Real World Testing Plan 2025

ethizo

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INTRODUCTION

The 21st Century Cures Act Final Rule mandates that health IT developers of certified health IT test the real-world use of health IT for interoperability, as defined by the Certification Criteria. DocToMe, Inc. has prepared a comprehensive Real World Testing plan to test its certified Health IT, ethizo EHR - Version 2.0

The functionality and use cases included in this testing effort include all certification criteria under 45 C.F.R. § 170.315(b)(1)-(3),(b)(10), (c)(1)-(3), (e)(1), (f)(1)-(2), (f)(7), (g)(7), (g)(9), (g)(10), and (h)(1) to which is certified, specifically:

- (b)(1) Transitions of Care
- (b)(2) Clinical Information Reconciliation and Incorporation
- (b)(3) Electronic Prescribing
- (b)(10) Electronic Health Information (EHI) export
- (c)(1) Clinical Quality Measures (CQMs) – Record and Export
- (c)(2) Clinical Quality Measures (CQMs) – Import and Calculate
- (c)(3) Clinical Quality Measures (CQMs) – Report
- (e)(1) View, Download, and Transmit to 3rd Party
- (f)(1) Transmission to Immunization Registries
- (f)(2) Transmission to Public Health Agencies – Syndromic Surveillance
- (f)(7) Transmission to Public Health Agencies – Health Care Surveys
- (g)(7) Application Access – Patient Selection
- (g)(9) Application Access – All Data Request
- (g)(10) Standardized API for patient and population services
- (h)(1) Direct Project

Real World Testing will be conducted in the entire calendar year of 2025 for all applicable criteria, with the objective of collecting and reporting results derived directly from the real-world use cases and their associated measures.

Plan Report ID Number	20240923doc
Developer Name	DocToMe, Inc.
Product Name(s)	ethizo EHR
Version Number(s)	2.0
Certified Health IT Product List (CHPL) ID(s):	15.05.05.3060.DOTM.01.00.1.200107
Developer Real World Testing Page URL	https://www.ethizo.com/real-world-testing/

JUSTIFICATION OF REAL-WORLD TESTING

Ethizo EHR has developed an Ambulatory system to ensure the timely availability of patient information within a multi-specialty care setting. The goal of the application is to provide ambulatory services with a summary of their clinical visits, follow-up requirements based on the clinical visit, chief complaints, results, medications, diagnoses, and/or relevant education materials. Given the variety of specialties in multi-specialty care settings, the testing will include four representative settings to demonstrate the success of the interoperability criteria and certified functionality.

The selected specialties—Cardiology, Nephrology, Pediatrics, and Internal Medicine—represent scenarios where documentation must be coordinated between providers and patients, both within and outside of a healthcare organization. These specialties are linked to a significant number of patients, making them ideal candidates for real-world testing. Furthermore, several certification criteria can be tested simultaneously across these specialties.

The criteria involving the Consolidated Clinical Document Architecture (C-CDA) documents will be tested, including:

- Transitions of care (§ 170.315(b)(1))
- Clinical information reconciliation and incorporation (§ 170.315(b)(2))
- View, download, and transmit to third party (§170.315(e)(1))
- Application access - patient selection (§ 170.315(g)(7))

- Application access - all data request (§ 170.315(g)(9))
- Standardized API for patient and population services (§ 170.315(g)(10))

Health information will be provided to patients through a portal to allow the export of healthcare records and sharing between organizations.

Additionally, the selected specialties support the following criteria:

- § 170.315(b)(3) Electronic prescribing
- § 170.315(b)(10) Electronic Health Information (EHI) export
- § 170.315(f)(1) Transmission to immunization registries
- § 170.315(f)(2) Transmission to public health agencies – syndromic surveillance
- § 170.315(f)(7) Transmission to public health agencies — health care surveys
- § 170.315(c)(1) Clinical Quality Measures (CQMs) - Record and export
- § 170.315(c)(2) Clinical Quality Measures (CQMs) - Import and calculate
- § 170.315(c)(3) Clinical Quality Measures (CQMs) - Report
- § 170.315(h)(1) Direct Project

We are following a release rollout methodology for Real World Testing. In this approach, modules with all implemented certification criteria are deployed in a real environment, and use cases are run for the criteria. This methodology allows for the testing of all ONC-required criteria in a shorter timeframe.

