GENERAL INFORMATION

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

Developer Name: Binh Pham, Si Pham, Anthony Nguyen, Tom Bui

Product Name(s): Universal EHR

Version Number(s): 2.0.0

Certified Health IT Product List (CHPL) Product Number(s): 15.04.04.2478.Univ.02.00.1.180312

Developer Real World Testing Plan Page URL: https://www.universalehr.com/rwt/default.aspx

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing.[i]

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

We will utilize functional testing to demonstrate Real World Testing in an outpatient clinic care setting. We will operate with an outpatient clinic to demonstrate and test each measurement/module, we will be able to collect data to demonstrate the overall accuracy and functionality of the system. Measures with insufficient real world testing data will be internally tested to verify functionality.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Describe approach(es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ Identify standard versions
- ✓ Indicate what certification criteria in which product(s) has been updated
- ✓ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products
- ✓ CHPL Product Number for each Health IT Module
- ✓ Method used for standard update (e.g., SVAP)
- ✓ Date notification sent to ONC-ACB
- ✓ If SVAP, date notification sent to customers
- ✓ Measure used to demonstrate conformance with updated standard(s)
- ✓ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?

For calendar year 2025, we are not planning to make any version updates on approved standards through the SVAP process.

Standard (and version)	None
Updated certification criteria and associated product	N/A
Method used for standard update	N/A
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A
USCDI updated certification criteria (and USCDI version)	N/A

DESCRIPTION OF MEASUREMENT/METRIC

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description
Measure 1: Send Patient Health Information via Direct Messaging	Universal EHR uses EMR Direct as its direct messaging vendor to send and receive direct messages containing patient health information from other providers for transition and continuity of care events. This measure tracks how many CCDAs are generated and successfully sent from the EHR to a 3rd party using direct messaging over a given time period. Any errors will be recorded and analyzed.
Measure 2: Incorporating Patient Health Information via Direct Messaging	Patient data received including medication list, problem list and allergy list can be incorporated and updated into the patient's chart accordingly. The number of CCDAs successfully received from a 3rd party via direct messaging and incorporated into Universal EHR will be recorded . Any errors will be recorded and analyzed.
Measure 3: Number of Electronic Prescriptions Successfully Sent	Universal EHR uses NewCropRx as its electronic prescribing vendor for providers to send prescriptions electronically. This measure tracks the rate of successful prescription transmissions from the EHR to pharmacies over a given time period. Any errors will be recorded and analyzed.
Measure 4: Export Patient Data	Authorized users will be able to download and export patient data/clinical summaries through CCDA format, both individually and in batches of the patient population of a clinician. This measure tracks the rate of successful exports. Any errors will be recorded and analyzed.
Measure 5: Report of Clinical Quality Measures	Users will be able to generate a report of Clinical Quality Measures from the Universal EHR that will be reported to CMS during the MIPS reporting period. This measure tracks the rate of successful generation of these reports. Any errors will be recorded and analyzed.
Measure 6: Patient Portal Use	Patients are able to access the Universal EHR's patient portal to view their health information, lab and offsite results, and audit data of their patient chart. This measure will track how many patients have logged into the portal over a given time period compared to the total number of patients seen within the testing period.
Measure 7: Transmission to Immunization Registries	Patient immunization records are recorded in the EHR and an HL7 immunization message will be generated and sent directly to CAIR (California Immunization Registry). This measure will track the rate of successful transmission of immunization messages from the EHR to the immunization registry over a given time period.
Measure 8: Transmission to Public Health Agencies – Syndromic Surveillance	Users will be able to export syndromic surveillance information from the EHR and export them to the state's registry via HL7 files. This measure will track the rate of successful file creations and transmission. Any errors will be recorded and analyzed.

Measure 9: Transmission to Public Health Agencies – Electronic Case Reporting	The system is expected to maintain a table of trigger codes that is automatically detected within patient encounters to create and transmit case reports that include the encounter and provider information, diagnoses, and the row and version of the trigger table.
Measure 10: Compliance of API Resource Query Support	This measure is tracking compliance of the EHR Module criteria functionality of support of API query of patient health information. Users should be able to transmit the data of both single and multiple patients via the API.
Measure 11: Decision Support Intervention	Universal EHR The system will be able to utilize both evidence-based and AI-driven predictive DSIs as clinical decision support tools to assist with providers to make informed solutions. Source attributes applicable to predictive DSIs should be verified to determine if they are fair, appropriate, valid, effective, and safe.

