

2024 Real World Testing Plan

Azalea EHR 4.0

Background

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.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. 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 Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result.

General Information

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

Developer Name: Azalea Health

Product Name(s): Azalea EHR

Version Number: 4.0

Certified Health IT Product List (CHPL) ID: 15.04.04.2688.Azal.04.02.1.221227

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

Justification for Real World Testing Approach

Azalea EHR is a complete certified electronic health record (EHR) with a primary focus on rural health clinics, primary care and multispecialty practices, and behavioral health providers.

Functionality within the EHR greatly overlaps regardless of care setting. As such, this Real World Testing plan aims to incorporate data from as many of these settings as possible.

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,” this test plan focuses on capturing and documenting successful utilization in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a “real world” implementation as possible.

Summative assessments will be conducted 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. Please note, some measures included in this plan involve the use of production data from real world use of Azalea EHR. These data are aggregated across multiple clients and no protected health information (as defined under HIPAA) or individually identifiable information is used or contained in the information provided for Real World Testing results.

Interactive testing will be 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. Interactive tests will require a live test as opposed to examining historical usage statistics. We will demonstrate the required certified capability in a semi-controlled setting as close to a “real world” implementation as possible.

Standards Updates (Including SVAP and USCDI)

Aside from obtaining 2015 Edition Cures Update certification, Azalea Health has not updated Azalea EHR to any new standards as part of SVAP as of August 31, 2023. All testing will be conducted against the 2015 Edition Cures Update version of the criteria.

Care Settings

True to our mission of helping underserved healthcare providers improve patient care and profitability, Azalea EHR largely focuses on providing solutions for the unique needs of rural health clinics behavioral health providers.

Measures Used in Overall Approach

Summative Assessment Metrics

The following metrics will be measured by viewing audit logs and other reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine “success” via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

Criterion 1: 170.315(b)(1) Transitions of Care (Cures Update)

- Measures: 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
- 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.
- Testing Method: 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.
- Relied Upon Software: Azalea EHR partners with phiMail Server to demonstrate conformity with this certification criterion. Azalea Health will therefore include phiMail in Real World Testing for this criterion.
- Expected Outcomes: Our expectation is there will be low to moderate utilization by providers with a high success rate.

Criterion 2: 170.315(b)(2) Clinical information reconciliation and incorporation (Cures Update)

- Measures: 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
- Justification: This criterion requires the ability of a certified Health IT module to take a CCDA received from 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 Azalea EHR users, it has been our experience that most providers using Azalea 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.
 - Testing Method: Azalea Health intends 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.
 - Expected Outcomes: The expectation is that there will be low utilization by providers with a high success rate when used.

Criterion 3: 170.315(b)(3) Electronic Prescribing (Cures Update)

- Measures: 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
- Justification: This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards.
- Testing Method: Azalea Health intends to demonstrate the required certified capabilities are effective by establishing the frequency in which successful eRx transactions are performed. This will be accomplished by examining reports from our eRx partner which 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.
- Relied Upon Software: Azalea EHR partners with Rcopia/DrFirst to demonstrate conformity with this certification criterion. Azalea Health will therefore include Rcopia/DrFirst in Real World Testing for this criterion.
- Expected Outcomes: The expectation is that there will be high utilization by providers with a high success rate.

Criterion 4: 170.315(b)(6) Data Export

- Measures: 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
- Justification: This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCD format according to specified standards and vocabulary code sets.
 - Testing Method: Azalea Health intends to establish how often data exports are performed to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
 - Expected Outcomes: The expectation is that there will be zero to low utilization of data exports for single and multiple patients by providers. In the event of zero utilization of the functionality, interactive testing methodology has been prepared below.

