

2015 Edition Certification Companion Guide

Clinical Quality Measures – Import and Calculate - 45 CFR 170.315(c)(2)

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

Version 1.2 – Last Updated 3/17/2017

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

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(c)(2). 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"> • If choosing Approach 1: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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. 	<ul style="list-style-type: none"> • Quality management system (§ 170.315(g)(4)) • Accessibility-centered design (§ 170.315(g)(5))

Regulation Text

Clinical quality measures – import and calculate.

- (i) Import. Enable a user to import a data file in accordance with the standard specified at § 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.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Clarifications:</p> <ul style="list-style-type: none"> • 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 a specific version of the 	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion, continued	<ul style="list-style-type: none"> • 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 tool (Cypress) 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. Note that for this criterion at § 170.315(c)(2), the Cypress testing tool is only capable of validating the correct calculation of CQMs for reports submitted in the corresponding QRDA Category III format. 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)(2), 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 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. [ONC FAQ #42] It is expected that all systems will test all measure and standards updates as a best practice. The Cypress tool is available for each CMS annual measure update and when there are late standards errata or CMS requirement changes to facilitate additional testing. • Systems that present for certification to § 170.315(c)(1), (c)(2), (c)(3) must explicitly demonstrate this criterion at § 170.315(c)(2). Those systems previously considered “self-contained” according to the 2014 Edition policy will no longer be deemed to meet certification for § 170.315(c)(2). [see also 80 FR 62650] • 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. 	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	<ul style="list-style-type: none"> • Technical outcome – A user can import 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 in order to perform calculations on the CQMs presented for certification. <p>Clarifications:</p> <ul style="list-style-type: none"> • A user of this health IT must be able to import a data file at any time selected without additional assistance from health IT developers. We are not prescribing how data is imported into a system (e.g., mapped to backend database or viewable to a provider as part of the patient record) and leave the determination at the discretion of the developer. [80 FR 62650] <ul style="list-style-type: none"> ○ <u>Testing and Certification</u>. 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. ○ <u>Surveillance</u>. 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). • This provision will streamline testing and certification by importing QRDA Category I files avoiding the need for systems to manually enter test patient data. It will also promote quality improvement and data sharing between systems by providing the systems the ability to import CQM data from other systems in a standardized format. [see also 80 FR 62650] • Providers and health systems should determine the protocols around when and how providers import CQM data. For testing, the health IT would need to demonstrate a user can import data formatted to QRDA Category I for one or more patients without needing additional developer support. [see also 80 FR 62651] 	<p>§ 170.205(h)(2) HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I (QRDA I), DTSU Release 3 (US Realm)</p>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i), continued	<ul style="list-style-type: none"> We would expect that health IT must be able to de-duplicate patient records, but do not prescribe how systems would demonstrate de-duplication. Developers have the discretion to determine the most suitable method for deduplication. [see also 80 FR 62651] De-duplication testing will require systems to identify two files with the same patient identifiers but different QRDA document identifiers. Testing will more robustly test the pathways by which a patient is included in the numerator and/or denominator, including exclusions and exceptions, of a measure. [see also 80 FR 62651] 	See above
(ii)	<ul style="list-style-type: none"> Technical outcome – The health IT must be able to calculate each CQM presented for certification. <p>Clarifications:</p> <ul style="list-style-type: none"> The Cypress testing tool is only capable of validating the correct calculation of CQMs for reports submitted in the QRDA Category III format. 	N/A

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 29, 2015
1.1	Included clarifications regarding testing and certification to versions of standards associated with the CMS annual measure updates, de-duplication, and testing for calculation.	Jan 10, 2017
1.2	Revised to include clarification about testing, certification, and surveillance expectations for paragraph (i).	Mar 17, 2017