

Test Procedure for §170.314 (a)(12) Image results

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)(12) Image results. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

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

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

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 the image results certification criterion is discussed:

- “Commenters requested a clear definition of “image” as well as “narrative interpretation.” Commenters asked whether both cardiology and pathology images are included or whether images were limited to radiology. A few commenters specifically suggested that images be limited to radiology and MRIs and not include photography or electrocardiograms (ECGs). One commenter suggested the inclusion of ECGs...It is outside the scope of this rulemaking to define the scope of images and narrative interpretations.”
- “We clarify that we did not propose nor are we requiring that EHR technology has to be able to store images to meet this certification criterion. EHR technology can meet this certification criterion by demonstrating a capability to directly link to images stored in the EHR system or providing a context-sensitive link to an external application which provides access to images and their associated narrative. By “context sensitive link” we mean that the link to the image will ideally include parameters that enable access to the images themselves rather than access to a system – which would require login, patient search, image selection, and (finally) image viewing.”
- “We clarified that the phrase “immediate electronic access” was intended to mean that a user should be able to electronically access images and their narrative interpretations directly and without, for example, having to login to a separate electronic system or repository. We stated that this access could be provided by multiple means, including, but not limited to, “single sign-on” and “secure identity parameter passing.”
- “We...do not explicitly require that this link provide “immediate access”...”
- “Finally, we emphasize that access to both narrative and imaging data must be available to the user. In cases where there is no narrative data (for example when a radiographic image has not yet been interpreted by a radiologist) there will obviously be no narrative available. Nonetheless, the EHR technology must be capable of retrieving and displaying the narrative information in order to meet this certification criterion.”

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 procedure is organized into two sections:

- **Indicate** – evaluates the capability for the EHR to electronically indicate to a user the availability of a patient’s images and associated narrative interpretations relating to radiographic or other diagnostic test(s)
 - The Vendor creates a patient record in their EHR and populates that patient record with Vendor-supplied narrative interpretations and associated images (or links to associated images) for two or more radiographic or other diagnostic test(s)
 - The Tester signs on to the EHR and validates that availability of the patient’s images and associated narrative interpretations is indicated by the EHR to the user electronically
- **Access** – evaluates the capability for the user to electronically access and display the patient’s images and narrative interpretations
 - Using the Vendor-identified EHR technology function(s), the Tester accesses and displays the patient’s images and narrative interpretations during the Indicate test for each of the radiographic or other diagnostic test(s)
 - The Tester validates that the displayed images and narrative interpretations are accurate and complete
 - The Tester validates that the images and associated narrative interpretations are accessed without requiring additional provider login, patient lookup or selection, or test/study selection
 - The images must be accessible for display within the EHR, but are not required to be stored within the EHR and may be contained within another application

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.12 – 1: Electronically Indicate

DTR170.314.a.12 – 2: Electronically Access

DTR170.314.a.12 – 1: Electronically Indicate

Required Vendor Information

VE170.314.a.12 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

- VE170.314.a.12 – 1.02: Vendor shall populate the existing patient's record with imaging result information for two or more radiological or other diagnostic tests, including both an image(s) and associated narrative interpretation(s), OR the Vendor shall populate the existing patient's record with access to imaging result information for two or more radiological or other diagnostic tests via a Vendor-supplied 3rd party system, including both an image(s) and associated narrative interpretation(s)
- VE170.314.a.12 – 1.03: Vendor shall populate the existing patient's record with imaging result information for two or more radiological or other diagnostic tests, including an image(s) without associated narrative interpretation(s), OR the Vendor shall populate the existing patient's record with access to imaging result information for two or more radiological or other diagnostic tests via a Vendor-supplied 3rd party system, including both an image(s) and without associated narrative interpretation(s)
- VE170.314.a.12 – 1.04: Vendor shall identify a user who has the ability to access and view radiological or other diagnostic test result information
- VE170.314.a.12 – 1.05: Vendor shall identify the EHR function(s) that are available to 1) electronically indicate the availability of a patient's images and associated narrative interpretations, and 2) electronically access a patient's images and associated narrative interpretations for radiological or other diagnostic tests

Required Test Procedures

- TE170.314.a.12 – 1.01: Using the Vendor-identified EHR function(s), the Tester shall log in to the EHR as a user who has the ability to view images and narrative interpretations
- TE170.314.a.12 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the EHR indicates the availability of the Vendor-supplied image(s) and associated narrative interpretations for the Vendor-supplied radiological or other diagnostic test result information for the Vendor-identified patient
- TE170.314.a.12 – 1.03: Using the Inspection Test Guide, the Tester shall verify that the EHR indicates the availability of the images and narrative interpretations
- TE170.314.a.12 – 1.04: Using the Vendor-identified EHR function(s), the Tester shall verify that the EHR indicates the availability of the Vendor-supplied image(s) with no narrative interpretations for the Vendor-supplied radiological or other diagnostic test result information for the Vendor-identified patient
- TE170.314.a.12 – 1.05: Using the Inspection Test Guide, the Tester shall verify that the EHR indicates the availability of the images for a radiological or other diagnostic test for which no narrative interpretation is available

Inspection Test Guide

- IN170.314.a.12 – 1.01: Using the Vendor-supplied test data, the Tester shall verify that the EHR electronically indicates the availability of the images and associated narrative interpretations entered by the Vendor for the test patient (for tests with narrative interpretations available)

DTR170.314.a.12 – 2: Electronically Access

Required Vendor Information

- Information as defined in DTR170.314.a.12 – 1, no additional information is required

Required Test Procedures

TE170.314.a.12 – 2.01: Using the Vendor-identified EHR function(s), the Tester shall log in to the EHR as a user who has the ability to access and view patient images and associated narrative interpretations for radiographic or other diagnostic tests

TE170.314.a.12 – 2.02: Using the Vendor-identified EHR function(s) and the test patient used for the DTR170.314.a.12 – 1: Electronically Indicate test, the Tester shall select the patient's record

TE170.314.a.12 – 2.03: Using the Vendor-identified EHR function(s), the Tester shall access and display the images and narrative interpretations used for the DTR170.314.a.12 – 1: Electronically Indicate test for the selected patient

TE170.314.a.12 – 2.04: Using the Inspection Test Guide, the Tester shall verify that the images and narrative interpretations are accessed without requiring additional patient lookup/selection or test/study selection

TE170.314.a.12 – 2.05: Using the Inspection Test Guide, the Tester shall verify that the images and are accessed without requiring additional patient lookup/selection or test/study selection for a test without a narrative interpretation

Inspection Test Guide

IN170.314.a.12 – 2.01: Using the Vendor-supplied test data, the Tester shall verify that the patient's images and narrative interpretations (where available) are accessed and displayed to the user and that this radiographic or other diagnostic tests information is accurate and complete

IN170.314.a.12 – 2.02: The Tester shall verify 1) that the images are accessible to the user within the EHR system OR via a context-sensitive link to an external application that provides access to images and their associated narrative interpretations, and 2) that the user accesses these images and narrative interpretations without requiring additional patient lookup or imaging test selection

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 and interoperable 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

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Document History

Version Number	Description	Date Published
1.0	Released for public comment	September 21, 2012

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