Criterion 5: 170.315(c)(1) Clinical quality measures (CQMs) - record and export

- Measures: Over a 270-day period (Q1 - Q3 of the calendar year):
 1. Number of measures recorded during the period
 2. Number of QRDA Category I files exported
- Justification: This criterion 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.
- Testing Method: Azalea Health intends to record the frequency that QRDA Category I data files are exported during the first 3 quarters of the calendar year to demonstrate the certified capability is available and effective, regardless of the frequency it is used..
- Expected Outcomes: The expectation is that there will be low to moderate utilization by providers with a high success rate.

Criterion 6: 170.315(c)(2) Clinical quality measures (CQMs) - import and calculate

- Measures: Over a 90-day period:
 1. Number of QRDA Category I files imported (if applicable)
- Justification: This criteria 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.
- Testing Method: Azalea Health intends to record the frequency that QRDA Category I data files are imported by providers and CQM calculations are updated accordingly to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is that there will be zero to low utilization by providers with a high success rate. In the event of zero utilization of the functionality, interactive testing methodology has been prepared below.

Criterion 7: 170.315(c)(3) Clinical quality measures (CQMs) - report (Cures Update)

- Measures: Over a 270-day period (Q1 - Q3 of the calendar year):
 1. Number of measures recorded during the period
 2. Number of QRDA Category III aggregate reports created over the period

- Justification: This criteria requires a certified Health IT module must be able to create a QRDA Category III data file to be used for transmitting ambulatory CQM data to CMS.
- Testing Method: Azalea Health intends to record the frequency that QRDA Category III files are exported by providers during Q1 of the calendar year (to correspond with CQM submission to CMS) to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is that there will be moderate utilization by providers with a high success rate.

Criterion 8: 170.315(e)(1) View, download, and transmit to 3rd party (Cures Update)

- Measures: 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
- 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.
- Testing Method: Azalea Health intends to record the frequency that patients are viewing, downloading, and/or 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.
- Relied Upon Software: Azalea EHR partners with phiMail Server to demonstrate conformity with this certification criterion. Azalea Health will therefore include phiMail in Real World Testing for this criterion.
- Expected Outcomes: Based on historical data, the expectation is that there will be moderate utilization by patients to view health information and, among those utilizing this functionality, zero to low utilization for download and/or transmit with a high success rate for all certified capabilities. In the event of zero utilization of a certified capability, interactive testing methodology has been prepared below.

Criterion 9: 170.315(f)(1) Transmission to public health agencies - immunization registries

- Measures: Over 3 separate unique 10-day periods within a 90-day window:
 1. Count of number of clients with immunization registry interface enabled
 2. Number (or percentage) of immunization records successfully submitted to the immunization registry
- Justification: This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format.

- Testing Method: Azalea Health intends to record the frequency that immunization data is successfully submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is that there will be moderate utilization by providers with a high success rate.

Criterion 10: 170.315(f)(2) Transmission to public health agencies - syndromic surveillance

- Measures: Over 3 separate unique 10-day periods within a 90-day window:
 1. Count of number of clients with syndromic surveillance interface enabled
 2. Total number of syndromic events created and submitted
- 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.
- Testing Method: Azalea Health intends 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.
- Expected Outcomes: This criterion applies only to urgent care, emergency department and inpatient settings. Azalea EHR serves a very limited number of urgent care settings and no emergency or inpatient departments. Therefore, the expectation is there will be zero to low adoption of this certified capability by Azalea EHR users. In the event of zero utilization of the functionality, interactive testing methodology has been prepared below.

Criterion 11: 170.315(f)(7) Transmission to public health agencies - health care surveys

- Measures: Over 3 separate unique 10-day periods within a 90-day window:
 1. Total number of health care surveys created
- Justification: This criterion requires the ability of a certified Health IT module to transmit health care survey information to a registry using a specified format.
- Testing Method: Azalea Health intends to record the frequency that health care survey files are generated for submission to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is there will be zero to low adoption of this certified capability by Azalea EHR users. In the event of zero utilization of the functionality, interactive testing methodology has been prepared below.

