Test Procedure for §170.304 (a) Computerized Provider Order Entry

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.

§170.304 (a) Computerized provider order entry**.** Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;
(2) Laboratory; and
(3) Radiology/imaging

[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 computerized provider order entry certification criterion is discussed:

- "We clarify that the adopted certification criteria related to CPOE pertain only to the ordering, and not to the delivery of results (reports or images)."

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, store, modify and retrieve the following order types in an ambulatory setting:

(1) Medications;
(2) Laboratory; and
(3) Radiology/imaging

The test procedure is not prescriptive about the method used to modify the problem list. For example, modifying an order does not require modifying an existing instance of an order. Modification may be accomplished through discontinuing/canceling an existing order and entering a new order.

This test procedure is organized into three sections:

- Record and Store - evaluates the capability to electronically enter and store orders for medications, laboratory, and radiology/imaging within the EHR system in an ambulatory setting
    - The Tester enters the NIST-supplied Test Data orders for medications, laboratory, and radiology/imaging
    - The Tester verifies that the orders are stored in the EHR

- Modify - evaluates the capability for a user to electronically modify entered orders for medications, laboratory, and radiology/imaging in the EHR in an ambulatory setting
    - The Tester displays the entered orders for medications, laboratory, and radiology/imaging
    - Tester modifies the medications, laboratory, and radiology/imaging orders
    - The Tester validates that the modified orders are accurate and complete

- Retrieve - evaluates the capability to retrieve and display the orders that have been previously entered into the EHR in an ambulatory setting
    - The Tester displays the orders for medications, laboratory, and radiology/ imaging entered during the test
    - The Tester validates that the displayed order data are accurate and complete

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.304.a – 1: Electronically Record and Store Orders in an Ambulatory Setting

DTR170.304.a – 2: Electronically Modify Orders in an Ambulatory Setting

DTR170.304.a – 3: Electronically Retrieve Orders in an Ambulatory Setting

DTR170.304.a – 1: Electronically Record and Store Orders in an Ambulatory Setting

Required Vendor Information

VE170.304.a – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.304.a – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter and store orders for medications, laboratory, and radiology/imaging, 3) modify orders for medications, laboratory, and radiology/imaging, and 4) retrieve orders for medications, laboratory, and radiology/imaging in an ambulatory setting

Required Test Procedure:

TE170.304.a – 1.01: Tester shall select order test data from one NIST-supplied test data set in TD170.304.a - 1

TE170.304.a – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter orders from the selected test data set in TD170.304.a–1 for medications, laboratory, and radiology/imaging

TE170.304.a – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the orders have been entered correctly and without omission

Inspection Test Guide

IN170.304.a – 1.01: Using the data in the selected NIST-supplied test data set in TD170.304.a – 1, Tester shall verify that the order test data are entered correctly and without omission

IN170.304.a – 1.02: Tester shall verify that the order data are stored in the patient's record for:

- medications
- laboratory
- radiology/imaging

DTR170.304.a – 2: Electronically Modify Orders in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.304.a – 1, no additional information is required

Required Test Procedure:

TE170.304.a – 2.01: Tester shall select order test data from one NIST-supplied test data set in TD170.304.a – 2 that corresponds to the data set selected for DTR170.304.a – 1: Electronically Record and Store Orders in an Ambulatory Setting

TE170.304.a – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the order data entered during the DTR170.304.a – 1: Electronically Record and Store Orders test, and shall modify the previously entered orders for medications, laboratory, and radiology/ imaging

TE170.304.a– 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the orders that were entered in TE170.304.a – 2.02 have been entered correctly and without omission

Inspection Test Guide

IN170.304.a – 2.01: Using the data in the selected NIST-supplied test data set in TD170.304.a – 2, Tester shall verify that the medication, laboratory, and radiology/imaging order data entered and stored during the DTR170.304.a – 1: Electronically Record and Store Orders test are accessed and modified correctly and without omission

IN170.304.a – 2.02: Tester shall verify that the modified orders are stored in the patient record correctly , including

- medications
- laboratory
- radiology/imaging

DTR170.304.a – 3: Electronically Retrieve Orders in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.304.a – 1, no additional information is required

Required Test Procedure:

TE170.304.a – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and display the orders the Tester entered during the DTR170.304.a – 1: Electronically Record and Store Orders and DTR170.304.a – 2: Electronically Modify Orders tests for medications, laboratory, and radiology/imaging

TE170.304.a – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the order data display correctly and without omission

Inspection Test Guide:

IN170.304.a – 3.01: Using the data in the NIST-supplied test data set in TD170.304.a – 3 that corresponds to the data set selected for DTR170.304.a – 1: Electronically Record and Store Orders in an Ambulatory Setting, Tester shall verify that the order data entered during the DTR170.304.a – 1: Electronically Record and Store Orders and DTR170.304.a – 2: Electronically Modify Orders tests display correctly and without omission, including

- medications
- laboratory
- radiology/imaging

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.

