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

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 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 this Certification Criterion is classified as revised from the 2011 Edition. This Certification Criterion meets

[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

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.

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 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."

- "'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."

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 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 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 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 [light smoker and heavy 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 a Complete EHR or EHR Module 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; current some day smoker; former smoker; never smoker; smoker, current status unknown; unknown if ever smoked; heavy tobacco smoker; light tobacco smoker.

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.

This test procedure is organized into three sections:

- Record – evaluates the capability to enter patient smoking status data
  - The Tester enters the ONC-supplied patient smoking status data
- 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 ONC-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(h)	Regulatory Referenced Standard
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 record patient smoking status
DTR170.314.a.11 – 2: Electronically change patient smoking status
DTR170.314.a.11 – 3: Electronically access patient smoking status

DTR170.314.a.11 – 1: Electronically Record Patient Smoking Status

Required Vendor Information

VE170.314.a.11 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.11 – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient smoking status, including, at a minimum, current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; unknown if ever smoked; heavy tobacco smoker; light tobacco smoker, 3) change patient smoking status, 4) and access patient smoking status

Required Test Procedure:

TE170.314.a.11 – 1.01: Tester shall select patient smoking status data from ONC-supplied test data set TD170.314.a.11 – 1

TE170.314.a.11 – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter the patient smoking status from the test data sets

TE170.314.a.11 – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient smoking status test data have been entered correctly and without omission

Inspection Test Guide:

IN170.314.a.11 – 1.01: Using the data in the ONC-supplied Test Data set TD170.314.a.11 – 1, Tester shall verify that the patient smoking status test data are entered correctly and without omission

IN170.314.a.11 – 1.02: Tester shall verify that the patient smoking status data and the SNOMED CT® codes are captured and stored in the patient's record, including

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

DTR170.314.a.11 – 2: Electronically Change Patient Smoking Status

Required Vendor Information

- As defined in DTR170.314.a.11 – 1, no additional information is required

Required Test Procedure:

TE170.314.a.11 – 2.01: Tester shall select the patient smoking status data from ONC-supplied test data set TD170.314.a.11 – 2

TE170.314.a.11 – 2.02: 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 entered during the DTR170.314.a.11 – 1: Electronically Record Patient Smoking Status test, and shall change the previously entered patient smoking status data

TE170.314.a.11 – 2.03: 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 – 2.02, and shall change the previously changed patient smoking status data until all eight iterations of electronically changing patient smoking status are completed

TE170.314.a.11 – 2.04: Using the Inspection Test Guide (below), the Tester shall verify that the patient smoking status data entered during TE170.314.a.11 – 2.02 and TE170.314.a.11 – 2.03 have been entered correctly and without omission

Inspection Test Guide

IN170.314.a.11 – 2.01: Using the data in the ONC-supplied Test Data set TD170.314.a.11 – 2, Tester shall verify that the patient smoking status data entered during the DTR170.314.a.11 – 1: Electronically Record Patient Smoking Status test and the DTR170.314.a.11 – 2: Electronically Change Patient Smoking Status are accessed and changed

IN170.314.a.11 – 2.02: Tester shall verify that the changed patient smoking status data and the SNOMED CT® codes are captured and stored in the patient's record, including

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

DTR170.314.a.11 – 3: Electronically Access Patient Smoking Status

Required Vendor Information

- As defined in DTR170.314.a.11 - 1, 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 and shall display the final patient smoking status data entered during the DTR170.314.a.11 – 2: Electronically Change Patient Smoking Status test

TE170.314.a.11 – 3.02: 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 – 3.01: Using the data in the ONC-supplied Test Data set TD170.314.a.11 – 3, 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

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date
1.0	Released for public comment	September 7, 2012