2015 Edition Certification Companion Guide

Transmission to Public Health Agencies – Syndromic Surveillance - 45 CFR 170.315(f)(2)

Links will be updated as available: **Final Rule Preamble** – **Test Procedure** – **Test Tool/Data** – **NIST Normative Test Process Document** – **MU Specification Sheet**

Version 1.1 – Last Updated 1/29/16

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 (see further clarification below)	No	Yes[1]	Objective 8

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(2). 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. 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

Transmission to public health agencies—syndromic surveillance. Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	***Technical Outcome:*** • The Health IT is able to create syndrome-based public health surveillance information for electronic transmission to public health agencies according to the HL7 2.5.1 standard, the PHIN Messaging Guide for Syndromic Surveillance Release 2.0, and the August 2015 Erratum to the PHIN Messaging Guide. ***Clarifications:*** • It is appropriate to distinguish between ambulatory settings from emergency department, urgent care and inpatient settings. This criterion requires the use of the HL7 2.5.1 standard, PHIN Messaging Guide Release 2.0, and August 2015 Erratum to the PHIN Messaging Guide for the inpatient setting (which includes emergency departments). • There is no certification requirement for the ambulatory setting. We note that the PHIN Messaging Guide Release 2.0 and Erratum does support the urgent care ambulatory setting and would be appropriate to use to that particular setting. [see also 80 FR 62665] • This certification criterion is not eligible for gap certification. We note that we adopted a voluntary criterion for ambulatory syndromic surveillance in the 2014 Edition Release 2 final rule (at § 170.314(f)(7)) for health IT to create syndrome-based syndromic surveillance information containing certain data. This 2015 Edition syndromic surveillance certification criterion (at § 170.315(f)(2)) requires an updated implementation guide (IG) and erratum for emergency department, urgent care, and inpatient settings. Any system certifying to this criterion at § 170.315(f)(2) must conform to the updated IG and erratum, and therefore this criterion is not gap certification eligible. We note that this 2015 Edition certification criterion for syndromic surveillance does not require any standard for the ambulatory setting, unless the technology is intended to be used in the urgent care setting. • The CDC published an erratum to the PHIN Messaging Guide Release 2.0 (August 2015). The Erratum consolidates Release 2.0 information and clarifies existing conformance requirements of the IG. We refer developers to the addendum for specific information about the clarifications it includes. [see also 80 FR 62665] • There is no transport standard required for this criterion. Developers have the flexibility to determine the transport standard(s) to implement. [see also 77 FR 54243]	§170.205(d)(4) Standard. HL7 2.5.1. Implementation specifications. PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 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
1.1	Updated to provide additional clarifications about the gap certification eligibility of this criterion.	Jan 29, 2016