Real World Testing Plan

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General Information

Developer Name:	OT EMR Inc.
Product Name(s):	OneTouch EMR
Version Number(s):	3
Certified Health IT Product List (CHPL) ID(s):	15.04.04.2821.OneT.03.00.1.180411
Developer Real World Testing Page URL:	https://www.onetouchemr.com/mu_disclosure.html

Justification For Real World Testing Approach

Currently, OneTouch EMR is marketed and sold in the ambulatory care settings for out patients only. For this reason, the Real World Testing plan will apply to this specialty care setting only. This Real World Testing plan of OneTouch EMR is for the following certification criteria for which OneTouch EMR is currently certified.

Care Coordination

§ 170.315(b)(1) Transitions of care
§ 170.315(b)(2) Clinical information reconciliation and incorporation
§ 170.315(b)(3) Electronic prescribing
§ 170.315(b)(6) Data export

Clinical Quality Measures

§ 170.315(c)(1)—record and export
§ 170.315(c)(2)—import and calculate
§ 170.315(c)(3)—report

Patient Engagement

§ 170.315(e)(1) View, download, and transmit to 3rd party Public Health

Application Programming Interfaces

§ 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

Electronic Exchange

§ 170.315(h)(1) Direct Project

Public Health Reporting

§170.315(f)(1) Transmission to immunization registries

Scenario 1 - Patient Data Services

Since OneTouch EMR works with ambulatory care settings, it provides functions to import, export and transmit clinical documents to third parties. Due to this, there are several certification criteria that can be tested simultaneously. All criteria involving the Consolidated Clinical Document Architecture (C-CDA) documents will be tested, including § 170.315(b)(1) Transitions of care, § 170.315(e)(1) View, download, transmit to 3rd party and § 170.315(h)(1) Direct Project and § 170.315(b)(6) Data export.

These criteria are met using the Kno2 and SurescriptsHISP as relied upon software to perform patient data services in both use cases (1a and 1b).

Use Case 1a - Patient Service

As OneTouch provides functions to import, export and transmit clinical documents to third parties therefore it is used in situations where documentation needs to be coordinated between providers and patients both within and outside of a healthcare organization. The shared documentation includes transitions of care documents, healthcare plan documents, health information provided to the patient through a portal, and the export of patient healthcare records. The transitions of care documents are shared between organizations using Edge protocol technology (Direct, SMTP email) and with the patient through a portal with the ability to view, download, and transmit. Additionally, the patient's health information can be shared with external organizations using an export function.

Use Case 1b - Data Export Service

Additionally, OneTouch supports the export of data in C-CDA format for a population of patients. This is useful in scenarios such as migration of the document system, or a research request, the Certified Health IT Module is capable of exporting the health information for the patient population.

Scenario 2 - Referrals

OneTouch EMR provides an “Application Programming Interface” API to providers to look up a patient's record and access patient data when a Transition of Care document or a Referral Note is received. OneTouch can also receive transition of care/referral summary documents formatted according to the standards adopted § 170.205(a)(3) and § 170.205(a)(4) and incorporate them into the correct patient chart. This function is part of the referrals functionality of OneTouch where a provider can refer a patient electronically to a different practice/health facility as well as receive the patient data electronically and incorporate it into existing patient record.

Use Case 2a - Referrals Send

A referring doctor (outside OneTouch) might want to look up a patient's record when a Transition of Care document or a Referral Note is received. OneTouch EMR provides an “Application Programming Interface” API to providers for accessing patients data along with publicly available documentation and developer policies/agreements. The API provides access to patients data based on patient ID or token and returns a full set of data or requested data set only which is based on Common Clinical Data Set. API also responds back with patient data associated with a specific date as well as with a specific date range.

The goal of this approach is to demonstrate that OneTouch certified API technology must be able to respond to requests for patient data for more than 95% of the time and response data is consistent with the requirements of the § 170.315(g)(7, 9-10) certification criterion.

Use Case 2b - Referrals Receive

OneTouch can also receive transition of care/referral summary documents formatted according to the standards adopted § 170.205(a)(3) and § 170.205(a)(4) and incorporate them into the correct patient chart. This function is part of the referrals functionality of OneTouch where a provider can refer a patient electronically to a different practice/health facility as well as receive the patient data electronically and incorporate it into existing patient record.

