

2015 Edition Certification Companion Guide

Patient-specific education resources - 45 CFR 170.315(a)(13)

Links will be updated as available: [Final Rule Preamble](#) – [Test Procedure](#) – [MU Specification Sheet](#)

Version 1.2 – Last Updated 3/24/16

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	No	Yes	Objective 5

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(a)(13). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) “paragraph (a)” 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 (a) 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)) ○ Amendments (§ 170.315(d)(4)) ○ Automatic access time-out (§ 170.315(d)(5)) ○ Emergency access (§ 170.315(d)(6)) ○ 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

Patient-specific education resources.

- (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with at least one of the following standard and implementation specifications:
 - (A) The standard and implementation specifications specified in § 170.204(b)(3).
 - (B) The standard and implementation specifications specified in § 170.204(b)(4).
- (ii) Optional. Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Clarifications:</p> <ul style="list-style-type: none"> • Compared to the 2014 Edition, a health IT developer no longer must include another means for identifying diagnostic or therapeutic reference information for capabilities other than the Infobutton standard. [see also 80 FR 62625] • Three specific conditions need to be satisfied for this criterion: <ul style="list-style-type: none"> ○ The health IT must be able to “electronically identify” education resources; ○ The education resources must be “patient specific”; ○ The education resources must be based on data included in the patient’s problem list and medication list. [FAQ #40] 	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	<ul style="list-style-type: none"> Technical outcome - A user can identify educational resources about a patient’s problem or medication in accordance with the HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2 standard and either Implementation Guide (IG) specified in: <ul style="list-style-type: none"> HL7 Implementation Guide (IG): Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1; or HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4. <p>Clarifications:</p> <ul style="list-style-type: none"> Developers can choose to either implement the Service-Oriented Architecture IG <u>or</u> the Context-Aware Knowledge Retrieval IG to meet certification requirements. 	<p>§ 170.204(b)(3) and (b)(4) HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2</p> <p>Implementation specifications. HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1</p> <p>Implementation specifications. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4</p>
(ii)	<ul style="list-style-type: none"> Technical outcome - A user can request that patient-specific education resources be identified based on the patient’s preferred language identified with the codes in the RFC 5646 standard. <p>Clarifications:</p> <ul style="list-style-type: none"> This provision is optional for certification. Infobutton only supports a value set of ISO 639-1 for preferred language and, therefore, testing and certification of preferred language for this certification criterion would not go beyond the value set of ISO 639-1. [see also 80 FR 62624] 	<p>§ 170.207(g)(2) Request for Comments (RFC) 5646</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 22, 2015
1.1	Revised to reflect this criterion is in scope for the CEHRT definition.	Dec 7, 2015
1.2	Revised to include clarification for Infobutton in the optional provision for certification	Mar 24, 2016