Test Procedure for § 170.314 (a)(3) Demographics

This document describes the test procedure for evaluating conformance of electronic health record (EHR) technology 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 http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (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 Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-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 (September 4, 2012). This certification criterion is included in the definition of a Base EHR.

§170.314(a)(3) Demographics.
   (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.
      (A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.
      (B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g) and whether a patient declines to specify a preferred language.

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[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.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.

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 (September 4, 2012), 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 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.

2014 EDITION PREAMBLE LANGUAGE

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 (September 4, 2012) where the demographics certification criterion is discussed:

- "…EHR technology is not required to display all the languages of the standard to meet the certification criteria. But, it must be capable of recording a patient's language according to any of the languages in the standard."
- "…EHR technology must record race and ethnicity according to the OMB standard by providing the option for one or more racial designations to be selected in a manner consistent with the standard."
- "EHR technology must also be capable of aggregating/mapping more granular race and/or ethnicity data to the minimum race and ethnicity categories in the standard if an EHR technology developer implements such an approach."
- "Comments on when the preliminary cause of death must be recorded and the measure exclusion are beyond the scope of this rulemaking."
- "Change" is used to mean the ability to alter or edit information previously recorded in EHR technology…In certification criteria in which this term is used, we stated that we do not intend for it to be interpreted to mean that information previously recorded would be able to be changed without the retention of prior value(s). Rather, a change must be retained as an audited event and in a viewable format that identifies the changed information in a patient's record (similar to how one might see changes represented in a word-processing application). How such changes are displayed is a design decision left to EHR technology developers."

2011 EDITION PREAMBLE LANGUAGE

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 (July 28, 2010) where the record demographics certification criterion is discussed:

- "In the Medicare and Medicaid EHR Incentive Programs proposed rule (75 FR 1855), CMS stated that race and ethnicity codes should follow current Federal standards. We note that the OMB race and ethnicity codes constitute a government-unique standard for the purposes of the National Technology Transfer and Advancement Act of 1995 (NTTAA). We have adopted this standard because it provides an easily understood structure and format for electronically transmitting the data elements identified in the meaningful use Stage 1 objective, the standard is readily available, in general it provides the best standard to use to support our policies goals."
- "…we do not believe that it would be appropriate to expand this certification criterion beyond what is required to support meaningful use. Again, as we have previously stated, this does not preclude an EHR technology developer from including the capability to record additional demographic information. Finally, consistent with the Medicare and Medicaid EHR Incentive Programs final rule, we have removed the capability to record insurance type from the certification criterion."

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 (September 4, 2012) where the demographics certification criterion is discussed:

- "Accordingly, we are adopting ISO 639-2 constrained by ISO 639-1. This will constrain ISO 639-2 to only the active languages in ISO 639-1, but will permit the use of the alpha-3 codes of ISO 639-2. As such it is a better approach than adopting solely ISO 639-2 or 639-1."
- "We have clarified that the certification criterion requires the recording of sex, which is consistent with the change made by CMS for its MU objectives and measures."
- "…we noted that the standard for classifying federal data according to race and ethnicity requires that the option for selecting one or more racial designations be provided."
- "…we proposed to revise the certification criterion to require that EHR technology be capable of recording that a patient declined to specify his or her race, ethnicity, and/or preferred language."

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 an HER technology to enable a user to electronically record, change, and access a patient's demographic data describing their:

- preferred language, according to the standard specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1
- sex

- race, according to the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997
- ethnicity, according to the Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997
- date of birth
- and for the inpatient setting, the preliminary cause of death

Per the Final Rule (September 4, 2012) criteria, the test procedure does not evaluate the ability to record, change and access other types of patient demographic information.

The test procedure is not prescriptive about the method used to change the patient demographics. For example, changing patient demographics does not require changing an existing instance of patient demographics. Changing may be accomplished through updating existing patient demographics or by entering new patient demographics.

Per the §170.207(f) standard for race and ethnicity, the EHR must be capable of recording more than one race and should not contain a category that allows users to select "multiracial." Additionally, per the §170.207(f) standard for race and ethnicity, if a Vendor permits the collection of additional categories beyond the minimum categories in the standard, the EHR should be capable of mapping the additional categories to the minimum categories.

The test procedure does not additionally verify the ability of an EHR technology to record mortality in association with preliminary cause of death.

ONC provides the test data for this test procedure.

