

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

This document describes the test procedure for evaluating conformance of EHR technology 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 <http://www.healthit.gov/certification> (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (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 Health Information Technology (HIT) Certification Program², is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-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. This certification criterion is included in the definition of a Base EHR.

§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.

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.

(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.

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 (September 4, 2012), 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.

2014 EDITION PREAMBLE LANGUAGE

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 (September 4, 2012) 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 technology 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 supplies the test data for this test procedure.

This test evaluates the capability for an EHR technology to capture an accepted or denied amendment 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. In addition, the test procedures verify that the amendment indicates the source of the information (e.g., patient or provider/organization). This certification criterion does not apply to EHR technology.

This test procedure is organized into two sections:

- 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 selects the patient’s record affected by an amendment request
 - [Assuming a scenario where a user accepts the amendment] The Tester appends the Vendor-supplied amendment (requested by a patient) to the affected patient record, **OR** the Tester verifies that the EHR technology displays a link that indicates the amendment’s location and 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 request and denial of the request
 - The Vendor selects the patient’s record affected by an amendment request
 - [Assuming a scenario where a user declines the amendment] The Tester appends the Vendor-supplied amendment request (from a patient) and denial of the request (from the

user) to the affected patient record, **OR** the Tester verifies that the EHR technology displays a link that indicates the location of the amendment request and denial of the request and 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 amendment request and denial of the request
- The Tester verifies that the appended or linked 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: Accept an Amendment to the Affected Patient Record

DTR170.314(d)(4) – 2: Deny an Amendment Request to the Affected Patient Record

DTR170.314(d)(4) – 1: Accept an Amendment to the Affected Patient Record

Required Vendor Information

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

VE170.314(d)(4) – 1.02: The Vendor shall identify how an accepted amendment request is appended or linked to a patient record.

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:

- 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) – 1.03: Using the Vendor-identified EHR function(s), the Tester shall record the source of the amended information (e.g., patient or provider/organization)

TE170.314(d)(4) – 1.04: 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) – 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 accepted amendment is associated with the patients' record

IN170.314(d)(4) – 1.02: The Tester shall verify that the EHR technology displays the appended amendment accurately and completely

IN170.314(d)(4) – 1.03: The Tester shall verify that the accepted amendment indicates the source of the amended information (e.g., patient or provider/organization)

IN170.314(d)(4) – 1.04: Tester verifies that the accepted amendment is appended to the affected record OR that a link indicates the location of the amendment and conveys to a user or enables a user to obtain the information associated with an amendment's acceptance

IN170.314(d)(4) – 1.05: 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 (This action may be recorded in the audit log)

DTR170.314(d)(4) – 2: Deny an Amendment to the Affected Patient Record

Required Vendor Information

VE170.314(d)(4) – 2.01: Using Vendor-supplied test data, the Vendor shall create a patient record in the EHR to be used for this test, to include patient name, medical record number, and date of birth

VE170.314(d)(4) – 2.02: The Vendor shall identify how an amendment request and denial of the request is appended or linked to a patient record

Required Test Procedures

TE170.314(d)(4) – 2.01: Using the Vendor-identified EHR function(s), the Tester shall select the patient record created in VE170.314(d)(4) –2.01

TE170.314(d)(4) – 2.02: Using the Vendor-identified EHR function(s), the Tester shall:

- Append the denied amendment request (from a patient) and denial of the request (from the user) to the patient's record in the EHR, OR
- Record information that provides a link to the location of the denied amendment request (from a patient) and denial of the request (from the user)

TE170.314(d)(4) – 2.03: Using the Vendor-identified EHR function(s), the Tester shall record the source of the denied amendment information (e.g., provider/organization)

TE170.314(d)(4) – 2.04: Using the Inspection Test Guide, the Tester shall verify that the information associated with the amendment's denial is accurate and complete

Inspection Test Guide

- IN170.314(d)(4) – 2.01: 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 denied amendment request and denial of the request is associated with the patients' record
- IN170.314(d)(4) – 2.02: The Tester shall verify that the EHR technology accurately and completely displays the appended denied amendment request and denial of the request
- IN170.314(d)(4) – 2.03: The Tester shall verify that the appended denied amendment request and denial of the request indicates the source of the information requested for amendment (i.e., patient or provider/organization)
- IN170.314(d)(4) – 2.04: Tester verifies that the denied amendment request and denial of the request is appended to the affected record OR a link that indicates this information's location and conveys to a user or enables a user to obtain the information associated with a denied amendment request and denial of the request
- IN170.314(d)(4) – 2.05: Tester verifies that the information associated with the denied amendment request and denial of the request includes date and time of: the patient's amendment request, denial of the amendment request, appending/linking of information associated with the denied amendment (This action may be recorded in the audit log)

TEST DATA

The Vendor shall supply the test data for this test procedure.

Vendor supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) - Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

Any test data provided shall focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's

discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

For Vendor-supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the 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 of Change	Date Published
1.0	Released for public comment	September 28, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Updated Approved Test Procedure Updates: <ul style="list-style-type: none">• In the Informative Test Description, removed the second bullet from the 'Acceptance' and "Denial" sections• Added [Assuming a scenario where a user accepts/denies the amendment] to the second bullet of the "Acceptance" and "Denial" sections of the Informative Test Description• Replaced 'denied amendment' or 'denied amendment information' with 'denied amendment request and denial of the request' in Informative Test Description and Normative Test Procedure• Removed TE170.314(d)(4) – 1.02 and TE170.314(d)(4) – 2.02 and modified test step numbering accordingly• In the Informative Test Description and Normative Test Procedure, clarified that a link must indicate the location of the amendment (or request and denial of the request) and convey to a user or enable a user to obtain the information associated with an amendment's acceptance or denial• Clarified in TE170.314(d)(4) – 2.04 and IN170.314(d)(4) – 2.04 that the Tester must verify the information associated with the amendment's denial is accurate and complete	March 21, 2014