Use Case 3 - MIPS Reporting

OneTouch EMR provides Clinical Quality Measures (CQM) which are used for MIPS to measure the quality of health care provided. OneTouch provides functionality to record and export data that would be necessary to calculate each CQM for which OneTouch is certified. OneTouch also provides a function to export patient-level eCQM data formatted to the HL7 QRDA Category I standard specified at §170.205(h)(2) that includes all of the data captured for each and every eCQM without the developer assistance.

All of the above functionality will be tested against these Clinical Quality Measures criteria i.e. § 170.315(c)(1)—record and export, § 170.315(c)(2)—import and calculate and § 170.315(c)(3)—report.

Use Case 4 - Electronic Prescribing

OneTouch provides an Electronic Prescribing or eRX module which enables user to create electronic prescriptions in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(2) and send them to the pharmacy. OneTouch also respond to change prescriptions (RxChangeRequest, RxChangeResponse), cancel prescriptions (CancelRx, CancelRxResponse) and renew prescriptions (RxRenewalRequest, RxRenewalResponse). Further, OneTouch relays back transaction status or error messages and verify transactions as per (b)(3)(ii)(A)(7) and (b)(3)(ii)(A)(8) and (b)(3)(ii)(A)(9).

All of the above functionality will be tested for real world interoperability and conformance as per the criteria related to § 170.315(b)(3) Electronic prescribing.

These criteria are met using the Surescripts eRx and MDToolbox, as relied upon software to perform electronic prescribing in this use case.

Use Case 5 - Public Health Reporting OneTouch provides a public health reporting module which enables users to create and send immunization data to immunization registries in accordance with (f)(1)(i)(A) standard defined in § 170.205(e)(4), (f)(1)(i)(B) standard specified in § 170.207(e)(3) for historical vaccines and (f)(1)(i)(C) § 170.207(e)(4) for administered vaccines.Further, it enables user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4). All of the above functionality will be tested for real world interoperability and conformance as per the criteria related to § 170.315(f)(1) Transmission to immunization registries.

Standards Updates (SVAP and USCDI)

Standard (and version)	All standard versions are those specified in USCDI v1.
Date of ONC ACB notification	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI updated certification criteria	None

Care Setting(s)

Ambulatory Care Setting: The Certified Health IT Developer, OT EMR Inc., markets its Modules in ambulatory care settings only, so this is the only care setting in which Real World Testing will occur.

Overall Expected Outcome(s)

- Real World Testing will demonstrate that the Health IT Module is conformant to the following certification criteria: § 170.315(b)(1) Transitions of care, § 170.315(e)(1) View, download, and transmit to 3rd party and § 170.315(h)(1) Direct Project.
- Real World Testing will demonstrate the ability of OneTouch EMR to export data as described in § 170.315(b)(6).
- Real World Testing will demonstrate that the Health IT Module is conformant to the following criteria involving the “Application Programming Interface” API including § 170.315(g)(7) Application access— patient selection, and § 170.315(g)(9) Application access— all data request, § 170.315(b)(2) Clinical information reconciliation and incorporation and 170.315(g)(10) Standardized API for patient and population services.
- Real World Testing will demonstrate that the Health IT Module is conformant to the following, Clinical Quality Measures criteria i.e. § 170.315(c)(1)—record and export, § 170.315(c)(2)—import and calculate and § 170.315(c)(3)—report.
- Real World Testing will demonstrate the ability of OneTouch EMR to do electronic prescription in accordance with § 170.315(b)(3).
- Real World Testing will demonstrate the ability of OneTouch EMR to transmit health information data to immunization registries in accordance with § 170.315(f)(1).

Schedule of Key Milestones

Key Milestone	**Date/Time Frame**
Release of documentation for the Real-World Testing to be provided to authorized representatives and providers. This includes surveys, specific instructions on what to look for, how to record issues encountered, and Customer Agreements.	December 1, 2023

Collection of information as laid out by the plan for the period.	January 1, 2024
Follow-up with providers and authorized representatives on a regular basis to understand any issues arising with the data collection.	Quarterly, 2024
Data collection and review.	Quarterly, 2024
End of Real-World Testing period/final collection of all data for analysis.	January 1, 2025
Analysis and report creation.	January 15, 2025
Submit Real World Testing report to ACB (per their instructions)	February 1, 2025

Measures Used - Use Case 1

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing of EHI i.e. (§ 170.315(b)(1), § 170.315(b)(6), § 170.315(e)(1), and § 170.315(h)(1)) across the two use cases demonstrated (patient and population services).