This test procedure is organized into three sections:

- Record – evaluates the capability for a user to enter patient demographic data into the EHR technology
    - For the ambulatory setting only: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards, the Tester enters one patient's preferred language, sex, race, ethnicity, and date of birth
    - For the inpatient setting only: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards, the Tester enters one patient's preferred language, sex, race, ethnicity, date of birth, and preliminary cause of death
    - For the ambulatory and inpatient settings: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards,
        - The Tester enters the test data with more than one race for a second patient
        - The Tester enters the test data in which a third patient declined to specify preferred language, race, and/or ethnicity

o   For the ambulatory and inpatient settings: The Tester verifies that the recorded demographic data are accurate and complete, and in conformance with the named standards

- Change – evaluates the capability for a user to change patient demographic data that were entered into the EHR during the Record test
  - o   For the ambulatory setting only: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards, the Tester displays and changes the patient's preferred language, sex, race, ethnicity, and date of birth data entered during the Record Patient Demographics test for all three patients
  - o   For the inpatient setting only: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards, the Tester displays and changes the patients' preferred language, sex, race, ethnicity, date of birth, and preliminary cause of death data entered during the Record Patient Demographics test for all three patients
  - o   For the ambulatory and inpatient settings: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards,
    - ▪   The Tester changes the entry for more than one race for the second patient
    - ▪   The Tester changes the entry stating that the third patient declined to provide preferred language, race, and/or ethnicity
  - o   For the ambulatory and inpatient settings: The Tester verifies that the changed demographic data are stored in the patients' records, that they are accurate and complete, and that they are in conformance with the named standards

- Access – Evaluates the capability for a user to access the patient demographic data that were entered into the EHR during the Record test and Change test
  - o   For the ambulatory setting only: Using the Vendor-identified EHR technology function(s), the Tester accesses and displays the patient's preferred language, sex, race, ethnicity, and date of birth data entered during the Record Patient Demographics and Change Patient Demographics tests for all three patients
  - o   For the inpatient setting only: Using the Vendor-identified EHR technology function(s), the Tester accesses and displays the patient's preferred language, sex, race, ethnicity, date of birth, and preliminary cause of death data entered during the Record Patient Demographics and Change Patient Demographics tests for all three patients
  - o   For the ambulatory and inpatient settings: Using the Vendor-identified EHR technology function(s), the provided test data, and the named standards, the Tester accesses and displays the entry for more than one race for the second patient
  - o   For the ambulatory and inpatient settings: Using the Vendor-identified EHR technology function(s),and the provided test data, the Tester accesses and displays the statement that the third patient declined to provide preferred language, race and/or ethnicity
  - o   For the ambulatory and inpatient settings: The Tester verifies that the displayed demographic 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:	
(f) Race and Ethnicity. Standard. The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," available at http://www.whitehouse.gov/omb/fedreg_1997standards.	
(g) Preferred language. Standard. As specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1. (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(a)(3) – 1: Electronically Record Patient Demographics

DTR170.314(a)(3) – 2: Electronically Change Patient Demographics

DTR170.314(a)(3) – 3: Electronically Access Patient Demographics

DTR170.314(a)(3) – 1: Electronically Record Patient Demographics

Required Vendor Information

VE170.314(a)(3) – 1.01: Vendor shall identify three patients with existing records in the EHR to be used for this test

VE170.314(a)(3) – 1.02: Vendor shall identify the EHR function(s) that are available to 1) enter a patient's preferred language, sex, race, ethnicity, date of birth, and (for inpatient setting only) preliminary cause of death in conformance with the standards for race, ethnicity and preferred language, 2) change these demographic data in conformance with the standards for race, ethnicity and preferred language, and 3) access these demographic data

VE170.314(a)(3) – 1.03: Vendor shall identify the EHR function(s) that are available to enter that a patient declined to specify race and/or ethnicity, and preferred language

VE170.314(a)(3) – 1.04: Vendor shall identify the EHR function(s) that are available to record more than one race for a patient

VE170.314(a)(3) – 1.05: Vendor shall submit documentation that lists the languages for which the EHR records a patient's preferred language, according to the named standard

VE170.314(a)(3) – 1.06: If a Vendor permits the collection of additional race and ethnicity categories beyond the minimum categories in the named standard, the Vendor shall submit documentation that describes how the EHR maps additional race and ethnicity

categories to the minimum categories (this could include, but is not limited to, a report)

Required Test Procedures

TE170.314(a)(3) – 1.01: Tester shall select the test data provided in TD170.314(a)(3) – 1

TE170.314(a)(3) – 1.02: Using the Vendor-identified EHR function(s) and three test patients, the Tester shall enter the provided demographic test data selected in TE170.314.a.3 – 1.01