The data and metrics collection for the RWT plan will be based on real patient data from the production environment. Logs will be reviewed to assess how often providers use the Ethizo EHR. The log data will include the length of time used to run queries and the data fields involved. Log files will be de-identified and analyzed in several areas, as outlined in the RWT plan.

STANDARDS UPDATES

Our product does not include any voluntary SVAP standards updates

MEASURES

Measure	Description	Certification Criteria
Completeness of sharing	This measure will catalogue the transport mechanisms used to demonstrate conformance to multiple certification criteria concerning the sharing	• § 170.315(b)(1) Transitions of care • § 170.315(e)(1) View, Download and Transmit to 3rd party • § 170.315(f)(1) Transmission to immunization registries • § 170.315(f)(2) Transmission to public health agencies – syndromic surveillance • § 170.315(f)(7) Transmission to public health agencies - • health care surveys
Clinical Quality	This measure will catalogue clinical quality measure to record, import, and export and calculate in a report to electronically create a data file for transmission of clinical quality measurement data.	• § 170.315(c)(1) Clinical Quality Measures (CQMs) - Record and export • § 170.315(c)(2) Clinical quality measures (CQMs) - import and calculate • § 170.315(c)(3) Clinical quality measures (CQMs) – report
API access	This measure will catalogue receive a request, respond to API requests with sufficient information to uniquely identify a patient, multiple patients and return a token that can be used by an application to subsequently execute requests for that patient's data.	• § 170.315 (g)(7): Application Access - Patient Selection • § 170.315 (g)(9): Application Access - All Data Request • § 170.315(g)(10) Standardized API for patient and population services
Communication	This measure will utilize for Direct communication for sending and receiving. The criteria which will demonstrate would be § 170.315(h) (1) Direct Project. (b)(3) Electronic Prescribing measure is tracking and counting how many NewRx electronic prescriptions were created and successfully sent from the ethizo EHR Module to DrFirst over the given interval. § 170.315(b)(10) allows patient or population in a format for ease of transfer and data sharing. test will assess the system's functionality across different care settings to	• § 170.315(h)(1) Direct Project • § 170.315(b)(3) Electronic Prescribing • § 170.315(b)(10) Electronic Health Information (EHI) export

	ensure seamless data export and interoperability with external systems.	
Completeness of response	This metric enables the receipt of a Clinical information reconciliation and incorporation formatted in accordance with the standards, must be able to demonstrate that the Clinical information reconciliation and incorporation received can be properly matched to the correct patient. It also demonstrates to see the volume of reconciliation and incorporation.	• § 170.315(b)(2) Clinical information reconciliation and incorporation

TEST PLAN

The following section details real world use cases for applicable certification criteria and their corresponding elements, namely, associated measures, care settings, justification of choice, test methodology and expected outcomes.

TEST CASE 1

Certification Criteria	**§ 170.315 (b)(1) Transitions of Care criterion**
Measure/Metric	Completeness of sharing
Care Settings	Nephrology
Relied Upon Software	HISP Direct
Justification	This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a C-CDA patient summary record, including ability to record all clinical data elements, and by sending the C-CDA patient summary record, the EHR demonstrates successful interoperability of an exchanged patient record with a 3rd party. This measurement shows support for Direct Edge protocol in connecting to a HISP for successful/unsuccessful transmission.
Test Methodology	The ethizo logs and system/DB logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export/import. This test methodology will primarily test the exchanging transition of care documents.
Expected Outcomes	This measure will track number of C-CDA files sent electronically via HISP either successfully or unsuccessful and track the Error rates. The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, to determine our measure count. We will report the numbers of C-CDAs sent over a three (3) month period A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the C-CDA patient summary record, including record required clinical data elements. In sending the CCDA patient summary record, the EHR will demonstrate ability to confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience. We will also track the unsuccessful files and Error rates will be tracked. We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

