Sightview software

2025 Real World Testing Plan
MDoffice 12.1

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	Created/Revised by	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_MDOv12.1
Developer Name	MDoffice, LLC
Product Name	MDoffice
Version Number(s)	12.1
Certified Health IT	ONC Certification Criteria for Health IT
Product List (CHPL) ID(s)	15.04.04.3205.Mdof.12.02.1.241028
Developer Real World Test Page URL	ONC Certification | Sightview

MDoffice

Table of Contents

1.Introduction

This test plan describes the testing approach and overall framework that will drive the testing of MDoffice, 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.

1.1 Scope

1.1.1 Applications in Scope

The following Sightview Software, LLC 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
MDoffice	12.1	(b)(1), (b)(2)(b0(10)

1.1.2 Criterion Detail

170.315	Criterion Name	Criterion Description
(b)(1)	Transitions of Care	Software must be able to create, send and receive transitions of care/ referral summaries via edge protocol; be able to detect valid and invalid transitions of care/referral summaries; display the data received in the transition of care/referral summary in human readable format; allow for the individual display of each section
(b)(2)	Clinical Information and Incorporation	Software can properly match a received Transition of Care/ Referral Summary to the correct patient; allow user to electronically and simultaneously display the patient's active data for medication, allergies and problem list from at least two list sources in a single view; User can review, validate and incorporate a patient's medication list, allergies and problem list; software can create a C-CDA document that includes the reconciled and incorporated data
(b)(10)	EHI Export	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.

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 RealWorld Testing plan will be applied to the Ophthalmology specialty care setting for the purposes of providing Real World Testing Results.

MDoffice EHR Version 12.1, hereafter may also be referred to as Health IT Module or CEHRT, supports multiple certification criteria:

- **o 170.315(b)(1) Transitions of Care**
- **o 170.315(b)(2) Clinical Information Reconciliation and Incorporation**
- **o 170.315(b)(10) EHI Export**

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, MDoffice, LLC 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 1.4.

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).

3 Standards Updates

This Section includes both required and voluntary standards update information, as applicable.

Standard (and version)	All Standards included in C-CDA R2.1
Certified Criteria	**170.315(b)(1) Transitions of Care**
Health IT Module CHPL ID	15.04.04.3205.Mdof.12.02.1.241028
Health IT Module Product ID	15.04.04.3205.Mdof.12.02.1.241028
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
Certification Criteria	**170.315(b)(2) Clinical Information Reconciliation and Incorporation**
Health IT Module CHPL ID	15.04.04.3205.Mdof.12.02.1.241028
Health IT Module Product ID	15.04.04.3205.Mdof.12.02.1.241028
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
Certification criteria	**170.315(b)(10) EHI Export**
Health IT Module CHPL ID	15.04.04.3205.Mdof.12.02.1.241028
Health IT Module Product ID	15.04.04.3205.Mdof.12.02.1.241028
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

All 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 – Ophthalmology and Optometry	MDoffice, LLC provides CEHRT that 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 patients 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)(1) Transitions of Care**
- **170.315(b)(2) Clinical Information Reconciliation and Incorporation**
- **170.315(b)(10) EHI Export**

The Heath IT Module is specifically marketed to ophthalmology and optometry practice settings. RWT will demonstrate that the Health IT Module exchanges EHI in the expected manner in ophthalmology care settings, specifically the interoperability related criteria of creating, sending, and receiving the CCDA, providing health information to the patient and providing patient data on demand.

RWT will demonstrate that the Health IT Module supports Edge Protocol via SMTP transport

6 Schedule of Key Milestones

Key Milestone	Date / Time Frame
Preparation of templates, instructions, forms, and schedules to be released to the platform's Subject Matter Experts as needed	01/31/2025
Test Environments Ready	03/31/2025
Perform Real World Testing	Q2, Q3, Q4 2025
Interim Report status of scheduling and/or testing issues, successes, remediation needs, fixes, deviations from test plan etc.	06/30/2025
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

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)(1) Transitions of Care	(i)(A) Send transition of care/referral
	(i)(B) Receive transition of care/referral
170.315(b)(2) Clinical Information Reconciliation and Incorporation	(ii) Correct Patient – received transition of care/referral can be correctly matched to the specific patient
	(iii) Reconciliation – user can review, validate, and incorporate a patient's medication list, allergies, and problems list
170.315(b)(10) EHI Export	(i)(A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information
	(i)(B) user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.
	(i)(D) Export is available in electronic and computable format

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): 170.315(b)(1) Transitions of Care

- Measure 1: Conformance to 170.315(b)(1)(i)(A) Transitions of care – Sending – This measure will track the export of CCD created by the CEHRT and monitor the ability to share the CCD with the intended recipient using Edge protocols.
- Measure 2: Conformance to 170.315(b)(1)(ii)(B) Transitions of care – Receiving - This measure will track the ability of the CEHRT to display the data received in the transition of care/referral summary in human readable format

Measure Justification: The CEHRT has been developed to provide the eye care provider with the ability to document, store and share EHI regarding a patient's visit in an ambulatory care setting. The CEHRT allows for the creation of the patient health information based on the patient visit, and according to the United States Core Data for Interoperability (USCDI) Version 1 data class and data element categories. The CEHRT allows for the sharing of CCDs between providers and patients both within and outside of the healthcare practice using Edge protocols.

