

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

This document describes the draft 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 Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. The document 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. These test procedures will be updated to reflect the certification criteria defined in the ONC Final Rule.

Note: This test procedure is scoped only to the criteria defined in 45 CFR Part 170 Subpart C of the Interim Final Rule (IFR) as published in the Federal Register on January 13, 2010. This test procedure will be updated to reflect updates to the criteria and standards as published in the ONC Final Rule. Questions about the criteria and standards should be directed to ONC.

CERTIFICATION CRITERIA

§170.302 (a) Drug-drug, drug-allergy, drug formulary checks

- (1) Alerts. Automatically and electronically generate and indicate in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and computerized provider order entry (CPOE).
- (2) Formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in §170.205(b).
- (3) Customization. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking.
- (4) Alert statistics. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.

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 Module¹ to:

- Electronically generate and indicate alerts in real time during computerized provider order entry (CPOE). Alerts evaluated are drug-drug, drug-allergy, and drug-age contraindications based on the patient's medication list, medication allergy list, and age;

¹ Department of Health and Human Services, 45 CFR Part 170 Proposed Establishment of Certification Programs for Health Information Technology, Proposed Rule, March 10, 2010.

- Enable certain users to deactivate, modify, and add rules for drug-drug, drug-allergy, and drug-age checking; and
- Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user during the test

Per ONC guidance, the capability to perform formulary checks should be deferred to a future test procedure and therefore is not included in this test procedure.

The test procedure for 170.302 (a)(3) requires the Vendor to identify a user with the system privileges required to perform the function and intentionally does not evaluate the Vendor's implementation of the concept of "administrator rights."

The Vendor supplies the test data for this test procedure.

This test procedure is organized into three sections:

- Generate and indicate alerts – evaluates the capability to generate and indicate alerts in real-time during computerized provider order entry (CPOE) for drug-drug, drug-allergy, and drug-age contraindications based on the patient's medication list, medication allergy list, and age
 - The Vendor identifies specific alerts available in the EHR and available CPOE orders which can be used to initiate those alerts.
 - The Tester enters new medication orders via CPOE and generates at least one each of drug-drug, drug-allergy, and drug-age alerts as identified by the Vendor
 - The Tester responds to all but one of the generated alerts and records the number of alerts to which they responded. The test procedure specifically asks that the Tester ignore (not respond to) one of the alerts. The intent of this activity is to generate actions which can be verified on the Alert Statistics reports.
 - The Tester validates that alerts are generated and indicated to the user in real-time during CPOE, are based on the patient's medication list, allergy list, and age, and are displayed as defined by the Vendor
- Customize – evaluates the capability for certain users to deactivate, modify (correct/update), and add rules for drug-drug, drug-allergy, and drug-age checking during CPOE
 - The Tester selects and displays drug-drug, drug-allergy, and drug-age alert rules generated in this test
 - The Tester modifies (corrects/updates) at least one each of the selected drug-drug, drug-allergy, and drug-age alert rules
 - The Tester deactivates at least one each of the selected drug-drug, drug-allergy, and drug-age alert rules
 - The Tester adds at least one new rule each for drug-drug, drug-allergy, and drug-age checking
 - The Tester validates that the selected drug-drug, drug-allergy, and drug-age rules have been modified and deactivated and that new drug-drug, drug-allergy, and drug-age rules have been added

- The Tester validates that the modified and new rules automatically and electronically generate drug-drug, drug-allergy, and drug-age alerts as described by the Vendor in real-time during CPOE
- The Tester validates that the deactivated rules are not generated during CPOE
- Track, record, and report alert statistics – evaluates the capability to track, record, and generate reports on the number of drug-drug, drug-allergy, and drug-age alerts responded to by a user
 - The Tester validates that the responses to the alerts generated and responded to in this test are tracked, recorded, and reported accurately and completely

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.a – 1: Automatically generate and indicate drug-drug and drug allergy alerts during CPOE

