

# 2015 Edition Certification Companion Guide

## Amendments - 45 CFR 170.315(d)(4)

Links will be made as available: [Final Rule Preamble](#) – [Test Procedure](#) – [Test Data](#)

Version 1.0 – Last Updated 10/22/2015

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	No	Not Included	N/A

### Certification Requirements

[Quality management system \(§ 170.315\(g\)\(4\)\)](#) and [accessibility-centered design \(§ 170.315\(g\)\(5\)\)](#) must be certified as part of the overall scope of the certificate issued to the product.

- 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.

### Regulation Text

Amendments. Enable a user to select the record affected by a patient’s request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.

(i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment’s location.

(ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request in at least one of the following ways:  
 (A) To the affected record.  
 (B) Include a link that indicates this information’s location.

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>• This certification criterion’s focus is to support the instance where a HIPAA covered entity agrees or declines to accept a patient’s request for an amendment. [see also <a href="#">77 FR 54174</a>]</li> <li>• Amendments are not specified to a particular format (i.e., free text or scanned). [see also <a href="#">77 FR 54175</a>]</li> </ul>	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
	<ul style="list-style-type: none"> <li>This certification criterion is meant to be a starting point from which more comprehensive capabilities and standards can be included to evolve over time, including greater standardization and automation. [see also <a href="#">77 FR 54175</a>]</li> </ul>	
(i) and (ii)	<ul style="list-style-type: none"> <li>Technical outcome – A user can select a patient’s record, and:               <ol style="list-style-type: none"> <li>For an accepted amendment, the health IT either appends the amendment to the patient’s record or includes a link to the amendment’s location;</li> <li>For a denied amendment, the health IT appends the request and denial of the request either to the affected record or includes a link that indicates the location of this information.</li> </ol> </li> </ul> <p><b>Clarification:</b></p> <ul style="list-style-type: none"> <li>The link is an alternative to appending the patient’s record and must convey to a user or enable a user to obtain the information associated with an amendment’s acceptance or denial. [see also <a href="#">77 FR 54175</a>]</li> <li>We do not require that accepted or denied amendments be appended to specific data in order for compliance to be demonstrated. There is some flexibility with how accepted or denied amendments are appended to an individual’s protected health information, recognizing that the type and scope of an amendment will vary based on the circumstances. [see also <a href="#">77 FR 54175</a>]               <ul style="list-style-type: none"> <li>For example, the affected record could include a link to documentation of an accepted or denied amendment, while still allowing, in the case of an accepted amendment, any necessary corrections to be incorporated directly into the record itself. [see also <a href="#">77 FR 54175</a>]</li> </ul> </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