§170.315(c)(3) Clinical quality measures (CQMs) – report

2015 Edition CCGs

Version 1.2 Updated on 08-04-2017

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-26-2015
1.1	Revised to include clarification about testing and certification to versions of standards associated with the CMS annual measure updates. Updated incorrect links.	01-10-2017
1.2	Revised to include an ONC approved alternative test procedure, tool, and data offered by the National Committee for Quality Assurance (NCQA).	08-04-2017

Regulation Text

Regulation Text

§170.315 (c)(3) *Clinical quality measures—report—*

Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) At a minimum, in accordance with the standards specified in §170.205(h)(2) and §170.205(k)(1) and (2).

(ii) *Optional.* That can be electronically accepted by CMS.

Standard(s) Referenced

Paragraph (c)(3)(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

§ 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

Paragraph (c)(3)(ii)

The standards will be specified by CMS in its regulations and program guidance. For more information please reference CMS's QRDA page.

Certification Companion Guide: Clinical quality measures (CQMs) – report

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	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(c)(3). 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:

- The specific version, number, and type of clinical quality measures (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 specific versions of the Quality Reporting Document Architecture (QRDA) Category I and Category III standards. Each year's QRDA standards are 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 versions of QRDA Category I and Category III standards as referenced in the CMS QRDA IG. ONC will evaluate the need for future rulemaking to align the versions of QRDA standards required for this certification criterion with the versions of QRDA standards in the CMS annual measure update.

- After technology is certified to specific CQMs for this 2015 Edition certification criterion at § 170.315(c)(3), 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 Program, may require developers upgrade their technology to the newest CQM specifications, but the technology is not required to be retested or recertified 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 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)(3)(i)

Technical outcome – A user can create a data file for transmission of CQM data in QRDA Category I (for individual level reports) and Category III (for aggregate reports) as specified in the HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I), DSTU Release 3 and Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) with September 2014 Errata, respectively or the corresponding version of the QRDA standard for the CMS annual measure update being certified.

Clarifications:

- No additional clarifications available.

Paragraph (c)(3)(ii) *Optional*

Technical outcome – As an optional provision, a user can create a data file for transmission of CQM data that can be electronically accepted by CMS.

Clarifications:

- The requirements for CMS reporting will be published by CMS in documents such as the CMS QRDA Implementation Guide. CMS will indicate in its regulations and program guidance whether this optional provision is required for participation in its programs. (Refer also to clarification above which applies to the entire criterion.)
- This provision is optional because providers may use the measures and the technology certified to this criterion for calculating and reporting measures to entities other than CMS programs. [see also 80 FR 62652]
- The testing tool(s) for 2015 Edition CQM criteria support testing to the CMS QRDA Implementation Guide requirements for the measures intended for certification. Conformance failures against the CMS QRDA Implementation Guide are displayed as warnings. The following links are references to CMS CQM reporting resources:
  - CMS and ONC eCQI Resource Center

- CMS Quality Measure Basics
- CMS EHR Incentive Program Resource Page (contains program requirements, reporting requirements, and other resources for each program year).

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