Test Procedure for §170.302 (i) Generate Patient Lists

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules¹ 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 document² 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 htt-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 (i) <u>Generate patient lists</u>. Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:

- (1) Problem list;
- (2) Medication list;
- (3) Demographics; and

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.

(4) Laboratory test results.

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 generate patient lists certification criterion is discussed:

- "It was our intention that Certified EHR Technology would be able to leverage the information, specifically the structured data it has available to it, to assist eligible professionals and eligible hospitals to generate patient lists. We have clarified this certification criterion to express this intent. Accordingly, we expect that Certified EHR Technology will be able to generate patient lists according to certain data elements for which structured data will be available: medical problems; medications; demographics; and laboratory test results."
- "...we have removed "patient's clinical information" and "specific conditions" from the certification criterion, and have reframed the certification criterion to more directly align with the meaningful use measure by changing "output" to "generate." We sought to clarify that we intended that Certified EHR technology would be capable of electronically producing or "generating" patient lists for an eligible professional or eligible hospital's subsequent use. We do not require as a condition of certification that time periods be associated with a patient list, but presumably time (i.e., the age of the information) could be one factor an eligible professional or eligible hospital could also use to sort their lists (e.g., patients with XYZ problem recorded in the past 3 months)."

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 select, sort, retrieve, and generate lists of patients according to data elements included in the Problem list, Medication list, Demographics, and Laboratory test results. Generated formats are evaluated in terms of online display, electronic file, or printed document. Other forms of generating the lists of patients are not considered within the scope of this criteria.

The Vendor supplies the test data for this test.

This test procedure is organized into three sections:

- <u>Select</u> evaluates the capability to electronically select lists of patients using data elements included in the Problem list, Medication list, Demographics, and Laboratory test results
 - The Tester selects two or more lists of patients matching Vendor-supplied data for data elements included in the Problem list, Medication list, Demographics, and Laboratory test results
 - The Tester validates that the patient lists are accurate and complete

- Sort and Retrieve evaluates the capability to electronically 1) retrieve lists of patients that were selected using the Vendor-supplied data for the data elements included in the Problem list,
 Medication list, Demographics, and Laboratory test results, and 2) sequence or arrange the data on each patient list using these data elements
 - The Tester retrieves and displays two or more lists of patients using data elements included in the Problem list, Medication list, Demographics, and Laboratory test results
 - The Tester sequences or arranges the data on each patient list using these data elements
 - The Tester validates that the patient data on each list are sequenced or arranged using data elements included in the Problem list, Medication list, Demographics, and Laboratory test results,
- Generate evaluates the capability to electronically produce the lists of patients as for an eligible professional or eligible hospital's subsequent use
 - The Tester electronically generates two or more lists of patients from the Select and Sort and Retrieve tests
 - The Tester validates that the electronically generated lists of patients are produced as an online display, electronic file or printed document, and that the lists are accurate and complete

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.i – 1: Electronically Select Lists of Patients

DTR170.302.i – 2: Electronically Sort and Retrieve Lists of Patients

DTR170.302.i – 3: Electronically Generate Lists of Patients

DTR170.302.i – 1: Electronically Select Lists of Patients

Required Vendor Information

VE170.302.i – 1.01: Vendor shall identify two or more types of lists of patients available for this test

VE170.302.i - 1.02: Vendor shall provide the test data for this test

VE170.302.i – 1.03: Vendor shall identify the EHR function(s) that are available to: 1) select lists of

patients based on data elements included in the Problem list, Medication list,

Demographics, and Laboratory test results, 2) sort and retrieve lists of patients

based on data elements included in the Problem list, Medication list,

Demographics, and Laboratory test results, and 4) electronically generate lists of patients based on data elements included in the Problem list, Medication list,

Demographics, and Laboratory test results

Required Test Procedure:

