§170.315(c)(1) Clinical quality measures (CQMs) – record and export

2015 Edition CCGs

Version 1.4 Updated on 02-28-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Revised to include clarification about testing and certification to versions of standards associated with the CMS annual measure updates.	01-10-2017
1.2	Revised to include clarification about testing, certification, and surveillance expectations for paragraph (c)(1)(ii).	03-17-2017
1.3	Revised to include optional manual testing utility language.	08-04-2017
1.4	Revised to include technology downtime for software upgrades language.	02-28-2020

Regulation Text

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§170.315(c)(1) *Clinical quality measures—record and export—*

(i) *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM.

Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) *Export.* A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:

(A) Formatted in accordance with the standard specified in §170.205(h)(2);

(B) Ranging from one to multiple patients; and

(C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

Standard(s) Referenced

Paragraph (c)(1)(ii)

§ 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

Certification Companion Guide: Clinical quality measures (CQMs) – record and export

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(c)(1). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(c) "paragraph (c)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (c) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer

attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- Health IT needs to be able to record all data necessary to successfully calculate selected clinical quality measures (CQMs).
- The specific version, number, and type of CQMs presented for certification are determined at the developer's discretion. We recommend developers consult any CMS or other programs' requirements around the specific version, number, or type of CQMs required for providers in determining the CQMs presented for certification.
- Certain CMS programs require or provide the option for electronic CQM (eCQM) reporting. These programs include the EHR Incentive Program, the Physician Quality Reporting System, the Hospital Inpatient Quality Reporting Program, the Comprehensive Primary Care (CPC) initiative, CPC Plus, and the Value-Based Payment Modifier Program. Each year, CMS issues annual updates to eCQMs

(herein referred to as the "CMS annual measure update(s)") which are published on the Electronic Clinical Quality Improvement (eCQI) Resource Center. The CMS annual measure updates rely upon a specific version of the Quality Reporting Document Architecture (QRDA) Category I standard. Each year's QRDA Category I standard is referenced in the corresponding CMS QRDA Implementation Guide (IG) associated with that program year and CMS annual measure update. The CMS QRDA IG also contains additional programmatic form and manner requirements necessary for reporting to CMS programs, which make it necessary for the corresponding testing tools to keep pace with these measure updates and CMS reporting requirements. Thus, health IT developers are permitted to be tested and certified to the applicable CMS annual measure update and use the corresponding version of QRDA Category I standard referenced in the CMS QRDA IG. ONC will evaluate the need for future rulemaking to align the version of QRDA Category I standard required for this certification criterion with the version of QRDA Category I standard in the CMS annual measure update.

- After technology is certified to specific CQMs for this 2015 Edition certification criterion at § 170.315(c)(1), technology is not required to recertify to the annual measure specification updates CMS issues to maintain 2015 Edition certification unless that product is relabeled. Said another way, other programs, such as the EHR Incentive Programs, may require developers to upgrade their technology to the newest CQM specifications, but the technology is not required to be retested or recertified for eCQMs already certified unless explicitly specified in other program requirements. [see also ONC FAQ #42] It is expected that all systems will test all measure and standards updates as a best practice. The testing tools are available for each CMS annual measure update and when there are late standards errata or CMS requirement changes to facilitate additional testing for products using eCQMs.
- For the purposes of automated testing to meet certification requirements, only errors (but not warnings) generated during testing would constitute a failure to meet certification requirements.

Paragraph (c)(1)(i)

Technical outcome – The health IT must be able to record all data necessary to calculate CQMs presented for certification.

Clarifications:

- Providers may employ many methods to capture the information required by CQMs. Information transferred from other systems can meet the requirement for "capture." [see also 77 FR 54230] We recommend developers include functionality that allows users to view any information transferred from other systems.
- ONC-Authorized Testing Labs (ONC-ATLs) are permitted to provide flexibility regarding data elements for manual entry where the measure allows multiple ways to express the same data criteria or alternate data criteria where appropriate.
- Data required for CQM exclusion or exceptions must be codified entries and may include specific terms defined by each CQM selected. Free text is permitted to be captured in addition to the minimum requirement to capture data as a codified entry.
- Specific reasons why an action was performed or not performed to determine whether the patient meets an exclusion or exception should be recorded as part of the generated QRDA Category I file.

Paragraph (c)(1)(ii)

Technical outcome – A user can export a data file formatted in accordance with HL7 QRDA Category I Release 3 or the corresponding version of the QRDA standard for the CMS annual measure update being certified for one or multiple patients that includes all of the data captured in (c)(1)(i) of this criterion.

Clarifications:

- A user of this health IT must be able to create these reports at any time selected without additional assistance from health IT developers. This will allow a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis. It also gives providers the ability to export their results to multiple programs, such as those run by CMS, states, and private payers, and/or reporting solutions, such as registries or other types of data intermediaries. While a user of this health IT must be able to create these reports at any time selected without additional assistance from health IT developers, health IT developers can claim technology downtime for software upgrades (to accommodate upgrades for the latest QRDA specification, for example). Health IT developers experiencing technology downtime for software upgrades should communicate their reason for technology downtime and when their technology will again be operational. [77 FR 54230 and 80 FR 62650]
  - Testing and Certification. Successful testing and certification does not require the evaluation of the time required to process a CQM data file. To illustrate, a delay between when a user initiates an export and receives the resulting data file would not, by itself, preclude successful testing of the technology or the issuance of a certification on the basis of those successful test results.
  - Surveillance. While the CQM export capability does not require that data be received instantaneously, a non-conformity would exist if surveillance revealed that processing or other delays were likely to substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis. [80 FR 62650] Similarly, a non-conformity would exist if delays were causing or contributing to users being presented with data files that no longer contained current, accurate, or valid data. To avoid these implementation issues and ensure that capabilities support all required outcomes, health IT developers should seek to minimize processing times and other delays to the greatest extent possible. We note also that any delays must be disclosed in accordance with 170.523(k)(1).
- Providers and health systems should determine the protocols around when and how providers export CQM data. As noted above, for testing, the health IT would need to demonstrate a user can export data formatted to QRDA Category I for one or more patients without needing additional developer support. [80 FR 62650]

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