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to the 2015 Cures Update criteria. If conformance to the criteria depends on any Relied Upon Software, this should be noted in your Real World Testing plan for any metrics that would involve use of that software in testing.

Measurement/Metric	Associated Certification Criteria	Relied Upon Software (if applicable)
Measure 1: Send Patient Health Information via Direct Messaging	170.315 (b)(1): Transitions of Care	PhiMail Server
Measure 2: Incorporating Patient Health Information via Direct Messaging	170.315 (b)(2): Clinical Information Reconciliation and Incorporation	
Measure 3: Number of Electronic Prescriptions Successfully Sent	170.315 (b)(3): Electronic Prescribing	NewCropRX
Measure 4: Export Patient Data	170.315 (b)(10): Electronic Health Information (EHI) Export	
Measure 5: Clinical Quality Measures	170.315 (c)(1): Clinical Quality Measures - Record and Export 170.315 (c)(2): Clinical Quality Measures - Import and Calculate 170.315 (c)(3): Clinical Quality Measures - Report	
Measure 6: Patient Portal Use	170.315(e)(1) View, download, and transmit to 3rd party	
Measure 7: Transmission to Immunization Registries	170.315 (f)(1): Transmission to Immunization Registries	
Measure 8: Transmission to Public Health Agencies – Syndromic Surveillance	170.315 (f)(2): Transmission to Public Health Agencies – Syndromic Surveillance	
Measure 9: Transmission to Public Health Agencies – Electronic Case Reporting	170.315 (f)(5): Transmission to Public Health Agencies – Electronic Case Reporting	

Measure 10: Compliance of API Resource Query Support	170.315(g)(7): Application access - patient selection 170.315(g)(9): Application access - all data request	PhiMail Server
Measure 11: Decision Support Intervention	170.315(b)(11): Decision Support Intervention	

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification
Measure 1: Send Patient Health Information via Direct Messaging	The ability to export electronic health information to other authorized organizations via direct messaging must be verified to be functional. This data should be received by the authorized and intended recipients.
Measure 2: Incorporating Patient Health Information via Direct Messaging	This measure allows authorized users to view transition of care summaries, and download and transmit them to other organizations, serving as another method of sharing EHI to other providers.
Measure 3: Number of Electronic Prescriptions Successfully Sent	Prescribing medications is an important aspect of health care and is a common form of treatment. The ability to send prescriptions electronically to patient's preferred pharmacy makes it more efficient for all parties involved. This measure will provide a numeric value on the success rate of prescription transmission from the EHR to pharmacies.
Measure 4: Export Patient Data	Batch data export enables authorized users to download data for multiple patients via CCDA and sending it to another care setting. This measure will provide a numeric value on the success rate of exporting patient data.
Measure 5: Report of Clinical Quality Measures	Providers enrolled in CMS (Medicare) are required to submit clinical quality measures for MIPS reporting annually. Users will generate a report from the EHR database that will satisfy the quality measure requirements to submit to CMS. This measure will provide a numeric value on the success rate of generating these reports.
Measure 6: Patient Portal Use	The use of patient portals enhances patient engagement by enabling patients to access their electronic medical records and facilitating secure patient-provider communication. This measure will provide a numeric value on how many patients logged into the portal and compare it to the number of patients seen over the same given time period.
Measure 7: Transmission to Immunization Registries	Some providers are required to report immunizations to their state immunization registry. This measure will provide a numeric value on the success rate of transmitting immunization messages via HL7 files from the EHR to the immunization registry.
Measure 8: Transmission to Public Health Agencies – Syndromic Surveillance	While Universal EHR has the capability to transmit HL7 messages and report to outside registries, to date we have not been asked to set up a real world connection to any such agency. In the meantime, we will conduct internal testing to ensure compliance.

Measure 9: Transmission to Public Health Agencies – Electronic Case Reporting	The transmission of case reports to public health agencies through trigger tables automates the process of notifying and informing local agencies that would have had to be done manually by staff otherwise.
Measure 10: Compliance of API Resource Query Support	Compliance of API resource query support is critical to ensure interoperability between different healthcare systems utilizing retrieving and querying health data effectively. Due to the low usage rate of our API by our clients and users, we will conduct real world testing using test patients to ensure compliance.
Measure 11: Decision Support Intervention	Utilization of evidence-based and predictive-based DSI (Decision Support Intervention) for patient in expectation of enhancing clinical decision-making must be tested and assessed to verify its accuracy, safety, and effectiveness within a real-world healthcare environment.

