

Test Procedure for §170.314(d)(4) Amendments

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document¹ is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program², is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011.*)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(d)(4) Amendments. Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (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 to the affected record or include a link that indicates this information's location.

¹ Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

² Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this Certification Criterion is classified as new from the 2011 Edition. This Certification Criterion meets at least one of the factors of new certification criteria: (1) The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or, (2) The certification criterion was previously adopted as “mandatory” for a particular setting and subsequently adopted as “mandatory” or “optional” for a different setting.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where amendments certification criterion is discussed:

- “...the proposed certification criterion does not address all of the requirements specified at 45 CFR 164.526 and that EHR technology certification is not a substitute for, or guarantee of, HIPAA Privacy Rule compliance.”
- “...the HITPC’s expectation [is]...this certification criterion ...be “kept as simple as possible and evolve over time to greater complexity, including potentially greater standardization and automation.””
- “...we have revised the language associated with “electronic link.” The “link,” which is an alternative to appending the patient’s record must convey to a user or enable a user to obtain the information associated with an amendment’s acceptance or denial.”
- “...the information appended or linked in the case of an accepted or denied amendment should at least have an indication as to the source of the information (i.e., patient or provider/organization).”
- “The final certification criterion does not require that accepted or denied amendments be appended to specific data in order for compliance to be demonstrated.”
- “...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.”
- “The terminology used in this certification criterion is meant to mirror the terms used in the HIPAA Privacy Rule at 45 CFR 164.526.”
- “...for example, if the amendment is accepted, “[t]he covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by...appending or otherwise providing a link to the location of the amendment.””
- “...we expect that [the electronic amendment] would be subject to the audit log requirements we have already specified (and which includes time and date stamp).”
- “We clarify that this certification criterion is not separately applied to any EHR Modules in order for them to be certified. An EHR technology developer needs to include such capability, however, if they seek certification for EHR technology that would meet the Base EHR definition.”
- “...that this certification criterion can only help support (and potentially make more efficient) a HIPAA covered entity’s compliance with the HIPAA Privacy Rule.”

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

The Vendor provides the test data for this test procedure.

This test evaluates the capability for a Complete EHR to enable a user to document a request for an amendment and collect relevant documentation related to the approval or denial of the request. For an acceptance of an amendment, the user must be able to append or provide a link to an accepted amendment. For a denial of an amendment request, the user must be able to append or provide a link to a request for an amendment and the denial of the request. A link for an accepted or denied amendment must convey the information associated with an amendment's acceptance or denial, and does not imply nor require an "electronic link" to the information. This certification criterion does not apply to EHR Modules.

This test procedure is organized into three sections:

- **Record** - evaluates the capability for a user to electronically record the patient's request for amendment
 - Using Vendor-supplied test data, the Vendor creates an existing patient record in the EHR technology
 - The Tester selects the patient record
 - The Tester records a patient's request for amendment
- **Acceptance**– evaluates the capability to electronically append acceptance of an amendment to the affected record or include a link that indicates the location of an accepted amendment
 - The Vendor updates the status of an amendment request to "accepted"
 - The Tester appends the Vendor-supplied amendment to the affected patient record, OR
 - The Tester verifies that the EHR technology displays a link that indicates the amendment's location that conveys to a user or enables a user to obtain the information associated with an amendment's acceptance
 - The Tester verifies that the EHR technology displays the appended amendment
 - The Tester verifies that the appended information indicates the source of the information (i.e., patient or provider/organization)
- **Denial** – evaluates the capability to electronically append an amendment request and denial of the request to the affected patient record or include a link that indicates the location of a denied amendment
 - The Vendor updates the status of an amendment request to "denied"
 - The Tester appends the Vendor-supplied amendment to the affected patient record, OR

- The Tester verifies that the EHR technology displays a link that indicates the amendment's location that conveys to a user or enables a user to obtain the information associated with an amendment's denial
- The Tester verifies that the EHR technology displays the appended amendment
- The Tester verifies that the appended information indicates the source of the information (i.e., patient or provider/organization)

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.d.4–1: Record a Patient's Request for an Amendment

DTR170.314.d.4–2: Accept an Amendment to the Affected Patient Record

DTR170.314.d.4–3: Deny an Amendment Request to the Affected Patient Record

DTR170.314.d.4–1: Record a Patient's Request for an Amendment

Required Vendor Information

VE170.314.d.4 – 1.01: Using Vendor-supplied test data, the Vendor shall create two patient records in the EHR to be used for this test, to include patient name, medical record number, and date of birth

