2015 Edition Certification Companion Guide

Clinical Quality Measures – filter - 45 CFR 170.315(c)(4)

Final Rule Preamble – **Correction Notice Preamble** – **Test Procedure** – **Test Tool/Data**

Version 1.2 – Last Updated 04/24/2017

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)
New	No	No	No	N/A

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(c)(4). 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))

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

Regulation Text

Clinical quality measures – filter.

(i) Record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.

(ii) Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section and be able to:

(A) Create a data file of the filtered data in accordance with the standards adopted in § 170.205(h)(2) and § 170.205(k)(1) and (2); and

(B) Display the filtered data results in human readable format.

(iii) Data.

(A) Taxpayer Identification Number.

(B) National Provider Identifier.

(C) Provider type in accordance with, at a minimum, the standard specified in § 170.207(r)(1).

(D) Practice site address.

(E) Patient insurance in accordance with the standard specified in § 170.207(s)(1).

(F) Patient age.

(G) Patient sex in accordance with the version of the standard specified in § 170.207(n)(1).

(H) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2).

(I) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	• 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 tool (Cypress) to keep pace with those 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. • 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
(i)	• Technical outcome – The health IT can record the data listed in (iii) in accordance with the identified standards where specified. ***Clarifications:*** • Clarifications for specific data can be found below for subparagraph (iii).	Refer to criterion subparagraph (iii) below for standards for data where specified.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(ii)(A)-(B)	• Technical outcome – The health IT can filter clinical quality measure (CQM) results at the patient and aggregate levels by each one and any combination of the data listed in (iii). The health IT must be able to create a data file of the filtered data in accordance with: o HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DSTU Release 3; o Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2; o Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1 (US Realm), September 2014; or o The corresponding version of the QRDA standard for the CMS annual measure update being certified. • The health IT must also be able to display the filtered data results in human readable format. ***Clarifications:*** • A Health IT Module must be able to filter by any combination of the proposed data elements (i.e., by any one (e.g., provider type) or a combination of any of the data elements). Testing will not cover all possible combinations, but the certification criterion requires all combinations can be demonstrated for certification. The number of combinations tested is at the discretion of the tester. [see also 80 FR 62653] • No particular workflow must be demonstrated for certification as long as the technical outcome can be achieved. [see also 80 FR 62653]	§170.205(h)(2) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture – Category I (QRDA I); Release 1, DTSU Release 3 (US Realm) § 170.205(k)(1) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) § 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[1]
(iii)(A) Taxpayer Identification Number (TIN)	***Clarifications:*** • Including TIN in this criterion offers a baseline for filtering by TIN data for certification. We would expect that any programs that may require CQM reporting using TIN would provide additional guidance on the level to use for participation in its programs. [see also 80 FR 62653]	N/A

[1] 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
(iii)(B) National Provider Identifier (NPI)	***Clarifications:*** • Including NPI in this criterion offers a baseline for filtering by NPI data for certification. We would expect that any programs that may require CQM reporting using NPI would provide additional guidance on the level to use for participation in its programs. [see also 80 FR 62653]	N/A
(iii)(C) Provider type	***Clarifications:*** • The CMS Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 maps the Medicare Provider/Supplier type to the relevant healthcare provider taxonomy codes. [see also 80 FR 62654] • When a provider registers for an NPI number, they are required to select at least one provider type code from the Code Set, but may select more than one code. However, the provider is required to select one code as the primary code. [see also 80 FR 62654] • The NPI record for a given provider contains all codes a provider selected, and it is expected that CQM results could be filtered by any one of the provider's selected codes (e.g., primary, secondary, tertiary, etc.). [see also 80 FR 62654] • Health IT Modules can present for certification to a more recent version of the Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy than the April 2, 2015 release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62612]	§ 170.207(r)(1) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015
(iii)(D) Practice site address	***Clarifications:*** • The Cypress testing tool for 2015 Edition CQMs criteria, including for CQM filtering, will test and validate to the HL7 postal format. Health IT developers and implementers should adhere to the guidance in the QRDA Category I and III standards adopted for this criterion for the HL7 postal format. [see also 80 FR 62654] Note that testing will test for the site address of the site that bills for care rather than the mailing address of the provider itself.	N/A
(iii)(E) Patient insurance	***Clarifications:*** • No additional clarifications available.	§ 170.207(s)(1) Source of Payment Typology Code Set Version 5.0 (October 2011)
(iii)(F) Patient age	***Clarifications:*** • For this certification criterion, it is intended that "patient age" is derived from the patient's date of birth, so that a user could query for patients older than a certain age, younger than a certain age, or between a range of ages. [see also 80 FR 62653]	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(iii)(G) Patient sex	***Clarifications:*** • The codes required are intended to present birth sex (i.e., the sex recorded on the patient's birth certificate) and not gender identity or reassigned sex. [see also 80 FR 62618]	§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows: (i) Male. M (ii) Female. F (iii)Unknown. nullFlavor UNK
(iii)(H) Patient race and ethnicity	***Clarifications:*** • Note that industry standards (including QRDA) require race and ethnicity be exchanged as separate fields. • The "Race & Ethnicity – CDC" code system includes over 900 concepts for race and ethnicity. [see also 80 FR 16816] A health IT developer is free to determine how the user interface is designed, including how many race and ethnicity values are displayed. No default minimum number of visible selections is expected or implied. During testing, however, any of the concepts for race and ethnicity may be tested. [see also 80 FR 62618] • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. o "Race & Ethnicity" - CDC code system OID: 2.16.840.1.113883.6.238 [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version of the "Race & Ethnicity" – CDC code system than Version 1.0. [see also 80 FR 62612]	§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(iii)(I) Patient problem list	***Clarifications:*** • For testing and certification, a Health IT Module only needs to demonstrate that it can filter by SNOMED CT® codes in the problem list value set referenced in the measure. While we indicated in the preamble of the 2015 Edition final rule that testing and certification would focus on the ability of a Health IT Module to filter by the parent level SNOMED CT® codes, we did so to address commenters' concerns about the level of complexity of filtering SNOMED CT® codes for patient problem lists and to lessen the testing and certification burden for health IT developers (80 FR 62655). After further evaluation and health IT developer feedback, we have determined that quality improvement goals can still be achieved and developer burden reduced by testing and certifying the ability of health IT to filter by SNOMED CT® codes in the problem list value set without requiring the mapping of child SNOMED CT® codes to parent SNOMED CT® codes. • We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62612]	§ 170.207(a)(4) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release

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	Dec 18, 2015
1.1	Revised to include clarification about testing and certification to versions of standards associated with the CMS annual measure updates.	Jan 10, 2017
1.2	Revised to clarify the requirements for filtering by SNOMED CT® codes for problem list data.	Apr 24, 2017