Encor-E Version 6
2023 Real World Testing Plan

General Information

Developer Name: Medisolv, Inc.
Product Name: Encor-E
Version Number: 6
Certified Health IT: 2015 Cures Act
Product List (CHPL) ID(s): 15.04.04.2922.ENCO.06.01.1.191011
Developer Real World Testing Page URL: https://medisolv.com/products/encor-quality-reporting-software/certification/

Justification for Real World Testing Approach

Encor-E consumes clinical data, normalizes that data into a common structure, and then generates eCQM results which can be exported to certified formats (QRDA-I, QRDA-III) for submission to regulatory entities. Our approach to testing is to verify data outputs using known data inputs against a standard-compliant testing system (Cypress), and then further testing is performed using real data, and results are verified across a range of implementations by clinical and engineering staff. The goal of this testing approach is to ensure that the product is fully tested across a wide range of real-world scenarios, including using actual clinical data and not just static datasets.

Standards Updates

Standards:

- Health Level 7 (HL7®) Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture Category I, Release 1, Standard for Trial Use (STU) Release 5.3, US Realm
- Health Level 7 (HL7®) Clinical Document Architecture (CDA®) R2 Implementation Guide: Quality Reporting Document Architecture (QRDA III) Release 1 – US Realm
- CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023
- CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians Programs; Implementation Guide for 2023

Updated Certification Criteria and Associated Product:

- Encor-E Version 6: 170.315(c)(1)
- Encor-E Version 6: 170.315(c)(2)
- Encor-E Version 6: 170.315(c)(3)

Health IT Module CHPL ID:

- 15.04.04.2922.ENCO.06.01.1.191011

Method used for Standard Update:

- SVAP

Date of ONC ACB Notification:

- 10/17/2022

Date of Customer notification:

- 12/16/2022

Conformance Measure:

- Conformance to QRDA-I Standard
- Conformance to QRDA-III Standard

USCDI Updated Certification Criteria:

- N/A

Schedule of Key Milestones

Key Milestone	Care Setting	Date/Timeframe
Real-World Testing documentation distributed to third-party partners for review	Third-Party Client Installation	10/17/2022
Real-World Testing documentation to be provided to all involved parties and responsibilities assigned	All	11/04/2022
2023 Initial Conformance Tests, not including testing in real-world environments	All	12/16/2022
2023 Real-World Environment Conformance tests	All	Quarterly throughout 2023
Data Aggregation and Review	All	December 2023
Analysis and report creation	All	January 2024
Submit Real World Testing report to ACB (per their instructions)	All	February 1, 2024

Measures Used in Overall Approach

This section outlines the measures used in the real world testing plan, and provides justification for those measures.

Measure Definitions and Associated Criteria

Measurement/Metric	Description	Associated Certification Criteria
Conformance to QRDA-I Standard	This measure tests the ability of Encor-E to export a conforming QRDA-I document according to published standards	170.315(c)(3)
Conformance to QRDA-III Standard	This measure tests the ability of Encor-E to export a conforming QRDA-III document according to published standards	170.315(c)(3)
Exports conform to manual input	This measure tests the ability of Encor-E to export a complete patient record in QRDA-I format which matches the direct input entry of the patient record	170.315(c)(1) 170.315(c)(3)
Measures Results conform for static data	This measure tests the ability of Encor-E to produce accurate measure results using known, static inputs to produce a desired output	1740.315(c)(2)
Measures Results conform for real-world data	This measure tests the ability of Encor-E to operate and produce accurate measure results using real-world data (not static)	1740.315(c)(2)
# of eCQMs Submitted to CMS (for sampled clients)	This measure test the ability of Encor-E to send data results (QRDA-I / QRDA-III) to CMS regulatory systems.	1740.315(c)(2) 170.315(c)(3)

Justification for Measures

Measurement/Metric	Justification
Conformance to QRDA-I Standard	This measure will ensure that the system is generating compliant QRDA-I Documents, which is required for certification and client data submission
Conformance to QRDA-III Standard	This measure will ensure that the system is generating compliant QRDA-III Documents, which is required for certification and client data submission
Exports conform to manual input	This measure will ensure that data which is directly entered into the system via the manual patient entry (as opposed to data automatically consumed from an outside system) can be exported completely and correctly.
Measures Results conform for static data	This measure ensures that the underlying eCQM engine, which is responsible for generating eCQM results from input data, is producing accurate results based on the latest version of the open-source Cypress project. This is the foundational requirement of the entire system.
Measures Results conform for real-world data	This measure helps to ensure that real-world results (those generated from actual client data, and not from static datasets) are also accurate and precise. This is much more difficult to measure, as data consumed from client systems can change suddenly and unexpectedly; therefore, this measure requires Medisolv staff to individually assess results across multiple end-user environments.
# of eCQMs Submitted to CMS (for sampled clients)	This measure tracks the actual submission of eCQM results to CMS, it tracks (for 10 sample clients) which measures were submitted to CMS as part of the regulatory submission cycle.

Care Settings

Care Setting	Justification
Hospital	The hospital care setting represents an installation of Encor-E in a hospital and/or critical access hospital environment. In this care setting, Encor-E would be used to generate, monitor, trend and submit Eligible Hospital eCQMs.
Ambulatory	The ambulatory care setting represents an installation of Encor-E in an Eligible Professional / Eligible Clinician environment. In this care setting, Encor-E would be used to generate, monitor, trend and submit Eligible Professional/Eligible Clinician eCQMS.

