Real World Testing Plan

Background & Instructions

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). 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 to develop 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 for 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 which approaches they will take. This Real World Testing plan template 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. Health IT Developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). 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 would expect 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. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the 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 Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**Century Cures final rule**)
  - ↳ *Section VII.B.5* — *"Real World Testing"*

General Information

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

Developer Name: Foothold Technology, Inc.

Product Name(s): AWARDS

Version Number(s): 3.0

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.1500.AWAR.03.00.1.171220

Developer Real World Testing Page URL:
https://footholdtechnology.com/human-services-software/meaningful-use/

Justification for Real World Testing Approach

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 the number of instances that certified capability is successfully utilized 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.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a 2-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing

Adoption rate will be 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 indicate a potential problem, of which there could be several different causes. 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 will be used to measure which certified actions were performed at the conclusion of a given time period. These 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.

Standards Updates (including standards version advancement process-SVAP and USCDI)

Foothold has not updated AWARDS to any new standards as part of SVAP or the Cures Update criteria as of this date. We will attest to CURES updates prior to the execution of the 2023 Real World Test.

Care Settings

AWARDS is marketed primarily to providers in the behavioral health space (most specifically intellectual and developmental disabilities (I/DD), mental health and other service areas). Most care settings have the criteria deployed in them, but not all criteria are used with the same frequency in all care settings. Some metrics will be pulled from different groups of providers than others.

Measures Used in Overall Approach

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Care setting(s) that are addressed
- ✓ Justification for selected measurement/metric
- ✓ Expected Outcomes

Adoption Rates

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of contracted customer agencies of the EHR	Identify the total number of instances (hosted site URL + db) of the certified Health IT system, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active customer agencies of the EHR	Identify the total number of instances (hosted site URL + db) of the certified Health IT system, regardless of care setting, participation in incentive programs, or use of certified capabilities, that have used the system in the 90 days prior to RWT Report creation.
Number of active users of EHR	Identify the total number of ***active*** users of the certified Health IT system, regardless of care setting, participation in incentive programs, or use of certified capabilities in the 90 days prior to RWT Report creation.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	Identify which certified capabilities are licensed separately from the base EHR license. Examples may include eRx, CQMs, public health, etc.
Number of contracted customer agencies with separately- licensed certified capability	Identify the number of current contracted customer agencies with each separately-licensed certified capability.
Number of contracted customer agencies with active use of the separately-licensed certified capabilities	Identify the number of active (in the last 90 days) contracted customer agencies who utilized each of the separately-licensed certified capability.

Summative Assessment Metrics

The following metrics will be measured by viewing audit logs and 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 three 30-day periods to reflect the 90 day reporting periods typically required for compliance with the federal incentive programs. Since Foothold's audit logs are rotated every 30 days, metrics will be captured in three separate 30 day increments.

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	Metric	Care Setting	Justification and Expected Outcome
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	Behavioral Health	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 data elements or have records in all sections. 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. Relied upon software: HealthShare by InterSystems. Our expectation is there will be moderate utilization by providers with a high success rate.

170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90 day period: 1) Number of times a user reconciled the medication list, medication allergies, or problem list data from a received or manually uploaded CCDA	Behavioral Health	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 or manually upload it to a patient's clinical documents records; 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 may elect to save any outside received CCDAs as mere attachments to the patient's file. We intend to record the frequency that providers are electronically reconciling and incorporating CCDAs to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Relied upon software for CCDA creation: HealthShare by InterSystems. Our expectation is there will be low utilization by providers with a high success rate.
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	Behavioral Health	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 relied-upon software, Rcopia by Dr. First. 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, Surescripts. Our expectation is there will be high utilization by providers with a high success rate.
170.315(b)(10) Electronic Health Information export	Over a 90 day period: 1) Number of times a data export was performed for a single patient 2) Number of times a data export was performed for multiple patients in a single transaction	Behavioral Health	This criterion requires the ability of a certified Health IT module to export any EHI for a single patient or for multiple patients on-demand by permitted users in real-time. We intend to demonstrate the certified capability is available and effective, regardless of the set of data included in the export set up by the user, which can vary in format as it is highly configurable. Our

			expectation is there will be moderate utilization by providers with a high success rate.
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 1 files exported 3) Number of QRDA Category 1 files imported (if applicable) 4) Number of QRDA Category 3 aggregate report(s) created over the period	Behavioral Health	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 1 format. C2 requires a certified Health IT module must be able to import data from a QRDA Category 1 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 1 formatted file and a QRDA Category 3 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 low utilization by providers with a high success rate.
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	Behavioral Health	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 CCDA documents 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 for CCDA creation: HealthShare by InterSystems. 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.
170.315(g)(7) Application access — patient selection	Over a 90 day period: 1) Count the number of API queries from an external source for a patient search.	Behavioral Health	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 and/or to request patient data based on unique identifiers. We

			intend to record the frequency that patient data 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.
170.315(g)(9) Application access — all data request	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 date range filter	Behavioral Health	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.
170.315(g)(10) Standardized API for Patient and Population Services	Over a 90 day period: 1) App registration: Number of applications that have exchanged a token with AWARDS' authorization server. 2) Authentication and app authorization: Number of times an application has been authenticated by a user and been authorized to view a single patient's record.	Behavioral Health	This criterion requires the certified Health IT module to provide access to the FHIR R4 API and have the application be registered. We intend to record the distinct number of applications that have been registered that have successfully exchanged a token with the authorization server and the number of user authentications that allow a patient's record to be viewed. This highlights the certified capability to use a SMART application to authorize a user and provide access securely to a patient's record. Our expectation is there will be low utilization by providers with a high success rate.

170.315(h)(1) Direct Project	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	Behavioral Health	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. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages 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 Direct Messages are 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 low utilization by providers with a high success rate.

Schedule of Key Milestones

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Behavioral Health	Q3 2024
Data collection	Behavioral Health	January 2025
Review and collate data	Behavioral Health	January 2025
Writing report	Behavioral Health	January 2025

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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