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§170.315(d)(11) Accounting of disclosures

- Certification Companion Guide (CCG)
- Conformance Method

Updated on 03-11-2024

Regulation Text

Regulation Text

§ 170.315 (d)(11) *Accounting of disclosures*—

Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

Standard(s) Referenced

Applies to entire criterion

§ 170.210(d) *Record treatment, payment, and health care operations disclosures*. The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

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

Regulation Text
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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	**ONC-ACB Verification**
The health IT developer will attest directly to the ONC-ACB to conformance with the § 170.315(d)(11) *Accounting of disclosures* requirements.	The ONC-ACB verifies the health IT developer attests conformance to the § 170.315(d)(11) *Accounting of disclosures* requirements.

Archived Version:
§170.315(d)(11) Test Procedure
Updated on 03-11-2024

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Certification Companion Guide: Accounting of disclosures

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.

Base EHR Definition	Real World Testing	Insights Condition	SVAP	Requires Updates
Not Included	No	No	No	No

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Technical outcome – The health IT records disclosures that are made for treatment, payment, and health care operations as these terms are defined at 45 CFR 164.501.

Clarifications:

- We expect that the date, time, patient identification, user identification, and the description of each disclosure would be automatically recorded by the health IT. [see also 77 FR 54252]
- A "description of the disclosure" could be a free text field that includes any information that could be readily and electronically associated with the disclosure. For example, some descriptive information could be included (e.g., the words "treatment," "payment," or "healthcare operations") separately or together as a general category. [see also 75 FR 44623 and 77 FR 54252]

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