direct

Product Name(s): Interoperability Engine

Version Number(s): 2023

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.1397.Inte.23.01.0.221216

Developer Real World Testing Plan Page URL:

https://patagoniahealth.com/advantages/federal-ehr-incentives/

Developer Real World Testing Results Report Page URL [if different from above]:

https://patagoniahealth.com/advantages/federal-ehr-incentives-real-world-testing-2023

CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]
NA		



WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

Product Name(s):	Patagonia Health EHR
Version Number(s):	5
CHPL Product Number(s):	15.04.04.2139.Pata.05.00.1.180420
Date(s) Withdrawn:	12/31/2022
Inclusion of Data in Results Report: [Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

Note: A single Real World Testing results report may address multiple products and certification criteria for multiple care settings.

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to **perform as intended by conducting and measuring observations of interoperability and data exchange**, our original test plan focused on capturing and documenting the number of instances that certified capability was successfully utilized in the real world.

In instances where no evidence exists due to low or zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we tested and demonstrated the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

As per the test plan, we leveraged a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing

Adoption rate was used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might be accounted for by patient volume, location or provider preference among



other reasons. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments were used to measure which certified actions were performed at the conclusion of a given time period where the minimum time period was 90 days and longer where possible. These results are typically obtained by generating reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

Interactive testing was used to demonstrate conformance to requirements where the adoption rate of a given certified capability is zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests were live tested as opposed to examining historical usage statistics. The goal being to demonstrate the certified Health IT module being used in a way consistent within a practice or care setting.

This approach allowed for the successful testing and obtaining results for each criterion. Detailed below in the Metrics and Outcomes section the reader will find evidential data in the form of a Summative result(s) or Interactive test outcome for each certified criteria for the Patagonia Health EHR.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

[] Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please complete the table below.

[X] No, none of my products include these voluntary standards.

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
CHPL Product Number	N/A
Conformance measure	N/A



Care Setting(s)

The expectation is that a developer's Real World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.

List each care setting that was tested.

- Public Health Systems
- Behavioral Health

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that successfully demonstrate that the certified health IT:

- 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.

(from 85 FR 25766)

Health IT developers could also detail outcomes that did <u>not</u> result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Within this section is a list of the results collected from the Patagonia Health solution Real World Testing measures as defined in their Real World Test plan. Outcomes are listed as **Pass**, **Pass with Exception**, **or Fail** determined by the success of obtaining testing results. This determination was based on a thorough review by the Patagonia Health team. A link is included within the **Outcomes** column in the table below to a subsequent **Outcomes Details** table. This second table matches each outcome with additional detailed information such as supporting resources and descriptions of the tests that were performed.

Key components include:

- Customer created a comprehensive Test Results Report which details customer environment, patient data utilized for tests, locations of testing
- Customer attempted Summative and/or Interactive Testing
- Customer collected audit logs to support spreadsheets and as necessary, screen shots that demonstrate proof of Interactive Testing for each criteria with "0" values in Summative Testing. These files are referenced and remain on file with Patagonia Health.



The following metrics were measured by viewing audit logs in the client's live production system for July 1 – September 30, 2023 with additional testing in Q4 2023 as well as Q1 2024 for Interactive tests. For each test, a screen shot was taken of the audit report criteria screen showing the auditing information being reported. The resultant report was then saved to show the usage (or lack thereof) of the criterion

Associated Criterion(a)	Measurement / Metric	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	EMR Direct	<u>Pass</u>	
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies and intolerance list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA		<u>Pass</u>	
170.315(b)(3) Electronic prescribing	Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	Therapy Brands NewCrop	Pass 1) 71,581 2) 66 3) 8,301 4) 1249	
170.315(b)(6) Data export	Over a 90-day period: 1) Number of times a data export was performed for a patient 2) Number of times a data export was performed for multiple patients in a single transaction 3) Number of times a data export was performed for all patients in a single transaction		Pass	

170.315(c)(1-3) Clinical quality measures (CQMs)	Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category I files exported 3) Number of QRDA Category I files imported (if applicable) 4) Number of QRDA Category III aggregate report(s) created over the period		<u>Pass</u>	
170.315(e)(1) View, download, and transmit to 3rd party	Over a 90-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method	EMR Direct	<u>Pass</u>	
170.315(f)(1) Transmission to immunization registries	Over a 90-day period: 1) Number (or percentage) of immunization records submitted to the immunization record		<u>Pass</u> 1) 8664	
170.315(f)(2) Transmission to public health agencies - syndromic surveillance	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of syndromic surveillance events created and submitted		<u>Pass</u>	
170.315(g)(7) Application access - patient selection	Number of requests for a patient ID or token Number of requests that provided sufficient information to provide a valid response Number of follow-up requests made using the provided patient ID or token		<u>Pass</u>	

170 215(a)(0)	1\ Ni	mbor of reguests for a	Doos	
170.315(g)(9) Application access - all data request	pat ma an req	mber of requests for a ient's Summary Record de by an application via all data category uest using a valid	<u>Pass</u>	
	2) Nui pat ma	ient ID or token mber of requests for a ient's Summary Record de by an application via		
	req pat	all data category uest using a valid ient ID or token for a ecific date range		

Outcome Details

The following sections contain additional descriptions and test results supporting documentation to provide more context for the testing outcomes defined in the Metrics and Outcomes table above.

170.315(b)(1) Transitions of care

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that CDA documents are able to be created and exported.

