REAL WORLD TESTING PLAN

GENERAL INFORMATION

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

Developer Name: Custom Computing Corporation

Product Name(s): Freedom Medical Systems® EHR

Version Number(s): v5.0 r3

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1306.Free.05.00.1.171223

Developer Real World Testing Page URL: https://knowledgebase.ccc-webservices.com/?ht_kb=real-world-testing

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

CCC's approach to real world testing is to partner with our clients to monitor and evaluate the use of Freedom Medical Systems® EHR in the family and pediatric care settings during the 2022 performance year based on the following use case scenarios:

Care Coordination Use Cases

- 170.315(b)(1) – Transition of Care
- 170.315(b)(2) – Clinical Information Reconciliation and Incorporation
- 170.315(b)(3) – Electronic Prescribing
- 170.315(b)(6) – Data Export

Patient Engagement Use Case

- 170.315(e)(1) – View, Download, and Transmit to 3rd Party

Electronic Exchange Use Case

- 170.315(h)(1) – Direct Project

CQM Use Cases

- 170.315(c)(1) – Record and Export
- 170.315(c)(2) – Import and Calculate
- 170.315(c)(3) – Report

Public Health Use Cases

- 170.315(f)(1) – Transmission to Immunization Registries
- 170.315(f)(2) – Transmission to Public Health Agencies – Syndromic Surveillance

Application Programming Interface Use Cases

- 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

The objective of our real world testing plan is to verify the extent to which Freedom Medical Systems® EHR is deployed and used in the real world setting while validating that it continues to demonstrate conformance to the certified criterion and functions as intended through the various use case scenarios used in the client's production environment.

Criteria	Justification
Logs	Under this measurement metric, the EHR will keep logs of the actions performed by the user, along with creating Reports for the same, depicting the increment in count for designated actions.
Compliance/Tools/Validation	Under this measurement metric, the ONC certified compliance tools and the Industry standard vendor tools will be used to evaluate the validation of the files and data exported from the EHR.
Self-Test	In this measurement metric, the user's functional flow and actions will be observed for data exchange and export.
Data Export	Under this measurement metric, the HER's capacity to export the data will be tested with the required standards.

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

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Method used for standard update	N/A
Date of ONC ACB notification -	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A

USCDI -updated certification criteria (and USCDI version)	As of April 2021, the product conforms to the 2015 Edition Cures Update requirements and meets the data classes and data elements required by the United States Core Data for interoperability (USCDI) for the following criterion: • 170.315(b)(1) – Transitions of Care • 170.315(b)(2) – Clinical Information Reconciliation and Incorporation • 170.315(e)(1) – View, Download, and Transmit to 3rd Party • 170.315(g)(6) – Consolidated CDA Creation Performance • 170.315(g)(9) – Application Access – All Data Request

MEASURES USED IN OVERALL APPROACH

Description of Measurement/Metric

Measurement/Metric	Description
170.315(b)(1): Data Export, Validation	1. When appropriate, the provider can refer the patient to another provider or clinic while using the system to create and transmit electronically a summary of care document to the referred provider or clinic. 2. The referral summary will contain all the patient health data which is recorded in the clinic during the patient visit. 3. A user can access a human-readable version of the received referral summary. 4. Metrics used during real world testing will include tracking the number of referral summaries generated and the number of referral summaries transmitted electronically per month over a defined measurement period.
170.315(b)(2): Self-Test, Validation	1. When the patient completes the referral visit, the referred clinic can send back the details of the visit as a referral summary, which can be received and reconciled in the system. 2. Users can verify the patient and data sent as part of the referral summary and the data can be reconciled and imported into the system. 3. Upon reconciliation, a new referral summary can be generated containing the reconciled data. 4. Metric used during real world testing will include tracking the number of referral summaries received and reconciled over a defined measurement period.

