Summary

This is the CY 2023 Real World Testing Plan for PARADIGM® 17.

Overall, we expect the Real World Testing will spotlight areas where our EHR application performs as expected, specifically demonstrates compliance to certification requirement standards for interoperability and functionality, and reveals areas where improvement(s) are merited.

Moreover, the data from the Real World Testing will help serve as a baseline for future testing. This testing serves as both a vehicle to record and benchmark current functionality and usability.

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General Information

Plan Report ID Number	20221018PARA17
Developer Name	QRS, Inc.
Product Name	PARADIGM®
Version Number	17
Certified Health IT Product List CHPL ID	15.04.04.2838.PARA.17.00.1.171228
Developer Real World Testing Page URL	http://www.qrshs.info

Justification for Real World Testing Approach

QRS, Inc. plans to test PARADIGM® EHR Version 17.

PARADIGM® EHR was developed, designed and markets to healthcare providers in ambulatory care settings spanning various medical specialties. We understand providers over various specialties have usage and clinical documentation needs unique to their own professional/specialty/patient base setting. Accordingly, we expect different specialties will present diverse measurement results.

Deciding factors for participant selection will be a combination of historical usage, scope of practice specialty, utilization of specific functionality, connections to immunization registries, public health agencies and authorized client representative permission to participate in the testing.

All testing will be performed on the client's server and/or workstation. Each client testing site participant will be informed of the type of information that will be accessed/captured from their system for testing purposes.

We expect data collection will occur without end-user interposition. This includes screen capture and/or report generation performed by the tester. Testing requiring interaction (observation) between the tester and end-user will be recorded. Recordings will be stored only at QRS, Inc. and destroyed after the testing process is deemed complete. Where applicable, the number of errors will be recorded and error rates calculated.

Where possible, we will use test patients. Real patient information will be de-identified.

We plan to utilize an appropriate validator in situations where we are unable to communicate with entities receiving a file (e.g., C-CDA validator, HL7 validator).

The QRS, Inc. team plans to review the data collected as well as feedback from testers and participating testing sites to identify areas of improvement for subsequent Real World Testing.

Testing Method(s)/Methodology(ies)

The following methodologies will be utilized during testing.
Log Files / Reports

- QRS, Inc. tester(s) will evaluate applicable audit logs and reports for historical activity as well as items that might not require proximate user intervention.

Polling

- End-users will be asked, based on the measure, if they use the functionality, how often and provide feedback regarding the usability.

Sandbox

- QRS' in-house virtualized environment

Scenario Testing

- Test cases will be used to evaluate end-to-end functioning of the program
  QRS, Inc. will evaluate how often the feature is used (numeric value) and the compliance (proper use / outcome).
  - System scenarios - Use-case scenarios - Role-based scenarios

Visual Inspection

- QRS, Inc. tester(s) will perform visual inspection to verify data is present, accurate and when applicable human readable. This method will also be used if negative testing is involved.

Care Setting(s)

PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings. Accordingly, our testing will occur in the ambulatory setting only.

We plan to test a minimum of three client practices. The number of client testing participants included may vary for each criterion/measure as we recognize not all have the same usage needs or perform the same activities in their respective specialty settings.

In settings where functionality is not widely used, we plan to utilize our sandbox environment for testing solely when needed, or in addition to client sites.

Standards Updates (Including Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDII)

Standard – Version	N/A
Updated Certification criteria and associated product	N/A
CHPL ID	N/A
Method used for standard	N/A
Date of ONC-ACB notification	N/A
Conformance measure	N/A
USCDI criteria – USCDI version	N/A

Applicable Certification Criteria

This plan includes real world testing measurements/metrics for the following criteria:

- 170.315(b)(1) - Transitions of Care
- 170.315(b)(2) - Clinical Information Reconciliation and Incorporation
- 170.315(b)(6) - Data Export
- 170.315(b)(7) - Security Tags - Summary of Care Send
- 170.315(b)(8) - Security Tags - Summary of Care Receive
- 170.315(c)(1) - Clinical quality measures (CQMs) - Record and Export
- 170.315(c)(2) - Clinical quality measures (CQMs) - Import and Calculate
- 170.315(c)(3) - Clinical quality measures (CQMs) - Report
- 170.315(e)(1) - View, Download, and Transmit to 3rd party
- 170.315(f)(1) - Transmission to Immunization Registries
- 170.315(f)(2) - Transmission to Public Health Agencies - Syndromic Surveillance
- 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
- 170.315(h)(1) - Direct Project

The measurement/metric elements noted for each criterion:

- Associated Certification Criteria
- Description of the Measurement/Metric
- Testing Method(s)/Methodology(ies)
- Justification for the Selected Measurement/Metric
- Care Setting(s)
- Expected Outcomes

Note: The elements for each measurement/metric are cited under the individual measures.

