iatricSystems

Real World Testing Plan

Real World Testing Plan Report ID, 20231206ia2

Product	Analytics on Demand
Developer	Iatric Systems, Inc
Version	2.0
CHPL Product Number	15.05.05.2760.ISAD.01.00.0.180412
Real-World Testing URL	https://www.iatric.com/real-world-testing

Use Case (Clinical Quality Management): Certified Health IT Developer has developed a certified Health IT module for healthcare providers to track and monitor electronic quality care measures (eCQMs) as part of healthcare improvement efforts. Criteria 170.315(c)(1) Record and Export, 170.315(c)(2) Import and Calculate, and 170.315(c)(3) Report will be tested to confirm the healthcare provider's ability to monitor selected measures' performance through the processing of their QRDA file format to calculate measure and display measure statuses.

Certified Health IT Module is marketed and actively in use by hospital healthcare settings. For this reason, the Real-World Testing plan will apply to a hospital setting. Criterion 170.315 (c)(1), 170.315 (c)(2), and 170.315 (c)(3) Report will be tested.

Criteria involved in testing include
170.315 (c)(1): Clinical Quality Measures - Record and Export
170.315 (c)(2): Clinical Quality Measures - Import and Calculate
170.315 (c)(3) Cures: Clinical Quality Measures - Report

Standard (and version)	Specified as required by ONC Health IT Certification Program, 2015 Edition-Cures
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

Overall expected outcomes will validate conformance to criteria 170.315 (c)(1) record and export, 170.315(c)(2) import and calculate, and 170.315(c.) (3) report (Cures) patient health data in the required file format for reporting measure data under 2015 Certified Edition software standards.

Key Milestone	Date/Timeframe
Initial Real-World Testing with current development healthcare facility partner where we have access to their system for testing and potential development using real patient data for real-world setting type testing.	1/15/24-3/31/24 (Q1)
Data collection and review as laid out by the plan to include follow-up with hospital partner	3/1/24-8/31/24 (Q2-Q3)
End of Real-World Testing Period with Results	January 2025
Analysis and Report Creation	January 2025
Submit Real World Testing Report to ACB	February 1, 2025*
**Timeline may be adjusted based on ACB's RWT Results due date*	

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the monitoring and reporting of clinical quality measures (eCQMs).

Measure 1: CQM record and export - This measure will assess the ability to import eCQM data (QRDA) files and use the associated data to record and export quality measure data from the QRDA file produced from the healthcare provider's EHR.

Certification Criterion and Measurement	**Requirement**
170.315(c)1 – Clinical Quality Measures - record and export	(i) – record all data necessary to calculate CQMs (ii) – export QRDA data file

Justification: C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category format. Facility users can provide QRDA files with the eCQMs that they have chosen to monitor and track in preparation for potential reporting to applicable CMS programs. Testing to validate conformance with criterion standards ensures the overall promotion of patient engagement.

Testing Methodology: CQM criteria, (c)(1), (c)(2), (c)(3), will be tested together. Users would have their EHR updated to include any updates related to quality measure version updates. C1 requires a certified Health IT Module to record required data, calculate CQMs from the recorded data, and export the data in QRDA format. C2 requires a certified Health IT module to import data from a QRDA formatted file and calculate the CQMs based on that data in the file. C3 requires a certified Health IT module to create a QRDA formatted file to potentially use for submission to CMS. Developer intends to test and validate the imported and calculated data against file data and the customer EHR system. quality measure performance is reflected in the numerator and denominator displayed. Because facilities can use other means to submit eCQMs to meet required CMS program requirements, Developer may not have the ability to test the submission of live data to not interfere with the client's annual reporting process. In this case, we would need to use a testing tool such as Cypress.

- Customers (users) would have their EHR updated to include any updates to eCQM measure specifications. When importing data, the facility user's QRDA file determines which eCQM measures they would like to monitor and track (the user is not limited to any specific number of eCQM measures to track/monitor).
- From there, the files are deduplicated to then process the file documents where they then are moved to the calculations folder which indicates to the application that the calculations need to run against the specific file being processed.
- Once processing is complete, all initial folders are then empty and free of any patient health information.
- To proceed with testing, to export QRDA documents on demand, a user would select the export navigation item within the application and add any applicable criteria filtering.

- Users then simply check a box to select the new export which the software will initiate the build process.
- The report status will indicate as pending then move to complete.
- To download the document to the specified format, the user will select the report link and export it to a local pc.
- Measure data imported, recorded, and calculated displays performance as reflected in the numerator and denominator of the quality measure.
- All functions and access are on the server within the customer's network

Expected Outcome**:** It is expected that quality measure data will record data and calculate measure statuses with the ability to export data files as expected for the quality measures that the healthcare provider has chosen to monitor and report. Testing results to confirm conformance to 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

Measure 2: CQM Import and Calculate - This measure will assess the ability to import quality measure data (eCQM) QRDA formatted files and use the associated data to calculate quality measure data from the QRDA file produced from the healthcare provider's EHR.

