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.

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. Real World Testing results reports 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

The following regulatory materials 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: Better Day™ Health

Product Name(s): Better Day™ Health

Version Number(s): 1.0

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2992.Bett.01.01.1.180625

Developer Real World Testing Page URL: https://www.betterdayhealth.com/products/

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 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive 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.

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 (SVAP). Interactive tests will require a live test as opposed to examining historical usage statistics. The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

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

DEVELOPER has not updated Better Day™ Health to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of the 2022 Real World Test.

Care Settings

Better Day™ Health markets to ambulatory clinics serving any range of specialties, from Orthopaedics to Family Medicine. The criteria, applicable metrics and associated testing methodologies are equivalent in all care settings.

Care Setting	Justification
Specialty Care Ambulatory	Users are primarily operate within the Orthopaedics clinical care setting with the following provider specialties: Orthopedic Surgeon, Physical Medicine & Rehabilitation, Podiatrist, Hand Surgeon, Interventional Pain Management, Neurosurgeon, Sports Medicine Physician, and Rheumatologist
Family Practice Internal Medicine	Users operate within the Family Medicine clinical care setting

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 licensed installs/users of EHR • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	Identify the total number of ***active*** installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

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 installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of ***active*** installs/users of a given 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 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.

Captured metrics will be internally measured in terms of counts of success divided by the discernible number of attempts detected in order to express success or failure for each identified measure within published plan results based on the overall rates of success.

None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Rate of successful CCDA creation 2) Rate of CCDAs successfully sent via edge protocols	All	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

	3) Rate of CCDAs successfully received via edge protocols		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.
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Rate that user successfully reconciled medication list data from a received CCDA 2) Rate that user successfully reconciled allergies and intolerance list data from a received CCDA 3) Rate that user successfully reconciled problem list data from a received CCDA	All	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.
170.315(b)(3) Electronic prescribing	Over a 90-day period: 1) Rate of success for prescriptions created 2) Rate of success for prescriptions changed 3) Rate of success for prescriptions canceled 4) Rate of success for prescriptions renewed	All	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.
170.315(b)(6) Data export	Over a 90-day period: 1) Rate of success for patient data export performed 2) Rate of success for data export performed for multiple patients in a single transaction 3) Rate of success for data export performed for all patients in a single transaction	All	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 real-world 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.
170.315(g)(7) Application access — patient selection	1) Rate of success for requests for a patient ID or token 2) Rate of success for requests that provided sufficient information to provide a valid response 3) Rate of success for follow-up requests made using the provided patient ID or token	All	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.
170.315(g)(8) Application access — data category request	1) Rate of success for requests for a patient's data made by an application via a data category request using a valid patient ID or token 2) Rate of success for requests for a patient's data made by an application via a data category request using a valid patient ID or token for a specific date range	All	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request patient data by category from the certified Health IT module. We intend to record the frequency that patient data requests by category 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)(9) Application access — all data request	1) Rate of success for requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token	All	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

	2) Rate of success for 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		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(h)(1) Direct Project	1) Rate of success for Direct Messages sent 2) Rate of success for Direct Messages sent delivered 3) Rate of success for Direct Messages received	All	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 moderate utilization by providers with a high success rate.

Interactive Testing

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available, either *because*:

- There is 0 adoption of the criteria in the real world, either due to unanticipated lack of interest or other factors. Where applicable, these factors are described below.
- There is good adoption of the criteria, but the certified capabilities were developed without anticipating the collection of metrics in mind, so real world demonstration of the criteria is provided to demonstrate that it functions in the real world.

High-Level Interactive Test Plan:

- **Care Settings**: All interactive testing will be performed for each of the care settings listed above.
- **Test Environment:** All interactive testing will be performed in a live, production environment.
    - The plan for interactive testing the criteria described below in the real world will be to engage with a Clinician in at least 2 Clinical Settings where the certified Health IT module is deployed as a representative sample to show that this certified capability works in the real world and that it works the same way in all settings.

- **Test Data**: Interactive testing will be performed using live patient data in the live production environment in order to be as representative as possible of real-world deployments. Precautions will be taken to reduce the risk of exposure of PHI.
    - Existing patients are already set up and regularly used in the live production environment for the purposes of training users and investigating issues.

Criterion	Interactive Test Plan	Care Setting	Justification and Expected Outcome
170.315 (g)(7): Application Access - Patient Selection meets170.315	Test user logs into test app as patient and looks up their test results. Test app queries the API that is available in the provider's deployment. Test patients will be used, they will be set up in the clinic's EHR in advance.	All	API Criteria will be tested via interactive testing with the following expected outcomes: ● Patient ID is accepted, and token is returned ● Patient CCDS data is visible in the app as either discrete data fields or as a CCDA
(g)(8): Application Access - Data Category Request meets170.315			
(g)(9): Application Access - All Data Request			

Schedule of Key Milestones

Real World test planning will commence in the first quarter of 2022. Each phase is *expected* to take 90-days to complete, with report writing to occur at the end of 2022/early 2023.

Key Milestone	Care Setting	Date / Timeframe
Scheduling and logistics	All	Q1 - 90-days
Data collection	All	Q2 - 90-days
Review and collate data	All	Q3 - 90-days
Writing report	All	Q4 - 90-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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