

# **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 a djustments to approaches are made throughout Real World Testing, the Health IT Developer should reflect these a djustments 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 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, <u>85 FR 25642</u> (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(s): 15.04.04.2751.Cent.EH.01.1.171226

Developer Real World Testing Page URL: <a href="https://www.cpsi.com/product-certification">https://www.cpsi.com/product-certification</a>

#### 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 via User Stories

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 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 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. Interactive tests will be

demonstrated by defining "user stories". 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)

CPSI has not updated Centriq EHR to any new standards as part of SVAP or the Cures Update criteria as of this date.

#### **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 and Ambulatory Surgery Centers 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. CAH 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.
Ambulatory Surgery Centers	Surgery centers, also known as ambulatory surgery centers (ASCs), are licensed, freestanding outpatient facilities. These centers are often physician-owned, may specialize in certain procedures, and are typically smaller than hospitals. Because they are ambulatory and don't typically include overnight stays, the use of the EHR is different than hospital systems.

#### 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).

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 and also can 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. Applications include eprescribing and Direct Messaging

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.  179
Number of active installs/users of EHR	Identify the total number of <i>active</i> installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.  100

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. Dr First eprescribing, Direct Messaging



Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.  Epres cribing 100 sites  Direct Mes saging 185 mailboxes
Number of installs/users that have used the certified capability in the preceding 365 days	Where a pplicable, identify the number of <i>active</i> installs/users of a given certified capability.  Epres cribing 100 sites  Direct Mes saging 185 mailboxes

### 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.

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) Number of CCDAs created  2) Number of CCDAs sent via edge protocols  3) Number of CCDAs received via edge protocols	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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 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 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	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and matchit 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) Number of prescriptions created  2) Number of prescriptions changed  3) Number of prescriptions canceled  4) Number of prescriptions renewed	<ul> <li>Critical Access         Hos pitals</li> <li>Pros pective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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 fromour 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) Number of times a data export was performed, whether for a single patient, multiple patients, or for all patients	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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(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 unencrypted email  4) Number of transmissions of health information by a patient or authorized representative using encrypted method	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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 moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.

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	<ul> <li>Critical Access         Hospitals</li> <li>Prospective         Payment System         Hospitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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	<ul> <li>Critical Access         Hospitals</li> <li>Prospective         Payment System         Hospitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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)(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	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	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 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 electronic case reports created and submitted	<ul> <li>Critical Access         Hos pitals</li> <li>Prospective         Payment System         Hos pitals</li> <li>Ambulatory         Surgery Centers</li> </ul>	This criterion requires the ability of a certified Health IT module to identify which encounters may be reportable and then create an electronic case report for transmission to a registry using a specified format. We intend to record the frequency that electronic case reports are created and submitted 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(f)(7)	Over 3 separate uni que 10-day	2)	Critical Access	This criterion requires the ability of a certified
Transmission	periods within a 90-day window:		Hospitals	Health IT module to transmit health care survey
to public	1) Total number of health care	3)	Prospective	information to a registry using a specified format.
health	surveys created and		Payment System	We intend to record the frequency that health
agencies —	submitted		Hospitals	care survey information is submitted to registries
health care		4)	Ambulatory	by providers to demonstrate the certified
surveys			Surgery Centers	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)(5) Transmission to public health agencies electronic case reporting
- §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.

#### • API Criteria:

The CPSI API certified capabilities are available in production deployments at customer sites. CPSI will engage with 2 Primary Care Provider clinics to demonstrate the certified capabilities function the same way in both settings, thereby representing Real World deployments across all Primary Care customers.

Criterion	Interactive Test Plan	Justification and Expected Outcome
§170.315(f)(5) Transmission to public health agencies — electronic case reporting	CPSI developed this workflow as an automatic workflow that runs in the background. Whenever a diagnosis, lab result or medication is entered, it is checked against a trigger table. When a match occurs, it creates a report and sends it to the Interface Management System (IMS). Reports can be viewed in the Interface Management System (IMS). Reports can be viewed in the Interface Management System (IMS) prior to being sent to a Registry.  CPSI will create 3 test patients, each one with a different encounter or parameter that matches the trigger code table, as well as representative data for that encounter, including:  Encounter diagnoses and their associated ICD10 code Provider's contact information Reason for visit Patient Name Sex Date of Birth Race and Ethnicity Preferred language Problems Medications Laboratory Tests Laboratory Values(s)/Result(s) Vital Signs Procedures Care Team Member(s) Immunizations Assessment and Plan of Treatment  CPSI will document the patient encounter in the Centriq EHR and satisfy the trigger conditions, then use visual inspection of the Interface Management System (IMS) to show that the trigger resulted in a transmission of the expected data for each patient to the Interface Management System (IMS).	Justification: There are no sites using Electronic Case Reporting. The reason for this is that when CMS and ONC reduced the number of public health reportable that were needed, most providers already had the required number and did not adopt this new functionality.  All facilities will be mandated to use this function in 2022, so there may be adoption later in 2021 but until then there is no way to demonstrate it in the live environment.  Expected Outcome: Interface Management System (IMS) system will show 3 case reports for patient encounters showing the expected CPSI patient data. Visual inspection will confirm that this functionality is available for deployment in a production environment and ready to be configured and deployed to a customer system.

§170.315(f)(7) Trans mission to public health agencies — health care surveys	CPSI will create 3 test patients, representing 2 Outpatient settings and 1 Urgent Care provider, 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: <a href="https://cda-validation.nist.gov/cda-validation/muNHCS.html">https://cda-validation/muNHCS.html</a> to confirm that the documents confirm to expected standards.	Justification: There are no sites using Health Care Survey Reporting. The reason for this is that when CMS and ONC reduced the number of public health reportable 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
170.315 (g)(7): Application Access - Patient Selection meets 170.315	Centriq is not certified in these. Centriq uses the Get Real Health certification for these criteria	
(g)(8): Application Access - Data Category Request meets 170.315		
(g)(9): Application Access - All Data Request		

# 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	<ul> <li>Critical Access Hospitals</li> <li>Prospective Payment System Hosp</li> <li>Ambulatory Surgery Centers</li> </ul>	90-days itals
Data collection	<ul> <li>Critical Access Hospitals</li> <li>Prospective Payment System Hosp</li> <li>Ambulatory Surgery Centers</li> </ul>	90-days itals
Review and collate data	<ul> <li>Critical Access Hospitals</li> <li>Prospective Payment System Hosp</li> <li>Ambulatory Surgery Centers</li> </ul>	90-days itals
Writing report	<ul> <li>Critical Access Hospitals</li> <li>Prospective Payment System Hosp</li> <li>Ambulatory Surgery Centers</li> </ul>	90-days itals

# **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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