Measures Used in Overall Approach

C-CDA exchange via Direct Messaging

Associated Certification Criteria	170.315(b)(1) Transitions of Care
Description of the Measurement/Metric	We will track send and receive transmissions errors utilizing monthly reports generated with data logs from MDToolbox, our third-party Direct Messaging vendor. Measurement(s)/Metric(s): • Number of CCDs created • Number of CCDs successfully sent • Rate of errors when CCDs are received • Rate of errors when CCDs are viewed
Testing Method(s)/Methodology(ies)	Log Files / Reports; Use-case
Justification for the Selected Measurement/Metric	A review of our monthly transmission reports and MDToolbox's direct message send/receive logs will confirm messages have been exchanged. It will also allow the tester to evaluate frequency.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	Maximum of 2% error rate for each send/receive transmission type over a three-month period.

Incorporate reconciled Patient Health Information received via Direct Messaging

Associated Certification Criteria	170.315(b)(2) - Clinical Information Reconciliation and Incorporation
Description of the Measurement/Metric	When incorporating the patient's health information, the system should match the CCD and the patient automatically. If there is a discrepancy with the patient demographic data, the user should be able to match the patient manually. Measurement(s)/Metric(s); • Number of successful patient identifications • Number of errors during incorporation
Testing Method(s)/Methodology(ies)	Log Files; Polling; Use-case; Visual Inspection
Justification for the Selected Measurement/Metric	A review of reconciliation logs will identify clients who utilize the functionality. Interviews/Polling of test sites identified above will let us know if proper patient identification/reconciliation occurs. The QRS tester may also test this measure using test patient data.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	Rate of successful identification of patient(s) and subsequent incorporation of Patient Health Information will be greater 95%.

Configure and Create data export summary

Associated Certification Criteria	170.315(b)(6) - Data Export
Description of the Measurement/Metric	Authorized end-users should be able to configure (timeframe, and other needed options) and create, at will, an export summary for patients that meets standards specification. Measurement(s): • Number of records extracted from the EHR • Number of records exported out of the EHR • Rate of successful validations
Testing Method(s)/Methodology(ies)	Log Files; Polling; Use-case; Role-based testing; Visual Inspection
Justification for the Selected Measurement/Metric	A review of reconciliation logs will identify clients who utilize the functionality. Interview/Polling of test sites identified above will let us know if they are able to configure without incident. We expect this functionality may not be widely used. The QRS tester may also test this measure using test patient data. Tester files will be run through a C-CDA validator.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	End-user is able to configure an export summary at any time without subsequent developer assistance. Exported CCDs will successfully validate. Number of records extracted from the EHR will match the number of exported CCDs. Successful validation rate is expected to be greater than 95%.

Generate and Export Clinical Data Summary

Associated Certification Criteria	170.315(b)(7) - Security Tags - Summary of Care Send
Description of the Measurement/Metric	A generated summary of care record, with and without errors and transmitted will be inspected for conformance. We will evaluate the number of CCDs generated with and without errors. Measurement(s)/Metric(s): • Number of C-CDAs successfully validated • Number of C-CDAs with validation errors • Rate of successful validations
Testing Method(s)/Methodology(ies)	Visual Inspection; Use-case; Sandbox
Justification for the Selected Measurement/Metric	We expect this functionality may not be widely used. The QRS tester may also test this measure using test patient data. All generated test files will be run through a C-CDA validator.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	Summary record will successfully validate via C-CDA validator. CCDs with errors will not pass C-CDA validation. Rates for both will be reported. Successful validation rate is expected to be greater than 95%.