170.315(b)(3): Validation, Logs, Compliance Tool	1. Using the integrated Rcopia e-prescribing platform, the system will be monitored for a defined measurement period to ensure the system allows permitted system users to perform the following actions: 1. Create a new prescription and associate a diagnosis (when appropriate) with the prescription prior to submitting electronically to a pharmacy; 2. Request and respond to prescription change requests; 3. Request and respond to cancel prescriptions requests; 4. Request and respond to renew prescriptions requests; 2. In a real world setting end-users of the integrated e-prescribing system can: 1. Perform real-time prescription drug benefit checks; 2. Receive and review Drug-Drug and Drug-Allergy interaction checks prior to completing a prescription; and 3. Review a patient's specific drug formulary for guidance and recommendations. 3. Metrics used during real world testing will include tracking the following metrics during the defined measurement period using various system logs and reports: 1. Number of prescriptions prescribed 2. Number of prescriptions transmitted electronically; 3. Number of change requests; 4. Number of cancellation requests; and 5. Number of renewal requests.
170.315(b)(6): Data Export, Validation, Self-Test	1. Whenever requested by another Clinic, Provider, Organization, or Registry, or when a provider moves to another clinic, the entire patient health data for a specific patient or a group of patients can be generated from the Freedom Medical System as a Patient Health Data export summary. 2. The export summary can be specific to a date, relative date range, or specific date range. 3. And, only the authorized users of the Freedom Medical System can define the path where the summary files will be exported and who can export the files. 4. The authorized users can also schedule a periodic export of the summary record. 5. The measurement metric would include tracking the number of CCDAs generated per month over the measurement period.
170.315(c)(1), (c)(2), (c)(3): Validation, Test Tool	1. In order to improve the Quality of Care, the providers can track their Quality scores through the Quality Measure report dashboard available in Freedom Medical Systems.

	2. The users can also successfully export QRDA I and QRDA III files from the system to manually submit them to the respective portal. 3. The providers can also import the QRDA files of patients from their other clinics and include them in this clinic's Quality Measure calculation. 4. The measurement metric would be the percentage of patient population for whom QRDA files are successfully generated. 5. And the percentage of patient population for whom QRDA files are imported.
170.315(e)(1): Reports, Logs	1. After a clinical visit, the patients can access their entire visit data through the Freedom Patient Portal. 2. The patients can login, view, download, and transmit their visit summary from the portal. 3. The measurement metric will include tracking the count of new patients (Patients and Patient Authorized users) who are given patient portal access per month, over the measurement period. 4. Tracking the count of unique patients, per month, who accessed any of their health data through patient portal over the measurement period. 5. Tracking the count of unique patients, per month, who downloaded or transmitted CCDAs through patient portal over the measurement period. 6. And, tracking the count of unique patients, per month, who accessed patient portal logs over the measurement period.
170.315(h)(1): Compliance, Tool	1. After a patient visit, the providers can electronically send the patient health data to another clinic or provider's Direct Address through the Direct Messaging service. 2. The clinic can also receive the patient data on its Direct address (Either organization specific, or provider specific) from another clinic or provider. 3. The measurement metric would include tracking the percentage of successful direct messages sent and received per month over the measurement period.
170.315(f)(1): Compliance, Tools, Logs	1. Whenever a patient visits the clinic to receive Immunization shots, the providers will record the Immunization data and send it electronically to the respective Immunization registry. 2. On sending the shot details, the registry will send acknowledgements, which can be reviewed in the Freedom Medical Systems Vaccine tracking dashboard. 3. In the scenario, where the clinic does not have patient past immunization data or would like to receive the patient future

	shot recommendation, then the providers can query the same from the registry. 4. The measurement metric would include tracking the number of successful Immunization submissions (VXUs) to an IIS per month, over the measurement period. 5. Along with tracking the number of successful query calls to an IIS, per month over the measurement period.
170.315(f)(2): Self-Test, Compliance	1. When permitted by state law, the system can generate a Syndrome based HL7 messages, which will be electronically sent to the associated public health registry. 2. The measurement metric will include tracking the percentage of successful syndromic surveillance message generation per month, over the measurement period.
170.315(g)(7), (g)(8), (g)(9): Tools, Validation	1. Patients can request their health data from the clinic through a third-party application. In this scenario, the clinic can share patient data from the system. 2. Patients can either request specific health data or the full health data set. 3. The measurement metric will include tracking the successful API transaction requests, per month, over the measurement period.

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria
Care Coordination	170.315(b)(1) - Transitions of Care 170.315(b)(2) - Clinical Information Reconciliation and Incorporation 170.315(b)(6) – Data Export
Clinical Quality Measures	170.315(c)(1) - CQMs Record and export 170.315(c)(2) - CQMs Import and Calculate 170.315(c)(3) - CQMs report
Patient Engagement	170.315(e)(1) - View, download, and transmit to 3rd party
Electronic Exchange	170.315(h)(1) - Direct Project
Public Health	170.315(f)(1) - Transmission to immunization registries 170.315(f)(2) - Transmission to public health agencies – syndromic surveillance
Application Programming Interface	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

