

Test Procedure for §170.314(a)(9) Electronic notes

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(a)(9) Electronic notes. Enable a user to electronically record, change, access, and search electronic notes.

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 two 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

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

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 the electronic notes certification criterion is discussed:

- “We did not propose, nor do we believe, that there is a standard and industry-wide accepted format for capturing electronic notes. Therefore, we agree with the commenters that suggested that a range of options be permitted for capturing notes, including templates and free text. We also note that in the Stage 2 final rule scanned notes that are text searchable are acceptable for inclusion in the numerator.”
- “...we have concluded that the search capability that EHR technology must demonstrate to meet this certification criterion should be limited to the ability to search within a note.”
- “...we appreciate the commenter’s suggestion that the capabilities included in this certification criterion be expanded to require EHR technology to be able to export electronic notes as CDA Level 2 documents, we decline to require EHR technology to demonstrate this capability as a condition of certification since such a capability would go beyond what we believe it is necessary to require for certification in support of MU.”

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.

This test evaluates the capability for a Complete EHR or EHR Module to enable a user to electronically record, change, access, and search electronic notes of a patient.

ONC provides the test data for this test procedure.

This test procedure is organized into four sections:

- Record - evaluates the capability for a user to enter electronic notes into the EHR
 - Using the Vendor-identified EHR function(s), a Vendor-identified patient with an existing record in the EHR, and provided test data, the Tester enters the electronic notes
 - The Tester verifies that the recorded electronic notes are stored in the patient’s record and that they are accurate and complete
- Change - evaluates the capability for a user to change electronic notes that have been entered previously into the EHR
 - Using the Vendor-identified EHR function(s) and provided test data, the Tester displays and changes each of the patient’s electronic notes entered during the Record electronic notes test

- The Tester validates that the changed electronic notes are stored in the patient's record and that they are accurate and complete
- Access - evaluates the capability for a user to access electronic notes that have been entered previously into the EHR
 - Using the Vendor-identified EHR function(s), the Tester accesses and displays the electronic notes entered during the Record and Change tests
 - The Tester validates that the accessed electronic notes are accurate and complete
- Search - evaluates the capability for a user to search within an electronic note that is stored in the patient's EHR
 - Using the Vendor-identified EHR function(s), the Tester selects an electronic note entered into the EHR during the Record or Change test
 - Using the Vendor-identified EHR function(s) and the specific search data in the ONC-supplied test data, the Tester searches for specific data (words or phrases) within the selected note
 - The Tester validates that the specific data (words or phrases) are found in the electronic note based on the specific search data used
 - Using the Vendor-identified EHR function(s), the Tester selects a second electronic note entered into the EHR during the Record or Change test
 - Using the Vendor-identified EHR function(s) and the specific search data in the ONC-supplied test data, the Tester searches for specific data (words or phrases) within the selected note
 - The Tester validates that the specific data (words or phrases) are found in the electronic note based on the specific search data used

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.9 – 1: Electronically Record Electronic Notes

DTR170.314.a.9 – 2: Electronically Change Electronic Notes

DTR170.314.a.9 – 3: Electronically Access Electronic Notes

DTR170.314.a.9 – 4: Electronically Search Electronic Notes

DTR130.314.a.9 – 1: Electronically Record Electronic Notes

Required Vendor Information

VE170.314.a.9 – 1.01: The Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.9 – 1.02: The Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) record the electronic notes, 3) change the electronic notes, 4) access the electronic notes, and 5) search the electronic notes

Required Test Procedure:

TE170.314.a.9 – 1.01: The Tester shall select electronic notes data from the provided test data

TE170.314.a.9 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select the patient's existing record and enter the electronic notes based on the test data selected in TE170.314.a.9 – 1.01

TE170.314.a.9 – 1.03: Using the Inspection Test Guide, the Tester shall verify that the electronic notes data are entered correctly and without omission

Inspection Test Guide:

