



§170.315(d)(4) Amendments

- [Certification Companion Guide \(CCG\)](#)
- [Conformance Method](#)

Updated on 03-11-2024

Regulation Text

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§ 170.315 (d)(4) *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.

1. *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.
2. *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:
 1. To the affected record.
 2. Include a link that indicates this information's location.

Standard(s) Referenced

None

Certification Dependencies

Design and performance: 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.

- [Quality management system \(§ 170.315\(g\)\(4\)\)](#): 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.

- Accessibility-centered design (§ 170.315(g)(5)): 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.

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

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Testing components

Attestation: As of September 21, 2017, the testing approach for this criterion is satisfied by attestation.

The archived version of the Test Procedure is attached below for reference.

System Under Test

The health IT developer will attest directly to the ONC-ACB to conformance with the §170.315(d)(4) *Amendments* requirements.

ONC-ACB Verification

The ONC-ACB verifies the health IT developer attests conformance to the §170.315(d)(4) *Amendments* requirements.

Archived Version:

§170.315(d)(4) Test Procedure

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Certification Companion Guide: Amendments

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product certification. The CCG is not a substitute for the requirements outlined in regulation and related ONC final rules. It extracts key portions of ONC final rules' preambles and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the [Certification Regulations page](#) for links to all ONC final rules or consult other regulatory references as noted. The CCG is for public use and should not be sold or redistributed.

The below table outlines whether this criterion has additional Maintenance of Certification dependencies, update requirements and/or eligibility for standards updates via SVAP. Review the Certification Dependencies and Required Update Deadline drop-downs above if this table indicates "yes" for any field.

<u>Base EHR Definition</u>	<u>Real World Testing</u>	<u>Insights Condition</u>	<u>SVAP</u>	<u>Requires Updates</u>
Not Included	No	No	No	No

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- There is no standard required for this certification criterion.

- 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 [77 FR 54174](#)]
- Amendments are not specified to a particular format (e.g., free text or scanned). [see also [77 FR 54175](#)]
- 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 [77 FR 54175](#)]

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Paragraphs (d)(4)(i) and (ii) Amendments

Technical outcome – A user can select a patient's record, and:

1. 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;
2. 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.

Clarification:

- 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 [77 FR 54175](#)]

- ONC does 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 [77 FR 54175](#)]

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 [77 FR 54175](#)]

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