TEST CASE 2

Certification Criteria	**§ 170.315(b)(2) Clinical information reconciliation and incorporation**
Measure/Metric	Completeness of response
Care/ Practice Settings	Internal Medicine
Relied Upon Software	NA
Justification	This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can receive a C-CDA patient summary record, and by incorporating the C-CDA patient summary record, the EHR demonstrates successful/unsuccessful interoperability of problems, medications, and medication allergies of patient record.
Test Methodology	The tester will identify a user that has received and incorporated a transition of care/referral summary document into the ethizo EHR. Once identified, the tester will visually confirm the following: • The document was matched with the correct patient • The user was able to reconcile data from the document and merge that data into the patient's Medication List, Medication Allergy List, and Problem List. ethizo logs will be identified and then analyzed to evaluate system's success and failure ratio.
Expected Outcomes	The measurement will produce numeric results over a given time frame interval. We will utilize various reports and audit logs, to determine measure count. If any errors or very low numeric counts are encountered, we will investigate further. We will capture this information from our system over a period of a minimum of three (3) months to provide an accurate sample of real world interoperability. A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the EHR can receive a C-CDA patient summary record. In incorporating the C-CDA patient summary record, the EHR will demonstrate successful interoperability of problems, medications, and medication allergies of patient record. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality. For unsuccessful files reconcile/incorporation an error rates will be tracked and trended over time. We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts

TEST CASE 3

Certification Criteria	**§ 170.315(b)(3) Electronic Prescribing**
Measure/Metric	Communication
Care/ Practice Settings	Cardiology
Relied Upon Software	DrFirst v4
Justification	This measure is intended to provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the ethizo EHR can create a NewRx electronic prescription message and transmit it to DrFirst v4.
Test Methodology	Logs generated by physician's prescription activities during the real world Testing will be used to analyze the structural validity of the messages created for interoperability between ethizo EHR and the DrFrist, reliability of established transportation mechanism, and utilization rates of implemented NewRx prescription transaction.
Expected Outcomes	The measurement will produce numeric results over a given interval. We will utilize reports/ audit logs, to determine (b)(3) measure count for successful prescription transaction. ethizo EHR real world testing audit report will also count error rates and it will be tracked and trended over time.

TEST CASE 4

Certification Criteria	**§ 170.315(b)(10) Electronic Health Information (EHI) Export**
Measure/Metric	Communication
Care/ Practice Settings	Internal Medicine
Relied Upon Software	NA
Justification	The § 170.315(b)(10) criterion is critical for ensuring the system's capability to facilitate the transfer and portability of Electronic Health Information. This function supports patient access to their health data and promotes interoperability by enabling healthcare providers to easily export and share comprehensive patient records with external systems. Testing across multiple specialties ensures that the functionality is robust and reliable in real-world scenarios where data transfer is essential.
Test Methodology	• The testing will be conducted in a production environment using real patient data. • Logs will be reviewed to monitor the frequency of export requests and the time taken for completion. • Test cases will simulate requests for both individual and population-level EHI exports. • De-identified patient data will be used to validate the accuracy and completeness of the exported information. • Compatibility of exported data will be checked by importing it into external systems to ensure compliance with standards for data exchange.
Expected Outcomes	• The system will successfully generate and export EHI for both individual patients and populations in a timely manner. • The exported data will be complete, accurate, and properly formatted to meet interoperability standards. • The system will support multiple specialties and care settings, demonstrating versatility in EHI export functionality. • Logs will indicate consistent and reliable export performance, with minimal errors or delays in data generation.

