REAL WORLD TESTING PLAN - EyeMD EMR Healthcare Systems, Inc.

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Certification Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. **While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.**

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- Real World Testing Resource Guide
- 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 Certification Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, 85 FR 25642 (May 1, 2020) (**ONC Cures Act Final Rule**)
    - *Section VII.B.5* — *"Real World Testing"*

GENERAL INFORMATION

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

Developer Name: EyeMD EMR Healthcare Systems, Inc.

Product Name(s): EyeMD EMR Electronic Records

Version Number(s): Version 2

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2725.EyeM.02.00.1.190501

Developer Real World Testing Plan Page URL: https://www.eyemdemr.com/compliance/meaningful-use-macra/

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, 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 generating 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. 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 UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

DEVELOPER has not updated CHITM to any new standards as part of SVAP or the Cures Update criteria as of this date.

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

Adoption Rate

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).

Measurement/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.)	• MDs: 1,642 • ODs: 827
Number of active installs/users of EHR	• MDs: 1,390 • ODs: 713

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

Measurement/Metric	Description
Certified capabilities that are licensed separately	E-Prescribing
Number of active installs/users of EHR	1,976 providers utilizing E-Prescribing
Number of installs/users that have used the certified capability in the preceding 365 days	1,976 providers who have utilized E-Prescribing

Care Setting(s)

CHITM is marketed primarily to…

Care Setting	Justification
Ambulatory Vision Care Providers (MDs, DOs, and ODs)	Being a specialty specific EMR, EyeMD EMR is expected to work the same across all ambulatory care settings for both medical-based practices as well as refractive/optical practices.

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.

	Metric	Care Setting	Justification and Expected Outcome
Criterion 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	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	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	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	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 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	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	Relied upon software: NewCrop This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate . Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will 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)(10) Electronic Health Information Export	Using a 90-day period: 1) Number of CCDAs exported equals patient count 2) Percentage of CCDAS pass inspection via EDGE Tool	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	This criterion requires the ability of a certified Health IT module to export USCDI clinical data for a population of patients for use in a different health IT product. We intend to verify the full export is equivalent to the patient count for a given time period, and that the files generated are consistent with C-CDA Templates for Clinical Notes. Our expectation is that there will be 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	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	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

	representative using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using encrypted method		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(g)(7) Application access — patient selection	1) Number of requests for a patient ID or token 2) Number of requests that provided sufficient information to provide a valid response 3) Number of follow-up requests made using the provided patient ID or token	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that patient ID requests are received by providers via API 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(g)(9) Application access — all data request	1) Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token 2) Number of requests for a patient's Summary Record made by an application via an all data category request using a valid patient ID or token for a specific data range.	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the USCDI from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API 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(g)(10) Standardized API for patient and population services	Over a 90-day period: 1) Number of authorized Patient Applications 2) Number of authorized Provider Applications 3) Number of authorized Bulk Applications 4) Number of patient data requests	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	This criterion requires the ability of a certified Health IT module to respond to requests for patient data through FHIR standards from authorized/registered applications. We intend to record the frequency that data is requested via FHIR applications to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is that there will be a low utilization with a high success rate. 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(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise . Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

Interactive Testing

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available, either because:
• There is 0 adoption of the criteria in the real world, either due to unanticipated lack of interest or other factors. Where applicable, these factors are described below.
• There is good adoption of the criteria, but the certified capabilities were developed without anticipating the collection of metrics in mind, so real world demonstration of the criteria is provided to demonstrate that it functions in the real world.

User Story 1	**Care Coordination**
Care setting	Ambulatory Vision Care Providers (MDs, DOs, and ODs)
What is the workflow these features were intended to Support?	*• Patients receiving or involved in a Transition of care who then receive a summary of this activity • Practice/provider receives a Referral note via Direct Message which is then incorporated into a client chart • Practice/provider prescribes medications, via a single sign-on into a certified 3rd party certified vendor • Active patients whose charts were exported using the certified CDA format*
Who are the human actors in a real-world setting?	*Patient, clinical staff, provider*
What are the systems involved in the story?	*EyeMD EMR (Version 2), NewCrop*
What external modules or systems will you rely on?	*NewCrop for e-prescribing*
What are the criteria used within this workflow?	*• § 170.315(b)(1) Transitions of care • § 170.315(b)(2) Clinical information reconciliation and incorporation • § 170.315(b)(10) Electronic Health Information export*
Which parts of the criteria cannot be tested using summative testing?	*None*
What is the rationale for not being able to provide metrics/summative testing for these elements?	*None*
Do we need an additional user story or mini user story to demonstrate the rest of the criterion?	*None*
What is the best way to prove this workflow functions in the real world?	*Functional demonstration*
What are the expected results of the test?	*•< 60% of all Transitions of Care documents completed are then downloaded or sent via Edge Protocol (Note: 100% are available for review in the Patient Portal and API) •< 30% of all received Transfers are then incorporated into/transferred to the patient's chart •70% of agencies that prescribe are sending e-prescriptions via NewCrop •< 30% of all active cases have exported a Clinical Summary using the certified CDA format*

