

2015 Edition Certification Companion Guide

Transmission to Public Health Agencies – Electronic Case Reporting - 45 CFR 170.315(f)(5)

Links will be updated as available: [FR preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool Supplemental Guide](#) – [MU Specification Sheet](#)

Version 1.0 – Last Updated 10/27/2015

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)
New	No	No	Yes ¹	Objective 8

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(5). 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. for which a certificate would be requested.

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))
<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)) ○ End-user device encryption (§ 170.315(d)(7)) • 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

Transmission to public health agencies – electronic case reporting.

- (i) Consume and maintain a table of trigger codes to determine which encounters may be reportable.
- (ii) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.
- (iii) Case report creation. Create a case report for electronic transmission.
 - (A) Based on a matched trigger from paragraph (ii).
 - (B) That includes, at a minimum:
 - The Common Clinical Data Set.
 - Encounter diagnoses. Formatted according to at least one of the following standards:
 - (i) The standard specified in § 170.207(i).
 - (ii) At a minimum, the version of the standard specified in § 170.207(a)(4).
 - The provider's name, office contact information, and reason for visit.
 - An identifier representing the row and version of the trigger table that triggered the case report.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Clarifications:</p> <ul style="list-style-type: none"> ○ A specific content exchange standard for electronic case reporting is not required to meet this criterion. [80 FR 62667] ○ The optional use of an ONC-approved test tool for case reporting using standards such as C-CDA, the Structured Data Capture (IHE SDC) Implementation Guide, or the Fast Health Interoperability Resources (FHIR) Structured Data Capture Implementation Guide may be available in the future. While not required to meet this criterion, testing through an ONC-approved test tool for case reporting would meet the requirements of this criterion. 	N/A
(i)	<ul style="list-style-type: none"> • Technical outcome – Health IT is able to consume and maintain a table of trigger codes to determine which encounters should initiate an initial case report being sent to public health. • No additional clarifications available. 	N/A
(ii)	<ul style="list-style-type: none"> • Technical outcome – Health IT can match a patient visit or encounter to the trigger code using the trigger code table. <p>Clarifications:</p> <ul style="list-style-type: none"> • No additional clarifications available. 	N/A
(iii)	<ul style="list-style-type: none"> • Technical outcome – When a trigger is matched in accordance with provision (ii), the Health IT Module electronically creates an initial case report with the specified data elements listed in this paragraph. <p>Clarifications</p> <ul style="list-style-type: none"> ○ We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. <ul style="list-style-type: none"> ▪ 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 the U.S. Edition of SNOMED CT[®] 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] 	<p>§ 170.207(i) ICD-10-CM</p> <p>§ 170.207(a)(4) SNOMED CT[®] U.S. Edition, September 2015 Release</p>

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 27, 2015