TE170.302.i – 1.01: Using the EHR function(s) identified by the Vendor, the Tester shall select two or

more lists of patients based on data elements included in the Problem list,

Medication list, Demographics, and Laboratory test results

TE170.302.i – 1.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the

selected lists of patients are based on data elements included in the Problem list,

Medication list, Demographics, and Laboratory test results

Inspection Test Guide

IN170.302.i – 1.01: Tester shall verify that two or more lists of patients based on data elements

included in the Problem list, Medication list, Demographics, and Laboratory test results are selected. TD170.302.i shows examples of data elements for selecting

lists of patients

DTR170.302.i - 2: Electronically Sort and Retrieve Lists of Patients

Required Vendor Information

• As defined in DTR170.302.i – 1, no additional information is required

Required Test Procedure:

TE170.302.i – 2.01: Using patient lists selected in the DTR170.302.i – 1: Electronically Select Lists of

Patients test and the EHR function(s) identified by the Vendor, the Tester shall retrieve and display two or more patient lists and sort (sequence/arrange) the data on each list based on data elements included in the Problem list, Medication

list, Demographics, and Laboratory test results

TE170.302.i – 2.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the

two or more lists of patients are sorted and displayed correctly according to the data elements included in the Problem list, Medication list, Demographics, and

Laboratory test results

Inspection Test Guide:

IN170.302.i – 2.01: Tester shall verify that the retrieved lists of patients are sorted and displayed

correctly according to the data elements included in the Problem list, Medication list, Demographics, and Laboratory test results, and that the lists are accurate and without omission. TD170.302.i shows examples of data elements for sorting

retrieved lists of patients

DTR170.302.i – 3: Electronically Generate Lists of Patients

Required Vendor Information

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

Required Test Procedure:

TE170.302.i – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall produce two

or more lists of patients from the DTR170.302.i - 1: Electronically Select Lists of

Patients test and the DTR170.302.i – 2: Electronically Sort and Retrieve Lists of

Patients test

TE170.302.i – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the

two or more generated lists of patients are produced correctly according to the data elements included in the Problem list, Medication list, Demographics, and

Laboratory test results

Inspection Test Guide

IN170.302.i – 3.01: Tester shall verify that the selected, sorted, and retrieved patient lists are

generated online, as an electronic file, or as a printed document correctly and

without omission

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 and interoperable 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

TD170.302.i: Examples of sets of data elements that could be included in the Problem list, Medication list, Demographics, and Laboratory test results for selecting, sorting, retrieving, and generating lists of patients for this test:

Example Data Elements - Set 1

Demographics: patient age <12 years old

Problem: asthmaMedication: Advair

Example Data Elements - Set 2

• Demographics: patient age >65 years old

Medication: has not received influenza vaccine in past 12 months

Example Data Elements - Set 3

Demographics: patient age >18 years old

• Problem: heart failure

Medication: Avandia

Laboratory Test Results: Total cholesterol: >200 mg/dl AND/OR

HDL-cholesterol: <40 mg/dl AND/OR LDL-cholesterol: >100 mg/dl AND/OR Triglycerides: >150 mg/dl AND/OR

Example Data Elements - Set 4

Demographics: patient age <50 years old
 Problem: coronary artery disease (CAD)

Medication: lisinopril

Laboratory Test Results: Total cholesterol: >200 mg/dl AND/OR

HDL-cholesterol: <40 mg/dl AND/OR LDL-cholesterol: >100 mg/dl AND/OR Triglycerides: >150 mg/dl AND/OR

Example Data Elements - Set 5

Demographics: all patients, all genders
 Problem: Diabetes Mellitus, Type 2

Medication: glyburide

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.9	Original draft version	March 22, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove "Pending" from header	August 13, 2010
1.1	Removed "draft" from introductory paragraph In the Informative Test Description • Added verbiage to Select and to Sort and Retrieve In the Normative Test Procedure section • Added verbiage to Sort and Retrieve Required Test Procedure In the Test Data section • Added another set of test data examples	September 24, 2010