

REAL WORLD TESTING PLAN

GENERAL INFORMATION

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

Developer Name: Nuance Communications Inc.

Product Name(s): Nuance Electronic Quality Measures

Version Number(s): 23.1

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2071.Nuan.22.04.1.221220

Developer Real World Testing Page URL: <https://www.nuance.com/healthcare/provider-solutions/quality-management-solutions/quality-measures/cures-act-real-world-testing.html>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Nuance seeks to comply with CMS requirements related to Real World Testing (RWT). Details in the Federal Register can be found here: <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification#p-3580>. This is required since Nuance's ECQM has been certified compliant with 2015 Edition criteria in § 170.315, specifically (c)(1) through (c)(3).

The Nuance Electronic Quality Measures system is a self-contained, hosted solution, that is accessible with a browser and Internet connection. Customers may optionally access the software directly since it has been designed to 1) receive QRDA-1 formatted data from the client through automated, secure transmissions, 2) process it through algorithms to determine outcomes, and 3) export the data for submission to CMS/TJC.

As part of RWT, we'll identify at least two customers for monitoring the entire process, and confirming outcomes and reports are consistent with their expectations.

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

Standard (and version)	ICD10CM, ICD10PCS, LOINC, RXNORM, SNOMEDCT All are updated/maintained separately by standards bodies such as CMS
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)	N/A

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

DESCRIPTION OF MEASUREMENT/METRIC

Measurement/Metric	Description
170.315(c)(1) Clinical quality measures (CQMs) – record and export	The ability to record clinical quality data, and to create the QRD1 export file for the measures selected by a provider for a selected time period. Patient records will be loaded into the system by our clients. Clients will be able to run exports to create QRDA 1 files on individual patients or on the facility as whole for a given time period. Relied Upon Software for product is SQL Server.
170.315(c)(2) Clinical quality measures (CQMs) — import and calculate	The ability to import a QRDA 1 file for the measures selected by a provider for a selected time period, and to properly calculate each measure outcome. Patient records will be loaded into the system by our clients. The clients will be able to run reports to verify the number of records they submitted to what was loaded into the system. Relied Upon Software for product is SQL Server.
170.315(c)(3) Clinical quality measures (CQMs) — report	Enable a user to electronically create a data file for transmission of clinical quality measurement data in the QRDA I or QRDA III formats for the facility or an individual patient, in accordance with published standards For all of the patient records loaded by the client, users can run reports to see the outcomes of their data. These numbers can be the patient counts, the breakdown of patients per measure and the results of the outcomes. The system will enable users to create QRDA I and QRDA III files that can be submitted to CMS for comparison of results. Relied Upon Software for product is SQL Server.

JUSTIFICATION FOR MEASUREMENT/METRIC

Measurement/Metric	Justification
170.315(c)(1) Clinical quality measures (CQMs) – record and export	The justification of this metric is to be compliant with the ability for the client to A) “record all of the data that would be necessary to calculate each CQM”, and B) “to export a data file at any time the user chooses and without subsequent developer assistance to operate”. Data to be recorded must be in QRDA1 format. The client will have the option to export, in QRDA1 format, an individual patient file or a file for the quarterly submission period. Patient records will be loaded into the system by our clients. Clients will be able to run exports to create QRDA 1 files on individual patients or on the facility as whole for a given time period. Relied Upon Software for product is SQL Server.
170.315(c)(2) Clinical quality measures (CQMs) — import and calculate - Import	The justification of this metric is to be compliant with the ability for the client to A) “import a data file in accordance with the standard specified in §170.205(h)(2) for one or multiple patients”, and B) “calculate each and every clinical quality measure for which it is presented for certification.” The data may be imported through the application (manually) or through the secure, automated feed of compliant QRDA1 files. Patient records will be loaded into the system by our clients. The clients will be able to run reports to verify the number of records they submitted to what was loaded into the system. Relied Upon Software for product is SQL Server.
170.315(c)(3) Clinical quality measures (CQMs) — report (Cures)	The justification of this metric is to be compliant with the ability for the client to “electronically create a data file for transmission of clinical quality measurement data”. These files can be used for submission to CMS. For all of the patient records loaded by the client, users can run reports to see the outcomes of their data. These numbers can be the patient counts, the breakdown of patients per measure and the results of the outcomes. The system will enable users to create QRDA I and QRDA III files that can be submitted to CMS for comparison of results. Relied Upon Software for product is SQL Server.

CARE SETTING(S)

Care Setting	Justification
Acute Care Facilities	The data that is used to calculate the outcomes for the Electronic Clinical Quality Measures is received from the participating Acute Care Facilities. The Electronic Clinical Quality Measures pertain to patient encounters and need to have that final bill data sent to us in the QRDA format for processing.

EXPECTED OUTCOMES

Measurement/Metric	Expected Outcomes
170.315(c)(1) Clinical quality measures (CQMs) – record and export - Export Feature	The provider will capture all data elements from the QRDA 1 file for the selected measure and be able to export the data. Patient records will be loaded into the system by our clients. Clients will be able to run exports to create QRDA 1 files on individual patients or on the facility as whole for a given time period. Relied Upon Software for product is SQL Server.
170.315(c)(2) Clinical quality measures (CQMs) — import and calculate - Import	The provider will load (import) a QRDA1 file into the application to verify the format of the file and calculate results of the outcome for the measures that were contained in the file. Patient records will be loaded into the system by our clients. The clients will be able to run reports to verify the number of records they submitted to what was loaded into the system. Relied Upon Software for product is SQL Server.
170.315(c)(3) Clinical quality measures (CQMs) — report	The expected outcome is to create valid QRDA I and QRDA III files for submission to CMS at the facility level or at the individual patient level. For all of the patient records loaded by the client, users can run reports to see the outcomes of their data. These numbers can be the patient counts, the breakdown of patients per measure and the results of the outcomes. The system will enable users to create QRDA I and QRDA III files that can be submitted to CMS for comparison of results. Relied Upon Software for product is SQL Server.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Update of Electronic Clinical Quality Measures to new 2022 specifications.	Acute Care Facilities	August 2023
Data Collection and Review	Acute Care Facilities	Aug 2023 – Feb 2024
Real World Test Plan creation and submission	Acute Care Facilities	October 2023
Conduct Real World Testing	Acute Care Facilities	Jan - Feb, 2024
Submit Real World Testing results	Acute Care Facilities	Dec 2024

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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