

§170.315(c)(2) Clinical quality measures (CQMs) – import and calculate

2015 Edition Test Procedure

Version 1.3 Updated on 06-29-2018

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	07-29-2016
1.1	Removed note to test one of the two alternatives and renumbered steps for paragraph (c)(2)(ii).	01-10-2017
1.2	<p>Added numbers to the Execute Any Time section for paragraph (c)(2)(i) and continued the numbering for the next sections (Setup and Import).</p> <p>Updated the numbering to restart at 1 for the SUT section of Calculate under paragraph (c)(2)(ii).</p> <p>Added a continued number to the section of Alternative: Cypress Certification API under the TLV of paragraph (c)(2)(ii).</p> <p>In paragraph (c)(2)(ii), updated the Alternative section to align with the correct steps a tester would take if using the Cypress Certification API.</p>	04-06-2018
1.3	Updated 'step #' to	06-29-2018

reference the actual step description and added clarifying language in the Alternative API section.

Regulation Text

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§170.315 (c)(2) *Clinical quality measures—import and calculate—*

(i) *Import.* Enable a user to import a data file in accordance with the standard specified in §170.205(h)(2) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Calculate each and every clinical quality measure for which it is presented for certification.

Standard(s) Referenced

Paragraph (c)(2)(i)

§ 170.205(h)(2) [HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I \(QRDA I\); Release 1, DSTU Release 3 \(US Realm\), Volume 1](#)

Additional Resources

§ 170.205(k)(1) [Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2](#)

§ 170.205(k)(2) [Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 \(US Realm\), September 2014](#)

Please consult the Final Rule entitled: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Testing components



ONC
Supplied
Test
Data

Paragraph (c)(2)(i)

System Under Test

Execute Any Time

1. The health IT developer supplies documentation outlining how a user can execute the import capability described in (c)(2)(i) any time the user chooses and without subsequent developer assistance to operate.

Setup

2. The Health IT Module provides the following information in order to enable the creation of the (c)(2)(i) "Cypress Gold Standard Test Data" which includes instructions to enable the recording of CQM data within patient record(s):
 - a. Name of the health IT developer;
 - b. Name of the Product;
 - c. List of CQMs to be certified; and
 - d. List of certification criteria to be tested

Import

3. Using the "Cypress Gold Standard Test Data" a user demonstrates the importing of reports formatted in accordance with the standard specified at § 170.205(h)(2) HL7 CDA® R2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3, Volume 1 for all of the data needed to calculate each of the clinical quality measures (CQMs) presented for testing, for one or multiple patients.

Test Lab Verification

Execute Any Time

1. The tester verifies that the health IT developer supplied documentation outlines that a user can perform an import as specified in (c)(2)(i) any time the user chooses and without subsequent developer assistance to operate.

Setup

2. The tester creates the "Cypress Gold Standard Test Data" based upon the information provided by the health IT developer, in Cypress, which will create a new (c)(2) test instance.

Import

3. Using visual inspection, the tester verifies that the Health IT Module can demonstrate the importing of CQM data specified in accordance to the standard at § 170.205(h)(2).

Paragraph (c)(2)(ii)

System Under Test

Calculate

1. The user calculates the aggregate reports for each of the CQMs for which they are seeking certification, based upon the imported and de-duplicated data set.
2. The Health IT Module submits an aggregate report for each of the CQMs to be certified.

Test Lab Verification

Calculate

1. The tester verifies that the Health IT Module can use the imported CQM data to calculate the aggregate data and display the report in accordance at a minimum to the standard at § 170.205(k) (1) Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 and § 170.205(k)(2) Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 using visual inspection.
2. Using Cypress, the tester:
 - a. uploads the aggregate report(s) submitted by the Health IT Module; and
 - b. displays and evaluates the accuracy of the submitted CQM results.

Packaging of Results

3. The tester generates a test artifact containing the following into a single archived file and any additional notes that the tester deems important:
 - a. all of the test data used to test (c)(2); and
 - b. all of the data generated by the Health IT Module.

Cypress Certification API (Alternative)

4. A tester may use the Cypress Certification API to upload the data file submitted by the Health IT Module. The tester can verify the results in Cypress as normal, however, the tester should manually verify that the Health IT Module can use the imported CQM data to calculate the aggregate data and display the report appropriately as well as the accuracy of the submitted CQM results for at least one CQM to ensure this functionality is present. The tester should still generate a test artifact containing the test data and all data generated by the Health IT Module into a single archive file, as usual. Testers are permitted to randomly select, at their discretion, which individual patient from the batch entry recording will be used to export a QRDA Category I file in order to demonstrate the functionality is present. The tester instructs the health IT developer to export the selected patient and confirms that this patient was exported.

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