Description of Measurement/Metric

Use Case 1a

As part of the Real World Testing requirements for § 170.315(b)(1), § 170.315(b)(6), § 170.315(e)(1), and § 170.315(h)(1), the developer has developed the following metrics for their testing plan:

Measure 1: Sharing Data. This measure will catalog the transport mechanisms used to share transitions of care documents and EHI, as well as track usage of the various transport mechanisms. Associated certification criteria include:

Associated Certification Criteria

Certification Criteria	Requirement
§ 170.315(b)(1) Transitions of care	(i)(A) Send transition of care/referral summaries (i)(B) Receive transition of care/referral summaries
§ 170.315(e)(1) View, download and transmit	(i)(B)(2) Download ambulatory summary using CCD Template (i)(C)(1) Transmit to third party
§ 170.315(h)(1) Direct Project	(i) Applicability Statement for Secure Health Transport (ii) Delivery Notification in Direct

Justification for Selected Measurement/Metric

OneTouch includes two functionalities of interest in this use case: (A) Send transition of care/referral summaries and (B) Receive transition of care referral summaries, including (C) XDM processing. Transitions of care documents are shared using Edge protocols (e.g., SMTP, Direct) while other EHI may be shared through the patient portal using downloads and encrypted or unencrypted transmissions. This metric will provide information on the types of transmissions deployed (e.g., what types of Edge protocols, downloads and unencrypted vs. encrypted transmission) and the frequency of usages.

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and email logs will be reviewed to determine the frequency and the transport mechanism used by providers for sending/receiving transitions of care using Edge protocols and downloading or transmitting EHI by patients using the patient portal. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes

It is expected that providers and patients (or their authorized representatives) will be able to share EHI using the transmission mechanisms provided. Error rates will be tracked and trended over time.

Use Case 1b

Measure 1: Data Export. This measure will assess functionality used to export data for a set of patients and all patients. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	Requirement
§ 170.315(b)(6) Data Export	(ii) Creation - Continuity of Care Document (iii) Timeframe configuration. (iii)(A) Set start and end date for export (iii)(B)(1) Create export summaries in real-time; (iii)(B)(1) Create export summaries based on a relative date and time (iii)(B)(1) Create export summaries based on a specific date and time

Justification for Selected Measurement/Metric

The export of the health information associated with a patient population is another way to share health information with an external organization. It is typically used for research or quality purposes to look for specific trends in the patient population. Export of a patient population is an administrative function only available to credentialed users. It is assumed that this function will be run as a scheduled activity as it will have a significant impact on the Health IT Module. This will provide a metric on the use of the export of EHI for a patient population associated with the Health IT Module.

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and email logs will be reviewed to ensure that the export function is operating properly and 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes

It is expected that authorized users will be able to export a set of export summaries for patients whose information is stored in the OneTouch. Error rates will be tracked and trended over time.

Measures Used - Use Case 2

The purpose of this use case is to test the Referrals module of OneTouch which involves showing patient information to referring providers using OneTouch “Application Programming Interface” APIs and incorporating patient information in OneTouch for received referrals. This includes all the criteria including § 170.315(g)(7) Application access— patient selection and § 170.315(g)(9) Application access— all data request and § 170.315(b)(2) Clinical information reconciliation and incorporation.

Description of Measurement/Metric

Use Case 2a

Measure 1: Patient Information Lookup. This measure will assess functionality used to access patient information using OneTouch Application Programming Interface” API. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	Requirement

§ 170.315(g)(7) Application access—patient selection	(i) Application access - patient selection (ii) Documentation
§ 170.315(g)(9) Application access—all data request	(i) Application access - all data request (ii) Documentation
§ 170.315(g)(10) Standardized API for patient and population services	(i) Data response. Respond to requests for data (ii) Search support. Respond to search requests for data consistent with the search criteria (iii) App registration (iv) Secure connection (v) Authentication and app authorization (vii) Documentation

Justification for Selected Measurement/Metric

Since OneTouch APIs only provide access to specific patient data through an ID or token to identify the patient, this will provide a metric on the use of APIs to access patient data. Additionally documentation requirements will be tested indirectly and verified through the review of the server log files.