IN170.314.a.9 – 1.01: Using the provided test data selected in TE170.314.a.9 – 1.01, the Tester shall verify that the electronic notes data are entered accurately

IN170.314.a.9 – 1.02: The Tester shall verify that the electronic notes are captured and stored in the patient's record

DTR170.314.a.9 – 2: Electronically Change Electronic Notes

Required Vendor Information

- As defined in DTR170.314.a.9 – 1, no additional information is required

Required Test Procedure:

TE170.314.a.9 – 2.01: The Tester shall select electronic notes data from the provided test data

TE170.314.a.9 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record, shall display the patient's electronic notes entered during the DTR170.314.a.9 – 1: Electronically Record Electronic Notes test, and shall change these notes based on the test data selected in TE170.314.a.9 – 2.01

TE170.314.a.9 – 2.03: Using the Inspection Test Guide, the Tester shall verify that the electronic notes changed during TE170.314.a.9 – 2.02 are changed correctly and without omission

Inspection Test Guide

IN170.314.a.9 – 2.01: Using the provided test data selected in TE170.314.a.9 – 2.01, the Tester shall verify that the electronic notes entered during the DTR170.314.a.9 – 1:

Electronically Record Electronic Notes test are changed accurately

IN170.314.a.9 – 2.02: The Tester shall verify that the changed electronic notes are captured and stored in the patient's record

DTR170.314.a.9 – 3: Electronically Access Electronic Notes

Required Vendor Information

- As defined in DTR170.314.a.9 – 1, no additional information is required.

Required Test Procedure:

TE170.314.a.9 – 3.01: Using the Vendor-identified EHR function(s), the Tester shall select a patient's existing record, and shall access and display the electronic notes that were changed during the DTR170.314.a.9 – 2: Electronically Change Electronic Notes test

TE170.314.a.9 – 3.02: Using the Inspection Test Guide, the Tester shall verify that these electronic notes display correctly and without omission

Inspection Test Guide

IN170.314.a.9 – 3.01: Using the provided test data, the Tester shall verify that the electronic notes being accessed display accurately

DTR170.314.a.9 – 4: Electronically Search Electronic Notes

Required Vendor Information

- As defined in DTR170.314.a.9 – 1, no additional information is required.

Required Test Procedure:

TE170.314.a.9 – 4.01: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record used during the DTR170.314.a.9 – 2 Electronically Change Electronic Notes test

TE170.314.a.9 – 4.02: Using the Vendor-identified EHR function(s), the Tester shall select an electronic note that was changed during the DTR170.314.a.9 – 2 Electronically Change Electronic Notes test

TE170.314.a.9 – 4.03: Using the Vendor-identified EHR function(s) and the specific search data (words or phrases) in the provided test data, the Tester shall search for the specific data within the selected electronic note

TE170.314.a.9 – 4.04: Using the Inspection Test Guide, the Tester shall verify that the specific data are found or not found in the electronic note

TE170.314.a.9 – 4.05: Using the Vendor-identified EHR function(s), the Tester shall select a second electronic note that was changed during the DTR170.314.a.9 – 2 Electronically Change Electronic Notes test

TE170.314.a.9 – 4.06: Using the Vendor-identified EHR function(s) and the specific search data in the provided test data, the Tester shall search for the specific data within the second electronic note selected

TE170.314.a.9 – 4.07: Using the Inspection Test Guide, the Tester shall verify that the specific data are found or not found in the second electronic note

Inspection Test Guide

IN170.314.a.9 – 4.01: Using the specific search data in the provided test data, the Tester shall verify that the specific data (words or phrases) used for searching the electronic notes are found or not found in those notes

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TEST DATA

Test data is provided with the Test Procedure to ensure that the functional and interoperable 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-Accredited Testing Laboratories (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 is 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.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The tester determines that the Vendor-selected message format requires some modification to the test data.
- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the provided test data shall strictly 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 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.

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
1.0	Released for public comment	September 14, 2012

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