

2025 Real World Testing Plan myCare Portal 4.0





Revision History

The Revision History table below provides a record of all revisions made to this document throughout its life cycle. Updates are tracked by date the revisions were made, the version number, a brief description of the changes made and reason, as well as the name of the reviser and the approver.

| Effective Date | Version # | Change Description/ Reason | Created/Revised | Reviewed by | Approved by |
|----------------|--------------|----------------------------------|-----------------|-------------|-------------|
| 08.06.2024 | 2024.1 | Sightview Revision | Lora Woltz | Lora Woltz | Lora Woltz |
| 10.29.2024 | 2025.1 | 2025 Update, add b10 | Lora Woltz | Lora Woltz | Lora Woltz |
| | | | | | |
| | | | | | |



Product Information

| Product Information | | |
|---|--|--|
| Plan Report ID Number: (ONC-ACB use only) | 2025RWTP_MCPv4 | |
| Developer Name | Sightview EHR Holdings, LLC | |
| Product Name | myCare Portal | |
| Version Number(s) | 4.0 | |
| Certified Health IT | ONC Certification Criteria for Health IT | |
| Product List (CHPL) ID(s) | 15.04.04.3206.myCa.04.03.1.241028 | |
| Developer Real World Testing Page URL | ONC Certification Sightview | |



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Introduction

This test plan describes the testing approach and overall framework that will drive the testing of Sightview EHR Holdings, LLC ONC Certification Criteria for Health IT software modules in order to comply to the ONC Health IT Certification program's Real World Testing Conditions of Certification requirement described in § 170.405 Real World Testing Version 1.4.

This document introduces:

- The scope of applications under test w/ associated criterion subject to real world testing
- Justification for Real World Testing Approach
- The testing methods/methodologies that will be used to demonstrate real world interoperability and conformance to the full scope of the certifications requirements
- The care setting description and justification of the care setting
- SVAP description (as applicable)
- Key real world testing milestone schedule
- Description of expected outcomes
- Measurement / Metric detail
- Justification of the real world testing approach

This test plan version (2025.1) is associated with the testing to be conducted in CY 2025.



1 Scope

1.1.1 Applications in Scope

The following Eye Care Leaders' CEHRT software platforms are subject to the real-world testing procedures outlined in this test plan for criterion certified to that platform, and as listed on the Certified Health IT Product List, as of August 31, 2024.

| Platform | Version | Criterion to be Tested |
|---------------|---------|---------------------------------|
| myCare Portal | 4.0 | (b)(10), (e)(1), (g)(7), (g)(9) |

Table 1

1.1.2 Criterion Detail

| §170.315 | Criterion Name | Criterion Description (includes, not limited to) |
|--|---|---|
| (b)(10) | EHI Export | EHR Software enables a user to timely create an export file(s) with all of a single patient's electronic health information stored at the time of certification; A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. The export file is in an electronic and computable format. |
| (e)(1) | View, Download and Transmit | Patient (and authorized representative) must be able to use internet based technology to view, download and transmit their health information to a 3 rd party |
| (g)(7) | Application Access – Patient Selection | Software must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to execute request for patient data; Documentation must be provided via publicly available hyperlink |
| (g)(9) Application Access – All Data Request | | Software must respond to requests for patient data (based on ID or other token); return data in a summary record format; respond to request for patient data associated with specific date and date range; Documentation must be provided via publicly available hyperlink |

Table 1.1 Note that full regulation text is available on the HealthIT.gov website for each criteria listed above.

Only functionality that is specific to the performance of successfully completing a task related to the criterion listed in Table 1.1 will be included in the real world testing execution.



2 Justification for Real World Testing Approach

Sightview Software, LLC Certified Health IT Modules are sold only to the Ophthalmology / Optometry specialty care settings. The certified functionality under test works the same for each care setting therefore the Real-World Testing plan will be applied to the Ophthalmology specialty care setting for the purposes of providing Real World Testing Results.

myCare Portal Version 4.0, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria:

- 170.315(b)(10) EHI Export
- o 170.315(e)(1) View, Download and Transmit
- 170.315(g)(7) Application Access Patient Selection
- 170.315(g)(9) Application Access All Data Request

The purpose of the system test is to demonstrate real world interoperability and conformance to the full scope of the platform's certification criterion's requirements and to evaluate the end-to-end system specifications and functionality related to specific certified criteria for the application under test (AUT). The system test will involve the external workings of the software from the user's perspective.