DTR170.302.a – 2: Customize drug-drug and drug-allergy rules

DTR170.302.a – 3: Track, record, and generate reports on alert statistics

DTR170.302.a – 1: Automatically generate and indicate drug-drug and drug allergy alerts during CPOE

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, active medication allergies, and age
- VE170.302.a – 1.03: Vendor shall identify at least one each of drug-drug, drug-allergy, and drug-age alert rules to be used for this test and CPOE medication orders which can be used to initiate the rules.
- 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, drug-allergy, and drug-age alerts based on patient medication list, medication allergy list, and age during computerized provider order entry (CPOE), 3) customize (deactivate, modify, and add) rules for drug-drug, drug-allergy, and drug-age checking, and 4) automatically and electronically track, record, and generate reports on the number of drug-drug, drug-allergy, and drug-age alerts responded to by a user

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, drug-allergy, and drug-age alerts

TE170.302.a – 1.02: Using the EHR function(s) and alert rules identified by the Vendor, the Tester shall respond to all but one of the generated alerts, and shall document the number of alerts responded to

TE170.302.a – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that drug-drug, drug-allergy, drug-age alerts are generated and indicated in real-time, can be responded to, 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, drug-allergy, and drug-age contraindication alerts based on medication list, medication allergy list, and age are generated and indicated in real-time
- all but one of the alerts are responded to
- the alerts are displayed as described by the Vendor in VE170.302.a-1.03

DTR170.302.a – 2: Customize drug-drug and drug-allergy rules

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 modify (update/correct) at least one each of drug-drug, drug-allergy, and drug-age alert rules used in the Generate and Indicate Alerts test

TE170.302.a – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall select and shall deactivate at least one each of the drug-drug, drug-allergy, and drug-age alert rules used in the Generate and Indicate Alerts test

TE170.302.a – 2.03: Using the EHR function(s) identified by the Vendor and new drug-drug, drug-allergy, and drug-age rules identified by the Vendor, the Tester shall add at least one each of drug-drug, drug-allergy, and drug-age alert rules

TE170.302.a – 2.04: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that certain users are able to deactivate, modify, and add drug-drug, drug-allergy, and drug-age alert rules

TE170.302.a – 2.05: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the modified and new drug-drug, drug-allergy, and drug-age alerts are generated, indicated, and responded to in real-time during CPOE and are displayed as described by the Vendor in VE170.302.a-1.03; and the Tester shall document the number of alerts responded to

TE170.302.a – 2.06: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the deactivated drug-drug, drug-allergy, and drug-age rules are not generated during CPOE

Inspection Test Guide

IN170.302.a – 2.01: Tester shall verify that at least one each of drug-drug, drug-allergy, and drug-age alert rules can be deactivated, modified, and added by certain users

IN170.302.a – 2.02: Tester shall verify that the modified and new drug-drug, drug-allergy, and drug-age alerts are generated, indicated, and responded to 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, medication allergy list, and age; and the Tester shall document the number of alerts responded to

IN170.302.a –2.03: Tester shall verify that the deactivated drug-drug, drug-allergy, and drug-age rules are not generated during CPOE

DTR170.302.a – 3: Track, record, and generate reports on alert statistics

Required Vendor Information

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

Required Test Procedure:

TE170.302.a – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall generate reports on the number of drug-drug, drug-allergy, and drug-age alerts responded to in the Generate and Indicate Alerts test and the Customize Rules test

TE170.302.a – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the reports are accurate and complete

Inspection Test Guide

IN170.302.a – 3.01: Tester shall verify (using the documentation from the Generate and Indicate Alerts test and Customized Rules test) that the number of user responses to drug-drug, drug-allergy, and drug-age alerts from those tests are automatically and electronically tracked, recorded, and reported, and are accurate and complete.

EXAMPLE TEST DATA

Test data for this test procedure is supplied by the Vendor.

CONFORMANCE TEST TOOLS

None