Criterion 12: 170.315(g)(7) Application access - patient selection

- Measures: Over a 30-day period:

1. Number of requests for a patient ID or token
 2. Number of requests that provided sufficient information to provide a valid response
 3. Number of follow-up requests made using the provided patient ID or token
- 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.
 - Testing Method: Azalea Health intends to record the frequency that patient ID requests are received by providers via FHIR R4 API to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
 - Expected Outcomes: The expectation is there will be moderate adoption of this certified capability by Azalea EHR users with a high success rate.

Criterion 13: 170.315(g)(9) Application access - all data request

- Measures: Over a 30-day period:
 1. Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token
 2. Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token for a specific date range
- 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 USCDI at one time in a summary record formatted according to the C-CDA Release 2.1 Continuity of Care Document (CCD) template from the certified Health IT module.
- Testing Method: Azalea Health intends to record the frequency that patient data requests for all categories are received and fulfilled via FHIR R4 API to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is there will be low utilization of this certified capability with a high success rate.

Criterion 14: 170.315(g)(10) Standardized API for patient and population services

- Measures: Over a 30-day period:
 1. Number of active applications on the API
 - a. Number of provider apps
 - b. Number of patient apps
 2. Number of launch types used
 - a. Number of stand-alone launches
 - b. Number of EHR launches

3. Number of applications authorized by the FHIR API
 - a. Number of applications authorized to receive single patient data
 - b. Number of applications authorized to receive multiple patients' data
- Justification: This criterion requires the certified Health IT module to provide a standardized API and supporting documentation that enable external applications to make requests for single patient's and multiple patients' data from the certified Health IT module. The Health IT module must be conformant to the base regulatory standard USCDIV1 and US Core 3.1.1 (or SVAP approved standards) as well as FHIR Bulk Data Access (Flat FHIR)(v1.0.1: STU 1).
- Testing Method: Azalea Health intends to record the number of external applications active on the FHIR R4 API and the types of launches utilized as well as the frequency that applications are authorized to receive single and multiple patients' data via the API to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Expected Outcomes: The expectation is there will be moderate utilization of this certified capability by patient, stand-alone apps and low utilization by provider and/or EHR launch apps - both with a high success rate.

Criterion 15: 170.315(h)(1) Direct Project

- Measures: Over a 90-day period:
 1. Number of Direct Messages sent
 2. Number of Delivery Notifications received
 3. Number of Direct Messages received
 4. Number of Delivery Notifications sent
- Justification: This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received.
- Testing Method: Azalea Health intends to establish how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used.
- Relied Upon Software: Azalea EHR partners with phiMail Server to demonstrate conformity with this certification criterion. Azalea Health will therefore include phiMail in Real World Testing for this criterion.
- Expected Outcomes: The expectation is that there will be low utilization by providers with a high success rate.

Interactive Testing Metrics

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available. Azalea EHR is focused on helping underserved providers,

including those designated as Rural Health Clinics. Due to a lack of adoption of the available functionality for the following certified criteria, these criteria will require interactive testing methods.

All interactive testing will be performed in the cloud-hosted production or near-production environment. A near-production test database will be representative of all Azalea EHR practices and will identify in all aspects to the way the EHR is deployed to each practice, except with regards to the data contained in the database. Therefore, all interactive testing will demonstrate that the certified capability works in the real world as deployed in the current production environment. Azalea Health will use screenshots and/or recorded workflows where appropriate to document these tests and keep as evidence of the results in the event that the ONC will want to verify the reported results. Precautions will be taken to reduce any risk of exposure of PHI.

Criterion 1: 170.315(b)(6) Data Export

- Justification: Historically, Azalea Health has not identified any users utilizing this particular certified capability. Clients typically elect to have multiple patient data exports completed by another method and do not perform this function themselves.
- Testing Method: Azalea Health will perform 5 individual single patient data exports and multiple patient data exports with approximately 50, 250, 500 and 1000 included patients to demonstrate that this certified capability is available to export individual as well as smaller and larger numbers of records..
- Expected Outcomes: The expectation is that the data exports will produce a separate .zip file containing the expected number of .xml files for each generated data export.