User Story 2	**Patient Engagement**
Care setting	Ambulatory Vision Care Providers (MDs, DOs, and ODs)
What is the workflow these features were intended to support?	Active patients who view and/or download their clinical information or upload information via a transmit to the Patient Portal
Who are the human actors in a real-world setting?	Patients
What are the systems involved in the story?	EyeMD EMR (Version 2)
> What external modules or systems will you rely on?	None
What are the criteria used within this workflow?	§ 170.315(e)(1) View, download, and transmit to 3rd party
Which parts of the criteria cannot be tested using summative testing?	None
What is the rationale for not being able to provide metrics/summative testing for these elements?	Not Applicable
Do we need an additional user story or mini user story to demonstrate the rest of the criterion?	None
What is the best way to prove this workflow functions in the real world?	Functional demonstration, collection of audit data showing access to portal as well as those who utilized functionality of portal.
What are the expected results of the test?	< 20% of patients with encounters between 1/1/2023 and 12/31/2023 accessed/viewed their summary information

User Story 3	**Electronic Exchange**
Care setting	Ambulatory Vision Care Providers (MDs, DOs, and ODs)
What is the workflow these features were intended to support?	
Who are the human actors in a real-world setting?	*Providers, clinical staff*
What are the systems involved in the story?	*EyeMD EMR (Version 2)*
> What external modules or systems will you rely on?	*Direct Messaging forwarded via Surescripts*
What are the criteria used within this workflow?	§ 170.315(h)(1) Direct Project
Which parts of the criteria cannot be tested using summative testing?	*None*
What is the rationale for not being able to provide metrics/summative testing for these elements?	*Not applicable*
Do we need an additional user story or mini user story to demonstrate the rest of the criterion?	*No*
What is the best way to prove this workflow functions in the real world?	*Functional Demonstration*
What are the expected results of the test?	100% of messages sent and received via a Direct messaging address

User Story 4	**API Usage**
Care setting	Ambulatory Vision Care Providers (MDs, DOs, and ODs)
What is the workflow these features were intended to support?	*• Requests for API access/configuration are received • Once connected, requests for client data via the API are received*
Who are the human actors in a real world setting?	*External HISP vendors, patients, Smart API vendors*
What are the systems involved in the story?	*EyeMD EMR (Version 2), Postmate*
> What external modules or systems will you rely on?	*Postmate*
What are the criteria used within this workflow?	*•§ 170.315(g)(7) Application access- patient selection •§170.315(g)(10) Standardized API •§ 170.315(g)(9) Application access- all data request*
Which parts of the criteria cannot be tested using summative testing?	*None*
What is the rationale for not being able to provide metrics/summative testing for these elements?	*Not applicable*
Do we need an additional user story or mini user story to demonstrate the rest of the criterion?	*No*
What is the best way to prove this workflow functions in the real world?	*Functional Demonstration*
What are the expected results of the test?	<30% of any API access/connections will have at least one request for client data

• **Care Settings**: All interactive testing will be performed for each of the care settings listed above.
• **Test Environment:** All interactive testing will be performed in a live, production environment. o Developer uses recorded GoToMeeting or LogMeIn Rescue for training and issues with existing clients in all care settings.
o The plan for interactive testing the criteria described below in the real world will be to engage with a Clinician in the Clinical Setting where the certified Health IT module is deployed as a representative sample to show that this certified capability works in the real world and that it works the same way in all settings.

• **Test Data**: Interactive testing will be performed using live patient data in the live production environment in order to be as representative as possible of real-world deployments. Precautions will be taken to reduce the risk of exposure of PHI. o Existing patients are already set up and regularly used in the live production environment for the purposes of training users and investigating issues.

Expected Outcomes

DEVELOPER will work with particular practices to gain access to system to remotely test API criterion.

Test user logs into test app as patient and looks up their test results. Test app queries the API that is available in the *provider's deployment.*

Test patients will be used, they will be set up in the clinic's EHR in advance.

Measurement/Metric	Expected Outcomes
170.315 (g)(7): Application Access - Patient Selection	Expected outcomes: • Patient ID is accepted, and token is returned • Patient USCDI or USCDI data is visible in the app as either discreet data fields or as a CCDA
(g)(10): Standardized API	
(g)(9): Application Access - All Data Request	

SCHEDULE OF KEY MILESTONES

Scheduling and logistics: Customer Service team will reach out to individual practices to identify those willing to work with EyeMD EMR Healthcare Systems to conduct testing. Scheduling to be completed by end of March 2025.

Data Collection: Majority of observation and data collection will be completed by June, with time allowed for individual practices that may experience delays.

Review & Collate data: Data review will be completed by end of September 2025.

Writing of Report: First draft of report to be prepared by end of October 2025, with team review prior to submission at end of 2025.

Real World test planning will commence in first quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur end of 2025/early 2026.

Key Milestone	Care Setting	Date/Timeframe
Scheduling & Logistics	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	90-days

Data collection	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	90-days
Review & Collate Data	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	90-days
Writing Report	Ambulatory Vision Care Providers (MDs, DOs, and ODs)	90-days

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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Date: November 7, 2024

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[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582