Scenario Testing can be used to best define the functionality related to the criteria to be tested. Use Case will represent the action(s) that are required to achieve the expected outcome of the test scenario. API testing will be used to test application programming interfaces where applicable. API testing is used to determine if the health IT's API meets expectations for functionality, reliability, performance and security. Therefore, myCare Portal 4.0, will use Test Scenario, Use Case and API (where applicable) based system testing methodologies in parallel to conduct the system test on the fully integrated applications, including external peripherals (HISP) as applicable, to check how components interact with each other and with the system as a whole during interoperability related actions that are defined in §170.140 Real World Testing Version 1.3.

The testing will be performed by the Product Compliance Officer with assistance by individual developers, subject matter experts or support team leads as required. The measures chosen are meant to reflect performance that will best demonstrate interoperability in a real-world scenario as is outlined in this Real-World Testing Plan. In certain cases, synthetic patient data may be used for data entry simulation. All nonconformities must be documented, and a mediation strategy detailed for each nonconformity. All nonconformities must be reported to ONC within 30 days of discovery.

Verification of the created patient record export does require interaction with a system external to the organization (and with a different vendor). myCare Portal performs EHI exporting via the use of an integrated EHR software platform.



3 Standards Updates

| Standard (and version) | All Standards included in C-CDA R2.1 | |
|--|--|--|
| Certified Criteria | 170.315(e)(1) View Download and Transmit | |
| Health IT Module CHPL ID | 15.04.04.3206.myCa.04.03.1.241028 | |
| Health IT Module Product ID | 15.04.04.3206.myCa.04.03.1.241028 | |
| Method used for standard update | Minimum Standard Code Sets | |
| Date of ONC-ACB notification | Not Applicable | |
| Date of customer notification (SVAP only) | Not Applicable | |
| USCDI-updated certification criteria (and USCDI version) | Version 1 | |

| Standard (and version) | All Standards included in C-CDA R2.1 | |
|--|--------------------------------------|--|
| Certification criteria | 170.315(b)(10) EHI Export | |
| Health IT Module CHPL ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Health IT Module Product ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Method used for standard update | Minimum Standard Code Sets | |
| Date of ONC-ACB notification | Not Applicable | |
| Date of customer notification (SVAP only) | Not Applicable | |
| USCDI-updated certification criteria (and USCDI version) | Version 1 | |

| Standard (and version) | All Standards included in C-CDA R2.1 | |
|--|--|--|
| Certified Criteria | 170.315(g)(7) Application Access – Patient Selection | |
| Health IT Module CHPL ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Health IT Module Product ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Method used for standard update | Minimum Standard Code Sets | |
| Date of ONC-ACB notification | Not Applicable | |
| Date of customer notification (SVAP only) | Not Applicable | |
| USCDI-updated certification criteria (and USCDI version) | Version 1 | |

| Standard (and version) | All Standards included in C-CDA R2.1 | |
|--|---|--|
| Certified Criteria | 170.315(g)(9) Application Access – All Data Request | |
| Health IT Module CHPL ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Health IT Module Product ID | 15.04.04.3204.Medf.10.02.1.241028 | |
| Method used for standard update | Minimum Standard Code Sets | |
| Date of ONC-ACB notification | Not Applicable | |
| Date of customer notification (SVAP only) | Not Applicable | |
| USCDI-updated certification criteria (and USCDI version) | Version 1 | |



4 Care Settings

4.1 Settings of Care Description

Sightview Software, LLC CEHRT platforms are considered to be an **Ambulatory Specialty Care Practice** type care setting for use in ophthalmology practices.