Receive and Import Clinical Data Summary

Associated Certification Criteria	170.315(b)(8) - Security Tags - Summary of Care Receive
Description of the Measurement/Metric	Visual inspection by the tester will confirm a human readable summary of care record was received. Tester will also verify document(s) are tagged restricted or not, and confirm only authorized users have access. Will we evaluate the number of CCDs imported with and without errors. Measurement(s)/Metric(s): • Number of C-CDAs successfully validated • Number of C-CDAs with validation errors • Rate of successful validations
Testing Method(s)/Methodology(ies)	Visual Inspection; Use-case; Role-based testing
Justification for the Selected Measurement/Metric	Visual inspection will confirm a human readable summary of care record was received. Utilizing role-based scenario will verify only an authorized user can perform certain tasks. We expect this functionality may not be widely used. The QRS tester may also test this measure using test patient data. The generated test files will be run through a C-CDA validator.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	A received summary of care record passes validation and can only be manipulated by an authorized user. CCDs with errors will not pass C-CDA validation. Rates for both will be reported. Successful validation rate is expected to be greater than 95%.

Collection and Reporting of individual CQMs

Associated Certification Criteria	Clinical quality measures (CQMs) 170.315(c)(1) - Record and Export 170.315(c)(2) - Import and Calculate 170.315(c)(3) - Report
Description of the Measurement/Metric	Evaluation of the number of measures exported, calculated accurately, and reported via QRDA III Measurement(s)/Metric(s): • Number of successful calculations • Number of calculations with errors • Rate of calculation errors • Number of successful validations • Number of validations with errors • Rate of validation errors
Testing Method(s)/Methodology(ies)	Log Files / Reports; Polling; Visual Inspection
Justification for the Selected Measurement/Metric	We will spot check patients cited in the reports and compare reported numbers against data entered in the EHR to ensure calculations are accurate. Test site polling will provide insight into any challenges of data entry vital for CQM calculation. We will also verify successful generation of the QRDA III file and validate via a QRDA validator.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	Successful CQM calculation and export of a validated QRDA III file. Error rate for calculations and validations will not exceed 1%.

Provide patients access to Patient Health Information sent to the Portal

Associated Certification Criteria	170.315(e)(1) - View, Download, and Transmit to 3rd party
Description of the Measurement/Metric	Evaluates number of patients who have portal accounts and have been provided access over a period of time. Measurement(s)/Metric(s): • Number of patients who access their portal account
Testing Method(s)/Methodology(ies)	Log Files / Reports; Visual Inspection; Polling; Use-case
Justification for the Selected Measurement/Metric	Review of log files and visual inspection of uploaded and downloaded files will allow testers to track frequency and compliance. Test site interviews will provide insight regarding their usage and their patient's comfort of use. Inspection of files will substantiate conformity.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties. Testing sites have a portal connection.
Expected Outcomes	End-user will log into the patient portal and is able to view, download and/or transmit files made available to them. Number of patients who accessed their portal account over a three-month period will be calculated.

Export Immunization Records

Associated Certification Criteria	170.315(f)(1) - Transmission to Immunization Registries
Description of the Measurement/Metric	We will verify immunizations recorded in the EHR are successfully sent to a public health agency. Measurement(s)/Metric(s): • Number of generated HL7 messages • Number of successfully transmitted HL7 messages • Rate of successful transmissions
Testing Method(s)/Methodology(ies)	Log Files / Reports; Use-case; Sandbox
Justification for the Selected Measurement/Metric	We will be able to verify data recorded in the EHR matches data exported to the public health agency in the HL7 message. We expect this functionality may not be widely used. Consequently, we may utilize our sandbox environment for testing. HL7 will be run through an HL7 validator to ensure conformance to standards. HL7 messages will be checked against the receiving registry's records.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties. Testing sites should have a connection to their state registry.
Expected Outcomes	HL7 messages meeting standard specifications are subsequently created and successfully sent to a public health agency. Total number of messages sent match registry records. Successful transmission rate is expected to be greater than 95%.

