

# 2015 Edition Certification Companion Guide

## Clinical Quality Measures – Report - 45 CFR 170.315(c)(3)

Links will be updated as available: [Final Rule Preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool Supplemental Guide](#)

Version 1.0 – Last Updated 10/26/2015

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
Revised	No	No	Included	N/A

### 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.

**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.

Privacy and Security (§ 170.315(d))	Design and Performance (§ 170.315(g))
<ul style="list-style-type: none"> <li>• If choosing Approach 1:               <ul style="list-style-type: none"> <li>○ <a href="#">Authentication, access control, and authorization (§ 170.315(d)(1))</a></li> <li>○ <a href="#">Auditable events and tamper-resistance (§ 170.315(d)(2))</a></li> <li>○ <a href="#">Audit reports (§ 170.315(d)(3))</a></li> <li>○ <a href="#">Automatic access time-out (§ 170.315(d)(5))</a></li> </ul> </li> <li>• If choosing Approach 2:               <ul style="list-style-type: none"> <li>• For each applicable P&amp;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&amp;S criteria would be deployed and used.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">Quality management system (§ 170.315(g)(4))</a></li> <li>• <a href="#">Accessibility-centered design (§ 170.315(g)(5))</a></li> </ul>

**Regulation Text**

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.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• The specific number and type of clinical quality measures (CQMs) presented for certification are determined at the developer’s discretion. We recommend developers consult any program requirements around the specific number or type of CQMs for providers in determining the CQMs presented for certification.</li> <li>• 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 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 <a href="#">ONC FAQ #42</a>]</li> <li>• Typically developers will certify for QRDA Category I and QRDA Category III to the same version of the measure specification(s), but it is not a requirement of certification. Developers should consult any program requirements regarding the version of measures that must be certified in order for a provider to participate in a particular program.</li> </ul>	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	<ul style="list-style-type: none"> <li>Technical outcome – A user can create a data file for transmission of CQM data in QRDA Category I (for individual level reports) <u>and</u> 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.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>No additional clarifications available.</li> </ul>	<p>§ 170.205(h)(2) <a href="#">HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I), DSTU Release 3 (US Realm)</a></p> <p>§ 170.205(k)(1) <a href="#">HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm)</a></p> <p>§ 170.205(k)(2) <a href="#">Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1 (US Realm), September 2014<sup>1</sup></a></p>

<sup>1</sup> Please download the entire file for the HL7 Implementation Guide for CDA® Release 2: QRDA - Category III DSTU Release 1 to access the Errata.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(ii)	<ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>The requirements for CMS reporting will be published by CMS in documents such as the CMS QRDA Implementation Guide.<sup>2</sup> CMS will indicate in its regulations and program guidance whether this optional provision is required for participation in its programs.</li> <li>This provision is optional because providers may use technology certified to this criterion for reporting to programs that do not require the same QRDA reporting provisions of CMS programs. [see also <a href="#">80 FR 62652</a>]</li> <li>The following links are references to CMS CQM reporting resources: <ul style="list-style-type: none"> <li><a href="#">CMS and ONC eCQI Resource Center</a></li> <li><a href="#">CMS Quality Measure Basics</a></li> <li><a href="#">CMS 2015 CQM Reporting Options</a></li> <li><a href="#">eCQM Library</a>.</li> </ul> </li> </ul>	The standards will be specified by CMS in its regulations and program guidance.

**Note:** 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.

**Version History**

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 26, 2015

<sup>2</sup> Available at: [https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm\\_library.html](https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html).