TEST CASE 5

Certification Criteria	**§ 170.315(c)(1) Clinical Quality Measures (CQMs) - Record and export** **§ 170.315(c)(2) Clinical quality measures (CQMs) - import and calculate** **§ 170.315(c)(3) Clinical quality measures (CQMs) – report**
Measure/Metric	Clinical Quality
Care/ Practice Settings	Pediatric and Internal Medicine
Relied Upon Software	NA
Justification	We are using the following Quality Measures for RWT CMS 123: Diabetes: Foot Exam. This measure will provide a count and list of electronic clinical quality measures (eCQMs) which are calculated and submitted to CMS for a given program, like MIPS. Clinical quality measures are only used for the respective CMS programs and any production measures should utilize submission to CMS. Because CQM criteria, 315(c)(1)-(c)(3), all work collectively together in the eCQM functionality of the EHR Module, this measurement is used for all three.
Test Methodology	The tester will evaluate the reports generated QRDA I and QRDA III by real-world users. The tester will identify the measures used by the customer and report how many files were generated for each measure. These (c)(1), (c)(2), (c)(3) measures will be triggered to track both, clinicians' click actions and system's responses when recording, importing, calculating and exporting CQM data
Expected Outcomes	The measurement will a count and list of eCQMs submitted to CMS over a given interval. We will ask our customer users to report on the number eCQMs they successfully and unsuccessful reported on to CMS which reveals compliance to the associated criteria listed above. A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the EHR can do calculations on the eCQM and that they are accepted by CMS. An unsuccessful measure submission indicates system errors which will be tracked and trended over time. We designed this measure to test general ambulatory sites that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

TEST CASE 6

Certification Criteria	**§ 170.315 (e)(1) View, Download, and Transmit to 3rd Party and export**
Measure/Metric	Completeness of sharing
Care/ Practice Settings	Cardiology
Relied Upon Software	NA
Justification	By performing logs audit on the Patient Portal, this approach is intended to verify that patients are able to access their health information according to the (e)(1) View, Download, and Transmit to 3rd Party and export criterion. Looking at the database level and logs will enable ethizo to identify any errors when patients attempted to view, download, or transmit their health information.
Test Methodology	The tester will identify a customer who has given ethizo PHR (Patient Portal) access to the patients. The tester will determine the number of patients (for a single customer) who accessed the Patient Portal and were able to successfully view, download, or transmit their health information. The tester will also verify that the appropriate logging for each action is recorded by the EHR.
Expected Outcomes	The ethizo report and system/DB logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test that the functionalities identified in the above criteria perform without an error. Error rates will be tracked and trended over time.

TEST CASE 7

Certification Criteria	**§ 170.315 (f)(1) Transmission to Immunization Registries** **§ 170.315(f)(2) Transmission to public health agencies – syndromic surveillance** **§170.315(f)(7) Transmission to public health agencies - health care surveys**
Measure/Metric	Completeness of sharing
Care/ Practice Settings	Internal Medicine
Relied Upon Software	NA
Justification	The measure completeness of Sharing will track the system's ability to transmit the health information to immunization registries, syndromic surveillance reporting and public health agency reporting in required formats. Based on the system generated logs; system will evaluate the success and error rates for the transmission.
Test Methodology	The tester will use the methodology to track status logs to electronic transactions and audit logs either the data was transmitted successfully, unsuccessful through outbound and inbound electronic channels.
Expected Outcomes	The ethizo report and system/DB logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing keep track that the users are able to submit data to registries and receive a response from the registry acknowledging that the message was successfully received or not. System will also track the failure of above criteria. Error rates will be logged and trended over time.

