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 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: CPSI (Computer Programs and Systems), Inc.

Product Name(s): Centriq EHR

Version Number(s): 15

Certified Health IT Product List (CHPL) ID: 15.04.04.3104.Cent.EH.02.1.220817

Developer Real World Testing Page URL: https://www.cpsi.com/resources/real-world-testing

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, for 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 running 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 the 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)

Centriq EHR has been updated to USCDI v1 specifications to conform to Cures Update criteria which utilize USCDI.

CARE SETTINGS

Centriq is marketed primarily to inpatient Critical Access Hospitals and is also used by specialists in that setting. Centriq also counts several Prospective Payment System Hospitals among its users. Centriq does not contain any specialty apps.

Care Setting	Justification
Critical Access Hospitals	CAHs receive certain benefits, such as cost-based reimbursement for Medicare services, which differs from other hospital payment systems. CAHs provide shorter term stays (4 day maximum) and work largely with long-term care facilities when sharing data. For these reasons, CAH may have different needs in their typically rural settings than other hospital systems and may utilize their EHR in different ways as a result.
Prospective Payment System Hospitals	PPS Hospitals are reimbursed on a fixed payment schedule and do not limit the number of days per patient stay. PPS hospitals may utilize their EHRs differently than CAH or ASCs due to their trading environments.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Care setting(s) which 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. 169
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. 71

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

The most common is using the Software as a Service (SaaS) where the software is provided for a monthly fee. Most of our software application licenses are without a limitation on the number of concurrent users that may access the application.

Some applications, including system access software, are on a per concurrent user basis. Applications that are per user are identified in the proposal by the listing of the number of user licenses, which can also be provided at the facility's option as a "site" license. When such software is a site license, the facility may provide access to as many concurrent users as desired without incurring any additional fees.

Example applications per user are EPCS and Direct Messaging.

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. See Above

Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability. E-prescribing – 71 sites Direct Messaging – 71 sites
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. E-prescribing – 71 sites Direct Messaging – 71 sites

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 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 of the following criteria were updated to the Cures Update version of criteria August 17, 2022 in the version 15 certification.

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 3) Number of CCDAs received	• Critical Access Hospitals • Prospective Payment System Hospitals	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 via connection to a HISP for a successful transmission. This will 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. Relied Upon Software: Updox

§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	• Critical Access Hospitals • Prospective Payment System Hospitals	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 that 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 prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. This functionality is provided by Dr First. 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(f)(1) Transmission to immunization registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Number (or percentage) of immunization records submitted to the immunization record	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of syndromic surveillance events created and submitted	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to transmit syndrome-based public health surveillance data to a registry using a specified format. We intend to record the frequency that syndromic surveillance data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.
§170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of reportable laboratory results created and submitted	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to transmit reportable laboratory tests and values/results to a registry using a specified format. We intend to record the frequency that reportable laboratory tests and values/results are submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

§170.315(f)(4) Transmission to cancer registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of cancer registry data records created and submitted	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format. We intend to record the frequency that cancer case information is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will continue to 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(f)(5) Transmission to public health agencies — electronic case reporting	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of patients reviewed by eCR feature 2) Total number of reports generated and sent to the CDC (AIMS) 3) Total number of responses received from the CDC	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to identify which encounters may be reportable and then generate an electronic case report for transmission to a registry using a specified format. We intend to record the frequency that electronic case reports are submitted to the CDC and the frequency that response reports are received back to the EHR, demonstrating successful transmissions from production environments to public health agencies. Successful transmissions to and from public health agencies will confirm adherence to expected standards, and demonstrate the certified capabilities are available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization with a high success rate.

§170.315(f)(7) Transmission to public health agencies — health care surveys	Over 3 separate unique 10-day periods within a 90-day window: Total number of health care surveys created and submitted	• Critical Access Hospitals • Prospective Payment System Hospitals	This criterion requires the ability of a certified Health IT module to transmit health care survey information to a registry using a specified format. We intend to record the frequency that health care survey information is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be 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.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available, because there is no adoption to date of these criteria in the Real World, either due either due to unanticipated lack of interest or other factors. Where applicable, these factors are described below.

CPSI will leverage interactive testing for the following criteria for Centriq:

- §170.315 (f)(4) Transmission to cancer registries
- §170.315(f)(7) Transmission to public health agencies — health care surveys

High Level Interactive Test Plan

- **Public Health Criteria Test Environment:**
  - CPSI Public Health certified capabilities were developed to be purchased as a separate module, which requires extensive configuration to be setup to be used. As such, CPSI will perform Interactive Testing for these criteria using a near-prod environment that is set up as a mirror of Real-World Deployed environments.

Criterion	Interactive Test Plan	Justification and Expected Outcome
§170.315(f)(4) Transmission to cancer registries	CPSI will create 3 different Oncology patients and their representative data in the CPSI production system. These test patients will include a test patient with a Cancer diagnosis with no treatment, as well as 2 patients with Cancer diagnoses with different prescribed treatments. CPSI will walk through the Centriq system, mimicking the intended workflow of an Oncology clinician and use the manual generation feature to generate 3 Cancer Case Report documents, then use visual inspection to confirm the documents include all the expected content for each patient per the required standard.	**Justification:** There are no customers currently using this certified capability in the field. CPSI has found that while providers initially signed up to use this feature, when CMS and ONC reduced the number of public health reportables that were needed, most providers already had the required number and did not adopt this new functionality. Additionally, CPSI does not have many Oncology specialist providers utilizing the Centriq product at this time. **Expected Outcome:** The Cancer Case Report documents will be generated for each patient and will include the correct value sets.

§170.315(f)(7) Transmission to public health agencies — health care surveys	CPSI will create 3 test patients, representing one Inpatient setting, one Emergency department setting, and one outpatient provider setting, and their representative data in the production system. CPSI will create health care survey documents and manually download the Healthcare Survey documents. CPSI will use the NIST healthcare surveys Release 1.2 validator found here: https://cda-validation.nist.gov/cda-validation/muNHCS12.html to confirm that the documents conform to expected standards.	**Justification:** There are no sites using Health Care Survey Reporting. CPSI has found that while providers initially signed up to use this feature, when CMS reduced the number of public health reportables that were needed, most providers already had the required number and did not adopt this new functionality. **Expected Outcome:** 3 Healthcare survey documents are created and pass validation

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in the first quarter of 2024. Each phase is expected to take 90 days to complete, with report writing to occur end of year 2024/early 2025.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	• Critical Access Hospitals • Prospective Payment System Hospitals	90 days
Data collection	• Critical Access Hospitals • Prospective Payment System Hospitals	90 days
Review and collate data	• Critical Access Hospitals • Prospective Payment System Hospitals	90 days
Writing report	• Critical Access Hospitals • Prospective Payment System Hospitals	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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