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
170.315(b)(1): Data Export, Validation	1. The CCDA's created during the defined measurement period will be processed through a validation tool to ensure conformance to the standards. 2. An increment in the count of CCDA's generated per month will justify that the system supports the capability to create referral summaries. 3. An increment in the count of CCDA's transmitted electronically per month using Edge protocol will justify that the system supports the capability to electronically transmit referral summaries.
170.315(b)(2): Self-Test, Validation	1. The system's capability to import, process, and, display the patient and data from a received CCDA in r1.1 or r2.1 will justify its compliance with the standards. 2. An increment in the count of CCDAs received and reconciled per month will justify the system's capability for CCDA reconciliation.
170.315(b)(3): Validation, Logs, Compliance Tool	1. The system's capability to perform the following actions using Rcopia e-prescribing platform will justify the conformance with the measure: 1. Create a new prescription and transmit electronically to the pharmacies 2. Request and respond to prescription change requests; 3. Request and respond to cancel prescriptions requests; 4. Request and respond to renew prescriptions requests; 5. Real-time prescription drug benefit check; 6. Receive and review Drug-Drug and Drug-Allergy interaction check; 7. Review patient specific drug formulary for guidance and recommendations; 2. An increment in the count of the followings actions will justify the real world use of the measure: 1. Number of new prescriptions generated; 2. Number of new prescriptions transmitted electronically; 3. Number of change requests; 4. Number of cancellation requests; and 5. Number of renewal requests;

170.315(b)(6): Data Export, Validation, Self-Test	1. Successful generation of CCDA files with all the elements as per CCD version R2.1, at the defined export path, for a defined export period, by an authorized user will justify the measure compliance. 2. An increment in the count of CCDAs generated per month over the measurement period will justify the compliance with the measure.
170.315(c)(1), (c)(2), (c)(3): Validation, Test Tool	1. The successful generation and export of QRDA files for each of the certified eCQM measures for entire relevant patient population will justify the compliance with the measure (c)(1). 2. Ability to import and incorporate QRDA files will justify the compliance with measure (c)(2). 3. An increment in the percentage patient population for whom QRDA I and QRDA III files are generated and successfully validated in the Cypress tool will prove its compliance to the (c)(3) measure.
170.315(e)(1): Reports, Logs	1. Freedom Patient Portal will allow the patients and patient authorized users to login to view, download, and transmit the patient health data. 2. The count increase in the measurement metric will help justify: Patient are successfully able to login to their Portal, Patients are able to View, Download and Email (Both Email and Direct Message) their health data, and Patients Authorized person is able to view, transmit, and download the patient health data
170.315(h)(1): Compliance, Tool	1. Increment in the count of successful electronic transmissions using Direct protocol from Freedom Medical Systems with a third party will justify the compliance with the measure.
170.315(f)(1): Compliance, Tools, Logs	1. An increment in the count of successful Immunization message generation which can be consumed by IIS will indicate the compliance with the measure standards. 2. Displaying the response message and the Query result will justify that the EHR is able to consume and process the responses sent from the IIS/Registry 3. Increment in the count of successful Query messages will help justify the QBP generation capability.
170.315(f)(2): Self-Test, Compliance	1. An increment in count in the count of successful generation of syndromic messages and its validation in the test tool will justify the compliance with the measure.
170.315(g)(7), (g)(8), (g)(9): Tools, Validation	1. An increment in the count of successful patient selection, retrieval of specific CCDS data element set, and the entire

	patient data from Freedom Medical Systems through the Postman application in forms of FHIR API will prove its adherence to the specified measures

Care Setting(s)

Care Setting	Justification
Family Practice, Pediatrics	Freedom Medical Systems is designed to be used in both of the care settings defined. We will test it at two client locations, one for each care setting, for a period of three months.

Expected Outcomes

Measurement/Metric	Expected Outcomes
170.315(b)(1): Data Export and Validation	1. The system is capable of generating a clinical summary (CCDA) conformant to the standards in 95% of real world testing cases. 2. The generated CCDA contains the reason for referral, referring provider name, and office contact. 3. When receiving CCDA's, the system is able to detect invalid CCDA's and notify the user of validation issues. 4. The system permits a user to display in a human-readable format the data included in the received CCDA. 5. The system permits a user to define the sequence and sections to be displayed from the received CCDA. 6. An increment in the count of CCDAs that are generated and transmitted using the edge protocol over a defined measurement period.
170.315(b)(2): Data Import and Processing	1. The system is able to consume and reconcile a CCDA in either r1.1 and r2.1 formats in 95% of real world test cases. 2. The system is able to validate 100% of received CCDA's. 3. The system can identify and match the correct patient based on the demographic elements contained within the received CCDA file.