CARE SETTING(S)

The expectation is that a developer's Real World Testing plan will address each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification
Outpatient Clinic	Universal EHR markets and provides services to outpatient clinic settings only, and therefore will focus on an outpatient primary care clinic setting concerning Real World Testing.

EXPECTED OUTCOMES

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes
Measure 1: Send Patient Health Information via Direct Messaging	This measure will track the number of CCDA files sent electronically to third parties via direct messaging. The amount of successful transmissions of this information through direct messaging will be compared to the total amount of attempted transmissions.
Measure 2: Incorporating Patient Health Information via Direct Messaging	This measure will track the success rate of receiving patient health information from a 3rd party in CCDA format and incorporating the information into the patient's chart. Once the CCDA has been received and downloaded, it is expected that the user will reconcile the CCDA and update, at minimum, the medication and allergy lists in the patient's chart. This will produce numeric results and be reported over a 3-month period.
Measure 3: Number of Electronic Prescriptions Successfully Sent	It is expected that all prescribed medication should be created and transmitted to the pharmacy through NewCropRx with no issues. This measurement will track the success rate of the prescription transmission and produce a quantifiable result over the testing period.
Measure 4: Export Patient Data	It is expected that authorized users will be able to successfully download and export patient data for multiple patients at a time. This

	measurement will produce a numeric result on the successful exports of patient data by authorized users compared to the number of total exports initiated.
Measure 5: Report of Clinical Quality Measures	This measurement will track the success rate of generating and exporting such reports and produce numeric results over a given time period. It is expected that the Clinical Quality Measures (CQM) report will be generated and exported successfully without any errors.
Measure 6: Patient Portal Use	This measurement will track the number of patients who logged in to the portal and compare it to the number of patients seen during given time period. This will produce numeric results. It is expected that patients will be able to successfully log in to their patient portal to securely view, download or transmit their health information.
Measure 7: Transmission to Immunization Registries	This measurement will track the success rate of the immunization message transmission and produce numeric results over a 3-month period. It is expected that HL7 immunization messages will export successfully and be transmitted to CAIR (CA Immunization Registry) with no errors. The transmitted information is expected to match the information on the patient's chart and the information that will be displayed by CAIR.
Measure 8: Transmission to Public Health Agencies – Syndromic Surveillance	This measurement will track the success rate of the message transmission and produce numeric results over a 3-month period. We will conduct internal testing to ensure compliance by testing the capability to send HL7 messages containing syndromic data. It is expected that the HL7 messages will be exported and transmitted successfully without errors.
Measure 9: Transmission to Public Health Agencies – Electronic Case Reporting	We will conduct internal testing to ensure functionality and compliance in a testing environment as the outpatient clinic we are utilizing functional testing with currently has protocol to manually transmit encounters containing these triggers.
Measure 10: Compliance of API Resource Query Support	We expect that the API will return the appropriate data for the specific patient requested. Third party users will be given access to the EHR through a client application via the API. The user must enter in the correct credentials in order to access the patient data.
Measure 11: Decision Support Intervention	It is expected that users will be able to access and provide feedback to Decision Support Interventions when applicable in the case that a patient profile triggers a distinct active rule. We will track the number of active rules within the system and compare them to those that had an intervention triggered. Feedback data of triggered rules will be collected and commented on.

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Release of documentation of Real World Testing to be provided to authorized representatives and providers testing the measurements/metrics.	Outpatient Clinic	12/1/2024
Begin data collection for specified measures.	Outpatient Clinic	1/1/2025
Meet with providers and authorized representatives to ensure Real World Testing protocols are effective.	Outpatient Clinic	2/1/2025
Follow up with providers and authorized representatives regarding data collection.	Outpatient Clinic	Quarterly, 2025
Data collection and review.	Outpatient Clinic	Quarterly, 2025
End of Real World Testing period, finalize collection of all data for analysis.	Outpatient Clinic	1/1/2026
Analysis and report creation.	Outpatient Clinic	1/15/2026
Submit Real World Testing report.	Outpatient Clinic	2/1/2026

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.[ii]

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.

Authorized Representative Name: **Binh Pham**

Authorized Representative Email: **binhpham@universalehr.com**

Authorized Representative Phone: **(714) 799-5005**

Authorized Representative Signature: Binh Pham

Date: 10/29/2024