Criterion 2: 170.315(c)(2) Clinical quality measures (CQMs) - import and calculate

- Justification: Historically, Azalea Health has not identified any users utilizing this particular certified capability. Clients typically elect to have data imports completed by another method and do not import these data files themselves.
- Testing Method: Azalea Health will generate a QRDA Category I file for 2 selected CQMs and import 2 patients from each measure into the system. The 2 CQMs will then be recalculated to show that both the import and calculate were successful.
- Expected Outcomes: The expectation is that the patients will be imported accurately and the data from the QRDA Category I files will be used to accurately calculate the appropriate CQMs.

Criterion 3: 170.315(e)(1) View, download, and transmit to 3rd party

- Justification: Historically, Azalea Health has not identified any patient portal users utilizing the download or transmit to 3rd party certified capability.

- Testing Method: Azalea Health will log into the patient portal as a patient and as an authorized representative for the patient. The patient's CCDA will be downloaded and saved by both individual accesses. The CCDAs will also be emailed to a direct address via phiMail. The actions will demonstrate that both download and transmit capabilities are in place and available for patient use.
- Expected Outcomes: The expectation is that the downloaded CCDA files will be sent to the desktop and able to be opened and viewed by the patient and/or authorized representative. The expectation for the transmitted file is that it will be successfully received at the intended email address and may be opened and viewed by the receiver.

Criterion 4: 170.315(f)(2) Transmission to public health agencies - syndromic surveillance

- Justification: Azalea EHR chose to certify to the Syndromic Surveillance criterion because of a small number of Urgent Care clinics utilizing the product. Azalea Health wanted to ensure that this certified capability was available to those clients. To date there has been no adoption or expressed interest. This interactive testing of the certified capability is to ensure that the feature is functional and available with creation of the appropriate automated interface in the production environment upon request.
- Testing Method: Azalea Health will create 3 test patients in an urgent care setting in our near-production environment. The 3 patients will consist of the NHCS test patient and 2 developer-created patients typical of those served by our clients. We will then follow the appropriate workflows to trigger the required messages to be automatically generated by the system. The resulting messages will be uploaded to the NIST syndromic surveillance HLv2 tool found here: <https://hl7v2-ss-r2-testing.nist.gov/ss-r2/#/home> to confirm that the PHIN ADT messages conform to the expected messaging guide standard. Testing will make use of both the context-based and context-free test tools.
- Expected Outcomes: The expectation is that:
 1. Appropriate PHIN ADT admission and discharge messages for syndromic surveillance will be automatically generated upon appropriate workflows built into the system.
 2. The PHIN ADT messages will pass the validation tool without errors.

Criterion 5: 170.315(f)(7) Transmission to public health agencies - health care surveys

- Justification: Azalea Health developed the Healthcare Surveys functionality to provide clients the opportunity to utilize this certified capability to attest to and participate in the public health measure. To date, we are unaware of any client utilizing this feature. Interactive testing of this certified capability is to ensure continued functionality and that clients may, at any time, generate the document and submit it through any method required by the program in which they choose to participate.
- Testing Method: Azalea Health will configure 3 test patients with data representative of typical Azalea EHR provider patients. The EHR will generate a health care survey CDA document for each patient. Azalea Health will manually upload each of the created

health care survey documents to the National Health Care Surveys IG Release 1.2 validator found here: <https://cda-validation.nist.gov/cda-validation/muNHCS12.html> to confirm that the documents conform to expected standards.

- Expected Outcomes: The expectation is that the generated file will pass the NHCS Validator without error.

Schedule of Key Milestones

Key Milestone	Date/Timeframe
Scheduling and logistics	180 days
Data Collection	90 days
Review and collate data	60 days
Write results report	30 days

Attestation

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.

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Date: 10 / 06 / 2023