Test Procedure for §170.314(a)(11) Smoking status

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 CRITERION

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)(11) Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

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 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 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 smoking status certification criterion is discussed:

- "We have now provided mappings to a set of SNOMED CT® concepts to assist the developers and implementers of EHR technology in the implementation of this requirement."

Description	SNOMED CT® ID
Current every day smoker	449868002
Current some day smoker	428041000124106
Former smoker	8517006
Never smoker	266919005
Smoker, current status unknown	77176002
Unknown if ever smoked	266927001
Heavy tobacco smoker	428071000124103
Light tobacco smoker	428061000124105

- "We have also expanded the number of available concepts from six to eight in order to better reflect the way that many EPs capture smoking status. We clarify that the eight smoking statuses provided here need not be the exact words that are displayed for a user. Rather, any appropriate concept or concepts that the EHR technology displays for an EP may be mapped to one or more compatible smoking status codes, but if an alternative approach is used, the EHR technology must ultimately be able to record the semantic representation of a patient's smoking status in at least one of these eight status. Further, these eight codes must be used as specified elsewhere in the final rule when smoking status is referenced, such as within the transition of care certification criterion."
- "We clarify that smoking status includes any form of tobacco that is smoked, but not all tobacco use. Working with CMS, we have added these eight value sets to NQF 0028, so that (for the portion of NQF 0028 that captures smoking status) an EP or EH can capture this data only once rather than twice."

- "We have added two smoking statuses to the standard adopted in § 170.207(h) in order to better reflect clinically relevant differences between smokers, and provide options that may in fact be preferable to many providers, while retaining the existing six codes from the 2011 Edition certification program in order to give EHR developers the option of migrating to the newer codes over time."
- "Since many EHR technology developers have asked questions about this certification criterion, we offer the following example of an implementation that would be acceptable: an EP user of CEHRT ABC is taking the social history from patient XYZ. The EP is using a template for facilitated data entry in the CEHRT. The template has options such as "smoker" and "nonsmoker." When the EP selects "smoker," several other options become available including "1-9 cigarettes/day" and "1/2 pack /day" and "1 pack/day" and "greater than 1 pack/day." The EP selects "1 pack/day," and moves on to other parts of the discussion with the patient. The CEHRT records (and displays) "1 pack/day" and maps this internally as SNOMED CT® concept 428071000124103 ("Current Heavy Smoker"). When a transition of care/referral summary is generated for exchange, the SNOMED CT® concept must be included, as well as the text description "heavy smoker" ("1 pack/day" and any other metadata could also be included as appropriate). Note that "heavy smoker" is not the only concept that is appropriate here, and we leave the decision regarding which of the eight codes is the most accurate descriptor of clinical intent to the judgment of those implementing the form, template, or other EHR data capture interface."
- "'Light smoker' is interpreted to mean less than 10 cigarettes per day, or an equivalent (but less concretely defined) quantity of cigar or pipe smoke. 'Heavy smoker' is interpreted to mean greater than 10 cigarettes per day or an equivalent (but less concretely defined) quantity of cigar or pipe smoke."

2011 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 smoking status certification criterion is discussed:

- "… we understand that a "current every day smoker" or "current some day smoker" is an individual who has smoked at least 100 cigarettes during his/her lifetime and still regularly smokes every day or periodically, yet consistently; a "former smoker" would be an individual who has smoked at least 100 cigarettes during his/her lifetime but does not currently smoke; and a "never smoker" would be an individual who has not smoked 100 or more cigarettes during his/her lifetime. The other two statuses (smoker, current status unknown; and unknown if ever smoked) would be available if an individual's smoking status is ambiguous. The status "smoker, current status unknown" would apply to individuals who were known to have smoked at least 100 cigarettes in the past, but their [sic] whether they currently still smoke is unknown. The last status of "unknown if ever smoked" is self-explanatory."