	4. The system is capable of displaying simultaneously for the user the incoming CCDA data as well as existing patient data prior to user reconciliation. 5. The system permits a user to reconcile the medication, allergies, and problems from a received CCDA file. 6. The system permits a user to generate a new CCDA with the reconciled data. 7. An increment in the number of CCDA's received and reconciled over a defined measurement period.
170.315(b)(3): Reports and Logs	1. The system is capable of supporting a user in performing the following actions in over 95% of real world test cases: 1. Creating a new prescription and associate a diagnosis (when appropriate) with the prescription prior to submitting electronically to a pharmacy; 2. Requesting and responding to prescription change requests; 3. Requesting and responding to cancel prescriptions requests; 4. Requesting and responding to renew prescriptions requests; 2. The system is capable of supporting end-users with: 1. Real-time prescription drug benefit checks; 2. Receiving Drug-Drug and Drug-Allergy interaction checks; and 3. Allowing the review of a patient's specific formulary for prescription guidance
170.315(b)(6): Data Export and Validation	1. The system is capable of exporting a clinical summary in CCDA r2.1 format in 95% of real world test cases. 2. An increment in the count of CCDA version R2.1 export for a single patient and multiple patients. 3. The system allows to define and modify the Export path and timeframe configuration only to the authorized users. 4. The authorized users are able to export the CCDA R2.1 for a specific date, relative date range, or a specified date range. 5. The system is capable of generating a human readable version of the CCDA document.
170.315(c)(1), (c)(2), (c)(3): Data Export and Submission	1. The system allows a user to run reports and produce an exportable QRDA file for each of the certified eCQM measures for 100% of the measure population. 2. The system provides a user the ability to import and incorporate QRDA files in 90% of real world test cases. 3. The system is able to export QRDA I and QRDA III files in the designated format and is able to pass the validations under the Cypress tool for more than 90% of its patient population.
170.315(e)(1): Patient Engagement and Reporting	1. Increment in the count of patients who are successfully able to login to Freedom Patient Portal and access their health data.

	2. Increment in the number of unique users per month who downloaded or transmitted the CCDA. 3. Increment in number of unique users per month, who accessed the patient portal logs. 4. Increment in count of Patient Authorized users who are successfully able to login to the Patient Portal to View, Download, and Transmit the Patient Health.
170.315(h)(1): Direct messaging send and receive	1. Freedom Medical Systems is able to send a Direct message to a third party formatted as a wrapped message with more than 90% accuracy. 2. The system is able to consume, process, and display the Direct message received from a third party with more than 90% accuracy. 3. Total number of Direct messages sent and received over the measurement period.
170.315(f)(1): Reports and Logs	1. The system is capable of generating and transmitting Immunization messages for each action type (New, Delete, and Update), to an IIS with a success rate of more than 90%. 2. The system is capable of displaying to the user the acknowledgement received from the registry in 95% of real world test cases. 3. The system is capable of performing immunization registry queries in greater than 95% of real world test cases. 4. The system is capable of displaying the query response received from the registry to the user in 95% of real world test cases.
170.315(f)(2): Export and Validation	1. The system is capable of generating an HL7 2.5.1 syndromic surveillance message containing the patient health information with zero errors in 95% of real world test cases using the NIST 2015 syndromic surveillance context-free test tool.
170.315(g)(7), (g)(8), (g)(9): Interoperability and Data exchange	1. The system is able to establish a trusted connection with an external application, in this case, the Postman application. 2. The system allows an external application such as Postman, to select a specific patient based on the Patient ID in more than 95% of the real world test cases. 3. The system also allows a user to retrieve a specific data category from CCDS elements for a selected patient for both a specific date and a specified date range, with a success rate greater than 90%. 4. The system allows a user to retrieve the entire CCDS data set for a selected patient for both: A specific date and a specified date range, with a success rate greater than 90%

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Release of the Real World Test Plan documentation to authorized representatives	Family Practice, Pediatrics	January 3, 2022
Client Identification and explanation of test cases	Family Practice, Pediatrics	January 17, 2022
Begin test execution and data collection	Family Practice, Pediatrics	Q2, 2022
Result collection as per the test plan	Family Practice, Pediatrics	Q3, 2022
Analysis and Report creation	Family Practice, Pediatrics	Q4, 2022
Submission of Test results	Family Practice, Pediatrics	Q1, 2023

ATTESTATION

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Authorized Representative Signature:

Date: 11/10/2021

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[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766) [ii] https://www.federalregister.gov/d/2020-07419/p-3582