

# 2015 Edition Certification Companion Guide

## Medication Allergy List - 45 CFR 170.315(a)(8)

Links will be updated as available: [Final Rule Preamble](#) – [Test Procedure](#) – [Test Data](#) Version 1.1 – Last Updated 12.18/2015

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
Unchanged	Yes	Yes	Included	N/A

### Certification Requirements

**Privacy and Security:** This certification criterion was adopted at § 170.315(a)(8). 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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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"> <li>• If choosing Approach 1:               <ul style="list-style-type: none"> <li>○ <a href="#">Authentication, access control, and authorization (§ 170.315(d)(1))</a></li> <li>○ <a href="#">Auditable events and tamper-resistance (§ 170.315(d)(2))</a></li> <li>○ <a href="#">Audit reports (§ 170.315(d)(3))</a></li> <li>○ <a href="#">Amendments (§ 170.315(d)(4))</a></li> <li>○ <a href="#">Automatic access time-out (§ 170.315(d)(5))</a></li> <li>○ <a href="#">Emergency access (§ 170.315(d)(6))</a></li> <li>○ <a href="#">End-user device encryption (§ 170.315(d)(7))</a></li> </ul> </li> <li>• If choosing Approach 2:               <ul style="list-style-type: none"> <li>○ For each applicable P&amp;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&amp;S criteria would be deployed and used.. Please see the 2015 Edition final rule correction notice at <a href="#">80 FR 76870</a> for additional clarification.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <a href="#">Safety-enhanced design (§ 170.315(g)(3))</a></li> <li>• <a href="#">Quality management system (§ 170.315(g)(4))</a></li> <li>• <a href="#">Accessibility-centered design (§ 170.315(g)(5))</a></li> </ul>

**Regulation Text**

Medication allergy list. Enable a user to record, change, and access a patient's active medication allergy list as well as medication allergy history:

- (i) Ambulatory setting. Over multiple encounters.
- (ii) Inpatient setting. For the duration of an entire hospitalization.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• We do not define “medications” for the purposes of testing and certification. For example, developers could choose to include over-the-counter medications and herbal supplements. [see also <a href="#">80 FR 62621</a>]</li> <li>• There is no standard required for this criterion.</li> </ul>	N/A
(i)	<ul style="list-style-type: none"> <li>• Technical outcome - For health IT to be certified for an ambulatory setting, it will need to be designed to enable the user to electronically record, change, and access a patient’s medication allergy list that has been documented over multiple encounters.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>• No additional clarifications available.</li> </ul>	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(ii)	<ul style="list-style-type: none"> <li>Technical outcome - For health IT to be certified for an inpatient setting, it will need to enable the user to electronically record, change, and access a patient's medication allergy list for the duration of an entire hospitalization, including multiple wards or units during the patient's stay.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>Technology does <b>not</b> need to cover multiple hospitalizations for the purposes of certification. [see also <a href="#">77 FR 54212</a>]</li> </ul>	N/A

**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	Made a copy edit.	Dec 18, 2015