Test Procedure for §170.314(a)(13) Family health history

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(a)(13) Family health history. Enable a user to electronically record, change, and access a patient's family health history according to:

(i) At a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) The standard specified in § 170.207(j).

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 revised 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 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 family health history certification criterion is discussed:

- "The proposed certification criterion required that EHR technology be able to, at minimum, electronically record, change, and access the health history of a patient's first-degree relatives."
- "…EHR technology must, at minimum, be capable of recording information about a patient's first degree relative in the patient's record and permitting a user to change and access that information as needed. EHR technology would not need to be able to access the records of a patient's first degree relatives."
- "…this certification criterion requires that EHR technology be capable of capturing family health history in structured data. Therefore, the certification criterion we have adopted does not permit unstructured/free text for certification because such entries would not constitute MU of CEHRT."
- "…we believe that SNOMED CT® is an appropriate terminology, and perhaps the best intermediate step, for coding family health history in structured data if one was not to use the HL7 Pedigree standard."
- "The HL7 Pedigree standard was originally released in 2007. Release 1 was recently reaffirmed by the American National Standards Institute (ANSI)… We have adopted this reaffirmed version ... An implementation guide for this standard is scheduled to be published shortly after this final rule. Although EHR technology will not be required to conform to the implementation guide for certification, the implementation guide will provide important guidance for use of the HL7 Pedigree standard with EHR technology."
- "We have finalized that EHR technology may meet this certification criterion by either being able to capture a patient's family health history in SNOMED CT® or in the HL7 Pedigree standard. Since the use of SNOMED CT® is required for meeting several other certification criteria, we do not believe that it will be a challenge to meet this certification criterion."
- "We emphasize, as specified in the § 170.300(b), when 'a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.' Thus, an EHR technology can demonstrate use of SNOMED CT® or the HL7 Pedigree standard 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.

This test evaluates the capability for a Complete EHR or EHR Module to enable a user to electronically record, change, and access family health history information according to, at a minimum, the IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release, or HL7 Version 3 Standard: Clinical Genomics; Pedigree.

The Vendor provides the test data for this test procedure. The test data will be required to designate family health history associated with first-degree family members, inclusive of parents, offspring, and siblings.

This test procedure is organized into three sections:

- Record – evaluates the capability for a user to enter a patient's family health history data into the EHR
    - Using Vendor–identified EHR function(s), a patient with an existing record in the EHR, the test data, and the named standards, the Tester enters the patient's family health history test data
    - The Tester validates that the recorded family health history data are accurate and complete, and in conformance with the named standards

- Change – evaluates the capability for a user to change a patient's family health history data that have been entered previously into the EHR
    - Using the Vendor-identified EHR technology function(s), the test data, and the named standards, the Tester displays and changes the patient's family health history data entered during the Record test
    - The Tester validates that the changed family health history data are accurate and complete, and in conformance with the named standards

- Access – evaluates the capability for a user to access a patient's family health history data that have been entered previously into the EHR
    - Using the Vendor-identified EHR technology function(s), the Tester accesses and displays the patient's family health history data entered in the Record and Change tests
    - The Tester validates that the displayed family health history data are accurate and complete, and in conformance with the named standards

REFERENCED STANDARDS

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	
(a)(3) Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).	
(j) Family health history. HL7 Version 3 Standard: Clinical Genomics; Pedigree, (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.13 – 1: Electronically Record a Patient's Family Health History

DTR170.314.a.13 – 2: Electronically Change a Patient's Family Health History

DTR170.314.a.13 – 3: Electronically Access a Patient's Family Health History

DTR170.314.a.13 – 1: Electronically Record a Patient's Family Health History

Required Vendor Information

VE170.314.a.13 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.13 – 1.02: Vendor shall specify whether they wish to use the SNOMED CT or HL7 Version 3 Standard: Clinical Genomics; Pedigree standards

VE170.314.a.13 – 1.03: Vendor shall identify the EHR function(s) that are available to 1) select the patient, 2) record the patient's family health history data, 3) change the patient's family health history data, and 4) access the patient's family health history data

Required Test Procedures

TE170.314.a.13 – 1.01: Tester shall select patient's family health history data for first-degree family members inclusive of parents, offspring and siblings

TE170.314.a.13 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select the test patient's existing record and enter the patient's family health history test data selected in TE170.314.a.13 – 1.01 as structured data inclusive of relationship to patient

TE170.314.a.13 – 1.03: Using the Inspection Test Guide, the Tester shall verify that the family health history data are entered correctly and without omission, and in conformance with the named standards

Inspection Test Guide

IN170.314.a.13. – 1.01: Using the test data selected in TE170.314.a.13 – 1.01 and the named standards, the Tester shall verify that the patient's family health history data are entered correctly and without omission, and in conformance with the named standards as structured data

IN170.314.a.13 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the patient's family health history data are captured and stored in the patient's record

DTR170.314.a.13 – 2: Electronically Change a Patient's Family Health History

Required Vendor Information

- As defined in DTR170.314.a.13 – 1, no additional information is required

Required Test Procedures

TE170.314.a.13 – 2.01: The Tester shall select patient's family health history data from the test data

TE170.314.a.13 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record, shall display the patient's family health history data entered during the DTR170.314.a.13 – 1: Electronically Record a Patient's Family Health History test, and shall change these data using the selected patient's family health history test data

TE170.314.a.13 – 2.03: Using the Inspection Test Guide, the Tester shall verify that the patient's family health history data changed during TE170.314.a.13 – 2.02, are changed correctly and without omission, and in conformance with the named standards

Inspection Test Guide

IN170.314.a.13 – 2.01: Using the test data selected in TE170.314.a.13 – 2.01 and the named standards, the Tester shall verify that the patient's family health history data entered during the DTR170.314.a.13 – 1: Electronically Record a Patient's Health History data test are changed correctly and without omission, and in conformance with the named standards

IN170.314.a.13 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall verify that the changed patient's family health history data are captured and stored in the patient's record

DTR170.314.a.13 – 3: Electronically Access a Patient's Family Health History

Required Vendor Information

- As defined in DTR170.314.a.13 – 1, no additional information is required.

Required Test Procedures

TE170.314.a.13 – 3.01: Using the Vendor-identified EHR function(s), the Tester shall select the existing patient record and shall access and display the family health history data entered during the DTR170.314.a.13: – 2 Electronically Change a Patient's Family Health History test

TE170.314.a.13 – 3.02: Using the Inspection Test Guide, the Tester shall verify that the patient's family health history data display correctly and without omission, and in conformance with the named standards

Inspection Test Guide

IN170.314.a.13 – 3.01: Using the test data and the named standards, the Tester shall verify that the family health history data changed in the DTR170.314.a.13 – 2: Electronically Change a Patient's Family Health History test display correctly and without omission, and in conformance with the named standards

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 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

The Office of the National Coordinator for Health Information Technology

Document History

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