Test Methodology: The CEHRT utilizes Updox as the HISP to perform authentication, encryption, trust verification and acknowledgement of responsibility to deliver the message utilizing SMTP transport protocol as specified in the Applicability Statement for Direct Secure Health Transport when securely routing messages from a sender's address to an intended recipient's address. Updox provides API Reporting that will allow for the retrieval of details about the transmissions of all DSM transmissions.

Scenario	MDN Status
When receiving a Direct message	Processed
When receiving a Direct message and successfully delivering to the Edge Client and sending HISP requested a Dispatched MDN	Dispatched
When receiving a Direct message and unable to deliver to Edge Client	Failure
When sending a Direct message and counterparty HISP doesn't send a Processed MDN within 60 minutes	Failure

Comparative Summaries will be collected using EHR audit and system logs to determine the frequency of and the transport mechanism used by providers. Log files obtained during Real World Testing will be de-identified and used for analysis to ensure that the creation and export of CCDA files is reflected in the API reporting provided by the HISP. Since the action of sending the CCDA to an intended recipient via HISP remains elective, we intend to demonstrate that the functionality is available and can be successfully utilized by the client, regardless of the frequency of use.

Expected Outcomes: It is expected that providers will be able to share EHI using the transmission mechanisms provided. It is expected that a higher rate of success will be seen for the creating and sending of a CCD versus the receipt of an external CCD. This is because of the lack of control over the quality of data occurring in an externally generated CCD and errors may exist that prohibit the acceptance of the CCD into the EHR.

Use Case 2: (Single Patient) Metrics: 170.315(b)(2) Clinical Information Reconciliation and Incorporation

- Measure 1: Conformance to 170.315(b)(2)(ii) Clinical Information Reconciliation and Incorporation – Correct Patient – This measure will track the ability of the CEHRT that a received transition of care/referral can be correctly matched to the specific patient.
- Measure 2: Conformance to 170.315(b)(2)(ii) Clinical Information Reconciliation and Incorporation – Reconciliation – This measure will track the ability that a user of the CEHRT can review, validate, and incorporate a patient's medication list, allergies, and problems list from a correctly matched transition of care/referral.

Measure Justification: Transitions of Care and/or referrals may be received electronically internally from provider to provider within the practice or externally from a different provider. Correctly matching the incoming or received health record to the appropriate patient and then performing the reconciliation of medication lists, allergies and problems is vital to patient safety and demonstrates the intention of data interoperability. The CEHRT allows for the receipt of an inward bound patient health summary, patient/record matching of the incoming transition of care and/or referral and reconciliation of medications, medication allergies and problem lists associated with the incoming CCD.

Test Methodology: The EHR will utilize a combination of audit and system logs to record the success or failure of actions related to patient matching and reconciliation within the EHR. The volume of naturally occurring transition of care or referrals received by the target clinic during the chosen RWT period cannot be anticipated prior to testing. Previous year testing concluded that the functionality was not adopted in the practices chosen for demonstration. In which case, the EHR's RWT team may initiate transactions involving synthetic patient data in order to generate a sufficient volume of transactions to demonstrate the measure. 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.

Expected Outcomes: It is expected that providers will be able to match and reconcile the medications, allergies and problem lists to the correct patient using the mechanisms provided. It is expected that the rate of usage will be low, with successful outcomes when utilized.

Use Case 3: (Single Patient) Metrics: 170.315(b)(10) EHI Export

- Measure 1: Conformance to 170.315 (b)(10)(i)(A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information
- Measure 2: Conformance to 170.315(b)(10)(i)(B) – Execute at any time – This measure will track the ability of the CEHRT to create an export summary in real time (i.e., on demand).
- Measure 3: 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.

Measure Justification: 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.

Test Methodology: 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. Log files obtained during RWT will be de-identified and reviewed to validate the proper functionality of the request process.

Expected Outcomes: 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.

7.2 Relied Upon Software

Management Plus EHR Version 7.22 requires the use of relied upon software for the following certified functions: 170.315(b)(1) Transitions of Care and 170.315(b)(2) Clinical Information Reconciliation and Incorporation. HISP services required for (b)(1) and (b)(2) are provided by Updox

1. The Regulatory Compliance Platform assists the EHR module with supporting certified capability related to care coordination and patient engagement including the creation of electronic health information documents required for referrals, transitions of care and to share with the patient;
2. Send/receive messages and attached documents to/from the HIPS via Direct Edge Protocol, provided by Updox

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 v1, 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

8.3 Testing Process Template Example

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

QA Tester's Log

Tester's Name		**Date Range Tested**		**Test Case (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

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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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