REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20211027doc

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 FOR REAL WORLD TESTING APPROACH

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 these two specialties, they have been selected for the real world testing. In addition, in 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 data category request§ 170.315(g)(8); Application access all data request" (§ 170.315(g)(9)). 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 used ONC required criteria(s) for measures are deployed at once and user can test them in shorter period of time. The factors that will use 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 (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

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 USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

Measurement/Metric	Description
Measure 1: Completeness of sharing	This measure will catalogue the transport mechanisms used to demonstrate conformance to multiple certification criteria concerning the sharing of §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 demonstrated single patient and population services. Data derived from: Care Settings/ Specialty:

	Total Number of Patients: Outcomes of sharing real patient(s) data (Success): Outcomes of sharing real patient(s) data (Failure): Number of error logs while sharing: Shared Successfully ratio %:
Measure 2: Clinical Quality	This measure will catalogue clinical quality measure to record, import, export and calculate in a report to electronically create a data file for transmission of clinical quality measurement data. It may include codified expressions of "patient reason," "system reason," or "medical reason." The criteria to demonstrate are §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 Data derived from: Care Settings/ Specialty: Reporting Period: Measure Description: Performance Rate: No. of IPP: No. of Denominator: No. of Exclusion: No. of Numerator: No. of Exceptions:
Measure 3: 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. Data derived from: Care Settings/ Specialty: Total Number of Patients: No. of requests received for direct communication. No. of requests sent through direct communication. Error logs while sending: Error logs while receiving: Success rate while send/receiving the Direct messages.
Measure 4: Conformance to API for Application access	This measure will catalogue receive a request, respond to requests with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. The criteria to demonstrate are § 170.315(g)(7) Application access - patient selection, § 170.315(g)(8) Application access – data category request and § 170.315(g)(9) Application access- all data request. Data derived from: Care Settings/ Specialty: Total Number of Patients: No of requests received: No of responses: Successfully interact with the API and process its response:

	Number of error logs while API connections: Successfully interact with the API ratio %:
Measure 5: 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 demonstrate to see the volume of reconciliation and incorporate. Data derived from: Care Settings/ Specialty: Total Number of Patients: No of files reconcile successfully: No of files incorporate successfully: No of Error logs while reconcile and incorporate: Success %:

ASSOCIATED CERTIFICATION CRITERIA

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria
Measure 1: Completeness of 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
Measure 2: Clinical Quality	§ 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 3: Communication	§ 170.315(h)(1) Direct Project
Measure 4: Conformance to API for Application access	§ 170.315(g)(7) Application access - patient selection
	§ 170.315(g)(8) Application access – data category request
	§ 170.315(g)(9) Application access- all data request
Measure 5: Completeness of response	§ 170.315(b)(2) Clinical information reconciliation and incorporation

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

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

Measurement/Metric	**Justification**
Measure 1: Completeness of sharing	This measure will catalogue the transport mechanisms used to demonstrate conformance to multiple certification criteria concerning the sharing of §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 demonstrated single patient and population services. This metric will provide information on the type of data exported 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 export. This test methodology will primarily test the conformance of the implementation.
Measure 2: Clinical Quality	This measure will catalogue clinical quality measure to record, import, export and calculate in a report to electronically create a data file for transmission of clinical quality measurement data. It may include codified expressions of "patient reason," "system reason," or "medical reason." **Test Methodology:** The ethizo EHR will display a report in which calculations against each measure will display based on given reporting period.
Measure 3: Communication	This measure will utilize for 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.
Measure 4: Conformance to API for Application access	This measure will catalogue and demonstrate to multiple criterion § 170.315(g)(7) Application access - patient selection, § 170.315(g)(8) Application access – data category request, § 170.315(g)(9) Application access- all data request; when system identified API receive a request, respond to requests with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. This metric will provide information on the type of data exported 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 API request, response and failure. This test methodology will primarily test the conformance of the implementation.
Measure 5: 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 demonstrate to see the volume of reconciliation and incorporate. **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 receiving. This test methodology will primarily test the conformance of the implementation.

CARE SETTING(S)

Care Setting	Justification
Ambulatory Care	The ethizo EHR for multi-specialty ambulatory care setting and deals with multispecialty. In Real World Testing we will use Cardiology, Nephrology, Pediatric and Internal Medicine because of major usage the health care providers have access to complete and accurate information, patients receive better medical care. With ethizo EHR Cardiology, Nephrology, Pediatric and Internal Medicine specialty, providers can have reliable access to a patient's complete health information, reduce errors, improve patient safety, and support better patient outcomes