Export Syndromic Surveillance Records

Associated Certification Criteria	170.315(f)(2) - Transmission to Public Health Agencies - Syndromic Surveillance
Description of the Measurement/Metric	We will verify syndromic information recorded in the EHR is successfully sent to a public health agency. Measurement(s)/Metric(s): • Number of generated HL7 messages • Number of successfully transmitted HL7 messages • Rate of successful transmissions
Testing Method(s)/Methodology(ies)	Log Files / Reports; Use-case; Sandbox
Justification for the Selected Measurement/Metric	We will be able to verify data recorded in the EHR matches data exported to the public health agency in the HL7 message. We expect this functionality may not be widely used. Consequently, we may utilize our sandbox environment for testing. HL7 will be run through an HL7 validator to ensure conformance to standards. HL7 messages will be checked against the receiving registry's records.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties. Testing sites should have a connection to their state registry.
Expected Outcomes	HL7 messages meeting standard specifications are subsequently created and successfully sent to a public health agency. Total number of messages sent match registry records. Successful transmission rate is expected to be greater than 95%.

Correctly identify a Patient based on query parameters

Associated Certification Criteria	170.315(g)(7) - Application Access - Patient Selection
Description of the Measurement/Metric	Tester will evaluate full-circle process for receiving a request (API call) and returning correct and complete data. Measurement(s)/Metric(s): • Number of successful API requests • Number of API request errors • Rate of API request errors
Testing Method(s)/Methodology(ies)	Log Files / Reports; Visual Inspection; Use-case
Justification for the Selected Measurement/Metric	Review of log files and visual inspection of API requests and responses will allow tester to validate data for completeness and correctness.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	The API request will return a C-CDA R2.1 Validated CCD containing requests for patient data for specified dates and/or within specified date range(s). Maximum of 4% error rate for API requests over a three-month period.

Respond to requests for Patient Data for specific parameters

Associated Certification Criteria	170.315(g)(8) - Application Access - Data Category Request
Description of the Measurement/Metric	Tester will evaluate full-circle process for receiving a request (API call) and returning correct and complete data. Measurement(s)/Metric(s): • Number of successful API requests • Number of API request errors • Rate of API request errors
Testing Method(s)/Methodology(ies)	Log Files / Reports; Visual Inspection; Use-case
Justification for the Selected Measurement/Metric	Review of log files and visual inspection of API requests and responses will allow tester to validate data for completeness and correctness.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	The API request will return a C-CDA R2.1 Validated CCD containing requests for patient data for specified dates and/or within specified date range(s). Maximum of 4% error rate for API requests over a three-month period.

Respond to requests for Patient Data for all data categories

Associated Certification Criteria	170.315(g)(9) - Application Access - All Data Request
Description of the Measurement/Metric	Tester will evaluate full-circle process for receiving a request (API call) and returning correct and complete data. Measurement(s)/Metric(s): • Number of successful API requests • Number of API request errors • Rate of API request errors
Testing Method(s)/Methodology(ies)	Log Files / Reports; Visual Inspection; Use-case
Justification for the Selected Measurement/Metric	Review of log files and visual inspection of API requests and responses will allow tester to validate data for completeness and correctness.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	The API request will return a C-CDA R2.1 Validated CCD containing patient data for all data categories requested. Maximum of 4% error rate for API requests over a three-month period.

Send and Receive Secure Health Information

Associated Certification Criteria	170.315(h)(1) - Direct Project
Description of the Measurement/Metric	Verify messages are wrapped using MDToolbox, our third-party Direct Messaging vendor. Measurement(s)/Metric(s): • Number of successful transmissions • Number of transmissions with error(s)
Testing Method(s)/Methodology(ies)	Logs Files / Reports; Visual Inspection
Justification for the Selected Measurement/Metric	Logs will confirm messages meet expected outcomes.
Care Setting(s)	PARADIGM® EHR is principally marketed to healthcare providers in ambulatory care settings across various specialties.
Expected Outcomes	Functionality supports interoperability and exchange for sending and receiving messages consistent with the Direct Project standards and protocols. We expect a maximum of 2% transmission error rate over a three-month period.

Schedule of Key Milestones

Key Milestones	Date/Timeframe
• Identify internal testing team • Identify viable Real World Testing client test sites	Q4, 2022
• Contact client sites identified as viable test sites regarding participation in QRS' Real World Testing	Q1, 2023
• Conduct preparative calls with client testing sites	Q1, 2023
• Data collection as blueprinted in the plan	Q1 – Q3, 2023
• Follow-up with client testing sites	Q1 – Q3, 2023
• Aggregate collected test data	Q4, 2023
• Analyze test results and generate report	Q4, 2023
• Finalize Real World Testing report	January, 2024
• Submit Real World Testing report to Drummond	February, 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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Date: 10.26.2022