Test Procedure for 170.314(f)(5) Cancer case information – ambulatory setting only

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 document[1] 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 Program[2], 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(f)(5) Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information.

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

[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

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 cancer case information certification criterion is discussed:

- "By designating [this] certification [criterion] as optional, EHR technology would not need to be certified to these certification criteria in order to satisfy the Complete EHR definition. The optional designation will permit EHR technology developers that support EPs intending to report on the associated MU menu objective and measure to still get certified to these certification criteria, but will alleviate the requirement that all Complete EHRs be certified to these certification criteria."
- "To clarify for MU purposes, if an EP seeks to meet the associated MU objective and measure, they will need EHR technology certified to these certification criteria, including the adopted standards and implementation guide, in order to have EHR technology that meets the CEHRT definition."

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, and access cancer case information. No standards are named for this criterion or used in this test procedure.

Test data, verified by the CDC, are provided for this test procedure.

This test procedure is organized into three sections:

- Record – evaluates the capability for a user to enter cancer case information into the EHR
    - Using the Vendor-identified EHR function(s), a Vendor-identified patient with an existing record in the EHR, and the provided test data, the Tester enters the cancer case information into the EHR
    - The Tester verifies that the recorded cancer case information is stored in the patient's record and that it is accurate and complete

- Change – evaluates the capability for a user to change cancer case information that has been entered previously into the EHR
    - Using the Vendor-identified EHR function(s) and the provided test data, the Tester displays and changes the cancer case information entered during the Record test
    - The Tester validates that the changed cancer case information is stored in the patient's record and that it is accurate and complete

- Access – evaluates the capability for a user to access the cancer case information that has been entered into the EHR
    - Using Vendor-identified EHR function(s), the Tester accesses and displays the cancer case information entered during the Record and Change tests
    - The Tester validates that the accessed cancer case information is accurate and complete

REFERENCED STANDARDS

None.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.f.5 – 1: Electronically Record Cancer Case Information

DTR170.314.f.5 – 2: Electronically Change Cancer Case Information

DTR170.314.f.5 – 3: Electronically Access Cancer Case Information

DTR170.314.f.5 – 1: Electronically Record Cancer Case Information

Required Vendor Information

VE170.314.f.5 – 1.01: Vendor shall create a test patient record in the EHR to be used for this test

VE170.314.f.5 – 1.02: Vendor shall identify a user with the authorization to use the EHR for recording, changing, and accessing cancer case information in a patient's record

VE170.314.f.5 – 1.03: Vendor shall identify the EHR function(s) that are available to record, change, and access cancer case information

Required Test Procedure

TE170.314.f.5 – 1.01: The Tester shall select cancer case information from the provided test data

TE170.314.f.5 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall sign on to the EHR as an authorized user, select the test patient's existing record, and enter the cancer case information selected in TE170.314.f.5 – 1.01

TE170.314.f.5 – 1.03: Using the Inspection Test Guide, the Tester shall verify that the cancer case information is entered correctly and without omission

Inspection Test Guide

IN170.314.f.5 – 1.01: Using the provided cancer case information selected in TE170.314.f.5 – 1.01, the Tester shall verify that the cancer case information is entered accurately

IN170.314.f.5 – 1.02: The Tester shall verify that the cancer case information entered during the test is captured and stored in the patient's record

DTR170.314.f.5 – 2: Electronically Change Cancer Case Information

Required Vendor Information

- As defined in DTR170.314.f.5 – 1, no additional information is required

Required Test Procedure:

TE170.314.f.5 – 2.01: The Tester shall select cancer case information from the provided test data

TE170.314.f.5 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record, display the cancer case information entered during the DTR170.314.f.1 – 1: Electronically Record Cancer Case Information test, and change this information based on the test data selected in TE170.314.f.5 – 2.01

TE170.314.f.5 – 2.03: Using the Inspection Test Guide, the Tester shall verify that the cancer case information changed during TE170.314.f.5 – 2.02 are changed correctly and without omission

Inspection Test Guide

IN170.314.f.5 – 2.01: Using the provided cancer case information, the Tester shall verify that the cancer case information entered during the DTR170.314.f.5 – 1: Electronically Record Cancer Case Information test are changed accurately

IN170.314.f.5 – 2.02: The Tester shall verify that the changed cancer case information is captured and stored in the patient's record

DTR170.314.f.5 – 3: Electronically Access Cancer Case Information

Required Vendor Information

- As defined in DTR170.314.f.5 – 1, no additional information is required

Required Test Procedure

TE170.314.f.5 – 3.01: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record, and access and display the cancer case information entered during the DTR170.314.f.5 – 1: Electronically Record Cancer Case Information and the DTR170.314.f.5 – 2: Electronically Change Cancer Case Information tests

TE170.314.f.5 – 3.02: Using the Inspection Test Guide, the Tester shall verify that the cancer case information is displayed correctly and without omission

Inspection Test Guide

IN170.314.f.5 – 3.01: Using the provided cancer case information, the Tester shall verify that the cancer case information being accessed displays accurately

TEST DATA

Test data are provided with the test procedure to ensure that the functional and interoperability 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 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.

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
1.1	Updated the Certification Criteria section with Certification Criterion and preamble language; Added introduction sentence to Test Data conditions list.	September 17, 2012