4.2 Settings of Care Justification

| Care Setting | Justification |
|--------------------------------------|--|
| Ambulatory Specialty Care Practice – | Sightview Software, LLC provides CEHRT that |
| Ophthalmology and Optometry | supports healthcare professionals in |
| | ophthalmology and optometry in outpatient |
| | ambulatory environments only. Ophthalmology |
| | and optometry are considered to be specialized |
| | areas of medicine. The software allows users to |
| | perform a wide range of functions that focus on |
| | all aspects of the patient's eye examination. The |
| | software is not used in other types of settings of |
| | care. Since the patient base, exam type and |
| | documentation content of ophthalmologists |
| | encompass all and more aspects of patient care |
| | used in optometry, all Real World Testing |
| | scenarios will be focused on the ophthalmology |
| | practice. |



5 Overall Expected Outcomes

RWT will demonstrate that the Health IT Module is conformant to the following certification criteria:

- 170.315(b)(10) EHI Export
- 170.315(e)(1) View, Download and Transmit
- 170.315(g)(7) Application Access Patient Selection
- 170.315(g)(9) Application Access All Data Request

The myCare Portal is not a standalone product and is only provided for use in combination with one of Sightview Software, LLC EHR products. myCare Portal is specifically marketed for use in ophthalmology and optometry practice settings as is in conjunction with the Sightview Software, LLC EHR. RWT will demonstrate that the myCare Portal functions promote interoperability by providing health information to the patient by capturing the CCD created by the EHR and allowing the authorized user, patient or authorized patient representative to view, download or transmit their EHI. EHI Exporting functionality is available with the integrated EHR software product and additionally, myCare Portal provides on demand API functionality for integrated EHRs.

6 Key Milestones

| Key Milestone | Date / Timeframe |
|---|------------------|
| Preparation of templates, instructions, forms, and schedules to be released | 01/31/2025 |
| to the platform's Subject Matter Experts as needed | |
| Test Environments Ready | 03/31/2025 |
| Perform Real World Testing | Q2, Q3, Q4 2025 |
| Interim Report status of scheduling and/or testing issues, successes, | 06/30/2025 |
| remediation needs, fixes, deviations from test plan etc. | |
| Soft deadline for testing completion | 09/31/2025 |
| Hard deadline for testing completion | 12/31/2025 |
| Detailed Test Data results submission | 01/15/2026 |
| Test Summary Report Finalized | 01/31/2026 |
| Preparation of templates, instructions, forms, and schedules to be released | 01/31/2025 |
| to the platform's Subject Matter Experts as needed | |



7 Measures Used

The CEHRT is certified to multiple criteria that must comply with Real World Testing requirements. The following outlines the measures and metrics used to demonstrate conformance to the following certification criterion:

| Measurement/Metric | Description |
|--|---|
| 170.315(b)(10) EHI Export | (i)(D) Export is available in electronic and computable format |
| 170.315(e)(1) View Download and Transmit | (i)(A)(1) View ambulatory summary in human readable format in the patient portal |
| 170.315(g)(7) Application Access - Patient Selection | (i) Identify a patient and return an ID or token that can be used by the application to execute requests for the patient's data |
| 170.315(g)(9) Application Access – All Data Request | (i)(B) API responds to request for patient data for a specific date or date range |

7.1 Measure Use Case(s)

The measure use cases listed below have been chosen to demonstrate interoperability in real world use. To cover all criteria, multiple use cases are required for this plan. Because the CEHRT manages multiple functions for the same patient, the following criteria may be tested simultaneously:

Use Case 1: (Single Patient) Metrics: 170.315(b)(10) EHI Export

• Measure 1: Conformance to 170.315(b)(10)(i)(D) – Electronic Format – This measure will track the ability of the CEHRT to create the EHI Export file in an electronic and computable format.

<u>Measure Justification</u>: The CEHRT can share patient healthcare information for a single patient or a group of patients with an external organization using an export function. This information is typically shared when there is a need for the full patient record and should be executable on demand, according to the date and time and destination location chosen by the requestor.

