Test Procedure for 170.314(f)(1) Immunization Information

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)(1) Immunization information. Enable a user to electronically record, change, and access immunization 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 this Certification Criterion is classified as revised from the 2011 Edition. This Certification Criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (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 has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that 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 immunization information certification criterion is discussed:

- No applicable quotes

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the submission to immunization registries certification criterion is discussed:

- "We are primarily concerned with Certified EHR Technology's ability to transmit the immunization information in a standardized format, and do not believe that it is necessary to specify a particular recipient in the certification criterion."
- "The CDC maintains an openly available list of updated CVX codes as well as a mapping of CVX codes to CPT codes on their website." "NDC codes were not adopted as a standard to represent immunizations and we do not believe that requiring their use for the purposes of demonstrating compliance with this certification criterion would be appropriate."
- "…we have revised the certification criterion to replace the word "transmit" with "submit" to better align this certification criterion with the meaningful use objective and measure."

Changes from 2011 to 2014 Edition

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 immunization information certification criterion is discussed:

- "We proposed two certification criteria for immunization registries that were essentially a split of the 2011 Edition EHR certification criterion for submission to immunization registries (§170.302(k))."
    - "We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access immunization information (data capture) and another that focused on the capability to electronically create immunization information for electronic transmission in accordance with specified standards."
    - "We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we did not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion…we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(k))."

  - "Additionally, for this certification criterion, we proposed to replace the terms "retrieve" and "modify" in the revised criterion with "access" and "change," respectively."
- "Commenters supported our proposed 'two certification criteria approach'."

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 immunization 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 immunization information into the EHR
  - Using the Vendor-defined EHR function(s), a Vendor-identified patient with an existing record in the EHR, and the provided test data, the Tester enters the immunization information
  - The Tester verifies that the recorded immunization information is stored in the patient's record and that it is accurate and complete

- Change – evaluates the capability for a user to change immunization information that has been entered previously into the EHR
  - Using the Vendor-identified EHR function(s) and provided test data, the Tester displays and changes the immunization information entered during the Record immunization information test
  - The Tester validates that the changed immunization 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 immunization information that has been entered into the EHR
  - Using Vendor-defined EHR function(s), the Tester accesses and displays the immunization information entered during the Record and Change tests
  - The Tester validates that the accessed immunization information is accurate and complete

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.f.1 – 1: Electronically Record Immunization Information

DTR170.314.f.1 – 2: Electronically Change Immunization Information

DTR170.314.f.1 – 3: Electronically Access Immunization Information

DTR170.314(f)(1) – 1: Electronically Record Immunization Information

Required Vendor Information

VE170.314.f.1 – 1.01: The Vendor shall identify an existing patient record in the EHR to be used for this test

VE170.314.f.1 – 1.02: The Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) record the immunization information, 3) change the immunization information, and 4) access the immunization information

Required Test Procedure

TE170.314.f.1 – 1.01: The Tester shall select immunization information from the provided test data

TE170.314.f.1 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select the vendor-identified test patient's existing record and enter the immunization information based on the test data selected in TE170.314(f)(1) – 1.01

TE170.314.f.1 – 1.03: Using the Inspection Test Guide, the Tester shall verify that the immunization information is entered correctly and without omission

Inspection Test Guide

IN170.314.f.1 – 1.01: Using the provided immunization information test data selected in TE170.314(f)(1) – 1.01, the Tester shall verify that the immunization information is entered correctly and without omission

IN170.314.f.1 – 1.02: The Tester shall verify that the immunization information entered during the Record test is captured and stored in the patient's record

DTR170.314.f.1 – 2: Electronically Change Immunization Information

Required Vendor Information

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

Required Test Procedure:

TE170.314.f.1 – 2.01: The Tester shall select immunization information from the provided test data

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

TE170.314.f.1 – 2.03: Using the Inspection Test Guide, the Tester shall verify that the immunization information changed during TE170.314(f)(1) – 2.02 is changed correctly and without omission

Inspection Test Guide

IN170.314.f.1 – 2.01: Using the provided test data selected in TE170.314(f)(1) – 2.01, the Tester shall verify that the immunization information entered during the DTR170.314(f)(1) – 1: Electronically Record Immunization Information test is changed correctly

IN170.314.f.1 – 2.02: The Tester shall verify that the changed immunization information is captured and stored in the patient's record

DTR 170.314.f.1 – 3: Electronically Access Immunization Information

Required Vendor Information

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

Required Test Procedure

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

TE170.314.f.1 – 3.02: Using the Inspection Test Guide, the Tester shall verify that this immunization information is displayed correctly and without omission

Inspection Test Guide

IN170.314.f.1 – 3.01: Using the provided immunization information test data, the Tester shall verify that the immunization information is accessed and that it displays correctly and without omission

TEST DATA

Test data are provided in 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 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.

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 7, 2012