Test Procedure for §170.302 (g) Smoking Status

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] 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://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. 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. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010*.)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302 (g) Smoking status. Enable a user to electronically record, modify, and retrieve the smoking status of a patient. 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.

[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

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 have adopted this certification criterion to fully support the final meaningful use objective and measure, which in response to comments has been revised to further clarify the purpose of the objective and measure. We therefore disagree with those commenters who stated that this certification criterion is too prescriptive. Concurring with CMS, we believe that the fields associated with this measure should mirror those expressed in the Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Interview Survey related to smoking status recodes.[3] Accordingly, the final certification criterion further specifies and slightly broadens the smoking statuses we expect Certified EHR Technology to be capable of recording."
- "… 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 everyday 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.[4] 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."

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, modify, and retrieve the smoking status of a patient. 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.

The smoking status types should mirror those expressed in the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Health Interview Survey related to smoking status recodes. The CDC smoking status recodes associated with the CDC smoking status types must be captured and stored in the patient's EHR. These stored recodes need not be displayed to the user.

[3] Smoking status recodes: http://www.cdc.gov/nchs/nhis/tobacco/tobacco_recodes.htm

[4] ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/datasets/DATA2010/Focusarea27/O2701a.pdf

The test procedure is not prescriptive about the method used to modify smoking status. For example, modifying a smoking status does not require modifying an existing instance of a smoking status. Modification 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 NIST-supplied patient smoking status data

- Modify – evaluates the capability to modify 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 modifies the previously entered patient smoking status data using NIST-supplied patient smoking status data

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

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirement(s)

DTR170.302.g – 1: Electronically record patient smoking status
DTR170.302.g – 2: Electronically modify patient smoking status
DTR170.302.g – 3: Electronically retrieve patient smoking status

DTR170.302.f – 1: Electronically Record Patient Smoking Status

Required Vendor Information

VE170.302.g – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test
VE170.302.g – 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, 3) modify patient smoking status, 4) and retrieve patient smoking status

Required Test Procedure:

TE170.302.g – 1.01: Tester shall select patient smoking status data from NIST-supplied test data set TD170.302.g – 1

TE170.302.g – 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

TE170.302.g – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient smoking status test data have been entered and the CDC smoking status recodes are captured correctly and without omission

Inspection Test Guide:

IN170.302.g – 1.01: Using the data in the NIST-supplied Test Data set TD170.302.g – 1, Tester shall verify that the patient smoking status test data are entered correctly and without omission

IN170.302.g – 1.02: Tester shall verify that the patient smoking status data and the CDC smoking status recodes are captured and stored in the patient's record, including

Smoking Status Recodes	Smoking Status
1	Current every day smoker
2	Current some day smoker
3	Former smoker
4	Never smoker
5	Smoker, current status unknown
9	Unknown if ever smoked

DTR170.302.g – 2: Electronically Modify Patient Smoking Status

Required Vendor Information

- As defined in DTR170.302.g – 1, no additional information is required

Required Test Procedure:

TE170.302.g – 2.01: Tester shall select the patient smoking status data from NIST-supplied test data set TD170.302.g – 2

TE170.302.g – 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 DTR170.302.f – 1: Electronically Record Patient Smoking Status test, and shall modify the previously entered patient smoking status data

TE170.302.g – 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 modified during TE170.302.g – 2.02, and shall modify the previously modified patient

smoking status data until all six iterations of electronically modifying patient smoking status are completed

TE170.302.g – 2.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient smoking status data entered during TE170.302.g – 2.02 and TE170.302.g – 2.03 have been entered correctly and without omission

Inspection Test Guide

IN170.302.g – 2.01: Using the data in the NIST-supplied Test Data set TD170.302.g – 2, Tester shall verify that the patient smoking status data entered during the DTR170.302.f – 1: Electronically Record Patient Smoking Status test and the DTR170.302.g – 2: Electronically Modify Patient Smoking Status are accessed and modified

IN170.302.g – 2.02: Tester shall verify that the modified patient smoking status data and the CDC smoking status recodes and stored in the patient's record, including

Smoking Status Recodes	Smoking Status
1	Current every day smoker
2	Current some day smoker
3	Former smoker
4	Never smoker
5	Smoker, current status unknown
9	Unknown if ever smoked

DTR170.302.g – 3: Electronically Retrieve Patient Smoking Status

Required Vendor Information

- As defined in DTR170.302.g - 1, no additional information is required

Required Test Procedure:

TE170.302.g – 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 DTR170.302.g – 2: Electronically Modify Patient Smoking Status test

TE170.302.g – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient smoking status test data display correctly and without omission

Inspection Test Guide

IN170.302.g – 3.01: Using the data in the NIST-supplied Test Data set TD170.302.g – 3, Tester shall verify that the current patient smoking status data modified in the DTR170.302.g – 2: Electronically Modify Patient Smoking Status test display correctly and without omission

TEST DATA

Test data is provided by NIST in this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data is 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 NIST-supplied 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 NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied 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 NIST-supplied 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.

TD170.302.g – 1: Electronically record patient smoking status

Smoking Status Type: current every day smoker

TD170.302.g – 2: Electronically modify patient smoking status (Test Data for six iterations of electronically modifying patient smoking status are included in order to allow the Tester to verify that the EHR is capable of performing the electronic modification of all of the smoking statuses.)

Modify the Smoking Status Type from current every day smoker to **current some day smoker**

Revised Patient Smoking Status

Smoking Status Type: current some day smoker

Modify the Smoking Status Type from current some day smoker to **former smoker**

Revised Patient Smoking Status

Smoking Status Type: former smoker

Modify the Smoking Status Type from former smoker to **never smoker**

Revised Patient Smoking Status

Smoking Status Type: never smoker

Modify the Smoking Status Type from never smoker to **smoker, current status unknown**

Revised Patient Smoking Status

Smoking Status Type: smoker, current status unknown

Modify the Smoking Status Type from smoker, current status unknown to **unknown if ever smoked**

Revised Patient Smoking Status

Smoking Status Type: unknown if ever smoked

Modify the Smoking Status Type from unknown if ever smoked to **current every day smoker**

Revised Patient Smoking Status

Smoking Status Type: current every day smoker

TD170.302.g – 3: Electronically retrieve patient smoking status

Revised Patient Smoking Status

Smoking Status Type: current every day smoker

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.5	Original draft version	February 26, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updates include: • removed “Pending from headers • updated six values for “smoking status”	August 13, 2010
1.1	Removed “draft” from introductory paragraph In the Informative Test Description section • Added information regarding smoking status recodes • Added “The test procedure is not prescriptive about the method used to modify smoking status. For example, modifying a smoking status does not require modifying an existing instance of a smoking status. Modification 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.” • Added “These stored recodes need not be displayed to the user.” In the Normative Test Procedure section • Added information about smoking status recodes In the Test Data section • Added clarification of the six iterations of the modify test data • Added sixth iteration of the modify test data • Changes Test Data for TD170.302.g – 3: Electronically retrieve patient smoking status	September 24, 2010