Required Test Procedures

TE170.314.d.4 – 1.01: Using the Vendor-identified EHR function(s), the Tester shall select the patient record created in VE170.314.d.4 –1.01

TE170.314.d.4 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall record a patient's request for an amendment in the EHR

TE170.314.d.4 – 1.03: Using the Vendor-identified EHR function(s), the Tester shall record a second patient's request for an amendment in the EHR

TE170.314.d.4 – 1.04: Using the Inspection Test Guide, the Tester shall verify that the amendment request for the selected patient record is accurate and complete

Inspection Test Guide

IN170.314.d.4 – 1.01: Using the Vendor-supplied test data, the Tester shall verify that the data included in the patients' record are accurate and complete; and that the amendments are associated with the patients' record

DTR170.314.d.4–2: Accept an Amendment to the Affected Patient Record

Required Vendor Information

VE170.314.d.4 – 2.01: Information as defined in DTR170.314.d.4-1, no additional information is required

Required Test Procedures

TE170.314.d.4 – 2.01: Using the Vendor-identified EHR function(s), the Tester shall select the amendment request recorded in TE170.314.d.4 – 1.02

TE170.314.d.4 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall indicate that the amendment request has been accepted

TE170.314.d.4 – 2.03: Using the Vendor-identified EHR function(s), the Tester shall:

- append the accepted amendment to the patient's record in the EHR, OR
- record information that provides a link to the location of the amendment

TE170.314.d.4 – 2.04: Using the Vendor-identified EHR function(s), the Tester shall record the source of the amended information (e.g., provider/organization)

TE170.314.d.4 – 2.05: Using the Inspection Test Guide, the Tester shall verify that the appended amendment information is accurate and complete

Inspection Test Guide

IN170.314.d.4 – 2.01: The Tester shall verify that the EHR technology displays the appended amendment accurately and completely

IN170.314.d.4 – 2.02: The Tester shall verify that the accepted amendment indicates the source of the amended information (i.e., patient or provider/organization)

IN170.314.d.4 – 2.03: Tester verifies that the affected amendment is appended to the affected record OR that a link conveys to a user or enables a user to obtain the information associated with an amendment's acceptance

IN170.314.d.4 – 2.04: Tester verifies that the amendment information includes date and time of: the patient's amendment request, acceptance of the amendment request, appending/linking of amendment information

DTR170.314.d.4–3: Deny an Amendment to the Affected Patient Record

Required Vendor Information

VE170.314.d.4 – 3.01: Information as defined in DTR170.314.d.4-1, no additional information is required

Required Test Procedures

TE170.314.d.4 – 3.01: Using the Vendor-identified EHR function(s), the Tester shall select the amendment request recorded in TE170.314.d.4 – 1.03

TE170.314.d.4 – 3.02: Using the Vendor-identified EHR function(s), the Tester shall indicate that the amendment request has been denied

TE170.314.d.4 – 3.03: Using the Vendor-identified EHR function(s), the Tester shall:

- append the denied amendment to the patient's record in the EHR, OR
- record information that provides a link to the location of the amendment

TE170.314.d.4 – 3.04: Using the Vendor-identified EHR function(s), the Tester shall record the source of the amended information (e.g., provider/organization)

TE170.314.d.4 – 2.05: Using the Inspection Test Guide, the Tester shall verify that the appended amendment information is accurate and complete

Inspection Test Guide

IN170.314.d.4 – 2.01: The Tester shall verify that the EHR technology displays the appended amendment accurately and completely

IN170.314.d.4 – 2.02: The Tester shall verify that the denied amendment indicates the source of the amended information (i.e., patient or provider/organization)

IN170.314.d.4 – 2.03: Tester verifies that the affected amendment is appended to the affected record OR that a link conveys to a user or enables a user to obtain the information associated with an amendment's denial

IN170.314.d.4 – 2.04: Tester verifies that the amendment information includes date and time of: the patient's amendment request, denial of the amendment request, appending/linking of amendment information

TEST DATA

This test procedure requires the vendor to supply the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional requirements identified in the criterion can be adequately evaluated for conformance
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
1.0	Released for public comment	September 28, 2012

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