TEST CASE 8

Certification Criteria	**170.315(g)(7) patient selection** **170.315(g)(9) all data request**
Measure/Metric	API access
Care/ Practice Settings	Nephrology and Pediatric
Relied Upon Software	NA
Justification	To ensure secure and authorized access to individual patients' Electronic Health Information (EHI) through the Ethizo custom API. This measure will track and monitor third-party developers' usage of these APIs, with a focus on patient selection and data access, whether it's a specific data category or the entirety of the data.
Test Methodology	Ethizo EHR will maintain comprehensive logs of all incoming API requests for patient data access, including their respective responses. These logs will undergo de-identification and serve as valuable resources for multifaceted analysis. This analysis encompasses aspects such as requester authentication, the utilization rates of available API endpoints, and the accuracy of responses. The purpose is to ensure the correct functionality of the APIs. In cases where we observe low adoption of any of the certified criteria mentioned above, the system's compliance will be further assessed. This assessment will include the use of synthetic data and ONC-approved testing tools in conjunction with real-world usage logs, thus ensuring the integrity and effectiveness of the system.
Expected Outcomes	We anticipate infrequent data access issues, and the functions outlined in the criteria above are expected to operate smoothly without errors.

TEST CASE 9

Certification Criteria	**170.315(g)(10) Standardized API for patient and population services**
Measure/Metric	API access
Care/ Practice Settings	Internal Medicine
Relied Upon Software	NA
Justification	Ethizo EHR provides access to specific patient data through the FHIR® interfaces, this will provide a metric on the use of FHIR® APIs to access patient data. Additionally, credentialing requirements will be tested indirectly, as only authorized users will have access to the patient's data. This will be further verified through the review of the log files.
Test Methodology	Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of § 170.315(g)(10) "Standardized API for patient and population services." For FHIR® APIs, this includes proper credentialing and validation that all required USCDI data elements are supported.
Expected Outcomes	• The API will successfully handle patient and population-level data requests. • Data exported via the API will be accurate, complete, and provided in a timely manner. • The system will demonstrate consistent performance in terms of response times and error rates. • An increase in patient and third-party application engagement with the system through API access. • The system will meet regulatory requirements for API performance, security, and data standardization. This testing will confirm the ability of the standardized API to support patient and population services effectively, ensuring full interoperability across healthcare systems.

TEST CASE 10

Certification Criteria	**§ 170.315(h)(1) Direct project**
Measure/Metric	Communication
Care/ Practice Settings	Nephrology
Relied Upon Software	HISP Direct
Justification	This measure will track Direct communication for sending and receiving. This metric will provide information on number of times sending and receiving the direct message and total number of patient and the frequency of usage.
Test Methodology	The ethizo logs and system/DB logs will be reviewed for each period to determine the frequency of use. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the sending and receiving. This test methodology will primarily test the conformance of the implementation
Expected Outcomes	Using ethizo EHR, It is expected that the measure identified above shall perform as per requirements to demonstrate conformance to § 170.315(h)(1) Direct project, with a substantial percentage of users able to securely exchange EHI with other trusted providers and parties. Success and failure logs will be maintained to track the behavior of the measure implemented.

KEY MILESTONES

Key Milestone	Care Setting	Date/Time frame
Release of documentation for the Real World Testing and submitted to SLI Compliance	Cardiology, Nephrology, Pediatric and Internal Medicine	October 15,2024
Begin collection of information as laid out by the plan	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2025
Onboarding selected providers/organizations to facilitate Real World Testing plan.	Cardiology, Nephrology, Pediatric and Internal Medicine	2nd Quarter 2025
Follow-up with providers and authorized representatives to understand any issues arising with the use of functionality	Cardiology, Nephrology, Pediatric and Internal Medicine	2nd Quarter, 2025
Data collection and review	Cardiology, Nephrology, Pediatric and Internal Medicine	3rd Quarter, 2025
End of Real World Testing period/final collection of all data for analysis.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2026
Analysis and report creation.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 5, 2026
Submit Real World Testing report	Cardiology, Nephrology, Pediatric and Internal Medicine	January 12, 2026

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: September 23, 2024