Test Methodologies

Measurement/Metric	Test Methodology
Conformance to QRDA-I Standard	Data is loaded into the application using Cypress configurations and test decks/data. QRDA-I files are output for each certified measure, and are run through the Cypress validation utilities to ensure compliance with the latest standards In addition, once the regulatory submission windows open, data is submitted either via the testing interface(s) where applicable, or via direct submission and verification. Clinical consultants compare rejections, measure differences, warnings, and associated errata to ensure that the data processed by Medisolv matches the results computed by regulatory entities. Issues which cannot be resolved locally are entered into JIRA for identification and resolution. This is a pass/fail metric; each QRDA-I file is either compliant and passes, or is not compliant, and appropriate changes are made to bring the system into compliance. This test is performed on an annual basis, but retesting may occur if changes, errata, or other updates are announced by regulatory agencies during the performance period.
Conformance to QRDA-III Standard	Data is loaded into the application using Cypress configurations and test decks/data. QRDA-III files are output and are run through the Cypress validation

	utilities to ensure compliance with the latest standards. In addition, once the regulatory submission windows open, data is submitted either via the testing interface(s) where applicable, or via direct submission and verification. Clinical consultants compare rejections, warnings, and associated errata to ensure that the data processed by Medisolv is accepted by regulatory entities Issues which cannot be resolved locally are entered into JIRA for identification and resolution with support of ONC/CMS/Measure Stewards. This is a pass/fail metric; QRDA-III files are either compliant and pass, or are not compliant, and appropriate changes are made to bring the system into compliance. This test is performed on an annual basis, but retesting may occur if changes, errata, or other updates are announced by regulatory agencies during the performance period.
Exports conform to manual input	Data templates are created and entered into the manual input module of the application. The patient data is then exported into a QRDA-I file; the generated QRDA-I file is then loaded back into the application, and the patient data is compared to the manually entered data. This is a pass/fail metric, either the data matches exactly, and the system is passed, or the data does not

	match, and appropriate modifications are made to the system. This test is performed on an annual basis.
Measures Results conform for static data	A full Cypress test deck is created for all certified measures. The test deck is imported into the application, and the measure results are generated. The resulting files are then passed back into Cypress for verification, which identifies a pass/fail for each measure. This is a pass/fail metric, but it is broken down by measure. It is possible that most measures pass and only some fail. Failures are brought back for investigation, and corrections are made, or JIRA tickets are created if the results cannot be reconciled. This test is performed on an annual basis, but retesting may occur if changes, errata, or other updates are announced by regulatory agencies during the performance period.
Measures Results conform for real-world data	Once per quarter, clinical consultants and/or engineering support staff manually investigate 10 patients across all enabled measures at a client installation. Pseudo-random selection is performed, attempting to ensure that patients are selected at random, but do not share the same measure/population strata, so that the 10-patient manual check verifies the maximum number of data points possible. Medisolv attempts to select a different client for comparison each quarter (i.e., if possible, we will not sample the same client more than once per year for the purpose of this quarterly measurement). Medisolv

	also attempts to rotate the care setting each quarter to ensure maximum coverage of care settings, e.g., if a hospital care setting is selected for quarter 1, an ambulatory care setting will be selected for quarter 2 (unless that is not possible). Each patient selected is verified against all measures they are members of, and the population strata result from the measure engine is compared to raw clinical data in the Medisolv systems. This metric is a percentage-based metric, for each of the 10 patients, a pass/fail result is documented by the investigator. Each care setting can then be given a percentage result, ranging from 0-100. Note specifically that 10 patients are selected for investigation, not 10 measure results. This can mean that a single patient may have more than one measure result, and each measure result is given a pass/fail. Therefore, it is possible to have any percentage result between 0 and 100, not just 0/10/20 etc. The overall result is considered a failure if it is not 100%, and errors/failures are brought back to the engineering team for investigation. Issues are corrected, if found, or else JIRA tickets are created if the issue cannot be resolved locally. This test is performed on a quarterly basis.
# of eCQMs Submitted to CMS (for sampled clients)	Once per year, clinical consultants and/or engineering support staff will validate how many eCQMs were submitted to CMS for a sampling of 10 operational clients (operational is defined as a client who

	performed a production submission to CMS in the calendar year). This is a count-based metric, the result will be stratified by eCQM, with an integer result per eCQM submitted; as an extension, if CMS111 was submitted by 3 of the sampled clients, the result for CMS111 will be 3; if CMS56 was not submitted by any client, it will not be included in the results. This test is performed on an annual basis.

Expected Outcomes

Measurement/Metric	**Expected Outcomes**
Conformance to QRDA-I Standard	QRDA-I documents produced by Encor-E should pass Cypress verification and should conform to the latest QRDA-I specification.
Conformance to QRDA-III Standard	QRDA-III documents produced by Encor-E should pass Cypress verification and should conform to the latest QRDA-III specification.
Exports conform to manual input	Data entered via the manual patient entry screen, exported into QRDA-1, and then ingested back into Encor-E should have 100% identical patient information, including all demographics and clinical data points. In addition, exporting the QRDA-I from Encor-E after ingestion should produce a functionally identical file (allowing for differences in metadata such as generation time, e.g.).

Measures Results conform for static data	A full cypress test of all certified measures should result in a clean pass with no issues, including C2 and C3 criteria (accuracy of calculations, accuracy of exported data, conformance to all applicable standards).
Measures Results conform for real-world data	It is expected that a manual examination of 10 patients per quarter provides adequate coverage of certified measures and capabilities. Combined with the extensive regulatory submission testing that is also performed whenever available, this permits Medisolv to ensure accuracy with a commercially reasonable approach. Expectations are that the system will have a 100% match with examined data. Discrepancies are brought back for investigation, and corrections are made, or JIRA tickets are created if the issue cannot be resolved locally.
# of eCQMs Submitted to CMS (for sampled clients)	It is expected that production submissions from the sample client systems were made to CMS, in keeping with regulatory requirements and schedules.

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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