REAL WORLD TESTING PLAN TEMPLATE

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 170.405). 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. 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. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. 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 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. **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 Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide – Coming Soon
- 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) (**ONC Cures Act Final Rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*

GENERAL INFORMATION

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

Developer Name: VisionWeb

Product Name(s): Uprise

Version Number(s):3.1

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2514.Upri.31.00.1.181031

Developer Real World Testing Page URL: https://visionweb.com/wp/costs-and-limitations/

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

- Summative Testing
- Interactive Testing

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 timeframe, and where possible, whether those actions were successful or unsuccessful. 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.

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. 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. Uprise is a single focus specialty on the eyecare industry. Very few Uprise providers qualify to participate in Quality Payment Programs. Of the providers that do qualify, a number applying for exclusion due to low volume and thresholds for direct messages and incoming Transition of Care CCDs. CCDs have a low adoption due to missing pertinent ophthalmic information. Due to the 0 adoption of a number of certified criteria across the board, most criteria will be demonstrated through interactive testing to show the feature works and is available for someone to use.

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

VisionWeb has not updated Uprise 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 SETTING

Care Setting	Justification
Ambulatory – Eyecare Specialty	Uprise is a single focus specialty on the eyecare industry.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

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-dayperiod 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. All criteria listed below were tested for the following care setting: Ambulatory – eyecare industry.

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

Criteria	Metric	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	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 low 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 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	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 in to 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. Number of prescriptions created 2. Number of acceptance of a transaction relayed back to the sender prescriptions changed 3. Number of times the system responded that	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

	there was a problem with the transaction 4. Number of times the system responded that a transaction requesting a return receipt had been received	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 for creating prescriptions with a high success rate.
§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	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 zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
§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	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 zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
§170.315(e)(1) View, download, and transmit to 3rd party (VDT)	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	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 zero adoption of this

	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	certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
§170.315(h)(1) Direct Project	5. Number of Direct Messages sent 6. Number of Direct Messages received	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

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 the following care setting: Ambulatory – eyecare industry.
- Test Environment: All interactive testing will be performed in a live, production environment.
- Test Data: Interactive testing will be performed using test patient data in the live production environment in order not adversely impact patient care. *All testing will be captured with Go-To-Meeting.*

- *Tester: The approach will be to test functionality using internal testers. This will help ensure certified capability in a live mirrored-setting while aiming to increase participation and reduce time/negative impact to Clinicians.*

Measurement/Metric	Interactive Test Plan	Justification and Expected Outcomes
§170.315(b)(6) Data export	DEVELOPER will work with TESTER to observe the following workflows: • Create Data Export for select patient(s) to be downloaded • Create Data Export for future time.	Data Export Criteria will be tested via interactive testing because there is 0 adoption or usage of this criteria in the real world due to low demand and limited adoption of CCDs. Expected Outcomes: • Data export can be created for single patient • Data export can be directly downloaded • Data export can be created at a future time

§170.315(c)(1-3) Clinical quality measures(CQMs)	DEVELOPER will work with TESTER to observe the following workflows:
	• Create a MIPS/CQM export by:
	  ○ Date Range
	  ○ Specific Patient
	• Download generated CQM file
	• Import CQM file in Patient Import
	
	We are certified to 10 CQMs and will test 3 of them.
		CQM Criteria will be tested via interactive testing because very few Uprise providers qualify to participate in Quality Payment Programs such as MIPS; leading to low usage of the CQMs. In addition, the CQMs are generated solely around the attestation submission timeframe (January – March), and for all patients. Importing CQM files has 0 adoption or usage of this criteria in the real world due to low demand.
		
		Expected outcomes:
		• CQM reports can be generated based on date range
		• CQM reports can be generated based on specific patient
		• CQM reports successfully generated and can be downloaded
		• CQM import successfully creates patients and exam data

§170.315(e)(1) View, download, and transmit to 3rd party (VDT)	DEVELOPER will work with TESTER to observe the following workflows: • Login to Patient Portal and validate CCDs (View, Download, and Transmit)	VDT Criteria will be tested via interactive testing because adoption of the Uprise's Patient Portal is moderate with the most common actions being outside certified criteria. Viewing and downloading CCDs is next to none, with transmission being 0. When patients access the portal, they are typically accessing their optical prescriptions to take it to a service to be filled; versus viewing/downloading their CCD. CCDs do not contain eyecare specific data, leading to low/no adoption and access by patients. Expected outcomes: • TESTER can successfully view and download CCDs in Portal

		• TESTER can successfully Transmit CCDs in Portal
§170.315(g)(7) Application access — patient selection §170.315(g)(9) Application access — all data request §170.315(g)(10) Standardized API for patient and population services	DEVELOPER will work with TESTER to observe the following workflows: • Access Certification API. Request login. • Login to Certification API. Enter demographics to request patient token. • Enter patient token and request clinical information based on date range • Access API in a single patient and multi-patient context	API Criteria will be tested via interactive testing because there is 0 adoption or usage of this criteria in the real world due to low demand, limited usability and lack of knowledge functionality exists. An important note regarding the criteria, g8 was removed due to limited time criteria and g10 was added to the test plan with the expectation it would be certified by the end of the year. Expected outcomes: • Token successfully sent after entering patient demographics • CCD Data can be filtered by date range • CCD Data can be viewed with all data • Clinical data can be viewed in FHIR format

SCHEDULE OF KEY MILESTONES

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

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Eyecare Specialty	90-days
Data Collection	Eyecare Specialty	90-days
Review and collate data	Eyecare Specialty	90-days
Write report	Eyecare Specialty	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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Date: 10/26/2022