Certification Criterion and Measurement	**Requirement**
170.315(c)(2) – Clinical Quality Measures - import and calculate	(i) – import QRDA data file (ii) – calculate each CQM presented for certification

Justification: This criterion requires the ability of a certified Health IT module to calculate eCQM data within QRDA files imported from the healthcare provider's EHR. Facility users can provide QRDA files with selected measures to be imported and data calculated and displayed for monitoring and tracking in preparation of potential eCQM reporting under the applicable CMS program. Testing to validate conformance with criterion standards ensures the overall promotion of patient engagement.

Testing Methodology: CQM criteria, (c)(1), (c)(2), (c)(3), will be tested together. Users would have their EHR updated to include any updates related to quality measure version updates. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA format. C2 requires a certified Health IT module to import data from a QRDA formatted file and calculate the CQMs based on that data in the file. C3 requires a certified Health IT module to create a QRDA formatted file to potentially use for submission to CMS. We intend to test and validate the imported and calculated data against file data and the customer EHR system. Quality measure performance is reflected in the numerator and denominator displayed. Because facilities can use other means to submit eCQMs to meet required CMS program requirements, we may not have the ability to test the submission of live data so not interfere with the client's annual reporting process. In this case, we would need to use a testing tool such as Cypress.

- Customers (users) would have their EHR updated to include any updates to eCQM measure specifications. When importing data, the facility user's QRDA file determines which eCQM measures they would like to monitor and track (user not limited to any specific number of eCQM measures to track/monitor).

- From there, the files are deduplicated to then process the file documents where they then are moved to the calculations folder which indicates to the application that the calculations need to run against the specific file being processed.
- Once processing is complete, all initial folders are then empty and free of any patient health information.
- To proceed with testing, to export QRDA documents on demand, a user would select the export navigation item within the application and add any applicable criteria filtering.
- Users then simply check a box to select the new export which the software will initiate the build process.
- The report status will indicate as pending then move to complete.
- To download the document to the specified format, the user will select the report link and export it to a local pc.
- All functions and access are on the server within the customer's network

Expected Outcome**:** It is expected that QRDA files will be imported without issue and that CQMs will record data and calculate measure statuses as expected. Testing results to confirm conformance to 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

Measure 3: CQM Report - This measure will assess the ability to import eCQM data (QRDA) files and use the associated data to calculate quality measure data from the QRDA file produced from the healthcare provider's EHR to create a report for eCQM submission.

Certification Criterion and Measurement	**Requirement**
170.315(c)(3) – Clinical Quality Measures - report	Create QDA Category III file for reporting

Justification: This criterion requires the ability of a certified Health IT module to calculate eCQM data within QRDA files imported from the healthcare provider's EHR. Facility users can provide QRDA files with selected measures to be imported and data calculated and displayed for monitoring and tracking in preparation of potential eCQM reporting under the applicable CMS program. Testing to validate conformance with criterion standards ensures the overall promotion of patient engagement.

Testing Methodology: CQM criteria, (c)(1), (c)(2), (c)(3), will be tested together. Users would have their EHR updated to include any updates related to quality measure version updates. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA format. C2 requires a certified Health IT module to import data from a QRDA formatted file and calculate the CQMs based on that data in the file. C3 requires a certified Health IT module to create a QRDA formatted file to potentially use for submission to CMS. We intend to test and validate the imported and calculated data against file data and the customer EHR system. Quality measure performance is reflected in the numerator and denominator displayed. Because facilities can use other means to submit eCQMs to meet required CMS program requirements, we may not have the ability to test the submission of live data to not interfere with the client's annual reporting process.in this case, we would need to use a testing tool such as Cypress.

- From there, the files are deduplicated to then process the file documents where they then are moved to the calculations folder which indicates to the application that the calculations need to run against the specific file being processed.
- Once processing is complete, all initial folders are then empty and free of any patient health information.
- To proceed with testing, to export QRDA documents on demand, a user would select the export navigation item within the application and add any applicable criteria filtering.
- Users then simply check a box to select the new export which the software will initiate the build process.
- The report status will indicate as pending then move to complete.
- To download the document to the specified format, the user will select the report link and export it to a local pc.
- All functions and access are on the server within the customer's network

Expected Outcome**:** It is expected that QRDA files will be imported to record and calculate data as expected and generate a report for eCQM submission. Testing results to confirm conformance to 2015 Certified Edition requirements. Error rates are tracked and analyzed over time.

This Real-World Testing plan is complete with the 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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