This measure will also determine how many 3rd party systems or applications are integrated and using the OneTouch FHIR API interface. This measure will allow us to verify our certified API is working with 3rd party applications to access USCDI patient data.

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and email logs will be reviewed to ensure that the APIs are operating properly and 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 APIs and validation that all required USCDI data elements are supported. This test methodology will primarily test the conformance of the implementation and frequency of use.

Expected Outcomes

It is expected that OneTouch APIs will be conformant to § 170.315(g)(7) Application access— patient selection, and § 170.315(g)(9) Application access— all data request and that response rate of the API is more than 95% of the time.
The measurement for § 170.315(g)(10) Standardized API for patient and population services will provide a count of FHIR application applications which have registered with our server for patient access as well as applications actively connecting to our FHIR server.

Use Case 2b

Measure 1: Clinical information reconciliation and incorporation. This measure will assess functionality used to reconcile clinical information and incorporate it into an existing patient record. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	**Requirement**
§ 170.315(b)(2) Clinical information reconciliation and incorporation	(i) General requirements - transition of care/referral summary format (ii) Correct patient (iii) Reconciliation - (iii)(c)(1) Medications (iii)(c)(2) Medication allergies (iii)(c)(3) Problems

Justification for Selected Measurement/Metric

The second part of the referrals module of OneTouch is to reconcile the clinical information (as received from outside OneTouch) and incorporate it into an existing patient record. It has two functionalities of interest 1) Identify correct patient record to incorporate data 2) Reconcile and update the patient record with medications; medication allergies; and problems data as received in transition of care/referral summary document. This enables OneTouch to always keep the patient health

record updated and record frequency of usage and error rate in identifying correct patient records based on clinical information received.

Testing Methodology

OneTouch EMR logs, audit logs and system logs will be reviewed to ensure that the received clinical data is correctly reconciled and determine the frequency of use along with error rate. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of clinical information reconciliation and incorporation and that the following data is incorporated correctly: medications; medication allergies; and problems. This test methodology will primarily test the conformance of the implementation, frequency of use and error rate of identifying correct patient records based on clinical information received.

Expected Outcomes

It is expected that OneTouch performs clinical information reconciliation and incorporation on correct patient records with 100% accuracy and that it is conformant to § 170.315(b)(2) Clinical information reconciliation and incorporation.

Measures Used - Use Case 3

All criteria involving the process of creating and exporting Clinical Quality Measures (CQM) data as per the Quality Reporting Document Architecture (QRDA) Category I (for individual level reports) will be tested. The measures include § 170.315(c)(1)—record and export, § 170.315(c)(2)—import and calculate and § 170.315(c)(3)—report.

Description of Measurement/Metric

Use Case 3

Measure 1: Record and Calculate CQMs. This measure will assess functionality used to record CQMs data, calculate and create CQM reports. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	Requirement
§ 170.315(c)(1)—record and export	(i) Record - data for every CQM (ii) Export - at any time with the developer assistance
§ 170.315(c)(2)—import and calculate	(i) Import (ii) Calculate
§ 170.315(c)(3)—report	(i) Clinical quality measures – report

Justification for Selected Measurement/Metric

OneTouch provides a user interface mechanism to record data, calculate the CQM measure and generate a report for each of the CQM measures based on standards specified in § 170.205(h)(2) and § 170.205(k)(1) and (2). It also provides a function to export the report to be used in CMS. This will provide the frequency of usage of CQMs as well as types of CQM measures reported i.e. the following 11 CQM measures. CMS50 Closing the Referral Loop: Receipt of Specialist Report, CMS68 Documentation of Current Medications in the Medical Record, CMS69 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan, CMS122 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%), CMS124 Cervical Cancer Screening, CMS127 Pneumococcal Vaccination Status for Older Adults, CMS130 Colorectal Cancer Screening, CMS131 Diabetes: Eye Exam, CMS138 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention, CMS139 Falls: Screening for Future Fall Risk, CMS147 Preventive Care and Screening: Influenza Immunization

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and email logs will be reviewed to determine the frequency of use and the list of different CQM measures reported by providers. Log files obtained during Real World Testing will be de-identified and used

for analysis in several areas to see if each CQM measure is calculated correctly and to record the frequency of use of each CQM measure . This test methodology will provide insight into which CQM measures are reported the most and identify any issues related to calculation of the CQM measure.