TE170.314(a)(3) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the patient demographic data entered in TE170.314(a)(3) – 1.02 are entered correctly and without omission, and in conformance with the standards for race, ethnicity and preferred language

Inspection Test Guide

IN170.314(a)(3) – 1.01: Using the provided test data selected in TE170.314(a)(3) – 1.01 and the standards named in the §170.314(a)(3) criterion, the Tester shall verify that the patient demographic data are entered correctly and without omission, and in conformance with the standards for race, ethnicity and preferred language

IN170.314(a)(3) – 1.02: The Tester shall verify that an entry of "multiracial" has not been used to record more than one race for the patient demographic data entered in TE170.314(a)(3) – 1.02

IN170.314(a)(3) – 1.03: If a Vendor permits the collection of additional race and ethnicity categories beyond the minimum categories in the named standard, the Tester shall examine the Vendor-provided documentation to determine that the EHR can map additional race and ethnicity categories to the minimum categories for the patient demographic data entered in TE170.314(a)(3) – 1.02

DTR170.314(a)(3) – 2: Electronically Change Patient Demographics

Required Vendor Information

- As defined in DTR170.314(a)(3) – 2, no additional information is required

Required Test Procedures

TE170.314(a)(3) – 2.01: Tester shall select the test data provided in TD170.314(a)(3) – 2

TE170.314(a)(3) – 2.02: Using the Vendor-identified EHR function(s) and the provided test data selected in TE170.314(a)(3) – 2.01, the Tester shall select the existing patient records, shall display the patient demographic data entered during the DTR170.314(a)(3) – 1: Electronically Record Patient Demographics test, and shall change the demographic test data

TE170.314(a)(3) – 2.03: Using the Inspection Test Guide, the Tester shall verify that the patient demographic data changed in TE170.314(a)(3) – 2.02 are changed correctly and without omission, and in conformance with the standards for race, ethnicity and preferred language

<u>Inspection Test Guide</u>

IN170.314(a)(3) – 2.01: Using the provided test data selected in TE170.314(a)(3) – 2.01 and the standards named in the §170.314(a)(3) criterion, the Tester shall verify that the patient demographic data entered during the DTR170.314(a)(3) – 1: Electronically Record Patient Demographics test are changed correctly and without omission, and in conformance with the standards for race, ethnicity and preferred language

IN170.314(a)(3) – 2.02: Using the provided test data selected in TE170.314(a)(3) – 2.01, the Tester shall verify that the changed demographic data are stored in the patients' records

IN170.314(a)(3) – 2.03: The Tester shall verify that an entry of "multiracial" has not been used to change more than one race

DTR170.314(a)(3) – 3: Electronically Access Patient Demographics

<u>Required Vendor Information</u>

- As defined in DTR170.314(a)(3) – 3, no additional information is required

<u>Required Test Procedures</u>

TE170.314(a)(3) – 3.01: The Tester shall select the test data provided in TD170.314(a)(3) – 3

TE170.314(a)(3) – 3.02: Using the Vendor-identified EHR function(s) and the provided test data selected in TE170.314(a)(3) – 3.01, the Tester shall select the patients' existing records and shall display the patient demographic data the Tester entered during the DTR170.314(a)(3) – 2: Electronically Change Patient Demographics

TE170.314(a)(3) – 3.03: Using the Inspection Test Guide, the Tester shall verify that the patient demographic Test Data display correctly and without omission, in conformance with the standards for race, ethnicity and preferred language

<u>Inspection Test Guide</u>

IN170.314(a)(3) – 3.01: Using the provided test data selected in TE170.314(a)(3) – 3.01, the Tester shall verify that the patient demographic data entered in the DTR170.314(a)(3) – 1: Electronically Record Patient Demographics test and changed in the DTR170.314(a)(3) – 2: Electronically Change Patient Demographics test display correctly and without omission

IN170.314(a)(3) – 3.02: Using the provided test data selected in TE170.314(a)(3) – 3.01, the Tester shall verify that the patient demographic data for race entered in the DTR170.314(a)(3) – 1: Electronically Record Patient Demographics test and changed in the DTR170.314(a)(3) – 2: Electronically Change Patient Demographics does not display an entry of "multiracial" to indicate more than one race

TEST DATA

ONC supplied test data are provided with the test procedure to ensure that the applicable 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-(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 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 applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. 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.

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 applicable 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.

Test Data for §170.314(a)(3) Demographics available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

CONFORMANCE TEST TOOLS

None

The Office of the National Coordinator for
Health Information Technology

Document History

Version Number	Description of Change	Date Published
1.0	Post-public comment draft	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012