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 smoking status certification criterion is discussed:

- "For the 2014 Edition EHR certification criteria, we proposed a "smoking status" certification criterion that replaced the terms "modify" and "retrieve" with "change" and "access," respectively.
- "We have added two smoking statuses [heavy smoker and light smoker] to the standard adopted in §170.207(h) in order to better reflect clinically relevant differences between smokers…"

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 EHR technology to enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

Smoking status types must include:

- Current every day smoker: an individual who has smoked at least 100 cigarettes during his/her lifetime and still regularly smokes every day
- Current some day smoker : an individual who has smoked at least 100 cigarettes during his/her lifetime and still regularly smokes periodically, yet consistently
- Former smoker: an individual who has smoked at least 100 cigarettes during his/her lifetime but does not currently smoke
- Never smoker: an individual who has not smoke 100 or more cigarettes during his/her lifetime
- Smoker, current status unknown: an individual who has smoked at least 100 cigarettes during his/her lifetime, but whether they currently still smoke is unknown
- Unknown if ever smoked: unknown if an individual has ever smoked
- Heavy tobacco smoker: an individual who smokes more than 10 cigarettes per day, or an equivalent (but less concretely defined) quantity of cigar or pipe smoke
- Light tobacco smoker: an individual who smokes less than 10 cigarettes per day, or an equivalent (but less concretely defined) quantity of cigar or pipe smoke

The test procedure is not prescriptive about the exact words that are displayed for a user. Rather any appropriate concept or concepts that the EHR technology displays for an EP may be mapped to one or more compatible smoking status codes, but if an alternative approach is used, the EHR technology must ultimately be able to record the semantic representation of a patient's smoking status in at least one of

these eight status. This test procedure is not prescriptive about which of the eight codes is the most accurate descriptor of clinical intent.

The test procedure is not prescriptive about the method used to change smoking status. For example, changing a smoking status does not require changing an existing instance of a smoking status. Changes may be accomplished through inactivating or deleting an existing smoking status in the patient's EHR and entering a new instance of the smoking status.

The Vendor supplies the test data for this test procedure.

This test procedure is organized into four sections:

- Show – demonstrates that all eight smoking statuses are contained within the EHR
  - The Vendor shows the Tester that all 8 smoking statuses are represented in some form within the EHR

- Record – evaluates the capability to enter patient smoking status data
  - The Tester enters the Vendor-supplied patient smoking status data. The Inspection Guide describes several methods by which the EHR can demonstrate conformance with the vocabulary requirement

- Change – evaluates the capability to change patient smoking status data that have been entered previously into the EHR
  - The Tester displays the patient smoking status data entered during the Record Patient Smoking Status test
  - The Tester changes the previously entered patient smoking status data using Vendor-supplied patient smoking status data

- Access – evaluates the capability to display the patient smoking status data that have been entered previously into the EHR during the test
  - The Tester displays the patient smoking status data entered during the test
  - The Tester verifies that the displayed patient smoking status data are accurate and complete

REFERENCED STANDARDS

§170.207 Vocabulary standard 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:	

(h) Smoking Status. Standard. Smoking status must be coded in one of the following SNOMED CT® codes:
(1) Current every day smoker. 449868002
(2) Current some day smoker. 428041000124106
(3) Former smoker. 8517006
(4) Never smoker. 266919005
(5) Smoker, current status unknown. 77176002
(6) Unknown if ever smoked. 266927001
(7) Heavy tobacco smoker. 428071000124103
(8) Light tobacco smoker. 428061000124105

NORMATIVE TEST PROCEDURES

Derived Test Requirement(s)

DTR170.314(a)(11) – 1: Electronically Show All Eight Smoking Statuses

DTR170.314(a)(11) – 2: Electronically Record Patient Smoking Status

DTR170.314(a)(11) – 3: Electronically Change Patient Smoking Status

DTR170.314(a)(11) – 4: Electronically Access Patient Smoking Status

DTR170.314(a)(11) – 1: Electronically Show All 8 Smoking Statuses

Required Vendor Information

VE170.314(a)(11) – 1.01: Vendor shall identify the EHR location(s) in which all eight smoking statuses are represented

Required Test Procedure

TE170.314(a)(11) – 1.01: Using the EHR location(s) identified by the Vendor, the Tester shall verify that all right smoking statuses are represented within the EHR

Inspection Test Guide

IN170.314(a)(11) – 1.01: Using the EHR location(s) identified by the Vendor, Tester shall verify that all eight smoking statuses are represented within the EHR

DTR170.314(a)(11) – 2: Electronically Record Patient Smoking Status

Required Vendor Information

VE170.314(a)(11) – 2.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314(a)(11) – 2.02: Vendor shall provide the test data for this test

VE170.314(a)(11) – 2.03: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient smoking status data that represents, at a minimum, heavy tobacco smoker; light tobacco smoker; current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; unknown if ever smoker, 3) change patient smoking status, 4) and access patient smoking status