Expected Outcomes

Based on the log files, the following information can be derived: access to the individual CQM Measures used for reporting, number of measures reported by different providers. It is expected that the calculation of each CQM measure if accurate and complete and error rate decreases over time.

Measures Used - Use Case 4

The purpose of this use case is to test the real world interoperability and conformance of its certified Electronic Prescribing or eRX module which is used by providers to electronically write and send prescriptions to pharmacies.

Description of Measurement/Metric

Use Case 4

Measure 1: Create, change, cancel or renew prescription. This measure will test usage of the electronic prescription system and assess the errors when creating prescriptions. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	Requirement
§170.315(b)(3) Electronic prescribing	(i) Enable a user to perform all of the following prescription-related electronic transactions (i)(A) Create new prescriptions (NEWRX). (i)(B) Change prescriptions (RXCHG, CHGRES). (i)(C) Cancel prescriptions (CANRX, CANRES). (i)(D) Refill prescriptions (REFREQ, REFRES).

	(i)(E) Receive fill status notifications (RXFILL). (i)(F) Request and receive medication history information (RXHREQ, RXHRES). (ii) For each transaction, receive and transmit the reason for the prescription

Justification for Selected Measurement/Metric

OneTouch provides a user interface in eRX module to create and send electronic prescriptions per the standard specified in § 170.205(b)(2) and, at a minimum, the version of the standard specified in § 170.207(d)(3). This metric will provide information on the types of electronic transactions (e.g., new prescriptions (NewRx), change prescriptions (RXCHG, CHGRES), cancel prescriptions (CANRX, CANRES) and refill prescriptions (REFREQ, REFRES) and receive fill status (RXFILL)). This will also provide information about Status, Error and Verify transactions.

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and prescription logs will be reviewed to determine the frequency electronic prescribing and transaction types. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to see whether each NewRx was successful or RXCHG/CANRX was subsequently used. This test methodology will provide insight into Rx transactions types used and status of these transactions.

Expected Outcomes

It is expected that providers will use the eRX module to send and receive the prescription transactions electronically and the reason for these prescriptions.

Measures Used - Use Case 5

The purpose of this use case is to test the real world interoperability and conformance of its certified public health reporting module which is used by providers to send immunization data to immunization registries.

Description of Measurement/Metric

Use Case 5

Measure 1: Create Immunization Data. This measure will test usage of the public health reporting system and assess the errors when creating and sending immunization data to immunization registries. The associated certification criterion is:

Associated Certification Criteria

Certification Criteria	**Requirement**
§170.315(f)(1) Transmission to immunization registries	(i) Create immunization information for electronic transmission in accordance with: (i)(A) The standard and applicable implementation specifications specified in § 170.205(e)(4). (i)(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines. (i)(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines. (ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

Justification for Selected Measurement/Metric

OneTouch provides a public health reporting module which enables users to create and send immunization data to immunization registries in accordance with (f)(1)(i)(A)

standard defined in § 170.205(e)(4), (f)(1)(i)(B) standard specified in § 170.207(e)(3) for historical vaccines and (f)(1)(i)(C) § 170.207(e)(4) for administered vaccines. This metric will provide information on the usage of the public health reporting module, such as number of immunizations sent as well as immunization forecast is requested. This will also provide information about the number of errors when creating, sending and retrieving immunization forecast from immunization registries.

Testing Methodology

OneTouch EMR logs, audit logs, system logs, and immunization logs will be reviewed to determine the frequency of public health reporting. Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to see the frequency of use of patient's evaluated immunization history. This test methodology will provide insight into the transmission to immunization registries and immunization forecast.

Expected Outcomes

It is expected that providers will use the public health reporting module to transmit immunization data to the immunization registries and request patient's evaluated immunization history and the immunization forecast from an immunization registry whose information is stored in the OneTouch. Error rates will be tracked and trended over time.

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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