EXPECTED OUTCOMES

Measurement/Metric	Expected Outcomes
Measure 1: Completeness of sharing	**§170.315(e)(1) View, Download and Transmit to 3rd party** 1) Patients and their authorized representatives can view, download, and transmit their health information to a 3rd party via internet-based technology. 2) The health IT must allow patients (and their authorized representatives) to view, laboratory test report(s); and diagnostic image reports. Additionally, patients (and their authorized representatives) must be able to view for specific settings: 3) Patients (and their authorized representatives) must be able to transmit the CCD summary created both (1) email transmission to any email address; and (2) an encrypted method of electronic transmission. 4) For all of the provisions (i.e. View, Download, and Transmit capabilities), patients and their authorized representatives must be able to select data associated with a specific date and select data within an identified time range. 5) For all of the provisions (i.e., View, Download, and Transmit capabilities), patients (and their authorized representatives) must be able to access information regarding the action (view, download, or transmit) that occurred, the date and time each action occurred using Network Time Protocol, the user who took the action, and the addressee to whom the summary was transmitted. 6) Errors in view, download transmission will be tracked and analyzed. **§ 170.315(b)(6) Data export** 1) Enable a user to create export summaries using the Continuity of Care Document document template that includes, at a minimum: The Common Clinical Data Set.

	2) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information. 3) Enable a user to set the date and time period within which data would be used to create the export summaries. This must include the ability to enter in a start and end date and time range. 4) Enable a user to set the storage location to which the export summary or export summaries are intended to be saved. **§170.315 (b)(1) Transitions of care** 1) Send and receive via edge protocol 2) Validate and display 3) Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards. **§170.315 (f)(1) Transmission to immunization registries** 1) Create immunization information for electronic transmission in accordance with administered and historical vaccines. 2) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry. **§170.315 (f)(2) Transmission to public health agencies – syndromic surveillance** Syndrome-based public health surveillance information for electronic transmission. **§170.315(f)(7) Transmission to public health agencies - health care surveys** Create health care survey information for electronic transmission in accordance with the standards.
Measure 2: Clinical Quality	1) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.” 2) Export. A user must be able to export a data file at any time the user chooses and without Ethizo EHR developer assistance to operate: a. Formatted in accordance with the standard b. Ranging from one to multiple patients; and c. That includes all of the data captured for each and every CQM to which Ethizo EHR was certified. 3) Import. Enable a user to import a data file for one or multiple patients and use such data to perform the capability. 4) Calculate each and every clinical quality measure for which it is presented for certification. 5) Enable a user to electronically create a data file for transmission of clinical quality measurement data

Measure 3: Communication	1) Applicability Statement for Secure Health Transport. Able to send and receive health information in accordance with the standard, including formatted only as a "wrapped" message. 2) Delivery Notification in Direct.
Measure 4: Conformance to API for Application access	1) It is expected to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. 2) Respond to requests for patient data (based on an ID or other token) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in a computable format. 3) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range. 4) Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in §170.205(a)(4) following the CCD document template. 5) Based on the log files, it is expected that the number of population 6) service applications connected to certified API technology increase over time, the following information can be derived: 7) Access to the sets of data elements used for the query/return, the total number of Data Access requests made, and the duration of the query/return. It is expected that access to the data elements is accurate and complete, that the total number of requests increases over time, and the duration of the query/return does not increase over time.
Measure 5: Completeness of response	1) Upon receipt of a transition of care/referral summary formatted according to the standards, technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient. 2) Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type: a. Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date. b. Enable a user to create a single reconciled list of each of the following: Medications; medication allergies; and problems. c. Enable a user to review and validate the accuracy of a final set of data. d. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s): i. Medications. At a minimum, the version of the standard specified in §170.207(d)(3); ii. Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(3); and

	iii. Problems. At a minimum, the version of the standard specified in §170.207(a)(4). 3) System verification. Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in §170.205(a)(4) using the Continuity of Care Document template.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Release of documentation for the Real World Testing to be provided to authorized representatives and providers running the ethizo EHR. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	Cardiology, Nephrology, Pediatric and Internal Medicine	October 15,2021
Begin collection of information as laid out by the plan.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2022
Meet with previously identified providers and authorized representatives to ensure that Real World Testing protocols are effective.	Cardiology, Nephrology, Pediatric and Internal Medicine	1st Quarter 2022
Follow-up with providers and authorized representatives to understand any issues arising with the data collection.	Cardiology, Nephrology, Pediatric and Internal Medicine	2nd Quarter, 2022
Data collection and review	Cardiology, Nephrology, Pediatric and Internal Medicine	3rd Quarter, 2022
End of Real World Testing period/final collection of all data for analysis.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 1, 2023
Analysis and report creation.	Cardiology, Nephrology, Pediatric and Internal Medicine	January 5, 2023
Submit Real World Testing report to SLI Compliance (per their instructions)	Cardiology, Nephrology, Pediatric and Internal Medicine	January 15, 2023

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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