TD170.304.a – 1: Record and Store Orders in an Ambulatory Setting

Orders Test Data - Set 1

TD170.304.a – 1.1: Medication Orders
- Amoxil 250 mg oral suspension, Disp #150 ml, Sig: Take 5 ml q8h X 10 days, 0 Refills
- Plavix 75 mg tablet, Disp #30, Sig: Take 1 tablet QD, 1 Refill
- Catapres 0.1 mg tablet, Disp #60, Sig: Take 1 tablet bid, 1 Refill

TD170.304.a – 1.2: Laboratory Orders
- Complete Blood Count w/ Differential (CBC), every other day times 3
- BUN, routine
- Creatinine, routine
- Triglycerides, routine
- Fasting Blood Glucose in AM

TD170.304.a – 1.3: Radiology/Imaging Orders
- Chest X-ray 2 views, routine, indication: pneumonia
- MRI without contrast, neck, routine, indication: neck pain

Orders test Data – Set 2

TD170.304.a – 1.4: Medication Orders
- Glyburide (Diabeta) 2.5 mg tablet, Disp # 60, Sig: Take 1 tablet PO, Q AM, 0 Refills
- atorvastatin calcium (Lipitor) 10 mg tablet, Disp # 60, Sig: Take 1 tablet PO Qday, 1 Refill
- candesartan cilexetil (Atacand), 16 mg tablet, Disp# 60, Sig: Take 1 tablet PO QDay, 1 Refill

TD170.304.a – 1.5: Laboratory Orders
- Cholesterol, routine
- Thyroid Stimulating Hormone (TSH), routine
- High-sensitivity C-reactive protein (HS-CRP), routine

TD170.304.a – 1.6: Radiology/Imaging Orders
- X-ray: AP Pelvis, Anteroposterior (AP) & Lateral/Right Hip, routine, indication: hip pain
- DXA scan (Bone Density test), routine, indication: osteoporosis

TD170.304.a – 2: Modify Orders in an Ambulatory Setting

Orders Test Data - Set 1

TD170.304.a – 2.1: Medication Orders
Modify the Amoxil order from q8h to **q12h**
Discontinue the Plavix order
Modify the dose for the Catapres order from 0.1 mg to **0.2mg**

TD170.304.a – 2.2: Laboratory Orders
Discontinue the Complete Blood Count w/ Differential (CBC) order
Modify the Triglycerides order from routine to **once a week times 3 weeks**

TD170.304.a – 2.3: Radiology/Imaging Orders
Modify the Chest X-ray 2 views order to **Chest X-ray 4 views**

Orders Test Data - Set 2

TD170.304.a – 2.4: Medication Orders
Modify candesartan cilexetil (Atacand) order from 16 mg tablet to **8 mg tablet**

TD170.304.a – 2.5: Laboratory Orders
Modify Cholesterol from routine to **fasting**

TD170.304.a – 2.6: Radiology/Imaging Orders
Modify X-ray: AP Pelvis, Anteroposterior (AP) & Lateral/Right Hip to **Bilateral Hip**

TD170.304.a – 3: Retrieve Orders in an Ambulatory Setting

Revised Orders Test Data - Set 1

Revised Medication Orders List

- Amoxil 250 mg oral suspension, Disp #100 ml, Sig: Take 5 ml **q12h** X 10 days, 0 Refills
- Catapres **0.2** mg tablet, Disp #60, Sig: Take 1 tablet bid, 1 Refill

Revised Laboratory Orders List

- BUN, routine
- Creatinine, routine
- Triglycerides, **once a week times 3 weeks**
- **Fasting Blood Glucose in AM**

Revised Radiology/Imaging Orders List

- **Chest X-ray 4 views**, routine, indication: pneumonia
- MRI without contrast, neck, routine, indication: neck pain

Revised Orders Test Data - Set 2

Revised Medication Orders List

- Glyburide (Diabeta) 2.5 mg tablet, Disp # 60, Sig: Take 1 tablet PO, Q AM
- atorvastatin calcium (Lipitor) 10 mg tablet, Disp # 60, Sig: Take 1 tablet PO Qday
- candesartan cilexetil (Atacand), **8 mg** tablet, Disp# 60, Sig: Take 1 tablet PO QDay

Revised Laboratory Orders List

- Cholesterol, **fasting**
- Thyroid Stimulating Hormone (TSH), routine
- High-sensitivity C-reactive protein (HS-CRP), routine

Revised Radiology/Imaging Orders List

- X-ray: AP Pelvis, Anteroposterior (AP) & Lateral/**Bilateral**,routine, indication: hip pain
- DXA scan (Bone Density test), routine, indication: osteoporosis

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.2	Original draft version	February 26, 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 clarify the definition of modify In the Normative Test Procedures Section • Added references to the Test Data section • Added verbiage instructing Tester to select only one data set from the Test Data • Added verbiage instructing Tester to select a data set from the Test Data that corresponds to the data set selected for DTR170.304.a – 1: Electronically Record and Store Orders in an Ambulatory Setting In the Test Data section: • Added an another test data set • Changed the word “change” to “modify” • Corrected “Disp #150 ml to “Disp #100 ml”	September 24, 2010