2015 Edition Certification Companion Guide

Transmission to Cancer Registries - 45 CFR 170.315(f)(4)

Links will be updated as available: **Final Rule Preamble** – **Test Procedure** – **Test Tool/Data** – **Test Tool Supplemental Guide** – **MU Specification Sheet**

Version 1.0 – Last Updated 10/29/2015

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[1]	Objective 8

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(4). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(f) "paragraph (f)" 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 (f) 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.

[1] For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.

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))
  ○ End-user device encryption (§ 170.315(d)(7))
• 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.
	• Quality management system (§ 170.315(g)(4))
	• Accessibility-centered design (§ 170.315(g)(5))

Regulation Text

Transmission to cancer registries. Create cancer case information for electronic transmission in accordance with:
(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2).
(ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	***Clarifications:*** • This certification criterion is intended for technology designed for the ambulatory setting. • We have not adopted a "cancer case information" certification criterion. This decision has no impact on the requirements of the 2015 Edition "transmission to cancer registries" certification criterion or the requirements of the IG. Certification to the 2015 Edition "transmission to cancer registries" criterion requires a Health IT Module to demonstrate that it can create a file with the necessary cancer case information in accordance with the IG. [see also 80 FR 62667] • "Cancer case information" is synonymous with the "cancer event reports" or "cancer reports" referred to in the HL7 Implementation Guide (IG) for CDA Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, DSTU Release 1.1.	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	• Technical outcome – The health IT can create cancer case information for electronic transmission in accordance with the HL7 IG for CDA Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, DSTU Release 1.1. ***Clarifications:*** • The CDC recently published an updated version of the Implementation Guide for reporting to cancer registries (HL7 IG for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, U.S. Realm) ("Release 1.1."). Release 1.1 involves technical corrections to Release 1. No new content has been included. We refer developers to the DSTU Release 1.1 for a full list of the updates. [see also 80 FR 62666] • Mapping to the North American Association of Central Cancer Registries (NAACCR) format is not included in the IG because the mapping rules are complex, and can change over time based on continued input and refinement by the cancer registry community. It is our understanding that the CDC will work closely with the cancer registry community to develop mapping rules for the IG and will incorporate the rules into the software tools CDC provides state cancer registries. In regard to concerns expressed about jurisdictional variations, all public health jurisdictions have adopted the HL7 IG Release 1 for cancer reporting and will be moving to the updated version published by the CDC. [see also 80 FR 62666]	170.205(i)(2) HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, April 2015
(ii)	• Technical outcome – The health IT can create cancer case information for electronic transmission using, at a minimum, the September 2015 Release of the U.S. Edition of SNOMED CT® and Version 2.52 of LOINC®. ***Clarifications:*** • We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. o SNOMED CT® OID: 2.16.840.1.113883.6.96 o LOINC® OID: 2.16.840.1.113883.6.1 [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 and a more recent version of LOINC® than Version 2.52 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]	§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 § §170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015

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