Required Test Procedure

TE170.314(a)(11) – 2.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter the Vendor-supplied patient smoking status data that represents a **heavy tobacco smoker**

TE170.314(a)(11) – 2.02: Using the Inspection Test Guide (below), the Tester shall verify that the patient smoking status test data have been entered correctly, without omission and in conformance with the vocabulary standard

Inspection Test Guide

IN170.314(a)(11) – 2.01: Using the Vendor-supplied patient smoking status data, Tester shall verify that the patient smoking status data are entered correctly and without omission

IN170.314(a)(11) – 2.02: Tester shall verify that the patient smoking status data entered during the test are associated with at least one of the required vocabulary standard descriptions and codes. Verification methods include, but are not limited to:

- verifying that the appropriate vocabulary description and code is displayed along with the patient smoking status data when the user is recording patient smoking status; or
- verifying that the EHR includes the capability to cross-reference (map) the user-displayed smoking status data to the appropriate vocabulary description and code; or
- verifying that the patient smoking status data stored in the EHR contains the appropriate vocabulary description and code

IN170.314(a)(11) – 2.03: Tester shall verify that the patient smoking status data and associated vocabulary standard description and code are stored in the patient's record

DTR170.314(a)(11) – 3: Electronically Change Patient Smoking Status

Required Vendor Information

- As defined in DTR170.314(a)(11) – 2, no additional information is required

Required Test Procedure

TE170.314(a)(11) – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the patient smoking status data entered during the DTR170.314(a)(11) – 2: Electronically Record Patient Smoking Status test, and shall change the previously entered patient smoking status data to the Vendor-supplied patient smoking status data that represents a **light tobacco smoker**

TE170.314(a)(11) – 3.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the patient smoking status data changed during TE170.314(a)(11) – 3.01, and shall change the previously changed patient smoking status data until all eight iterations of electronically changing patient smoking status are completed. The eight iterations include changing the Vendor-supplied smoking status data that represents a:

- **Heavy tobacco smoker** to a **light tobacco smoker**
- **Light tobacco smoker** to a **current every day smoker**
- **Current every day smoker** to a **current some day smoker**
- **Current some day smoker** to a **former smoker**
- **Former smoker** to a **never smoker**
- **Never smoker** to a **smoker, current status unknown**
- **Smoker, current status unknown** to a **unknown if ever smoked**
- **Unknown if ever smoked** to a **heavy tobacco smoker**

TE170.314(a)(11) – 3.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient smoking status data entered during TE170.314(a)(11) – 3.01 and TE170.314(a)(11) – 3.02 have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(11) – 3.01: Tester shall verify that the Vendor-supplied patient smoking status data, entered during the DTR170.314(a)(11) – 2: Electronically Record Patient Smoking Status test and the DTR170.314(a)(11) – 3: Electronically Change Patient Smoking Status, are accessed and changed

IN170.314(a)(11) – 3.02: Using the Vendor-supplied patient smoking status data, Tester shall verify, for each of the eight iterations, that the changed patient smoking status data and associated vocabulary standard description and code are stored in the patient's record

DTR170.314(a)(11) – 4: Electronically Access Patient Smoking Status

Required Vendor Information

- As defined in DTR170.314(a)(11) - 2, no additional information is required

Required Test Procedure

TE170.314(a)(11) – 4.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the final patient smoking status data entered during the DTR170.314(a)(11) – 3: Electronically Change Patient Smoking Status test

TE170.314(a)(11) – 4.02: Using the Inspection Test Guide (below), the Tester shall verify that the patient smoking status test data display correctly and without omission

Inspection Test Guide

IN170.314(a)(11) – 4.01: Using the Vendor-supplied patient smoking status data that represents a **heavy tobacco smoker**, Tester shall verify that the current patient smoking status data changed in the DTR170.314(a)(11) – 2: Electronically Change Patient Smoking Status test display correctly and without omission

TEST DATA

The Vendor shall supply the test data for this test procedure.

Vendor-supplied test data shall 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. 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.

For Vendor-supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the 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

Document History

Version Number	Description of Change	Date
1.0	Released for public comment	September 7, 2012
1.1	Delivered for National Coordinator Approval	December 4, 2012
1.2	Posted Approved Test Procedure	December 14, 2012