<u>Test Methodology:</u> The myCare Portal requires the use of a Sightview Software, LLC integrated EHR platform to perform EHI exporting as the USCDI data elements received from the integrated EHR is duplicative of the data elements included in the EHI Export File generated by the EHR. EHR System logs and audit file records will be reviewed during the testing period to determine the frequency of data export requests. EHI Export is not widely used in the daily clinic scenario so it may be necessary for the Tester to initiate the export request as a naturally occurring Data Export request may not be done by the target clinic during the chosen RWT period. For this reason, we intend to demonstrate that the functionality is available and can be successfully utilized by the client, regardless of the frequency of use.

<u>Expected Outcomes</u>: It is expected that the authorized users will be able to generate an electronic and computable EHI export file using the export function on demand. It is expected that there will be a very low rate of usage with a high success rate.



Use Case 2 (Single Patient): 170.315(e)(1) View, Download and Transmit

Measure 1: Conformance to 170.315(e)(1)(i)(A)(1) – View - This measure will track the ability of the
patient/authorized patient representative of the myCare Portal to view in human readable format an
ambulatory summary that has been sent to the patient portal.

<u>Measure Justification:</u> The CEHRT includes the ability to transfer the human readable health summary to the proprietary patient portal where the patient can view, download, and transmit the health care summary. The transitions of care, referrals and patient health care summaries are shared between organizations and the patient portal using Edge Protocol technology. Health Summaries are generated for each patient visit and for each update to the health record upon finalization of the patient exam by the overseeing provider.

<u>Test Methodology:</u> The myCare Portal will require an integrated Sightview Software, LLC CEHRT to generate the patient's health care summary. Audit and system logs will be generated and reviewed to determine the frequency and success versus error rate of health summary transport to the patient portal. Log files may be de-identified and used for analysis of the ability to view the health summary record from the portal account. Actual viewing of the health summary is a voluntary action by the patient and therefore the compliance to this functionality will be measured by the availability and effectiveness of the function, regardless of the frequency of use.

<u>Expected Outcome</u>: It is expected that a health summary file will be generated and sent to the patient's portal account and that the health summary can be viewed in human readable format. It is also expected that the health summary will be generated for each patient encounter or update to the patient record. Based on the previous year's RWT findings, it is expected that there will be a high rate of availability of the health summary in the portal, with a moderate to low view rate.

Use Case 3 (Single Patient): 170.315(g)(7), (9) Application Access

The following criteria may be tested simultaneously:

Use Case 2A: 170.315(g)(7) Application Access – Patient Selection

• Measure 1: Conformance to 170.315(g)(7)(i) – Identify – This measure will track the ability of the API to identify a patient and return an ID or token that can be used by the application to execute requests for the patient's data

Use Case 2B: 170.315.(g)(9) Application Access- All Data Request

- Measure 1: Conformance to 170.315(g)(9)(i)(A) Unique Patient all records This measure will track the
 ability of the API to respond to a request for patient data for all data categories of the CCD for the unique
 patient.
- Measure 2: Conformance to 170.315(g)(9)(i)(B)- Date/Date Range Request API responds to request for patient data for a specific date or date range

Measure Justification for 170.315(g)(7, 9): APIs enable patients to view, download, or transmit their health information using any application of their choice that is configured to meet the technical specifications of the API in the provider's CEHRT. API technology is intended to accommodate the full range of API certified functionalities to pull patient data for a single patient. These measures will look at the performance of the certified API technology to manage multiple functionalities at once. Performance will pertain to token creation and the ability of the API to pull all category data for the chosen date or date range.



<u>Test Methodology:</u> The API requires an active patient portal account along with a Sightview Software, LLC CEHRT. RWT will review the ability of the CEHRT to authenticate user credentials to create a token for the unique patient and then the ability to access the PHI data for the patient with the search criteria or input through the patient application. Data accessed can be downloaded in the form of a CDA XML or by HTML human readable format. Date ranges and CDA subsections may be queried separately or together.

System logs will be reviewed for error codes indicating a bad request response or unauthorized credentials. Log files will be de-identified and used for analysis to ensure proper functionality. The API feature of the CEHRT is not utilized in normal day to day practice. The API feature of the CEHRT is not utilized in normal day to day practice. Real World Testing may require the direct initiation of an API event(s) by the tester in conjunction with the CEHRT client's application under test.

