ethizo

Real World Testing Plan

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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 2015 Edition 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), (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)(6) Data 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 2023 for all applicable criteria, with the objective of collecting and reporting results derived directly from the real world use cases and their associated measures.

GENERAL INFORMATION

Plan Report ID Number	20221104doc
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://ethizo.com/real-world-testing/

JUSTIFICATION OF REAL WORLD TESTING

eithzo EHR has developed an Ambulatory system to ensure the timely availability of patient information within the multi-specialty care setting. The goal of the application is to provide ambulatory services with a synopsis of their clinical visits, follow-up requirements based upon the clinical visit, chief complaints, results, medications, diagnosis and/or relevant education materials. Multi-specialty care settings may have many different combinations of specialties, so this testing will include 4 settings that are representative of the certified functionality and demonstrate the success of the interoperability criteria. Since Cardiology, Nephrology, Pediatric and Internal Medicine specialties represent all settings where documentation needs to be coordinated between providers and patients both within and outside of a healthcare organization and large number of patients are linked with the specialties selected for the real world testing. In addition, while examining these specialties; there are several certification criteria that can be tested simultaneously for Real World Testing.

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)); Data export § 170.315(b)(6); View, download, and transmit to 3rd party (§ 170.315(e)(1)); § 170.315(g)(7) Application access - patient selection, Application access all data request (§ 170.315(g)(9)) and (§ 170.315(g)(10)) Standardized API for patient and population services. Health information provided to the patient through a portal to export of patient healthcare records and shared between organizations.

Additionally, Cardiology, Nephrology, Pediatric and Internal Medicine specialty does support criterion

- § 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

Application access- all data request does support the export of patient data. So, Real World Testing has been included for these measures.

We are following release rollout methodology for Real World Testing. In this methodology, modules with all certification criteria implemented are deployed on real environment and we run use cases for criteria. Advantage of this methodology is that all ONC required criteria(s) for measures are deployed at once and can be tested in shorter period of time. The factors that will be used for data and stats collection in the Real World Plan metrics will be driven from real patient data from production environment. Logs will be reviewed to determine how often providers use the ethizo EHR, embedded in the log data (for the purposes of Real World Testing) will be the length of time used to run the queries and the data fields used for the query. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas, which are mentioned in RWT plan.

STANDARDS UPDATES

Standard (and version)	All standards versions are those specified in the 2015 Edition
Updated certification criteria and associated product	Not Applicable
Health IT Module CHPL ID	15.05.05.3060.DOTM.01.00.1.200107
Method used for standard update	Not Applicable
Date of ONC-ACB notification	Not Applicable
Date of customer notification (SVAP only)	Not Applicable
Conformance measure	Not Applicable
USCDI-updated certification criteria (and USCDI version)	Not Applicable

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(b)(6) Data export • §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(h)(1) Direct Project • § 170.315(b)(3) Electronic Prescribing
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	• § 170.315(b)(2) Clinical information reconciliation and incorporation

	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.	

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	Cardiology, Nephrology, Pediatric and Internal Medicine
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 C-CDA 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	Cardiology, Nephrology, Pediatric and 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, Nephrology, Pediatric and Internal Medicine
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)(6) Data export**
Measure/Metric	Completeness of sharing
Care/ Practice Settings	Cardiology, Nephrology, Pediatric and Internal Medicine
Relied Upon Software	NA
Justification	The measure is intended to ensure that the number of transactions through CCCDA files, along with the success and failure rate, for each scenario listed in the (b)(6) Data export testing method. This approach is intended to demonstrate the real-world volume of Data Portability files that are processed by ethizo EHR v2.0
Test Methodology	The real world testing method for (b)(6) Data Export is based on the ethizo EHR v2.0 Data Portability testing procedure. For this criterion, the objective is to verify if customers can create a data export file. The tester will analyze a user's EHR/database to determine when the customer used the Data Export functionality to generate a C-CDA document and under what circumstances (e.g., real-time, scheduling, date range). Once identified, the tester will report the number of successful and unsuccessful transactions under each scenario.
Expected Outcomes	It is expected that the data export file (C-CDA) was successfully generated for each of the scenarios • Listed in the testing method • On real-time/on-demand • Specific date range defined by the user In case if any error arises, system will count the error rates and it will be tracked, trended over time.

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	Cardiology, Nephrology, 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 byreal-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, Nephrology, Pediatric and Internal Medicine
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 errors. 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	Cardiology, Nephrology, Pediatric and 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)(10) Standardized API for patient and population services**
Measure/Metric	API access
Care/ Practice Settings	Cardiology, Nephrology, Pediatric and 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	It is expected that data access issues are rare and that the functionalities identified in the above criteria perform without errors. Error rates will be tracked across these functions as part of a base line for the initial testing year.

TEST CASE 9

Certification Criteria	**§ 170.315(h)(1) Direct project**
Measure/Metric	Communication
Care/ Practice Settings	Cardiology, Nephrology, Pediatric and Internal Medicine
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/Timeframe
Release of documentation for the Real World Testing and submitted to SLI Compliance	Cardiology, Nephrology, Pediatric and Internal Medicine	October 15,2022
Begin collection of information as laid out by the plan.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2023
Onboarding selected providers/organizations to facilitate Real World Testing plan.	Cardiology, Nephrology, Pediatric and Internal Medicine	2nd Quarter 2023
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, 2023
Data collection and review	Cardiology, Nephrology, Pediatric and Internal Medicine	3rd Quarter, 2023
End of Real World Testing period/final collection of all data for analysis.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2024
Analysis and report creation.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 5, 2024
Submit Real World Testing report	Cardiology, Nephrology, Pediatric and Internal Medicine	January 10, 2024

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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