§170.315(a)(8) Medication allergy list

2015 Edition CCGs

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Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-22-2015
1.1	Made a copy edit.	12-18-2015

Regulation Text

Regulation Text

§170.315 (a)(8) *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 only.* Over multiple encounters.
(ii) *Inpatient setting only.* For the duration of an entire hospitalization.

Standard(s) Referenced

None

Certification Companion Guide: Medication allergy list

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.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Unchanged	Yes	Included	Yes

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 presented 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.

Table for Privacy and Security

- 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))
  - 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:
  - 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.

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.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- There is no standard required for this criterion.
- 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 80 FR 62621]

Paragraph (a)(8)(i)

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.

Clarifications:

- No additional clarifications available.

Paragraph (a)(8)(ii)

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.

Clarifications:

- Technology does not need to cover multiple hospitalizations for the purposes of certification. [see also 77 FR 54212]

Content last reviewed on May 20, 2020