Test Procedure for §170.302 (a) Drug-drug, drug-allergy interaction checks

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 (a) Drug-drug, drug-allergy interaction checks
(1) Notifications. Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).

[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.

(2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

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 drug-drug, drug-allergy interaction checks certification criterion is discussed:

- "For the purposes of testing and certification, we leave it entirely up to Complete EHR and EHR Module developers to innovate in this area and provide capabilities that are both easy to use and prevent medical errors."
- "Our revisions focus on Certified EHR Technology's capability to allow certain users (e.g., those with administrator rights) with the ability to adjust notifications provided for drug-drug and drug-allergy checks (e.g., set the level of severity for which notifications are presented)."
- "We clarify for commenters that our inclusion of CPOE in the certification criterion is meant to indicate that notifications should occur based on new medication orders, in addition to a patient's current medications and medication allergies, as they are being entered. In response to the other commenter's request for clarification, we believe that notifications will occur during the order-entry workflow."

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:

- Automatically and electronically generate and indicate notifications in real-time at the point of care using computerized provider order entry (CPOE). Alerts evaluated are drug-drug and drug-allergy contraindications based on the patient's medication list and medication allergy list
- Enable certain users to adjust the notifications provided for drug-drug and drug-allergy interaction checking

The Vendor supplies the test data for this test procedure.

This test procedure is organized into two sections:

- Generate and indicate notifications – evaluates the capability to generate and indicate in real-time notifications at the point of care during computerized provider order entry (CPOE) for drug-drug and drug-allergy contraindications based on the patient's medication list and medication allergy list
  - The Vendor identifies specific alerts available in the EHR and available CPOE orders that can be used to initiate those alerts
  - The Tester enters new medication orders via CPOE and generates at least one each of drug-drug and drug-allergy notifications identified by the Vendor

- The Tester validates that the notifications are generated and indicated to the user in real-time during CPOE, are based on the patient's medication list and medication allergy list, and are displayed as defined by the Vendor

- Adjust notifications – evaluates the capability for certain users to make adjustments to drug-drug and drug-allergy interaction checking
  - The Tester selects and displays the drug-drug and drug-allergy notification adjustment capabilities identified by the Vendor for this test
  - The Tester adjusts at least one each of the selected drug-drug and drug-allergy notification rules; an example of an adjustment would be changing the level of severity of a notification for all user types or a specific user-type, for instance, causing the suppression of a drug-drug interaction notification for all CPOE users or only for cardiologists who order digoxin and furosemide together for the same patient
  - The Tester validates, in real-time during CPOE, that the selected drug-drug and drug-allergy notifications have been adjusted as described by the Vendor

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.a – 1: Automatically Generate and Indicate Drug-drug and Drug-allergy Notifications

DTR170.302.a – 2: Adjust Drug-drug and Drug-allergy Interaction Checks

DTR170.302.a – 1: Automatically Generate and Indicate Drug-drug and Drug-allergy Notifications

Required Vendor Information

VE170.302.a – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.302.a – 1.02: Vendor shall provide and configure the test data for this test including patient's active medications and active medication allergies

VE170.302.a – 1.03: Vendor shall identify at least one each of drug-drug and drug-allergy notifications to be used for this test and CPOE medication orders that can be used to initiate the notifications

VE170.302.a – 1.04: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) generate and indicate, in real-time, drug-drug and drug-allergy notifications based on patient medication list and medication allergy list during computerized provider order entry (CPOE), 3) adjust notifications for drug-drug and drug-allergy interaction checking and 4) enable the Tester to serve as a user with the specific ability to adjust notifications

Required Test Procedure:

TE170.302.a – 1.01: Using the EHR function(s) and alert rules identified by the Vendor, the Tester shall select the patient's existing record, enter new medication orders using CPOE, and generate at least one each of drug-drug and drug-allergy notifications

TE170.302.a – 1.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that drug-drug and drug-allergy notifications are generated and indicated in real-time and are displayed as described by the Vendor in VE170.302.a-1.03

Inspection Test Guide

IN170.302.a – 1.01: Tester shall verify that:

- New medication orders are entered via computerized provider order entry (CPOE)
- At least one each of drug-drug and drug-allergy notifications based on the patient's medication list and medication allergy list are generated and indicated in real-time
- The alerts are displayed as described by the Vendor in VE170.302.a-1.03

DTR170.302.a – 2: Adjust Drug-drug and Drug-allergy Interaction Checks

Required Vendor Information

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

Required Test Procedure:

TE170.302.a – 2.01: Using the EHR function(s) identified by the Vendor, the Tester shall select and shall adjust at least one each of drug-drug and drug-allergy notifications used in the DTR170.302.a – 1: Automatically Generate and Indicate Drug-drug and Drug-allergy Notifications test

TE170.302.a – 2.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that only certain users are able to adjust drug-drug and drug-allergy notifications

TE170.302.a – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the adjusted drug-drug and drug-allergy notifications are generated and indicated in real-time during CPOE and are displayed as described by the Vendor in VE170.302.a-1.03

Inspection Test Guide

IN170.302.a – 2.01: Tester shall verify that at least one each of drug-drug and drug-allergy notifications are adjustable by the user with the specific ability to adjust notifications as identified by the Vendor

IN170.302.a – 2.02: Tester shall verify that the adjusted drug-drug and drug-allergy notifications are generated and indicated in real-time during CPOE, are displayed as described by

the Vendor in VE170.302.a-1.03, and are based on the patient's medication list and medication allergy list

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

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.8	Original draft version	April 8, 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” in introductory paragraph In the Informative Test Description section, page 3: • Added clarification to the example for adjust notifications	September 24, 2010