A query on historical audit logs for 90-day periods was performed for the 170.315(b)(1) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test

demonstrating a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

Results Supporting Documents



170.315(b)(2) Clinical Information Reconciliation and Incorporation

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that CDA documents are able to be imported, matched to a patient, reconciled and new CDA documents created and exported.

A query on historical audit logs for 90-day periods was performed for the 170.315(b)(2) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate

Results Supporting Documents

Please Contact Patagonia Health for any Results spreadsheets and screenshots if needed.

170.315(b)(3) Electronic Prescribing

Summary Description

Pass Method: Summative Testing

The purpose of this test was to show that an active connection from EHR customer sites to an ePrescribing solution was deployed. A query on historical audit logs for 90-day periods was performed for the 170.315(b)(3) criterion. The resulting totals show that this module was active throughout the period and therefore demonstrates a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a high success rate.

Results Supporting Documents

170.315(b)(6) Data Export

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that our customer can export patient data from our EHR without any assistance from Patagonia Health.

A query on historical audit logs for 90-day periods was performed for the 170.315(b)(6) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards and vocabulary code sets. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a realworld setting contain all the necessary data elements. Therefore, we intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be very low utilization by providers with a high success rate.

Results Supporting Documents

Please Contact Patagonia Health for any Results spreadsheets and screenshots if needed.

170.315(c)(1-3) Clinical Quality Measures (CQMs)

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that the EHR meets the QRDA reporting requirement for the designated care settings.

A query on historical audit logs for 90-day periods was performed for the 170.315(c)(1-3) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category I format. C2 requires a certified Health IT module must be able to import data from a QRDA Category I formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module must be able to create a QRDA Category I formatted file and a QRDA Category III aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

Results Supporting Documents



170.315(e)(1) View, Download, and Transmit to 3rd Party

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that the EHR provides patients access to a patient portal with the ability to view, download, and send their health care records for the designated care settings.

A query on historical audit logs for 90-day periods was performed for the 170.315(e)(1) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.

Results Supporting Documents

Please Contact Patagonia Health for any Results spreadsheets and screenshots if needed.

170.315(f)(1) Transmission to Immunization Registries

Summary Description

Pass Method: Summative Testing

The purpose of this test was to show that the EHR is able to transmit immunization data to a registry and meets the reporting requirement for the designated care settings.

A query on historical audit logs for 90-day periods was performed for the 170.315(f)(1) criterion. The resulting totals show that this module was active throughout the period and therefore demonstrates a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Results Supporting Documents



170.315(f)(2) Transmission to Public Health Agencies — Syndromic Surveillance

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that the EHR is able to transmit syndrome-based public health surveillance data to a registry and meets the reporting requirement for the designated care settings.

A query on historical audit logs for 90-day periods was performed for the 170.315(f)(2) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the ability of a certified Health IT module to transmit syndrome-based public health surveillance data to a registry using a specified format. We intend to record the frequency that syndromic surveillance data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Results Supporting Documents

Please Contact Patagonia Health for any Results spreadsheets and screenshots if needed.

170.315(g)(7) Application Access — Patient Selection

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that the EHR is able to fulfill an API request that enables external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data.

A query on historical audit logs for 90-day periods was performed for the 170.315(g)(7) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that patient ID requests are received by providers via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Results Supporting Documents



170.315(g)(9) Application Access — All Data Request

Summary Description

Pass Method: Interactive Testing

The purpose of this test was to show that the EHR is able to fulfill an API request that enables external applications to request all categories of patient data defined in the CCDS from the certified Health IT module.

A query on historical audit logs for 90-day periods was performed for the 170.315(g)(9) criterion. Due to low or zero adoption of this criteria, Patagonia Health demonstrated the module function in their system as an interactive test demonstrating a compliant result.

Justification

This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

Results Supporting Documents



KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Public Health Systems Behavioral Health	Q1 – Q2 2023
Data collection	Public Health Systems Behavioral Health	Q2 – Q4 2023
Review and Collect Data	Public Health Systems Behavioral Health	Q4 2023
Writing Report	Public Health Systems Behavioral Health	Q4 2023 - 2024
Patagonia Health executed summative testing to show that the criteria are functional. The following metrics were pulled from transaction logs as detailed in the outcomes section above: 170.315 (b)(3) Electronic Prescribing 170.315 (f)(1) Transmission to immunization registries	Public Health Systems Behavioral Health	Q3 2023 e-prescribing Immunizations
Patagonia Health executed interactive testing to show that the criterion are functional. The following metrics were tested interactively as detailed in the outcomes section above: • 170.315 (b)(1) Transitions of care • 170.315 (b)(2) Clinical Information Reconciliation and Incorporation • 170.315 (b)(6) Data Export • 170.315 (c)(1-3) Clinical Quality Measures (CQMs) • 170.315 (e)(1) View, Download, and Transmit to 3rd Party • 170.315 (f)(2) Transmission to public health agencies — syndromic surveillance • 170.315(g)(7) Application access—patient selection • 170.315(g)(9) Application access—all data request	Public Health Systems Behavioral Health	Q3 – Q4 2023



ATTESTATION

The Real World Testing Results Template must include the following attestation signed by the Health IT Developer Authorized representative.

Note: The Results 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 Results Report 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 F	Representative Name <u>:</u>	Zeke B. G. Zecca	
Authorized F	Representative Email:	zeke@patagoniahealtl	n.com
Authorized F	Representative Phone:	(919) 238-4780	
Authorized F	Representative Signature:	Zoko B.G. Zocca	
Date <u>:</u>	1/29/24		