<u>Expected Outcomes</u>: It is expected that the CEHRT will perform API calls with a minimum of error. The API feature of the myCare Portal is not utilized in normal day to day practice. Real World Testing may require the direct initiation of an API event(s) by the myCare Portal's RWT team in conjunction with the CEHRT client's application under test. Error rates will be tracked and trended over time.



7.2 Relied Upon Software

myCare Portal Version 4.0 requires the use of an integrated CEHRT Sightview EHR Module and the Certified Health IT module Regulatory Compliance Platform (RCP) Version 2.0. as relied upon software for the following certified functions: 170.315(e)(1) View, Download, and Transmit and 170.315(b)(10) EHI Export.

- The RCP module assists the EHR module with supporting certified capability related to care coordination
 and patient engagement including the creation of electronic health information documents (CCD) required
 for referrals, transitions of care and to share with the patient; the CCD is then passed from the EHR to the
 Portal using RCP.
- 2. Send/receive messages and attached documents to/from the HIPS via Direct Edge Protocol
- 3. The integrated CEHRT is responsible for the generation of the actual patient health information that is transmitted to the myCare Portal and included in the EHI Export file.

Furthermore, myCare Portal Version 4.0 requires the use of an Sightview Software, LLC certified EHR to provide the patient health information that is populated on the CCD. Real World Testing may utilize multiple EHRs to best demonstrate the interoperability of 170.315(e)(1) View, Download, and Transmit and 170.315(b)(10) EHI Export between the EHR and the myCare Portal.

8 Test Methods

8.1 Test Requirements and Resources

- Test or staging environment this environment is to be ready to accept an installed and functional copy of the CEHRT to be tested
- Installed CEHRT is to be configured to exactly mirror the CEHRT in use by the client in production
- Network LAN / Internet to simulate the real business and user environment.
- Computer to simulate a user environment in the real world.
- Synthetic Patient Data In order to protect patient identity, the CEHRT development team will use
 synthetic patient data to model the demographics and medical history of realistic patient health data. This
 modeled data will mirror a typical patient encounter(s) in order to generate the system and use case
 outcomes that are subject to RWT.
- Data will include all elements found in the USCDI, allergies, medications, care plans, ICD10 and CPT codes as needed to align with the scenario and use case under test.
- Trading Partner Access allows for third party confirmation of successful send/receipt of CCDA.

8.2 Justification of Mirrored Environment and Synthetic Data

Synthetic Patient Data – In order to protect patient identity, or to initiate the use of certified functionality that may not be naturally triggered by the client, the CEHRT development team may use synthetic patient data to model the demographics and medical history of realistic patient health data. This modeled data will mirror a typical patient encounter(s) in order to generate the system and use case outcomes that are subject to RWT. Data will include all elements found in the USCDI v. 1., allergies, medications, care plans, ICD10 and CPT codes as needed to align with the scenario and use case under test



Testing Process Template Example

| Health IT Module Name and Version: | Certified Criterion: | | |
|--|-------------------------|-----------------|--|
| Test Case ID: | Test Case | Test Case | |
| | Description: | | |
| Created By | Reviewed By | Regulation Text | |
| | _ | Citation: | |

QA Tester's Log

| Tester's Name | Date Range | Test Case | |
|---------------|------------|----------------|--|
| | Tested | (Pass/Fail/Not | |
| | | Executed) | |

| S# | Preconditions: |
|----|--------------------------------|
| 1 | Test environment configured |
| 2 | Access to accepted browser |
| 3 | Installed Health IT Module |
| 4 | Valid Username and password |
| 5 | Test data available |
| 6 | Interoperability Hub available |

| S # | Test Data Requirement |
|--------|-----------------------|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| | |
| | |

Test Conditions

| Step# | Step Details | Expected Results | Actual Results | Performs to Expectation |
|-------|--------------|---------------------|----------------|-------------------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |



9 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.

Lin Woffe

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Date: 10.29.2024